MISTI BLESSING, an individual, and DAVID R. BLESSING, an individual, Plaintiffs-Petitioners, -vs- JOHNSON & JOHNSON, a corporation, JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC., a corporation, ETHICON, INC., a corporation, ABC CORPORATION 1-10 (said names being fictitious and unknown), and JOHN DOE, M.D.'s 1-10 (said names being fictitious and unknown), Defendants-Respondents.	SUPREME COURT OF NEW JERSEY DOCKET NO. 065714 CIVIL ACTION ON CERTIFICATION FROM SUPERIOR COURT, APPELLATE DIVISION DOCKET NO. A-003561-08T3 ENTERED MARCH 5, 2010 SAT BELOW: HON. SUSAN L. REISNER, J.A.D. HON. AMY PIRO CHAMBERS, J.A.D.

BRIEF OF *AMICUS CURIAE* NEW JERSEY LAWSUIT REFORM ALLIANCE IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

PRELIMINARY STATEMENT

The New Jersey Lawsuit Reform Alliance ("NJLRA") submits this Brief as *Amicus Curiae* in support of Respondents, Johnson & Johnson, Johnson & Johnson Health Care Systems Inc. and Ethicon, Inc. (collectively, "Johnson & Johnson" or "Defendants"). As explained in Johnson & Johnson's Brief in Opposition to the Petition for Certification, and as held by the Appellate Division below, Plaintiffs' claims in this case are untimely under a straight-forward application of the relevant statute of limitations. The Appellate Division also correctly concluded that, based on the facts of this case, an evidentiary hearing was unnecessary.

Moreover, the Appellate Division's conclusions are consistent with the predominant policy and equitable concerns underlying New Jersey's Products Liability Act and the State's public policy of protecting the relationship between the pharmaceutical and medical device industry and our economy and public health. Preserving and protecting New Jersey's business and economic environment requires prompt resolution of claims of product-related injury. Requiring pharmaceutical companies to defend against claims long after the injury occurred places an unfair burden on the defendants to oppose allegations after evidence has been lost and the memories of witnesses have faded. Moreover, extending the time in which a product-related claim may be pursued may subject defendants to perpetual litigation, depriving them of the efficiency of coordinated litigation and

the predictability of a known end to the allegations. Further, overlooking the statute of limitations and long-established discovery rule based on allegations like those of these Plaintiffs will discourage internal review boards and risk assessment by pharmaceutical companies. Indeed, the statute of limitations may be eviscerated where there is, or may be, action by the federal Food & Drug Administration ("FDA") or where the plaintiffs rely on the absence of publicity. A cause of action for failure to warn may be used by plaintiffs to toll the limitations period.

Finally, imposing on trial courts an obligation to conduct a full evidentiary hearing in cases where there is no issue of credibility would be an unwarranted and wasteful expenditure of judicial resources. If a trial court, in its discretion, believes that a plaintiff's testimony is sufficient to ascertain whether the discovery rule should be invoked that determination should not be disturbed.

The Appellate Division correctly concluded that the Plaintiffs in this case, aware of the injuries and informed of both their product-related cause and fault, could reasonably have brought their claims at the time of the injuries in 2002, and thus, the case should be barred by the two-year statute of limitations. Moreover, the Appellate Division correctly concluded that an evidentiary hearing was unnecessary, as the credibility of the Plaintiff was not in dispute. For these

reasons, NJLRA respectfully submits this brief in support of affirming the Appellate Division's decision.

INTEREST OF *AMICUS CURIAE*

The NJLRA is a statewide, bipartisan group of individuals, businesses and organizations dedicated to improving New Jersey's civil justice system. NJLRA believes that a balanced civil justice system fosters public trust and motivates professionals, sole proprietors and businesses to provide safe and reliable products and services, while ensuring that truly injured people are compensated fairly for their losses. Such a system is critical to ensuring fair and open courts, maintaining and attracting jobs, and fostering economic growth in New Jersey.

STATEMENT OF FACTS

The NJLRA adopts and incorporates by reference the Statement of Facts contained in the Brief of Defendants-Respondents Johnson & Johnson, Johnson & Johnson Health Care Systems Inc. and Ethicon, Inc. In Opposition to Plaintiff-Petitioners' Petition for Certification, dated April 12, 2010. (Defs.' Br. 5-9).

