SYLLABUS

(This syllabus is not part of the opinion of the Court. It has been prepared by the Office of the Clerk for the convenience of the reader. It has been neither reviewed nor approved by the Supreme Court. Please note that, in the interest of brevity, portions of any opinion may not have been summarized.)

Vonnie Cornett v. Johnson & Johnson and Cordis Corp. (A-88/89-10) (066671)

Argued January 30, 2012 -- Decided August 9, 2012

CUFF, P.J.A.D. (temporarily assigned), writing for a unanimous Court.

In this appeal, the Court considers whether plaintiff filed her complaint within the statute of limitations, whether the law of Kentucky or New Jersey applies, and whether the various state statutory and common law claims in this case are preempted by federal law governing approval of the Cypher® stent, a Class III medical device that was subject to the rigorous pre-market approve (PMA) process of the Food & Drug Administration (FDA).

Billie Cornett resided in Kentucky and suffered from coronary artery disease. On December 16, 2004, Billie received an implant of a Cypher® stent, manufactured by Cordis Corp., a wholly-owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Jersey. Billie also had diabetes. Use of the Cypher® stent on a patient with coronary heart disease and diabetes is considered "off-label" but not necessarily medically contraindicated. On May 18, 2005, five months after surgery, Billie suffered a subacute stent thrombosis in the area where the Cypher® stent was placed. He died on May 31, 2005, as a result of the thrombosis. Billie lived and worked in Kentucky. He received all medical care in Kentucky.

On September 15, 2008, Vonnie Cornett, the executor of the estate of Billie Cornett, and others from sixteen states and New Jersey filed forty-eight complaints against defendants Johnson & Johnson and Cordis for injuries allegedly resulting from use of the Cypher® stent. In response to a motion to dismiss that argued all causes of action pled by plaintiffs were preempted by the Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act (FDCA), plaintiffs requested permission to file an amended complaint and did so bearing the Cornett caption. All complaints have been consolidated and the Cornett complaint was designated the Master Complaint. Defendants moved to dismiss the amended Master Complaint. The motion judge dismissed the amended Master Complaint in its entirety.

The motion judge held the Cornett complaint time-barred and all claims preempted by federal law. On appeal, the Appellate Division affirmed the dismissal of the Cornett complaint as time-barred. Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 382-83 (App. Div. 2010). The panel concluded a conflict of laws existed and the law of Kentucky governed, and held the complaint barred by Kentucky's one-year statute of limitations. The panel held the following claims were not preempted by federal law: manufacturing defect; failure to warn of approved and off-label uses to the extent plaintiffs alleged failure to satisfy federal disclosure requirements or federal limitations on off-label promotion within the statutory safe harbor; and breach of express warranty to the extent plaintiffs based their claim on voluntary statements relating to approved uses or off-label uses outside the safe harbor. The panel held the remaining claims, other than the breach of implied warranty, preempted by federal law. In addition, the panel held the Product Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11, subsumed the breach of implied warranty claim; therefore, the motion judge properly dismissed this claim.

The Supreme Court granted the parties' cross-petitions for certification to consider whether the Cornett complaint is time-barred and whether the failure to warn of approved and off-label uses and breach of express warranty claims are preempted by federal law. 205 N.J. 317 (2011).

HELD: The Cornett complaint is time-barred. The failure to warn claim as to approved and off-label uses is preempted, except to the extent plaintiffs base the claim on allegations of deliberate non-disclosure or fraudulent representations of known adverse information apart from defendants' failure to comply with FDA disclosure requirements or promotion of off-label uses outside the safe harbor. The breach of express warranty claim is also preempted, except to the extent plaintiffs allege defendants have made voluntary statements to third parties beyond and different from the information on the approved label or packaging.

1. A New Jersey court will apply the statute of limitations of another state if that state has a greater interest in the litigation. When this state and another state have conflicting statutes of limitations, the Court applies the same test governing choice of substantive law. Choice of law is not an issue unless there is a real conflict between the law of two jurisdictions. In Kentucky, a personal injury action must "be commenced within one (1) year after the cause of action accrued . . . ." Ky. Rev. Stat. Ann. § 413.140(1)(a). Generally, a cause of action accrues at the time of the harm; however, in some cases the cause of action accrues when the plaintiff discovers the injury or should have reasonably discovered it. The question is at what point did information become available that would have alerted a reasonable person to begin an inquiry into a possible cause of action? (pp. 9-14)

2. N.J.S.A. 2A:14-2 provides that a cause of action for personal injury must be filed within two years of accrual of the cause of action. In a product liability action, a cause of action generally accrues on the date of injury. However, the discovery rule is applied to product liability actions, including actions alleging defects in medical devices. Here, it is clear that no conflict of laws exists between New Jersey and Kentucky. Both states apply the discovery rule. Kentucky requires filing of a complaint within one year of accrual of the cause of action; New Jersey requires filing within two years of accrual. This difference, however, does not create a true conflict of laws, unless the differences are offensive or repugnant to the public policy of this state. Applying Kentucky law, the Court concludes that a person exercising reasonable diligence should have discovered by December 2006 that the Cypher® stent implanted in December 2004 may have caused the May 18, 2005 thrombosis. Accordingly, the September 15, 2008 complaint was not timely, and the Cornett action was properly dismissed. (pp. 14-18)

3. Plaintiffs' failure to warn and breach of express warranty claims implicate the preemption rule. An applicant for pre-market approval (PMA) of a Class III device must demonstrate its safety and effectiveness. PMA incorporates an FDA finding that a device is safe and effective under the conditions of use included on the label and that the label is not false or misleading. In addition, Congress has provided a safe harbor for manufacturers of Class III devices to "disseminate" to health-care providers peer-reviewed articles or "reference publications" "concerning the safety, effectiveness, or benefit of a use not described in the approved labeling . . . ." 21 U.S.C.A. §§ 360aaa, 360aaa-1. Congress chose to include in the Medical Device Amendments of 1976 (MDA) an express preemption provision against state standards for PMA devices that would be stricter than the MDA, but a state common law claim may also be impliedly preempted. On the other hand, when the so-called fraud-on-the-FDA claim is founded on deliberate non-disclosure of material information or deliberate misrepresentations of known facts, the claim may not be preempted. (pp. 18-29)

4. The permissible theories of a product liability action are manufacturing defect, defective design, or failure to warn through adequate warnings or instructions. N.J.S.A. 2A:58C-2. The standard for liability is that the product is "not reasonably fit, suitable or safe for its intended purpose . . . ." Ibid. The FDA-approval of the Cypher® stent, including the label and instructions, communicates that defendants demonstrated the safety and effectiveness of the product for its approved uses. Defendants who comply with FDA requirements are granted a rebuttable presumption that the labeling is adequate. The failure to warn claim in this case falls within the rebuttable presumption and the Court affirms its dismissal. Moreover, to the extent plaintiffs' failure to warn claim is based solely on a contention that defendants obtained FDA approval for the device only after submitting fraudulent representations to or withholding material information from the FDA, the Court affirms its dismissal. To the extent plaintiffs' failure to warn claim is based on other allegations of wrong-doing apart from defendants' failure to comply with FDA disclosure requirements, it is not preempted. To the extent plaintiffs' failure to warn claim is founded on promotion by defendants of off-label uses of the device beyond the safe harbor, that claim is not preempted. However, to the extent the breach of express warranty claim is based on statements not approved by the FDA or mandated by the FDA about the use or effectiveness of the product for on-label or off-label uses, a breach of express warranty claim may proceed because federal law requires any warranty statement to be truthful and accurate. If discovery reveals this claim is based solely on representations or statements derived from the FDA approved label or packaging, a motion for summary judgment would be appropriate. (pp. 29-40)

The judgment of the Appellate Division is **AFFIRMED AS MODIFIED**.

