SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION

In re: Accutane Litigation	: Appellate Docket No.: A-4760-14T1 : : Civil Action : : ON APPEAL FROM Superior Court, : Law Division, Atlantic County : : Case No. 271 (MCL) : : Sat Below: : Hon. Nelson C. Johnson, J.S.C. :

Brief of Amicus Curiae
The HealthCare Institute of New Jersey

McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 622-4444
Attorneys for Amicus Curiae,
The HealthCare Institute of
New Jersey

Edward J. Fanning, Jr.
David R. Kott
Of Counsel

Edward J. Fanning, Jr.
David R. Kott
Gary R. Tulp
On the Brief

TABLE OF CONTENTS

Table of Authorities ii

Statement of Interest and Preliminary Statement 1

Procedural History and Statement of Facts 3

Argument 3

I. The New Jersey Legislature Passed the Product Liability Act to Reduce the Burden on the State's Domestic Pharmaceutical Manufacturers by Recognizing the Reliability and Sufficiency of FDA Approval. 3

II. New Jersey Jurisprudence Narrowly Limits Exceptions To the Presumption of Adequacy to Intentional Misconduct. 11

III. Plaintiffs' Espoused Standard Is Inconsistent with the Legislature's Intent. 13

Conclusion 17

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

Ziliak v. AstraZeneca LP,
324 F.3d 518 (7th Cir. 2003) 10

STATE CASES

Bailey v. Wyeth, Inc.,
424 N.J. Super. 278 (Law Div. 2008), aff'd, DeBoard v. Wyeth, Inc., 422 N.J. Super. 360 (App. Div. 2011), certif. denied, 211 N.J. 274 (2012) 5, 10, 12, 14, 16

In Re: Accutane Litig.,
No. 271 (MCL) (Law Div. Apr. 2, 2015) 10, 11, 12

Kendall v. Hoffmann-La Roche Inc.,
209 N.J. 173 (2012) 9, 11, 15

McDarby v. Merck & Co.,
401 N.J. Super. 10 (App. Div. 2008) 12

Perez v. Wyeth Labs. Inc.,
161 N.J. 1 (1999) 9, 11, 12, 13, 14

Rowe v. Hoffmann-La Roche Inc.,
189 N.J. 615 (2007), overruled in part on other grounds, P.V. v. Camp Jaycee, 197 N.J. 132 (2008) 7, 8, 9

Shackil v. Lederle Labs.,
116 N.J. 155 (1989) 8

Spinden v. Johnson & Johnson,
177 N.J. Super. 605 (App. Div. 1981) 10

Upjohn Co. v. MacMurdo,
562 So.2d 680 (Fla. 1990) 10

Zaza v. Marquess & Nell, Inc.,
144 N.J. 34 (1996) 8

FEDERAL STATUTES

Pub. L. 59-384, 34 Stat. 768, § 7 (1906) 5

STATE STATUTES

N.J.S.A. § 2A:58C-4 ..... 7, 9, 13

OTHER AUTHORITIES

Pharmaceuticals, N.J. Business Portal, http://www.nj.gov/njbusiness/industry/pharmaceutical..... 3

N.J. Dep't of Lab. and Workforce Devel., New Jersey Key Industry Clusters, http://lwd.dol.state.nj.us/labor/lpa/pub/lmv/cluster%20handout.pdf..... 3, 4

Susan Warner, As Businesses Wander, New Jersey Fights Back, N.Y. Times, July 4, 2004, sec. 14, at 2..... 4

Renee Morad & Riley McDermid, Exciting Time for Biotech in New Jersey, BioSpace (June 25, 2015)..... 5

State Health Facts: Prescription Drugs, Henry J. Kaiser Family Found. (2014)..... 5

Paul J. Newby & Bob Johnson, Overview of Alternative Rapid Microbiological Technologies, in Rapid Microbiological Methods in the Pharmaceutical Industry 29 (Martin C. Easter, ed., 2003)..... 5

FDA, Fiscal Year 2014: Justification of Estimates for Appropriations Committees 143-44 (Apr. 2013)..... 6

Ctr. for Drug Eval. & Res., FDA, Drug Safety Report: Advances in FDA's Safety Program for Marketed Drugs 9 (Apr. 2012)..... 6

Tufts Ctr. for the Study of Drug Devel., PR Tufts CSDD 2014 Cost Study (Nov. 18, 2014)..... 6

STATEMENT OF INTEREST AND PRELIMINARY STATEMENT

The HealthCare Institute of New Jersey (HINJ) submits this brief as amicus curiae in support of Defendants-Respondents Hoffmann-La Roche Inc. and Roche Laboratories Inc.