PROCEDURAL HISTORY

Johnson & Johnson moved for summary judgment, based on the two-year statute of limitations. On March 3, 2009, the Superior Court, Law Division, granted Defendants' motion and dismissed Plaintiffs' Complaint with prejudice. Plaintiffs appealed, and by *per curiam* opinion dated March 5, 2010, the Appellate

Division affirmed the grant of summary judgment. On March 22, 2010, Plaintiffs petitioned for certification. This Court granted certification on June 3, 2010. Blessing v. Johnson & Johnson, et al., 202 N.J. 345 (2010).

ARGUMENT

I. The Appellate Division Correctly Concluded That the Plaintiffs' Cause of Action Accrued at the Time of Her Injuries.

Plaintiffs' claims in this case are governed by a two-year statute of limitations. N.J.S.A. 2A:14-2. Although the statute of limitations normally begins to run at the time of injury, in certain cases the statute does not begin to run "until the injured party discovers, or by an exercise of reasonable diligence and intelligence should have discovered that he may have a basis for an actionable claim." Lopez v. Swyer, 62 N.J. 267, 272 (1973).

The key elements of this so-called "discovery rule" are "the injured party's awareness of the injury and the fault of another." Savage v. Old Bridge-Sayreville Med. Group, P.A., 134 N.J. 241, 243(1993). In applying the "discovery rule," the court must determine whether the facts present would alert a reasonable person, exercising ordinary diligence, that he or she was injured due to the fault of another. Caravaggio v. D'Agostini, 166 N.J. 237, 246 (2001). In this context, "knowledge of fault denotes only facts suggesting the possibility of wrongdoing." Savage, 134 N.J. at 248. In other words, "'knowledge of fault' for purposes of the discovery rule

has a circumscribed meaning: it requires only the awareness of facts that would alert a reasonable person exercising ordinary diligence that a third party's conduct may have caused or contributed to the cause of the injury and that the conduct itself might possibly have been unreasonable or lacking in due care." Id. Knowledge of fault, however, does not require knowledge of a basis for legal liability or of a specific cause of action. Id.

In cases involving injuries incurred as a result of medical treatment, fault is typically considered self-evident and knowledge is acquired simultaneously with knowledge of causation and injury. See Caravaggio, 166 N.J. at 246; Tramutola v. Bortone, 118 N.J. Super. 503, 512-13(App. Div. 1972)(fault evident where wrong tooth was extracted). In every case identified by Plaintiffs involving a medical injury where knowledge of fault was not acquired simultaneously with knowledge of injury, the plaintiff received some independent assurance suggesting an innocent alternative explanation for the injury. See, e.g., Caravaggio, 166 N.J. at 253 (plaintiff lacked knowledge of physician's potential fault in breaking of rod placed in leg during surgery, because he indicated that there must have been something "structurally wrong" with it); Martinez v. Cooper Hospital-University Medical Center, 163 N.J. 45, 58 (2000)(plaintiff lacked knowledge of potential fault, because physician indicated "that everything was done properly"); Lynch v. Rubacky, 85 N.J. 65, 67-68 (1981)(plaintiff

lacked knowledge of physician's potential fault for severe ankle pain, because he continually indicated pain was due to original injury and healing process); Lopez v. Swyer, 115 N.J. Super. 237, 241 (App. Div. 1971), aff'd 62 N.J. 267, 272 (1973)(plaintiff lacked knowledge of physician's potential fault, because he explicitly informed plaintiff's husband "this was not malpractice").

In this case, Plaintiff received no assurances, and, in fact, was expressly informed that the failure of the sutures to dissolve as intended caused her injuries. Thus, the medical malpractice cases relied on by Plaintiffs are inapposite. Pursuant to the discovery rule and based on this Plaintiff's deposition testimony, fault was self-evident to Plaintiffs. A reasonable person, having experienced two prior Cesarean sections, would certainly not regard a six-month post-operative infection that caused bleeding, holes in her abdomen, and the reopening of her incision, and required corrective surgery including the removal of sutures, which resulted in additional bleeding, immobility, and prolonged pain and suffering for another six months, as an expected consequence of either the surgery or the use of surgical sutures. These are the circumstances that made fault self-evident to this Plaintiff and triggered her duty to investigate. Nevertheless, Plaintiff testified her doctor told her the sutures failed to perform as intended. Her knowledge of fault in 2002 was both self-evident and informed. Thus, the Appellate Division correctly concluded

that the statute of limitations began to run at the time of Plaintiff's injuries.

There is no law that requires plaintiffs to know the medical science, or "why and wherefore" of product defect. The mere fact that this Plaintiff contends she did not know the absorption rate of the sutures has no impact on Plaintiff's knowledge of injury, causation and fault, the statute of limitations or the discovery rule.