JUSTICE LaVECCHIA and JUDGES WEFING, RODRIGUEZ, and FUENTES (all temporarily assigned) join in JUDGE CUFF's opinion. CHIEF JUSTICE RABNER and JUSTICES ALBIN, HOENS, and PATTERSON did not participate.

SUPREME COURT OF NEW JERSEY
A-88/89 September Term 2010
066671

VONNIE CORNETT, individually
and on behalf of the estate
of BILLIE CORNETT, deceased,

Plaintiff-Appellant
and Cross-Respondent,

v.

JOHNSON & JOHNSON and CORDIS
CORP.,

Defendants-Respondents
and Cross-Appellants.

Argued January 30, 2012 - Decided August 9, 2012

On certification to the Superior Court,
Appellate Division, whose opinion is
reported at 414 N.J. Super. 365 (2010).

Bruce D. Greenberg argued the cause for
appellant and cross-respondent (Lite DePalma
Greenberg, attorneys; Mr. Greenberg, Mayling
C. Blanco, Peter E. Seidman and Alastair
Findeis, members of the New York bar, on the
briefs).

Peter C. Harvey argued the cause for
respondents and cross-appellants (Patterson
Belknap Webb & Tyler, attorneys).

Ellen Relkin submitted a brief on behalf of
amicus curiae Kentucky Justice Association
(Weitz & Luxenberg, attorneys).

JUDGE CUFF (temporarily assigned) delivered the opinion of the Court.

On December 16, 2004, Billie Cornett received a drug-eluting stent to treat coronary artery disease. Five months later, a blood clot formed near the site of the stent and Billie Cornett suffered a subacute stent thrombosis. Eleven days later, he died. On September 15, 2008, his widow, Vonnie Cornett, filed suit in New Jersey seeking damages for the injuries suffered by her husband and his estate.

This appeal requires this Court to consider whether Vonnie Cornett filed her complaint within the statute of limitations, which requires this Court to determine whether the law of Kentucky or New Jersey applies to this case. The stent used in this case is a Class III medical device that was subject to the rigorous pre-market approval (PMA) process of the Food & Drug Administration (FDA). Therefore, we must also decide whether the various state statutory and common law claims are preempted by federal law governing approval of this medical device.

We conclude that the Kentucky statute of limitations governs this case and that Kentucky applies a discovery rule to product liability actions involving latent injuries and illnesses, but Cornett did not timely file her complaint. We also conclude that the great bulk of the state statutory and common law claims are preempted by federal law. The exceptions are the failure to warn claim for approved use to the extent it involves wrongdoing apart from defendants' failure to comply

with FDA disclosure requirements and for off-label use of the stent to the extent defendants improperly promoted that device, and the breach of express warranty claim for voluntary statements to third parties that deviate from the approved label and packaging information material.[1]

I.

A.

Billie Cornett resided in Kentucky and suffered from coronary artery disease. On December 16, 2004, Billie received an implant of a Cypher® stent to treat this condition. The Cypher® stent is manufactured by Cordis Corp., a wholly-owned subsidiary of Johnson & Johnson, which is a New Jersey corporation with its principal place of business in New Jersey.

The purpose of a stent is to prevent narrowing of an artery. The Cypher® stent is coated in a slow-release chemotherapy drug, Sirolimus, intended to inhibit or prevent the artery from narrowing through the buildup of new tissue. Sirolimus inhibits cell growth by blocking a key protein involved in cellular division. It is alleged that the polymer used to bind the drug to the bare metal of the stent irritates the wall of the artery. Also, in some patients Sirolimus prevents a thin layer of endothelial cells from growing over the

[1] At oral argument, defendants withdrew their challenge to the failure to dismiss the manufacturing defect claim.

stent after implantation, which creates a substantial risk of abrupt formation of a blood clot on the exposed stent.

Billie Cornett also had diabetes. Use of the Cypher® stent on a patient with coronary heart disease and diabetes is considered "off-label" but not necessarily medically contraindicated.[2] The Cypher® stent label recommended that patients should take aspirin or Plavix® for three months after implantation of the stent to prevent formation of a blood clot at the stent site.

On May 18, 2005, five months after surgery, Billie Cornett suffered a subacute stent thrombosis in the area where the Cypher® stent was placed. He died on May 31, 2005, as a result of the thrombosis. Billie Cornett lived and worked in Kentucky. He received all medical care in Kentucky.

B.

On September 15, 2008, Vonnie Cornett, the executor of the estate of Billie Cornett, and others from sixteen states and New Jersey filed forty-eight complaints against defendants Johnson & Johnson and Cordis for injuries allegedly resulting from use of the Cypher® stent, a medical device produced and distributed by defendants. In response to a motion to dismiss that argued all causes of action pled by plaintiffs were preempted by the

[2] As discussed in this opinion, "off-label" uses of a medical device are not contrary to law.

Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C.A. § 360c to 360m, plaintiffs requested permission to file an amended complaint and did so bearing the Cornett caption. The amended complaint asserted nine causes of action: strict liability for defective design, defective manufacture, and failure to warn; breach of implied warranty; breach of express warranty; consumer fraud; punitive damages; wrongful death; and loss of consortium. All complaints have been consolidated and the Cornett complaint has been designated the Master Complaint.[3] Defendants moved to dismiss the amended Master Complaint. The motion judge dismissed the amended Master Complaint in its entirety.[4]

The motion judge held the Cornett complaint was time-barred, and all claims were preempted by federal law. He

[3] Designation of a complaint as a master complaint is an administrative device to manage complex, consolidated cases efficiently and economically. In re Mercedes-Benz Tele Aid Contract Litig., 257 F.R.D. 46, 56 (D.N.J. 2009). The designation permits application of some of the case management techniques associated with a mass tort designation, such as filing of a standard pleading, motions and orders; common dispositive motions for issues that lend themselves to aggregate treatment; and a standard plan and schedule for discovery. See R. 4:38A; Administrative Directive #10-07; N.J. Judiciary, Mass Tort (Non-Asbestos) Resource Book (3d ed. 2007), available at http://www.judiciary.state.nj.us/mass-tort/MassTortSOP-NonAsbestosNovember2007WebVersion.pdf. Although a single complaint is designated the master complaint, each civil action remains distinct for purposes of judgment. In re Propulsid Prods. Liab. Litig., 208 F.R.D. 133, 141 (E.D. La. 2002).