Issue to Be Addressed and the Public Interest Therein

HINJ seeks to participate to explain the significant impact on pharmaceutical manufacturing and development that would result from disregarding the Legislature's intent as expressed in the Product Liability Act (PLA or "Act"). The PLA was adopted to reduce the burden on that important industry by permitting manufacturers to satisfy their warning obligations – absent exceptional circumstances involving intentional misconduct – by gaining approval of their medicine warnings through the extensive federal regulatory process. The Legislature carefully weighed the competing interests at stake and concluded that New Jersey's interests are best balanced by according substantial deference to the federal Food and Drug Administration's (FDA) expertise and close regulatory scrutiny. Accepting Plaintiffs' view of the PLA would circumvent the Legislature's intent, depart from existing judicial interpretations of the Act, and risk harm to New Jersey businesses and worldwide medical innovation. The decision below should be affirmed.

Identity of the Applicant and Its Special Interest, Involvement, and Expertise in Respect Thereof

HINJ is a trade association for the research-based biopharmaceutical and medical technology industry in New Jersey. Founded in 1997 and comprised of 24 of New Jersey's major pharmaceutical and medical technology manufacturers, HINJ serves as a unified voice for New Jersey's life sciences industry and seeks to build awareness of the industry's impact on New Jersey's quality of life and economic well-being. The organization also strives to raise awareness and understanding of, and public support for, the research-based pharmaceutical and medical technology industry among New Jersey's elected and appointed officials, media, citizens, and opinion leaders. HINJ seeks to advance the development and implementation of sound public health and business policies that support the interests of New Jersey, its people, and its research-based life sciences industry. A list of HINJ's 24 member organizations is attached to this brief as Addendum A.

HINJ respectfully requests that this Court grant its application to appear as amicus curiae and consider the arguments briefed herein.

PROCEDURAL HISTORY AND STATEMENT OF FACTS

HINJ adopts and incorporates by reference the Procedural History and Factual Background relating to this case set forth in the Defendants-Respondents' Brief filed in connection with this appeal on November 6, 2015.

ARGUMENT

I. THE NEW JERSEY LEGISLATURE PASSED THE PRODUCT LIABILITY ACT TO REDUCE THE BURDEN ON THE STATE'S DOMESTIC PHARMACEUTICAL MANUFACTURERS BY RECOGNIZING THE RELIABILITY AND SUFFICIENCY OF FDA APPROVAL.

A reversal of the trial court's decision would have deleterious effects on New Jersey's vital pharmaceutical industry and would frustrate significant legislative intent and public policy. The breadth of those interests, and the suitability of deference to the FDA as a means to protect them, cannot be understated.

New Jersey is a global hub of the pharmaceutical industry, and has made New Jersey a world leader in scientific innovation. The State is home to 13 of the world's 20 largest pharmaceutical companies. See Pharmaceuticals, N.J. Business Portal, http://www.nj.gov/njbusiness/industry/pharmaceutical. The State's biopharmaceutical industry employs more than 100,000 people, representing nine percent of all U.S. pharmaceutical jobs. Workers at those companies earn more than $15 billion in wages. See N.J. Dep't of Lab. and Workforce Devel., New Jersey

Key Industry Clusters, http://lwd.dol.state.nj.us/labor/lpa/pub/lmv/cluster%20handout.pdf. The size and continued growth of this industry have led to its key role in New Jersey's economy. In 2004, acting State Treasurer John E. McCormac described these businesses as "our No. 1 industry." Susan Warner, As Businesses Wander, New Jersey Fights Back, N.Y. Times, July 4, 2004, sec. 14, at 2.