The Appellate Division's conclusions are also consistent with the underlying purpose of New Jersey's statute of limitations. This Court has often stated that the purposes of statutes of limitations are to stimulate litigants to pursue their claims within a reasonable time so that the opposing party may have a fair opportunity to defend itself, to penalize dilatoriness and to provide a measure of security and stability to potential defendants. See Gantes v. Kason Corp., 145 N.J. 478, 486 (1996); Savage, 134 N.J. at 248; Rivera v. Prudential Property & Casualty Ins. Co., 104 N.J. 32, 39(1986); O'Keeffe v. Snyder, 83 N.J. 478, 491 (1980). Plaintiffs' claim in this case lapsed because they failed to pursue it within a reasonable time. Within two years of Plaintiff's injuries, other products liability actions were commenced against these Defendants for similar injuries. In addition, Plaintiffs contend that numerous adverse events were reported to the FDA. Had Plaintiffs conducted a reasonable investigation at the time of Plaintiff's injuries, they could and would have discovered the pending

litigation, as well as the alleged adverse event reports, and brought a timely claim.

The very means by which Plaintiff claims to have "discovered" her claims support the conclusion that timely investigation would have resulted in timely litigation. Plaintiff testified she saw a television program and heard that someone else had a problem with the sutures. There is no suggestion that the television program that spurred Plaintiff to action attributed fault to Defendants. Indeed, Plaintiff testified that, once she learned others had suffered similar injuries, she chose to explore the issue further and was contacted by an attorney. Other complaints were relevant to this Plaintiff. Had she made any inquiry in 2002 into whether someone else alleged a problem with the sutures that failed to dissolve as intended and caused her injuries or whether the sutures were the subject of other complaints or adverse event reports, she would have discovered the same thing she contends she discovered in 2006 and promptly pursued her claims. Instead, Plaintiff did nothing, asked no questions, and her claims lapsed.

Moreover, the Appellate Division's conclusions are consistent with the fundamental difference between medical malpractice and products liability claims under New Jersey law. In the cases relied on by Plaintiffs, the discovery rule tolled the statute of limitations on medical malpractice claims, where the potential defendant provided the injured party misleading

information regarding fault or negligence -- an essential element of establishing a claim. Such a conclusion is consistent with the application of the discovery rule as an equitable remedy. Under New Jersey's products liability law generally, and Plaintiffs' complaint in this case specifically, however, product defect claims are subject to a strict liability standard -- which requires no finding of fault on the part of the defendant. See, e.g., Greenway Dev. Co. v. Borough of Paramus, 163 N.J. 546, 556 (2000). The discovery rule is a rule of equity. Lopez, 62 N.J. at 273. As such, this Court must not only determine whether equity should permit a potential plaintiff, who is unaware of a cause of action, to pursue her claim, but also whether equity should require a party to defend against stale allegations. Id. at 274-75.

In this case, it would be inequitable to compel Defendants to defend a more than five year old products liability claim based on the contention that Plaintiff was unaware of Defendants' alleged "fault," when "fault" is not an element of the cause of action alleged. This Court implicitly endorsed such a distinction in Savage, observing that "the issue is not whether plaintiff should be deemed constructively aware that a defect in the product caused her condition, but rather whether she should have been aware of the possibility that a lack of care in administering the medication had caused her condition." Savage, 134 N.J. at 249. Inasmuch as "lack of care" is irrelevant to liability in a products claim, it would be

inequitable to toll the statute of limitations because Plaintiffs contend their knowledge of injury and causation and that the sutures failed to dissolve as intended does not equate with knowledge of "fault."

For these reasons, the Appellate Division's conclusion that Plaintiffs' cause of action accrued at the time of her injury should be affirmed and Plaintiffs' case was correctly dismissed as barred by the two-year statute of limitations.

II. The Appellate Division Correctly Concluded That Plaintiffs Fail to Satisfy the Requirements of Equitable Estoppel.

Plaintiffs' contention that the statute of limitations should be tolled because Defendants concealed information regarding the defect in the sutures from the "medical community" cannot be credited. Plaintiffs do not identify the information that Defendants allegedly concealed so as to cause Plaintiffs to miss the filing deadline. Defendants' mere denial of liability, alleged failure to warn or discontinuance of the product is not sufficient to toll the statute of limitations. Otherwise, the statute of limitations would be tolled in perpetuity in every products liability case.