[4] Because dismissal of the Master Complaint affected all consolidated actions, the judge also dismissed each consolidated complaint.

emphasized that plaintiffs relied heavily on decisions involving medications rather than medical devices and on cases decided before Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). The motion judge noted prescription medications are not subject to the express preemption provision of the statutory scheme governing approval of medical devices.

The motion judge did not permit plaintiffs to file another amended complaint regarding the express warranty claim because plaintiffs had already received one opportunity to file an amended complaint. Furthermore, the motion judge observed that the express warranty claim is based on the patient information guide and product identification card provided to the patient at surgery. However, that information had been approved by the FDA, and "is nothing more than a defective labeling/failure to warn claim," and preempted. Finally, the motion judge found the complaint lacked any allegations that the use of the device was off-label.

On appeal, the Appellate Division affirmed the dismissal of the Cornett complaint as time-barred. Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 382-83 (App. Div. 2010). The panel concluded a conflict of laws existed and the law of Kentucky, the place plaintiff's decedent resided, governed, id. at 381-82, and held the complaint barred by the Kentucky one-year statute of limitations, id. at 382-83. Addressing the

merits of the various causes of action pled in the Master Complaint, the panel held the following claims were not preempted by federal law: manufacturing defect; failure to warn of approved and off-label uses to the extent plaintiffs alleged failure to satisfy federal disclosure requirements or federal limitations on off-label promotion within the statutory safe harbor;[5] and breach of express warranty to the extent plaintiffs based their claim on voluntary statements relating to approved uses or off-label uses outside the safe harbor. Id. at 405-06. The panel held the remaining claims, other than the breach of implied warranty, preempted by federal law. Ibid. The panel held the Product Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11, subsumed the breach of implied warranty claim; therefore, the motion judge properly dismissed this claim. Id. at 404.

This Court granted the parties' cross-petitions for certification to consider whether the Cornett complaint is time-barred and whether the failure to warn of approved and off-label uses and breach of express warranty claims are preempted by federal law. 205 N.J. 317 (2011). We also granted the motion of the Kentucky Justice Association to appear as amicus curiae.

[5] As described infra, the manufacturer of an approved device may disseminate information to the medical community about uses of the device other than as expressly approved by the FDA as long as it complies with applicable regulations.

We now affirm with modification the judgment of the Appellate Division.

II.

The Appellate Division found a conflict of laws existed. Applying the "most significant relationship" test of the Restatement (Second) of Conflict of Laws § 145 (1971), recognized in P.V. v. Camp Jaycee, 197 N.J. 132, 138-43 (2008) as the appropriate test, the panel held that Kentucky law applied. Cornett, supra, 414 N.J. Super. at 379-82. The panel cited the long-term residency of the Cornetts in Kentucky and the medical care provided to Billie in Kentucky. Id. at 379. The panel also noted that Billie's health care providers purchased the Cypher® stent in Kentucky and his post-operative care occurred in that state. Ibid. Finally, Billie's health care providers received the warnings provided in that state. Id. at 380. Accordingly, the panel determined the one-year Kentucky statute of limitations applied and the complaint was untimely. Id. at 382. In doing so, the panel held that Kentucky law did not apply the discovery rule to product liability claims. Id. at 377.

Cornett argues the Appellate Division misapplied the most significant relationship test and this state's discovery rule. Defendants respond the Appellate Division correctly concluded Kentucky law applied to plaintiff's claim, and it is barred by

the Kentucky statute of limitations. In the alternative, they argue the New Jersey discovery rule would not alter the outcome.

Amicus curiae Kentucky Justice Association argues the Appellate Division panel misconstrued and misapplied Kentucky law. Amicus contends the discovery rule is not limited to medical malpractice actions and has been applied to product liability actions. Furthermore, under Kentucky law, the statute of limitations is triggered when a plaintiff becomes aware that he has been injured, and when a plaintiff became aware of the injury or should have become aware of the injury is a question of fact for resolution by a jury.

III.

The threshold issue is whether the Cornett complaint was filed within the statute of limitations. Given the residence of plaintiff and the venue of the litigation, the question of which law applies depends, in part, on which state's choice-of-law rules apply. In Heavner v. Uniroyal, Inc., 63 N.J. 130, 135-42 (1973), this Court rejected the rule that the statute of limitations of the forum state automatically applies. The Court held a New Jersey court will apply the statute of limitations of another state, if that state has a greater interest in the litigation. Id. at 140-41. In Gantes v. Kason Corp., 145 N.J. 478, 484 (1996), this Court held that when this state and another state have conflicting statutes of limitations, we apply

the same test governing choice of substantive law. See also Dreier, Keefe, and Katz, Current N.J. Products Liability & Toxic Torts Law, § 20:2-2 at 540 (2011). Thus, if a choice-of-law determination is necessary, it is made on an issue-by-issue basis, Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 621 (2007), and may result in the application of the law of more than one state to the several claims in a matter, Gantes, supra, 145 N.J. at 495-96. However, choice of law is not an issue unless there is a real conflict between the law of two jurisdictions. P.V., supra, 197 N.J. at 143; Rowe, supra, 189 N.J. at 629.

A.

The Kentucky statute of limitations for personal injuries caused by defective products is governed by Ky. Rev. Stat. Ann. § 413.140(1)(a), which provides that a personal injury action must "be commenced within one (1) year after the cause of action accrued . . . ." Generally, a cause of action accrues at the time of the harm, Caudill v. Arnett, 481 S.W.2d 668, 669 (Ky. 1972); however, in some cases the cause of action accrues when the plaintiff discovers the injury or should have reasonably discovered it. Kentucky adopted the discovery rule for medical malpractice actions in 1970, Tomlinson v. Siehl, 459 S.W.2d 166, 168 (Ky. 1970), and clarified its ruling in 1971, Hackworth v. Hart, 474 S.W.2d 377, 379 (Ky. 1971). In 1979, the Supreme Court of Kentucky extended the discovery rule to tort actions

for injury from a latent disease caused by exposure to harmful substances, including asbestos, "whether the action be based on negligence or on a products liability theory." Louisville Trust Co. v. Johns-Manville Prods. Corp., 580 S.W.2d 497, 501 (Ky. 1979). In doing so, the court explained its extension of the discovery rule as follows:

> We see no compelling policy-based reason for a distinction between when a plaintiff injured by medical malpractice and when a plaintiff injured by latent disease caused by exposure to a harmful substance must bring a lawsuit or be barred by limitations.
>
> Our own review of foreign authorities convinces us that this statement in Birnbaum's ["First Breath's" Last Gasp: The Discovery Rule in Products Liability Cases, 13 Forum 279 (1977)] is correct: "The clear trend, in most jurisdictions in cases dealing with drugs, chemicals and asbestos has been to apply some variation of the discovery rule which is based on equitable considerations. Courts have felt that the injured party should be allowed to have his day in court when his injury was of an inherently unknowable nature."
>
> [Id. at 500-01 (quoting Birnbaum, supra, at 285).]