Because of the importance of the pharmaceutical industry to New Jersey, the State Legislature has significant familiarity with the industry and frequently considers bills that impact manufacturers and other important industry participants. See, e.g., An Act Concerning the Dispensing of Certain Biological Products, A-2477, 216th Leg. (2015); An Act Establishing the New Jersey Rare Disease Advisory Council, A-4056, 216th Leg. (2015); An Act Concerning Health Benefits Coverage for Oral Anticancer Medications and Supplementing Various Parts of Statutory Law, S-1834, 214th Leg. (2010).

Pharmaceutical companies also play a vital role in delivering healthcare to citizens of New Jersey and patients around the world. The impact of products developed by New Jersey's pharmaceutical industry is substantial, as reflected by its production of many new medicines and breakthrough medical technologies every year. Through the first half of 2015, "16 of the 27 new drugs approved by the FDA came from companies with a

significant footprint in New Jersey." Renee Morad & Riley McDermid, Exciting Time for Biotech in New Jersey, BioSpace (June 25, 2015).

These New Jersey businesses distribute their innovative products throughout the country. Ninety-seven percent of U.S. retail prescription pharmaceutical sales take place outside of New Jersey. See State Health Facts: Prescription Drugs, Henry J. Kaiser Family Found. (2014). Because of the broad distribution of pharmaceutical medicines, the FDA – working together with the industry – heavily regulates the efficacy and safety of medicines and medical devices. Indeed, "[t]he pharmaceutical industry is one of the most heavily regulated industries in the world." Paul J. Newby & Bob Johnson, Overview of Alternative Rapid Microbiological Technologies, in Rapid Microbiological Methods in the Pharmaceutical Industry 29 (Martin C. Easter, ed., 2003).

The federal government has a long history of regulating the pharmaceutical industry. Since the enactment of the Pure Food and Drug Act of 1906, the federal government has established standards for medicine labels. See Pub. L. 59-384, 34 Stat. 768, § 7 (1906). As a result of this prolonged experience, the FDA is well-suited to establish requirements for what constitutes an adequate medicine warning. See Bailey v. Wyeth, Inc., 424 N.J. Super. 278, 327 (Law Div. 2008) ("[T]he New

Jersey Legislature and the New Jersey Supreme Court have acknowledged the FDA's authority and experience in determining appropriate warnings in the labeling of prescription drugs."), aff'd, DeBoard v. Wyeth, Inc., 422 N.J. Super. 360 (App. Div. 2011), certif. denied, 211 N.J. 274 (2012). The FDA has used that expertise to set stringent and comprehensive safety standards. Moreover, FDA review continues even after initial approval of a medicine. The FDA now seeks to spend $200 million annually to monitor the safety and efficacy of drugs that are currently available to consumers. See FDA, Fiscal Year 2014: Justification of Estimates for Appropriations Committees 143-44 (Apr. 2013). As a result of those increased resources, since 2008, the FDA has required post-market labeling changes more than 65 times. See Ctr. for Drug Eval. & Res., FDA, Drug Safety Report: Advances in FDA's Safety Program for Marketed Drugs 9 (Apr. 2012).

Complying with FDA and other regulations requires enormous financial commitments to bring new medicines to market. The FDA can take 16 months or more to review a New Drug Application, and obtaining FDA marketing approval for a new prescription drug costs nearly $2.6 billion. See Tufts Ctr. for the Study of Drug Devel., PR Tufts CSDD 2014 Cost Study (Nov. 18, 2014). Even after approval, manufacturers must spend hundreds of millions of dollars to comply with post-approval obligations. Id. That

extensive and costly process gives thorough consideration to the risks and benefits of a particular therapy and the warnings that should be provided with it. Unwarranted litigation only adds to the already vast expenditures made in connection with meeting the FDA's strict regulatory requirements.

Recognizing those challenges and seeking to ease the burden on manufacturers, in 1987 the New Jersey Legislature enacted the PLA. As part of that comprehensive statutory overhaul of product-liability law in New Jersey, the Act established that warnings for medicines approved by the FDA are presumed adequate. See N.J.S.A. § 2A:58C-4 ("If the warning or instruction given in connection with a drug or device . . . has been approved or prescribed by the [FDA] under the 'Federal Food, Drug and Cosmetic Act,' . . . a rebuttable presumption shall arise that the warning or instruction is adequate.").

