**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| **TERENCE LAVERTY and SHERRY LAVERTY,** | ) | |
| **Plaintiff,** | ) | |
| **vs.** | ) | **Case No. 15 C 9485** |
| **SMITH & NEPHEW, INC.,** | ) | |
| **Defendant.** | ) | |

## MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Terence and Sherry Laverty[1] have sued Smith & Nephew, Inc., asserting tort claims under Illinois law for negligence, strict products liability, and loss of consortium. Smith & Nephew has moved for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c). For the reasons stated below, the Court denies Smith & Nephew's motion.

### Background

The Court takes the following facts from the Lavertys' complaint, accepting them as true for the purposes of the present motion. *See Satkar Hosp., Inc. v. Fox Television Holdings*, 767 F.3d 701, 703 (7th Cir. 2014). The 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act of 1938 (FDCA) classifies medical devices in three categories based on their function and risk. Class III devices are the most heavily regulated, for they are devices that either "present[] a potential unreasonable

[1] To avoid confusion, the Court will refer to the Lavertys individually by their first names.

risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). The FDCA and MDA require that before a manufacturer may introduce a new Class III device to the market, the manufacturer must provide "reasonable assurance" to the Food and Drug Administration (FDA) that the device is safe and effective. *See id.* § 360e(d)(2). This "reasonable assurance" is given through what is known as "premarket approval," a rigorous process through which a manufacturer must submit detailed information concerning the safety and efficacy of the new device for the FDA to review and consider. If the FDA accepts the manufacturer's "reasonable assurance" of the product's safety and efficacy, it grants or conditionally grants premarket approval, whereupon the manufacturer can begin to introduce the product into the market. *See id.*

Smith & Nephew is the designer, manufacturer, and distributor of a Class III device known as the Birmingham Hip Resurfacing System (BHR). The BHR is a metal-on-metal hip resurfacing prosthesis composed of a stemmed femoral head and a hemispherical acetabular cup. In May 2006, the FDA granted conditional premarket approval to Smith & Nephew for its BHR. The FDA's approval letter to Smith & Nephew imposed conditions on the commercial distribution of the BHR, including a requirement to make post-market reports to the FDA regarding the device's safety and efficacy. Failure to comply with these conditions, the letter said, would constitute a violation of the FDCA.

In March 2011, doctors implanted one of these devices into Terence Laverty's

right hip during a full arthroplasty surgery. After his surgery, Terence experienced severe pain that progressed over time, eventually becoming so severe that he could barely walk. Upon discovering that the BHR that had been implanted during his arthroplasty procedure had failed and was contributing to his pain, his doctors advised him to undergo revision surgery to replace the BHR. Terence underwent a right total hip revision arthroplasty in October 2015, during which physicians confirmed that the original BHR inserted in 2011 had failed.

Later that month, the Lavertys filed this lawsuit. In their complaint, they alleged that after the FDA granted conditional premarket approval but prior to Terence's surgery, Smith & Nephew became aware of defects in the BHR and the fact that those defects were causing serious harm. The Lavertys claimed that Smith & Nephew "received hundreds of adverse reports regarding the BHR but [ ] delayed its reporting to the FDA and, when Smith & Nephew did communicate adverse reports, it did not do so properly but in fact attempted to blame others for adverse events." Compl., dkt. no. 1, ¶ 12. They alleged that Smith & Nephew "only initiated follow up inquiry on a fraction of adverse events reported directly to the FDA by patients regarding the BHR" and that "[d]espite wide evidence of the BHR's wearing down more quickly and severely than anticipated, Smith & Nephew failed to take appropriate action to determine the cause and provide a solution." *Id.* ¶¶ 13, 14. And the Lavertys claimed that Smith & Nephew did not "appropriately advise the FDA, medical community or general public of the problems." *Id.* ¶ 14.

These failures, according to the Lavertys, constituted violations of FDA regulations promulgated under the FDCA and applicable to Smith & Nephew's BHR as

a Class III device. Based on these alleged violations, the Lavertys asserted state tort claims for negligence (count 1) and strict products liability (count 2). They also asserted a claim of loss of consortium (count 3) on behalf of Sherry, who allegedly "suffered a loss of services, support, affection, society, companionship and consortium of her husband" as a result of Smith & Nephew's claimed misconduct. *Id.* ¶ 47. Smith & Nephew answered the Lavertys' complaint in November 2015, and discovery commenced. In April 2016, Smith & Nephew moved for partial judgment on the pleadings.

**Discussion**

The parties appear to agree that the Lavertys' negligence and strict products liability claims are based on theories of manufacturing defect and failure to warn. Smith & Nephew denies these claims but does not dispute the propriety of bringing them insofar as they rely on a manufacturing defect theory. Smith & Nephew contends, however, that insofar as these claims are grounded in a theory of tortious failure to warn, they are either expressly preempted under the MDA or impliedly preempted under the FDCA.