Then, in 1991, the Supreme Court of Kentucky applied the discovery rule in a product liability action involving latent injuries caused by exposure to a component of a log home kit. Perkins v. Ne. Log Homes, 808 S.W.2d 809 (Ky. 1991). In doing so, the court clarified the distinction between knowledge of

injury and knowledge of the causal connection between the product and the disease, stating "in the circumstances presented the statute of limitations commences from the date the plaintiff knew or should have discovered 'not only that he has been injured but also that his injury may have been caused by the defendant's conduct.'" Id. at 818–19 (quoting Raymond v. Eli Lily & Co., 371 A.2d 170, 171 (N.H. 1977)).

Since that time, Kentucky courts and state and federal courts applying Kentucky law have applied the discovery rule to product liability actions alleging latent disease or injury caused by exposure to harmful substances, including medical devices. See, e.g., Whalen v. Stryker Corp., 783 F. Supp. 2d 977, 980–81 (E.D. Ky. 2011) (applying Kentucky discovery rule to product liability action for injury caused by implantable pain pump); Blanton v. Cooper Indus., Inc., 99 F. Supp. 2d 797, 801–03 (E.D. Ky. 2000) (applying Kentucky law, court recognized application of discovery rule for latent injuries caused by a product or substance, but found personal injury actions filed eight years after discovery of groundwater contamination linked to various cancers and five to seven years after multi-party personal injury action filed seeking damages for personal injuries linked to contamination untimely).

To be sure, the Supreme Court of Kentucky recently refused to extend the discovery rule to a product liability action

alleging a defect in a piece of electrical equipment. Fluke Corp. v. LeMaster, 306 S.W.3d 55, 56 (Ky. 2010). The Court also held the facts did not warrant application of the discovery rule because the "injury or offending instrumentality" was immediately evident. Id. at 61. Importantly, the Court reiterated that the discovery rule applies to product liability cases "involving latent injuries, latent illnesses, or professional malpractice . . . ." Id. at 56.

In short, contrary to the holding of the Appellate Division, Kentucky recognizes and applies the discovery rule to product liability actions involving latent injuries and latent illnesses. Vonnie Cornett alleges her husband suffered a latent injury caused by the drug used to coat the stent implanted in his body, thereby permitting the Kentucky discovery rule to be applied in this case.

Kentucky recognizes a distinction between knowledge of harm and knowledge of injury. Perkins, supra, 808 S.W.2d at 819; Louisville Trust, supra, 580 S.W.2d at 501; Whalen, supra, 783 F. Supp. 2d at 980. Application of the discovery rule requires an evaluation of what plaintiff knew about the cause of decedent's harm and when she knew it. Stated differently, the question is at what point did information become available that would have alerted a reasonable person to begin an inquiry into a possible cause of action? Under Kentucky law, whether a

plaintiff should have known or commenced an inquiry and when she was put on notice of a possible cause of action is a question of fact reserved to a jury. Lipsteuer v. CSX Transp., Inc., 37 S.W.3d 732, 737 (Ky. 2000). However, in the face of uncontroverted facts of actual notice or inquiry notice, the issue may be resolved by motion. Ibid.

B.

The next question is whether the New Jersey law on this issue conflicts with Kentucky law. N.J.S.A. 2A:14-2 provides that a cause of action for personal injury must be filed within two years of accrual of the cause of action. In a product liability action, a cause of action generally accrues on the date of injury. McGlone v. Corbi, 59 N.J. 86, 94 (1971). However, the discovery rule is applied to product liability actions, including actions alleging defects in medical devices, Baird v. American Medical Optics, 155 N.J. 54, 66 (1998), and actions alleging inadequate warnings of risks associated with a drug, Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 191-94 (2012), where the relationship between a plaintiff's injury and a defendant's fault is not self-evident.

As noted by Justice Long in Kendall, the discovery rule addresses the person who is unaware that he or she has a cause of action. Id. at 193. Yet, legal and medical certainty or understanding the legal significance of known facts is not

required for a claim to accrue. 209 N.J. at 193. Moreover, a plaintiff may not delay filing a claim until she obtains an expert to support the claim. Ibid. Rather, "[i]n cases in which fault is not self-evident at the time of injury, a plaintiff need only have 'reasonable medical information' that connects an injury with fault to be considered to have the requisite knowledge for the claim to accrue." Id. at 193-94 (quoting Vispisiano v. Ashland Chem. Co., 107 N.J. 416, 435 (1987)).

C.

Here, it is clear that no conflict of laws exists between New Jersey and Kentucky. Both states apply the discovery rule. Although Kentucky does not apply the discovery rule to all product liability actions, it does apply the discovery rule to latent injuries caused by product defects. To be sure, Kentucky requires filing of a complaint within one year of accrual of the cause of action; New Jersey requires filing within two years of accrual. This difference, however, does not create a true conflict of laws between these states, unless the differences are offensive or repugnant to the public policy of this state. State Farm Mut. Auto. Ins. Co. v. Estate of Simmons, 84 N.J. 28, 41-42 (1980); Wilson v. Faull, 27 N.J. 105, 123 (1958).

Here, the difference between the statute of limitations of each state is the length of time each state allows an injured

person to commence a personal injury action. In Kentucky, the Legislature has determined one year is sufficient; in New Jersey, the period is two years. This difference does not implicate the fundamental public policy of this state. Both limitation periods assure that personal injury actions will be filed promptly, while simultaneously discouraging stale claims. Gantes, supra, 145 N.J. at 486-87; Emberton v. GMRI, Inc., 299 S.W.3d 565, 573 (Ky. 2009).[6]

The Cornett claim falls squarely within the Kentucky discovery rule. Vonnie Cornett alleges a latent injury at the site of the drug-eluting stent implanted five months before her husband's death. This is the type of claim to which Kentucky law permits application of the discovery rule. The uncontroverted facts of record also permit resolution of the timeliness of this complaint as a matter of law.

On April 24, 2003, the FDA approved the pre-market application of the Cypher® stent for "use by physicians in patients with atherosclerotic obstructive coronary disease for whom the device is not contraindicated and in accordance with physicians' clinical judgment." It cautioned that any advertising should not include indications or claims not

[6] Even if a true conflict between the laws of Kentucky and New Jersey existed on this issue, we have no quarrel with the application of Kentucky law in this case. See Cornett, supra, 414 N.J. Super. at 379-82.

included in the FDA approval, citing use in diabetic patients. The approval letter also set limits and requirements on its approval, including the need to review clinical results and approve any changes to the device's label. The FDA's PMA of the Cypher® stent has never been revoked, suspended, or otherwise interrupted since April 2003. On the other hand, because the Cypher® stent is a PMA device, the FDA continues to monitor and regulate all aspects of the product, including its marketing, labeling and manufacturing.