In creating that presumption, the Legislature deferred to the FDA's longstanding expertise in regulating medicines and medical devices, and it sought to protect manufacturers who obtain FDA approval because FDA regulations sufficiently "deter New Jersey pharmaceutical companies from manufacturing unsafe prescription drugs." Rowe v. Hoffmann-La Roche Inc., 189 N.J. 615, 625 (2007), overruled in part on other grounds, P.V. v. Camp Jaycee, 197 N.J. 132 (2008). New Jersey has chosen to defer to the FDA's experienced judgment in nearly all cases, and

that decision is a proper exercise of the State's prerogative to determine its role in the regulatory process.

Given the FDA's expertise and the New Jersey Legislature's statutory deference to it, the PLA sought to reduce unnecessary, duplicative regulation of the pharmaceutical industry to limit the burden on the State's domestic pharmaceutical manufacturers, while recognizing the robust regulatory oversight of medicines that the FDA approval process provides to ensure patient safety. To reduce that burden, the PLA "limit[s] the expansion of products-liability law by creating absolute defenses and rebuttable presumptions of nonliability." Shackil v. Lederle Labs., 116 N.J. 155, 187 (1989).

Courts repeatedly have recognized that, in establishing those limits, the Legislature "carefully balanced" the need to protect individuals against the need to protect manufacturers of medical products from undue burdens. See Rowe, 189 N.J. at 626 ("The Legislature carefully balanced the need to protect individuals against the need to protect an industry with a significant relationship to our economy and public health."); see also Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 47-48 (1996) ("The Legislature intended for the [PLA] to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality." (citation and quotation marks omitted)). The balance had become

unfairly tilted against manufacturers, so the PLA was enacted to "limit[] the liability of manufacturers of FDA-approved products by reducing the burden placed on them by product liability litigation." Rowe, 189 N.J. at 626; see also Kendall v. Hoffmann-La Roche Inc., 209 N.J. 173, 194 (2012) ("In particular, in enacting the PLA, the Legislature intended to reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation."). The Legislature "re-balance[d] the law in favor of manufacturers" who comply with FDA regulations. See Rowe, 189 N.J. at 623 (quotation marks omitted); see also Perez v. Wyeth Labs. Inc., 161 N.J. 1, 25 (1999) (finding that a standard under which "the duty to consumers is met by compliance with FDA regulations" is "fair and balanced").

Deference to FDA-approved warnings is a central component of the PLA. Pursuant to the plain language of the PLA and consistent with the intent of the Legislature, the presumption that a warning is adequate applies to any FDA-approved medicine warning. So long as an FDA-approved warning is "given in connection with a drug or device," the presumption of adequacy must apply. N.J.S.A. § 2A:58C-4.

Contrary to Plaintiffs' view, even apart from the presumption, a warning need not be as comprehensive as those at issue in this litigation to be found adequate. In fact, even

courts applying more generous adequacy standards routinely find warnings that are less explicit and comprehensive than Accutane's warnings to be adequate as a matter of law. See, e.g., Bailey, 424 N.J. Super. at 320 (warning adequate as a matter of law even though, "[w]hen [plaintiff] ingested Provera, the labeling did not contain a risk of breast cancer warning"); Spinden v. Johnson & Johnson, 177 N.J. Super. 605, 607-08 (App. Div. 1981) (warning of "[a]n increased risk of thrombo-embolic disease associated with the use of hormonal contraceptives" held adequate as a matter of law); accord Ziliak v. AstraZeneca LP, 324 F.3d 518, 521 (7th Cir. 2003) (affirming decision holding warning adequate as a matter of law where label warned that "rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported following the inhaled administration of corticosteroids"); Upjohn Co. v. MacMurdo, 562 So.2d 680, 681, 683 (Fla. 1990) (warning "that breakthrough bleeding, spotting, and change in menstrual flow are adverse reactions" held adequate as a matter of law in case alleging "excessive and continuous menstrual bleeding which ultimately necessitated a hysterectomy to stop the bleeding").