"Preemption is an affirmative defense, and pleadings need not anticipate or attempt to circumvent affirmative defenses." *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010) (internal citation omitted). This is why a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is not the appropriate vehicle for a preemption challenge: affirmative defenses "typically turn on facts not before the court at [the dismissal] stage." *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir. 2012). However, "when all relevant facts are presented, the

court may properly dismiss a case before discovery—typically through a Rule 12(c) Motion for Judgment on the Pleadings—on the basis of an affirmative defense." *Id.* "A motion for judgment on the pleadings under Rule 12(c) of the Federal Rules of Civil Procedure is governed by the same standards as a motion to dismiss for failure to state a claim under Rule 12(b)(6)." *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015) (internal quotation marks omitted). Accordingly, a court may grant a Rule 12(c) motion only where it is clear from the pleadings that the plaintiffs will be unable to maintain their cause of action in light of the facts presented.

**A. Express preemption**

In addition to categorizing classes of medical devices and defining how those devices are to be regulated, the MDA includes an express preemption provision for products liability claims against Class III medical device manufacturers:

> [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 chapter 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 chapter.

21 U.S.C. § 360k(a). Smith & Nephew contends that this provision expressly preempts the Lavertys' failure-to-warn claims because they seek to hold Smith & Nephew to standards of safety or effectiveness that are "different from, or in addition to," the standards imposed under the MDA.

In support of this argument, Smith & Nephew relies upon *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005), in which the Seventh Circuit found a plaintiff's failure-to-warn claims expressly preempted under the MDA. There, plaintiffs sued the manufacturer of a Class III medical device that had received premarket approval. They

claimed that the manufacturer had learned of an anecdotal report that revealed that the device, a brain implant intended to suppress tremors in persons with Parkinson's disease, could malfunction and cause death or serious injury in persons with the implant who underwent a dental procedure known as "diathermy." *Id.* at 485. The device manufacturer provided a warning about diathermy in its manuals for physicians and patients as required pursuant to the conditions the FDA imposed in granting premarket approval, but it did not modify the warning after learning of the anecdotal report until three months after the injured plaintiff underwent diathermy treatment and sustained injuries from his implant malfunctioning. *Id.* at 486. Plaintiffs asserted state-law failure-to-warn claims based on the manufacturer's failure to provide post-sale warnings prior to the injury. *Id.*

The Seventh Circuit observed that section 360k(a) "sets three conditions for preemption": (1) there must be a requirement a state establishes or continues with respect to a medical device; (2) there must be "a relevant federal requirement under the FDCA applicable to the device at issue"; and (3) the state requirement "must be 'different from, or in addition to,' the federal requirement." *Id.* at 487 (quoting 21 U.S.C. § 360k(a)). The parties in *McMullen* agreed that the first two conditions were satisfied—state-law failure-to-warn claims created a state-established requirement with respect to the medical device, and premarket approval regulations created federal requirements concerning warnings for the device. *McMullen*, 421 F.3d at 487–88. The parties disputed, however, whether the state law requirement would impose obligations that were different from or in addition to federal requirements. Plaintiffs contended that it would not, because the manufacturer "was obligated, under parallel state and federal

laws, to send a 'timely' warning." *Id.* at 488. According to plaintiffs, state tort law and two federal regulations simultaneously imposed this timeliness requirement. Plaintiffs claimed the manufacturer violated both federal and state law by responding to the anecdotal report with an additional warning after, rather than before, the dental procedure that led the implanted device to malfunction.

The Seventh Circuit affirmed the district court's decision granting summary judgment for the device manufacturer on preemption grounds. In doing so, the court analyzed the two federal regulations plaintiffs contended were parallel to their state-law failure-to-warn claims. The first regulation imposed a duty on manufacturers to track recipients of the manufacturer's device to ensure "'the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act).'" *Id.* at 489 (quoting 21 C.F.R. § 821.1). The described remedies "give the Secretary of Health and Human Services the discretion to issue or withhold warnings concerning medical devices based on the Secretary's assessment of the risks, and to issue recall orders" if the Secretary so chooses. *McMullen*, 421 F.3d at 489. The court therefore determined that the tracking requirement under section 821.1 "does not impose on the manufacturer the obligation to make warning or recall decisions unilaterally, nor does it authorize the manufacturer to do so," which would be necessary in light of the premarket approval requirement that a manufacturer must request permission from the FDA before issuing revised warnings. *Id.*

The second regulation permitted but did not require a manufacturer "to temporarily amend a warning pending FDA approval of the proposed warning." *Id.* The

court explained that requirements under this regulation were not parallel to plaintiffs' state-law failure-to-warn claim because the federal regulation permitted a course of conduct rather than obligating it. "Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *Id.* Because plaintiffs sought to hold defendants accountable for failing to do something federal law permitted but did not require, the court found that the asserted state-law failure-to-warn claims were preempted because they would impose requirements "different from, or in addition to" federal law.