In April 2004, one year after approval, Cordis received multiple warning letters from the FDA based on inspections of its Warren, New Jersey facility concerning systemic manufacturing deficiencies and adulterated Cypher® stents. In December 2006, the FDA announced that its Circulatory System Devices Advisory Panel (Advisory Panel) would examine thrombosis risks of Cypher® stents. The Advisory Panel concluded: 1) late stent thrombosis from drug-eluting stents was a problem; 2) there was a significantly increased risk of late stent thrombosis associated with death and myocardial infarction in patients who received drug-eluting stents for off-label indications as compared to those patients who received these stents for on-label uses; and 3) patients receiving stents should take Plavix® for an extended period of time.

Applying Kentucky law, we conclude that a person exercising reasonable diligence should have discovered by December 2006 that the drug-eluting stent implanted in December 2004 may have caused the May 18, 2005 thrombosis. Accordingly, the September 15, 2008 complaint was not timely, and the Cornett action was properly dismissed.

IV.

In spite of the dismissal of the Cornett action, we must address defendants' preemption claims because forty-eight complaints remain. Our consideration of this issue does not require a choice-of-law analysis because preemption is governed by federal law.

The Appellate Division held that all but three of the claims asserted in the amended Master Complaint are preempted by federal law. The three remaining claims are: 1) a manufacturing defect claim; 2) a failure to warn claim concerning approved and off-label uses; and 3) a breach of express warranty claim, but we need not address the manufacturing defect claim. See n.1. The surviving failure to warn claim concerning approved and off-label uses is limited to the allegation of failure to satisfy federal requirements on disclosure or federal limitations on off-label promotion within the safe harbor. The breach of express warranty claim is limited to the allegations of voluntary statements relating to

approved uses or voluntary statements about off-label uses that were outside the safe harbor.

Defendants argue that the Appellate Division incorrectly concluded that some, but not all, of plaintiffs' claims were preempted by federal law. Specifically, they contend that the failure to warn and breach of express warranty claims are preempted by federal law and United States Supreme Court precedent. Plaintiffs respond the amended Master Complaint adequately alleges parallel conduct; therefore, the breach of warranty and failure to warn claims are not preempted by federal law.

A.

1.

The use of a Cypher® stent on a person, such as Billie Cornett, who suffered from coronary artery disease and diabetes is an off-label use, which is permissible under the terms of the MDA. Plaintiffs' failure to warn and breach of express warranty claims implicate the preemption rule, which requires a brief examination of the purpose of the regulatory scheme, "'the ultimate touchstone' in every pre[]emption case." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485, 116 S. Ct. 2240, 2250, 135 L. Ed. 2d 700, 716 (1996) (quoting Retail Clerks Int'l Ass'n v. Schermerhorn, 375 U.S. 96, 103, 84 S. Ct. 219, 223, 11 L. Ed. 2d 179, 184 (1963)).

The MDA imposes "detailed federal oversight" on the introduction of new medical devices onto the market. Riegel, supra, 552 U.S. at 316, 128 S. Ct. at 1003-04, 169 L. Ed. 2d at 898. The level of federal oversight varies depending on the risks the devices present. Ibid. Class III devices, like the Cypher® stent, are given the greatest oversight and subjected to a rigorous PMA process. Id. at 317, 128 S. Ct. at 1004, 169 L. Ed. 2d at 898; see also Lohr, supra, 518 U.S. at 477, 116 S. Ct. at 2246-47, 135 L. Ed. 2d at 710. An applicant for PMA of a Class III device must demonstrate its safety and effectiveness for "the persons for whose use the device is represented or intended" and "with respect to the conditions of use prescribed, recommended, or suggested in the label . . . ." 21 U.S.C.A. § 360c(a)(2)(A)-(B). The applicant thus has to provide, among other things: 1) "a detailed description of the proposed conditions of use of the device," 21 U.S.C.A. § 360c(a)(3)(D)(i); 2) a sample label delineating the intended uses, 21 U.S.C.A. § 360e(c)(1)(F); and 3) "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective," 21 U.S.C.A. § 360e(c)(1)(A). A manufacturer also is required to give adequate directions for the use of a medical device such that a "layman can use a device safely and for the

purposes for which it is intended[,]" 21 C.F.R. § 801.5, and conform to section 801.15 requirements governing the appearance of the label.

PMA incorporates an FDA finding that a device is safe and effective under the conditions of use included on the label and that the label is not false or misleading. 21 U.S.C.A. § 360e(d)(1)(A), (d)(2). The manufacturer may not change the label, even to add warnings, until it submits the proposed change as part of a supplemental PMA application and obtains FDA approval. 21 U.S.C.A. § 360e(d)(6); see also Riegel, supra, 552 U.S. at 319, 128 S. Ct. at 1005, 169 L. Ed. 2d at 900. This preserves the balance during the rigorous PMA process between the imperative of safety and Congress's recognition of the importance of off-label uses to the continuing improvement of medical practice. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349-51, 121 S. Ct. 1012, 1017-19, 148 L. Ed. 2d 854, 861-63 (2001).

After approval, the devices are subject to additional reporting requirements. 21 U.S.C.A. § 360i(a)(1), (3). These include the obligation to: 1) inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know, 21 C.F.R. § 814.84(b)(2); and 2) report incidents in which the device may have caused or contributed to death or serious

injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, 21 C.F.R. § 803.50(a). Riegel, supra, 552 U.S. at 319–20, 128 S. Ct. at 1005, 169 L. Ed. 2d at 900. "The FDA has the power to withdraw [PMA] based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Ibid. (citing 21 U.S.C.A. §§ 360e(e)(1), 360h(e) (recall authority)).

Two decades after it enacted the MDA, Congress clarified that off-label uses of devices were not illegal per se by denying the FDA any power "to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C.A. § 396. See Buckman, supra, 531 U.S. at 350, 121 S. Ct. at 1018, 148 L. Ed. 2d at 862; Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989). Congress also provided a safe harbor for manufacturers of Class III devices to "disseminate" to health-care providers peer-reviewed articles or "reference publications" "concerning the safety, effectiveness, or benefit of a use not described in the approved labeling . . . ." 21 U.S.C.A. §§ 360aaa, 360aaa-1.[7]

[7] The safe harbor provisions discussed here, 21 U.S.C.A. §§ 360aaa through 360aaa-6, expired on September 30, 2006 pursuant

However, if a manufacturer wishes to disseminate such information, it must also apply for approval for the new use or certify it intends to do so. 21 U.S.C.A. § 360aaa-3(a).

Adherence to these rules makes the safe harbor absolute; "[n]otwithstanding . . . any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with" these rules "shall not be construed . . . as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device." 21 U.S.C.A. § 360aaa-6(b). The safe harbor thus mitigates the effect of 21 C.F.R. § 801.4 that requires even manufacturers that engage in no promotion of off-label uses to add label warnings about any off-label use of which they have notice. Riley, supra, 625 F. Supp. 2d at 781-83.