The trial court found that, here, the manufacturer went far beyond what is required. See In Re: Accutane Litig., No. 271 (MCL) (Law Div. Apr. 2, 2015) (slip op. at 20) ("Taken as a whole, the warning system crafted by Defendants conveys a

meaning as to potential risks and consequences that is unmistakable.") As Judge Johnson observed, such warnings, which have earned FDA approval, "are entitled to the benefit of our state's rebuttable presumption of adequacy and are deemed adequate as a matter of law." Id. This Court should adhere to the intent of the Legislature and accord appropriate protection to manufacturers who obtain FDA approval of their warnings.

II. NEW JERSEY JURISPRUDENCE NARROWLY LIMITS EXCEPTIONS TO THE PRESUMPTION OF ADEQUACY TO INTENTIONAL MISCONDUCT.

The weighty policy considerations that underlie the Legislature's careful consideration of this issue create a "virtually dispositive" "super presumption" of adequacy. See Perez, 161 N.J. at 25 ("[C]ompliance with FDA standards should be virtually dispositive of such claims."); Kendall, 209 N.J. at 195 ("Indeed, in Perez we created what can be denominated as a super-presumption . . . ; only in the 'rare case' will damages be assessed against a manufacturer issuing FDA-approved warnings."). Given the strength of the presumption, in all but a few narrow circumstances, the FDA's determination that a warning is adequate resolves the issue.

New Jersey courts have recognized that the presumption of adequacy is not absolute. Exceptions to the presumption protect those who are wrongfully injured. To balance the interests at stake, courts have recognized that two types of intentional

misconduct may overcome the presumption of adequacy: (1) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, or (2) intentional manipulation of the post-market regulatory process. See Perez, 161 N.J. at 25; Bailey, 424 N.J. Super. at 311, 319, 323-24; DeBoard, 422 N.J. Super. at 362 (affirming Bailey as "legally unassailable"); McDarby v. Merck & Co., 401 N.J. Super. 10, 63 (App. Div. 2008) (recognizing exception for intentional, "economically-driven manipulation of the post-market regulatory process"); accord In Re: Accutane Litig., No. 271 (MCL) (Law Div. Apr. 2, 2015) (slip op. at 19).

Those exceptions have been delineated narrowly by the courts to prevent "over deterrence . . . [that] could impede and delay manufacturers from research and development of new and effective drugs, force beneficial drugs from market, lead to shortages in supplies and suppliers of pharmaceuticals, and create unnecessary administrative costs." Perez, 161 N.J. at 25 (citing Michael D. Green, Statutory Compliance and Tort Liability: Examining the Strongest Case, 30 U. Mich. J.L. Ref. 461, 466-67 (1997)). Without evidence of deliberate action — whether concealment, nondisclosure, or economic manipulation — the PLA's presumption that FDA-approved warnings are adequate applies, and a manufacturer may not be held liable for a failure to warn.

III. PLAINTIFFS' ESPOUSED STANDARD IS INCONSISTENT WITH THE LEGISLATURE'S INTENT.

The standard proposed by Plaintiffs would strip the PLA's presumption of all its force by removing both its intentionality and materiality requirements. If such a standard were adopted, the presumption could be rebutted in virtually every case, merely by contending that a particular warning could have been worded differently, that the precise timing of FDA communications could have been different, or that the manufacturer considered the financial performance of its product.

Plaintiffs argue that the statutory presumption entitles the defendant to nothing more than a weak jury instruction that FDA approval should be considered among other facts, rendering it indistinguishable from any other fact in evidence. See Pls.' Br. at 46. That view of the standard ignores the Legislature's thoughtful decision to accord far more substantial weight to the results of FDA review. Plaintiffs' view also cannot be reconciled with New Jersey courts' insistence that N.J.S.A. § 2A:58C-4 affords a virtually dispositive super-presumption, nor with the Legislature's intent to create meaningful protection for pharmaceutical manufacturers.