One of the landmark cases on equitable tolling, and the one on which these Plaintiffs rely, is Trinity Church v. Lawson-Bell, 394 N.J. Super. 159 (App. Div. 2007). In Trinity Church, the Appellate Division held that the doctrine tolls the statute of limitations when the defendant "engages in conduct that is calculated to mislead the plaintiff into believing that it is

unnecessary to seek civil redress" or "wrongfully conceals or withholds information which it has a duty to provide to the plaintiff, thus causing the plaintiff to miss a filing deadline." Id. at 171 (citations omitted). A plaintiff must act with reasonable diligence after obtaining information needed to file suit and cannot rely on equitable estoppel if it has the information in time to comply with the statute of limitations. Id. at 171-72. The plaintiff in Trinity Church failed to satisfy the requirements, but also had all the information it required to file timely litigation or conduct a timely investigation after it was on notice of problems. Id. at 173-74.

Likewise, these Plaintiffs do not satisfy the requirements of equitable tolling. Beyond the allegation that Defendants convened a Quality Board, or risk assessment team, which discussed the PANACRYL™ suture and tracked and analyzed complaints, Plaintiffs take issue with Defendants' decision to discontinue the stand-alone suture in lieu of adding a warning. At the time, Defendants prepared a Media Standby Statement, Pa320, which Plaintiff told the Appellate Division she may have discovered if she performed research after her March 2002 surgery. See Plaintiff-Appellants' App. Div. Brief at 20. In the Media Standby Statement, Defendants identify, among other things, (1) "reported more foreign body reactions to PANACRYL suture, as a percentage of product sold, than for sutures that provide short-term wound support;" (2) "inflammation and

rejection" as foreign body reactions seen with the suture; and (3) "reported cases of significant inflammation and infection" as "serious reactions to PANACRYL suture." Pa320. The Media Standby Statement includes candid information about reported cases of foreign body reactions to the sutures.

Plaintiffs also suggest that Defendants "deceived their own sales force" in a Q&A designed to help sales representatives answer questions from the medical community. See Plaintiff-Appellants' App. Div. Brief at 11, 20. However, the Q&A on which Plaintiffs rely, Pa319, is nearly identical to the Media Standby Statement. Compare Pa319 with Pa320. The competent evidence merely reveals that Defendants discontinued the sutures. The Appellate Division correctly held there is no evidence that Defendants caused Plaintiffs to miss the filing deadline.

Moreover, the PANACRYL™ suture complaints filed prior to 2006 are evidence that Defendants did not conceal information so as to cause stale claims. In the Ordway complaint, filed in October 2003, Da1, the plaintiff asserted product defect claims which this Plaintiff could and would have discovered if she timely investigated. For example, Ms. Ordway alleged:

(1) "During 2002, Defendants … were aware that Panacryl had only been minimally tested and that this product contained a material and/or coating that was toxic to human skin tissue." Da5 at ¶ 26.

(2)Defendants "failed to perform adequate testing and/or the limited testing that they did perform indicated that such suture material was prone to cause infection and the destruction of human skin tissue … ." Da6 at ¶ 27.

(3) Defendants "marketed and sold the Panacryl product without conducting reasonable testing, including long-term testing of the product as to its safety." Da6 at ¶ 29.

(4) Defendants were negligent in "failing to perform life-time animal tests on Panacryl or ignoring results of initial animal studies." Da10-11 at ¶ 47h.

(5) Defendants are liable for fraud in "failing to disclose that Panacryl was subject to cause tissue damage …;" "concealing that Panacryl was not fully tested, …;" "misrepresenting that Panacryl had been tested and was safe …;" "representing that Panacryl would be absorbed by the body …;" and "misrepresenting that the product had been safety tested … [.]" Da12-13 at ¶ 51.

(6) "Defendants made the misrepresentations … with the intention: (a) that Plaintiff's doctors and the medical community would rely on them …, and (b) that the FDA would rely on them in permitting the use of Panacryl sutures." Da13 at ¶ 56.

Had Plaintiffs timely investigated, they could have discovered the same basis for their product defect claims as those alleged in Ordway. Plaintiffs' attorneys contend the other complaints, and specifically Ordway, are irrelevant to this litigation. Putting to one side that the other complaints were not irrelevant to Plaintiff when she saw on television that another patient (or other patients) had problems with sutures, in their reply brief, Plaintiffs state that Ms. Ordway's physician may have had other patients with adverse reactions, "put two and two together and advise Ms. Ordway of the possibility that Panacryl was the culprit." Prb5-6. Plaintiffs themselves, therefore, depend on the conclusion that Defendants did not conceal information and that the medical community was not misled.