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to a sunset provision in the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 401(e), 111 Stat. 2296, 2364. Riley v. Cordis Corp., 625 F. Supp. 2d 769, 781 n.6 (D. Minn. 2009). To fill the gap created by expiration of the statute, the FDA published a good practices guide on the subject. FDA, Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Jan. 2009), available at http://www.fda.gov/oc/op/goodreprint.html (last visited July 18, 2012). The publication shows that "the FDA currently takes a position consistent with [21 U.S.C.A. §§ 360aaa through 360aaa-6] regarding the distribution of information about off-label uses . . . ." Riley, supra, 625 F. Supp. 2d at 782 n.7; Guidance for Industry, supra.

2.

Congress chose to include in the MDA an express preemption provision against state standards for PMA devices that would be stricter than the MDA:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.
>
> [21 U.S.C.A. § 360k(a).]

Three cases generally inform the question of whether the MDA preempts a state statutory or common law negligence action against a manufacturer of an allegedly defective medical device or whether the state law claim is a permissible parallel claim.

In Lohr, supra, 518 U.S. at 480–81, 116 S. Ct. at 2248, 135 L. Ed. 2d at 712–13, the plaintiff received a pacemaker that she alleged had a defective lead that caused the device to fail, which, in turn, caused a "complete heart block" requiring emergency surgery. The Court held that the plaintiff's state law claims were not preempted by federal law emphasizing that the particular device implanted in the plaintiff was not approved for use through a device-specific PMA process. Id. at

478-80, 503, 116 S. Ct. at 2247-48, 2259, 135 L. Ed. 2d at 711-12, 726. Therefore, the express preemption provision of the MDA did not apply. Id. at 501, 116 S. Ct. at 2258, 135 L. Ed. 2d at 725. Thus, 21 U.S.C.A. § 360k(a) preempts state law claims only when: 1) there is a federal requirement specific to a particular device; 2) a state law requirement relates to the safety or effectiveness of a device or to any other matter included in a requirement applicable to the device; and 3) a state requirement is different from or in addition to a federal requirement. Id. at 500-02, 116 S. Ct. at 2257-58, 135 L. Ed. 2d at 724-26. Parallel state claims are not preempted because they do not impose additional requirements or burdens on the manufacturer. Id. at 495-96, 116 S. Ct. at 2255-56, 135 L. Ed. 2d at 721-22.

In Riegel, supra, 552 U.S. at 321-22, 128 S. Ct. at 1006, 169 L. Ed. 2d at 901, the Court set forth a new two-prong analysis for determining whether a plaintiff's state law claims are preempted by U.S.C.A. § 360k(a). First, a court must determine whether the FDA has imposed requirements for the device. Ibid. Second, a court must determine whether the common law claims are based on state requirements different from or in addition to the federal requirements for the device. Ibid.

In Riegel, a surgeon used a Class III device, a catheter approved under the PMA regime, during a coronary angioplasty procedure on a patient whose condition made its use contraindicated. Id. at 320, 128 S. Ct. at 1005, 169 L. Ed. 2d at 900. The plaintiff asserted failure to warn claims grounded in state law. Ibid.

The Court held the PMA regime imposes labeling requirements specific to individual devices unlike general labeling duties under state law. Id. at 322–23, 128 S. Ct. at 1007, 169 L. Ed. 2d at 902. As such, the PMA regime established federal requirements for the device. Ibid. If the general state common law labeling duties are different from or in addition to the requirements imposed by federal law, the state common law claim is preempted by U.S.C.A. § 360k(a). Id. at 322, 128 S. Ct. at 1006, 169 L. Ed. 2d at 901. The Court reiterated the rule announced in Lohr that to escape preemption, the state claim premised on a violation of FDA regulations must be based on state common law duties parallel to but not in addition to federal requirements. Id. at 330, 128 S. Ct. at 1011, 169 L. Ed. 2d at 906 (citing Lohr, supra, 518 U.S. at 495, 116 S. Ct. at 2255, 135 L. Ed. 2d at 721).

A state common law claim may also be impliedly preempted. In Buckman, supra, 531 U.S. at 349 n.4, 121 S. Ct. at 1018 n.4, 148 L. Ed. 2d at 862 n.4, the Court held that state law claims

brought by individuals based on intentional misrepresentations to the FDA during or after the PMA process are barred. The Court held only the federal government is authorized to sue for failure to comply with the MDA provisions, including providing false or misleading information. Ibid. This so-called state fraud-on-the-FDA claim could interfere with the government enforcement effort; therefore, such claims are barred. Id. at 348-51, 121 S. Ct. at 1017-19, 148 L. Ed. 2d at 861-63.

The Court also elaborated on the circumstances in which parallel state claims will be preempted. It explained that a traditional state law cause of action is one that provides the required elements of a state cause of action with no reference to federal requirements as the measure of the reasonableness or wrongfulness of the manufacturer's conduct. Id. at 351-52, 121 S. Ct. at 1019, 148 L. Ed. 2d at 863. Thus, regardless of how a plaintiff styles a state claim, if the claim depends on the alleged violation of a federal requirement, it is functionally equivalent to a claim grounded solely on the federal violation, and is impliedly preempted. Id. at 352-53, 121 S. Ct. at 1019-20, 148 L. Ed. 2d at 864.

On the other hand, when the so-called fraud-on-the-FDA claim is founded on deliberate non-disclosure of material information or deliberate misrepresentations of known facts, the claim may not be preempted. In Desiano v. Warner-Lambert & Co.,

467 F.3d 85, 86-87 (2d Cir. 2006), aff'd sub nom. Warner-Lambert Co. v. Kent, 552 U.S. 440, 128 S. Ct. 1168, 170 L. Ed. 2d 51 (2008), the court considered whether a Michigan statute immunizing drug makers from liability for products approved by the FDA, except in cases of misrepresentation or withholding of information by drug makers, failed in the face of the Buckman implied preemption rule. The court held such fraud-based claims survive the Buckman rule. Id. at 98. In doing so, Judge Calabresi clarified the limits of the Buckman implied-preemption rule. He said:

> Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. Buckman underscored this fact, finding implied preemption of a newly-fashioned state cause of action only where (1) no presumption against federal preemption obtained, and (2) the cause of action, by assigning liability solely on the basis of fraud against the FDA, imposed significant and distinctive burdens on the FDA and the entities it regulates.
>
> [Ibid.]

The court also identified three features of the claim that precluded preemption: 1) the general presumption against preemption, id. at 93-94; 2) a fraud-based state claim in a traditional product liability action has been a long-recognized basis for liability, id. at 94-95; and 3) proof of fraud on the

FDA is not an element of the product liability claim pled by the plaintiffs, id. at 96-97.

B.