Plaintiffs also seek to distort the meaning of Perez to read intentionality out of the PLA. Plaintiffs misread Perez to

argue that "the Supreme Court used the word 'deliberate' to qualify 'concealment,' but did not use analogous language in regards [sic] to its reference to the alternative of 'non-disclosure of after-acquired knowledge of harmful effects.'" Pls.' Br. at 44. Reading Perez without abridgement, the Court required "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." Perez, 161 N.J. at 25. Lest there be any confusion that the Court required deliberate nondisclosure, the Court noted that "it is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects[.]" Id. at 20-21 (emphasis added). Whether the allegation sounds in concealment or nondisclosure, Perez requires deliberate action. See id. That requirement is consistent with the intent of the Legislature and the interpretations of the Supreme Court and this Court. It has not been read out of the statute.

The mere presentation of an expert witness whose testimony takes issue with the results of the FDA's regulatory review process should not rebut the presumption of adequacy. See Bailey, 424 N.J. Super. at 312-13. The FDA spends months or years allowing the nation's regulatory experts to carefully consider and evaluate the sufficiency of a warning. According deference to a witness retained to dispute the judgment of the

FDA would – absent evidence of intentional misconduct – devalue the agency's expertise and ignore the respect that the Legislature intended that it be accorded. Such testimony does not rebut the presumption.

Adopting Plaintiffs' view of the standard – and allowing juries to consider imposing liability in cases, like this one, involving robust patient warnings – would have serious negative repercussions for New Jersey's pharmaceutical industry. Manufacturers could no longer rely on the lengthy and costly FDA approval process to satisfy concerns about the adequacy of warning labels. Instead, regardless of the thoroughness of an approved warning, juries would be free to second-guess the FDA's judgment. Such a regime would stifle innovation and slow the process of bringing important new therapies to market – the exact opposite outcome the Legislature intended when adopting the PLA.

If Plaintiffs' interpretation were the law in New Jersey, the presumption would be overcome in any case in which evidence can be cherry-picked from a voluminous record to make allegations like those here. But as the Supreme Court's and this Court's decisions show, those types of criticisms do not overcome the presumption of adequacy. See, e.g., Kendall, 209 N.J. at 195 ("[O]nly in the 'rare case' will damages be assessed against a manufacturer issuing FDA-approved warnings." (emphasis

added) (quoting Perez, 161 N.J. at 25)); Bailey, 424 N.J. Super. at 324 (concluding that, although certain manufacturer conduct "may have been less than exemplary," presumption not overcome), aff'd, DeBoard, 422 N.J. Super. at 362 (affirming Bailey as "legally unassailable").

Nor would faithfully applying the PLA and honoring the intent of the Legislature compromise patient safety. Continuing to require intentionality and materiality would adhere to the Legislature's guidance while still prohibiting and deterring intentional misconduct. When those elements are absent, the courts should defer to the FDA's expertise and robust regulatory process. That approach, mandated by the PLA, ensures appropriate oversight of the industry without stifling the innovation that bolsters New Jersey's economy and advances the broader public health.

CONCLUSION

For the foregoing reasons, this Court should affirm New Jersey's virtually dispositive, super-presumption of adequacy and uphold the trial court's ruling that the warnings at issue here were adequate as a matter of New Jersey law.

Respectfully submitted,

McCARTER & ENGLISH, LLP
Attorneys for Amicus Curiae
The HealthCare Institute of
New Jersey

By: _____
Edward J. Fanning, Jr.
A Member of the Firm

Dated: November 9, 2015

ADDENDUM A

Member Companies of The HealthCare Institute of New Jersey (HINJ)

Abbott Point of Care, Inc.

Allergan

Amgen

Amicus Therapeutics, Inc.

Astellas Pharma U.S., Inc.

BD

Bayer HealthCare Pharmaceuticals

Bristol-Myers Squibb Company

C.R. Bard, Inc.

Catalent Pharma Solutions

Celgene Corporation

Daiichi Sankyo, Inc.

Eli Lilly and Company

Emisphere Technologies, Inc.

Immunomedics, Inc.

Johnson & Johnson

Merck & Co., Inc.

Novartis Pharmaceuticals Corporation

Novo Nordisk, Inc.

Pfizer Inc.

Roche Diagnostics Corporation

Shire

Stryker

Sunovion Pharmaceuticals Inc.