Accordingly, the Appellate Division's conclusion that the statute of limitations is not tolled by the doctrine of equitable estoppel was proper and should be affirmed.

III. The Appellate Division Correctly Concluded that an Evidentiary Hearing was not Warranted.

In cases where the credibility of witnesses is an issue in determining the applicability of the discovery rule, an evidentiary hearing is warranted. Lopez, 62 N.J. at 275. Where such concerns do not exist, however, "affidavits, with or without depositions, may suffice" Id. This Court has previously concluded that where "the record [] unquestionably establishes plaintiffs' awareness of the essential facts, no formal hearing [is] necessary to resolve the discovery rule issue. Lapka v. Porter Hayden Co., 162 N.J. 545, 558 (2000). The determination of whether to conduct a hearing is matter for the discretion of trial court. Lopez, 62 N.J. at 275.

Here, neither party disputes that Plaintiff was aware that she had suffered an infection, that the infection was caused by the use of the sutures, and that the sutures failed to dissolve as intended. The issue in this case centers on whether that knowledge was legally sufficient to alert Plaintiff that her injuries may have been caused by the fault of another. The trial court and Appellate Division's determination that this purely legal issue could be resolved without a wasteful and unnecessary evidentiary hearing was sound and should be affirmed.

IV. The Appellate Division Should be Affirmed in light of the NJPLA and Public Policy.

The Appellate Division's decision is consistent with the underlying purpose of the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq. ("NJPLA"). The NJPLA, as this Court has previously noted, was enacted to limit "the liability of manufacturers of FDA-approved products by reducing the burden placed on them by product liability litigation." Rowe v. Hoffmann-La Roche, 189 N.J. 615, 626 (2007); see also Shackil v. Lederle Laboratories, 116 N.J. 155, 187 (1989) (NJPLA evidenced "an intent to limit the expansion of products-liability law"). In Rowe, the Court further observed, "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." 189 N.J. at 626.

These Plaintiffs challenge Defendants' decision to discontinue marketing PANACRYL™ as a stand-alone suture rather than add a warning to the package insert, Pa423; Pa424. Adoption of Plaintiffs' equitable estoppel argument based on Defendants' actions - particularly in the absence of any evidence that Defendants caused Plaintiffs' delay - will discourage Quality Boards, or risk assessment teams, and deter medical device manufacturers from discussing, recommending and/or taking any corrective or remedial action. Such a result is antithetical to the predominant purpose of the NJPLA as it applies to FDA-approved products.

Plaintiffs' equitable tolling argument also may eviscerate the statute of limitations entirely in cases involving FDA-approved medical devices and medications. Every plaintiff may rely on a potential recall, investigation or other FDA action to toll the statute of limitations. Additionally, plaintiffs will seek to be excused for their delay if investigations are not publicized on television, in the print media or on the internet. Even if there is publicity, plaintiffs may rely on failure to warn claims - or the other causes of action that form the basis for their complaints - to support their tolling argument. The effect, again, will be to discourage internal review boards and risk assessment. Further, defendants will remain without protection from stale claims. There will be no uniformity of standards and predictability in connection with the statute of limitations or the discovery rule.

Equitable estoppel may deny a defendant "the benefit of the statute of limitation where, by its inequitable conduct, it has caused a plaintiff to withhold filing a complaint until after the statute has run." Trinity Church, 394 N.J. Super. at 171 (citation omitted). The principle, however, must be limited to those circumstances if the statute of limitations and discovery rule are to have any meaning and rationale supported in equity and if the intent is to promote fairness with predictability and uniformity of outcome. In this case, the Appellate Division recognized that Plaintiffs fail to satisfy the "exacting" requirements of equitable estoppel and that Plaintiffs had

information in sufficient time to comply with the statute of limitations. PETa9-10. Most compelling is that Plaintiffs fail to offer any competent evidence that Defendants caused them to miss the filing deadline.

Finally, Plaintiff herself contends she knew in 2002 that the sutures caused her injuries because they failed to dissolve as intended. The facts provided by Plaintiff more than satisfy the standard of knowledge that is required to start the limitations period. There is no evidence that Plaintiff was misled or dissuaded from filing litigation, and she concedes that Defendants did not prevent her from investigating. This case fits the rule, not the exception, and in the interests of equity and uniformity of result, as well as public safety, this Court should apply the rule and affirm the Appellate Division.

CONCLUSION

For all of the forgoing reasons, and all the reasons stated in Defendants' papers, the decision of the Appellate Division should be affirmed.

Respectfully submitted,

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Dated: September 8, 2010