1. Failure to Warn.

Plaintiffs' failure to warn claim is based on the PLA. A product liability action is defined as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. 2A:58C-1b(3). The permissible theories of liability are manufacturing defect, defective design, or failure to warn through adequate warnings or instructions. N.J.S.A. 2A:58C-2. The standard for liability is that the product is "not reasonably fit, suitable or safe for its intended purpose . . . ." Ibid.

As to claims grounded in the failure of the manufacturer to provide adequate warnings, the Appellate Division noted the PLA "defined an adequate product warning 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 . . . .'" McDarby v. Merck & Co., 401 N.J. Super. 10, 62 (App. Div. 2008) (quoting N.J.S.A. 2A:58C-4), appeal dismissed, 200 N.J. 267 (2009). However, when the failure to warn claim implicates the label of or information provided with a medical

device, the prospect of preemption of the state law PLA claim arises. Kemp v. Medtronic, Inc., 231 F.3d 216, 236-37 (6th Cir. 2000), cert. denied, 534 U.S. 818, 122 S. Ct. 48, 151 L. Ed. 2d 19 (2001). Here, the Cypher® stent underwent the rigorous and individualized PMA process for Class III medical devices. The approval provided by the FDA communicates that defendants demonstrated the safety and effectiveness of the product for its approved uses. Moreover, that approval includes the label and instructions that accompany the device. The totality of the approval represents a specific federal requirement. Id. at 228. See also Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919, 929-30 (5th Cir. 2006); Riegel v. Medtronic, Inc., 451 F.3d 104, 118 (2d Cir. 2005), aff'd, 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008); McMullen v. Medtronic, Inc., 421 F.3d 482, 487-88 (7th Cir. 2005), cert. denied, 547 U.S. 1003, 126 S. Ct. 1464, 164 L. Ed. 2d 246 (2006); Horn v. Thoratec Corp., 376 F.3d 163, 170 (3d Cir. 2004).

Moreover, the Legislature recognized the preeminent role of federal regulation of drugs and medical devices by including a rebuttable presumption of the adequacy of labels and instructions in the PLA. N.J.S.A. 2A:58C-4 provides that a manufacturer that "communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the

persons by whom the product is intended to be used," will not be liable for a failure to warn under the PLA. Defendants who comply with FDA requirements are granted a rebuttable presumption that the labeling is adequate. Ibid. To overcome this presumption, a plaintiff asserting a failure to warn claim based on an inadequate label or instructions has stricter pleading requirements. A plaintiff must plead specific facts alleging "'deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects,'" Rowe, supra, 189 N.J. at 626 (quoting Perez v. Wyeth Labs., Inc., 161 N.J. 1, 24 (1999)), or "manipulation of the post-market regulatory process," McDarby, supra, 401 N.J. Super. at 63. This pleading specificity also serves to permit a determination whether a failure to warn claim is preempted by the MDA or is a permissible parallel state claim.

The amended Master Complaint grounds the failure to warn claim on concealment and/or material misrepresentations and understatements of the risks of the approved uses of the Cypher® stent, the risks associated with off-label uses of the device, and the need for long-term use of Plavix® or aspirin post-implantation. Specifically, the amended Master Complaint asserts defendants failed to inform the medical community and the general public about the unapproved uses of the device and that instructions for post-implantation therapy were not part of

the PMA process. The amended Master Complaint also alleges this conduct violated the PLA and parallel federal requirements, including general and specific conditions of the PMA of the device and regulations prohibiting promotion of adulterated and misbranded product and off-label marketing. Plaintiffs assert that an action invoking parallel state statutory and common law is necessary because "[t]he FDA has not adequately responded to the misconduct" cited by plaintiffs, and the agency "lacks the wherewithal to enforce its own requirements."

We, of course, review plaintiffs' factual allegations indulgently in the context of a motion to dismiss. Printing Mart-Morristown v. Sharp Elecs. Corp., 116 N.J. 739, 746 (1989). The failure to warn claim alleged by plaintiffs includes approved and off-label uses of the device. As to the approved uses of the Cypher® stent, the failure to warn claim relates to the duration of post-implantation anti-platelet therapy and the lack of comparative studies of the Cypher® stent and alternative devices. This claim is nothing more than a challenge to the adequacy of the information required by the FDA during the PMA process and label approved by the agency. This failure to warn claim falls within the PLA rebuttable presumption and the Riegel express preemption rule. We affirm its dismissal.

Moreover, to the extent plaintiffs' failure to warn claim is based solely on a contention that defendants obtained FDA

approval for the device only after submitting fraudulent representations to or withholding material information from the FDA, this claim falls squarely within the Buckman implied preemption rule. We affirm its dismissal. So, too, plaintiffs' failure to warn claim is preempted and dismissed to the extent that it can be established solely by evidence of fraud on the agency.

To permit these claims to proceed would directly interfere with the acknowledged exclusive authority of the FDA to enforce the FDCA. 21 U.S.C.A. § 337(a).[8] Furthermore, the claims threaten the delicate regulatory scheme created by Congress that simultaneously requires agency approval of medical devices, either through the rigorous PMA process or the more limited process for a device substantially equivalent to a predicate device,[9] and enforcement of disclosure requirements necessary to its work, while encouraging further research and development of medical devices and refraining from interfering with the practice of medicine. The enforcement mechanism is robust. The FDA may investigate allegations of fraud, 21 U.S.C.A. § 372, and may seek injunctive relief, 21 U.S.C.A. § 332, and civil

[8] 21 U.S.C.A. § 337(a) provides "[e]xcept as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." None of the exceptions in § 337(b) pertain to the claims asserted by plaintiffs.

[9] This process is commonly referred to as the § 501(k) process.

penalties, 21 U.S.C.A. § 333(f)(1)(A). It may also seize the device, 21 U.S.C.A. § 334(a)(2)(D), and pursue criminal prosecution, 21 U.S.C.A. § 333(a). The panoply of options available to the FDA permits the agency to pursue the remedies it considers appropriate under the particular circumstances of each instance of suspected fraud, while fulfilling its other regulatory responsibilities. A fraud-on-the-FDA claim has the potential to interfere with this delicate balance.

On the other hand, to the extent plaintiffs' failure to warn claim is based on other allegations of wrong-doing apart from defendants' failure to comply with FDA disclosure requirements, it is not preempted. Plaintiffs have alleged 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 PMA process, and misrepresented to the general public and medical community that the Cypher® stent was non-thrombogenic.[10] 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

[10] Thrombogenic is defined as "[p]ertaining to a thrombus or a factor that causes a thrombus." Mosby's Medical Dictionary (8th ed. 2009).

not an element of the claim and it can be proved by evidence other than by evidence of fraud on the FDA.

The failure to warn claim concerning off-label uses is based on a failure to warn the medical community and the general public of adverse information gathered about the device and that instructions for post-implantation therapy were not part of the PMA process. As noted by the Appellate Division, this failure to warn claim may implicate the MDA safe harbor. An off-label use may not be an "intended use" under the PLA or MDA; nevertheless, if defendants complied with the safe harbor requirements of the MDA in disseminating information about the off-label uses of the device, plaintiffs' claim is preempted. Cornett, supra, 414 N.J. Super. 401-02. To the extent, however, plaintiffs' failure to warn claim is founded on promotion by defendants of off-label uses of the device beyond the safe harbor, the claim is not preempted. Riley, supra, 625 F. Supp. 2d at 781-82.

We add the following caveat. We have assessed plaintiffs' claim at an early stage in the proceedings. Defendants filed the motion to dismiss soon after plaintiffs filed the amended Master Complaint. Defendants have not filed an answer. The amended Master Complaint contains many allegations that can reasonably be interpreted as a preempted fraud-on-the-FDA claim. On the other hand, the amended Master Complaint, read

indulgently and in its entirety as we are compelled to do, presents a colorable claim that avoids Buckman implied preemption. If discovery reveals that the failure to warn claim is nothing more than a private action to enforce FDA statutes and regulations, or that plaintiffs' claim is no more than a challenge to the approval of the device or label, or that proof of fraud on the FDA is an element of their claim, or that defendants' off-label promotional activities fall within the MDA safe harbor, defendants may move for summary judgment, and the trial court should not hesitate to grant such relief, if appropriate. See NCP Litig. Trust v. KPMG, LLP, 187 N.J. 353, 384-85 (2006) (finding shareholder trust stated colorable claim of auditor negligence barring application of in pari delicto requiring denial of motion to dismiss but permitting appropriate summary judgment motion following discovery). At this early stage of the proceedings, however, dismissal of this claim, as limited, is not appropriate.

2. Breach of Express Warranty.

In the amended Master Complaint, plaintiffs allege defendants breached express warranties by manufacturing, marketing, packaging, labeling and selling the Cypher® stent while misstating the risks of injury, without providing warnings of the misstatements in the labeling or packaging, and without modifying or excluding any express warranties. In addition,

plaintiffs allege that defendants manufactured, marketed, packaged, labeled, and sold the Cypher® stent without counteracting the negative health effects of coronary artery disease in a safe and permanent manner and without injury. Plaintiffs also allege defendants manufactured, marketed, packaged, labeled and sold the Cypher® stent to plaintiffs and caused serious physical injury, pain and suffering. The Appellate Division held that to the extent plaintiffs alleged an express warranty was created by the package labeling or packaging, it was preempted. Cornett, supra, 414 N.J. Super. at 403-04. However, to the extent the breach of express warranty claim is based on voluntary statements, i.e., statements not approved by the FDA or mandated by the FDA about the use or effectiveness of the product for on-label or off-label uses, a breach of express warranty claim may proceed because federal law requires any warranty statement to be truthful and accurate. Id. at 404. As limited, an express warranty claim based on state law does not impose additional requirements or obligations on defendants and is not preempted. Ibid.

Plaintiffs contend that the MDA does not preempt an express warranty claim based on the information contained in FDA approved product labels and packaging inserts. We disagree.

Following Riegel, generalized state common law theories of liability, such as alleged in the amended Master Complaint, are

precisely the types of claims preempted by the MDA. Horn, supra, 376 F.3d at 173; Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1100-01 (6th Cir. 1997); Riley, supra, 625 F. Supp. 2d at 788; Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 279-80 (E.D.N.Y. 2009). Plaintiffs' breach of express warranty claim is just such a generalized common law theory of liability.

In Horn, the plaintiff alleged the defendant manufactured a heart valve in a defective manner and failed to warn of the alleged defects. 376 F.3d at 173. The court noted these claims would require a change of an approved design or a change of an approved label, which would require further FDA review and approval, and are tantamount to imposition of greater or different requirements than the FDA imposed PMA requirements. Id. at 176-77. In Martin, the Court of Appeals for the Sixth Circuit emphasized that a breach of express warranty claim based on approved labels of an FDA-approved device is preempted. Martin, supra, 105 F.3d at 1100-01. The court explained that a state requirement that the manufacturer provide information about a device other than as required by the FDA imposes requirements "different from and in addition to" those imposed by the agency. Id. at 1101.

As in Horn and Martin, in order to succeed on the breach of express warranty claim, plaintiffs must show that the label

provides inaccurate or insufficient information in spite of FDA approval following the rigorous PMA process. Success on this state law claim would inevitably impose greater requirements than those already established by the MDA. This claim is, therefore, preempted.

On the other hand, to the extent plaintiffs allege defendants have deviated from the labeling and instructions for use through voluntary statements to third parties in the course of its marketing efforts, this claim is not preempted. Horn, supra, 376 F.3d at 179; Riley, supra, 625 F. Supp. 2d at 787-88; Horowitz, supra, 613 F. Supp. 2d at 285. As with the failure to warn claim, we decide this issue in the context of a motion to dismiss and have viewed the allegations in support of this claim indulgently. If discovery reveals this claim is based solely on representations or statements derived from the FDA approved label or packaging, a motion for summary judgment would be appropriate.

V.

In summary, we hold the Cornett complaint is time-barred and affirm the order dismissing this complaint. We also hold the failure to warn claim as to approved and off-label uses is preempted, except to the extent plaintiffs base the claim on allegations of deliberate non-disclosure or fraudulent representations of known adverse information apart from

defendants' failure to comply with FDA disclosure requirements or promotion of off-label uses outside the safe harbor. The breach of express warranty claim is also preempted, except to the extent plaintiffs allege defendants have made voluntary statements to third parties beyond and different from the information on the approved label or packaging.

VI.

The judgment of the Appellate Division is affirmed as modified.

JUSTICE LaVECCHIA and JUDGES WEFING, RODRIGUEZ, and FUENTES (all temporarily assigned) join in JUDGE CUFF's opinion. CHIEF JUSTICE RABNER and JUSTICES ALBIN, HOENS, and PATTERSON did not participate.

SUPREME COURT OF NEW JERSEY

NO. A-88/89 SEPTEMBER TERM 2010

ON CERTIFICATION TO Appellate Division, Superior Court

VONNIE CORNETT, individually
and on behalf of the estate
Of BILLIE CORNETT, deceased,

Plaintiff-Appellant
and Cross-Respondent,

v.

JOHNSON & JOHNSON and CORDIS
CORP.,

Defendants-Respondents
and Cross-Appellants.

DECIDED August 9, 2012

Justice LaVecchia PRESIDING

OPINION BY Judge Cuff (temporarily assigned)

CONCURRING/DISSENTING OPINIONS BY

DISSENTING OPINION BY

CHECKLIST	AFFIRMED AS MODIFIED	
CHIEF JUSTICE RABNER	----------	----------
JUSTICE LaVECCHIA	X	
JUSTICE ALBIN	----------	----------
JUSTICE HOENS	----------	----------
JUSTICE PATTERSON	----------	----------
JUDGE WEFING (t/a)	X	
JUDGE RODRIGUEZ (t/a)	X	
JUDGE CUFF (t/a)	X	
JUDGE FUENTES (t/a)	X	
TOTALS	5	