The Supreme Court made a similar decision in 2008. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Court held that the FDA's premarket approval process preempted state-law tort claims requiring a manufacturer to design and manufacture its device to be safer than the model approved by the FDA. Smith & Nephew contends that the Lavertys' claims are similar to the claims found preempted in *Riegel* and are indistinguishable from the failure-to-warn claims found preempted in *McMullen*. Like the plaintiffs in *McMullen*, the Lavertys seek to bring failure-to-warn claims against a Class III device manufacturer whose duties to warn and report the federal government carefully prescribes. Like the preempted claims in *McMullen*, Smith & Nephew argues, the Lavertys' claims would impose requirements on manufacturers that are additional to and different from those set forth in the federal law and regulations governing the premarket approval process.

As the Seventh Circuit has observed, however, *McMullen* and *Riegel* were both careful to point out that section 360k is "limited"; states may continue to impose

requirements on Class III devices as long as they are not "different from, or in addition to," those imposed under federal law. *See Bausch*, 630 F.3d at 552. The court in *McMullen* made clear that state law requirements are not preempted under section 360k(a) where those requirements are "genuinely equivalent" to federal requirements. *McMullen*, 421 F.3d at 489. The court explained that where there are "both state and federal requirements to [the same] effect, then the state requirements will not be different from, or in addition to, the federal requirements." *Id.* at 488. The Supreme Court recognized the same limits to section 360k in *Riegel*, in which the Court held that "[section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). Put differently:

> The Supreme Court thus has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, but it does not extend protection from liability where the claim is based on a violation of federal law. In other words, where state law is parallel to federal law, section 360k does not preempt the claim.

*Bausch*, 630 F.3d at 552.

In *Bausch*, the Seventh Circuit found that section 360k did not expressly preempt manufacturing defect claims plaintiffs asserted under Illinois state law. The plaintiff in that case sued the manufacturer of a Class III medical device claiming that the hip replacement system that she received failed and caused injuries as a result of the manufacturer's noncompliance with federal manufacturing standards. *Id.* at 549. The manufacturer argued that section 360k preempted the plaintiff's manufacturing defect claim, and the district court agreed, finding that although section 360k might "leave

room for a claim based on 'a state regulatory enactment,' . . . common law claims would be different from or in addition to federal law and thus would be preempted." *Id.* at 552 (quoting *Bausch v. Stryker Corp.*, 2008 WL 5157940, at *5 (N.D. Ill. Dec. 9, 2008)).

The Seventh Circuit disagreed with the notion that section 360k leaves no room for common law products liability claims and found that the plaintiff's claims were not expressly preempted under the MDA. In so doing, the court observed that Class III medical device manufacturers "who subject their Class III medical devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they *comply* with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's *violation* of federal law." *Id.* at 550.

The Lavertys argue that this case is just like *Bausch* because they seek to hold Smith & Nephew accountable for failing to warn pursuant to the obligations imposed under federal law. Specifically, the Lavertys contend that in the letter granting premarket approval to Smith & Nephew for the BHR, the FDA imposed certain post-approval obligations on Smith & Nephew. Among those obligations was a requirement to conduct a post-approval study and submit reports biannually for the first two years and annually for the next eight years following premarket approval. The Lavertys contend that after Smith & Nephew had received premarket approval, it became aware of defects in the BHR. Compl., dkt. no. 1, ¶ 11. They allege that despite receiving "hundreds of adverse reports," Smith & Nephew "delayed its reporting to the FDA and, when [it] did communicate adverse reports, it did not do so properly but in fact attempted to blame others for adverse events." *Id.* ¶ 12. The Lavertys claim that "Smith & Nephew only initiated follow up inquiry on a fraction of adverse events reported

directly to the FDA by patients regarding the BHR." *Id.* ¶ 13. Accordingly, say the Lavertys, Smith & Nephew "[f]ailed to achieve compliance with the FDA's post-market reporting by failing to fulfill the agreed-upon requirements for the study that needed to be conducted regarding BHR." *Id.* ¶ 35(d).

Smith & Nephew argues that publicly available information shows that the FDA has found it in compliance with its post-approval reporting obligations. It points to Internet archive records that it claims "demonstrate[] that through January 10, 2011 the FDA had found [Smith & Nephew's] post-approval study to be 'adequate' and noted that its status reports were 'on time.'" Def.'s Reply, dkt. no. 27, at 6. This means, according to Smith & Nephew, that the Lavertys are either seeking to impose additional obligations under state law (forbidden under section 360k as explained in *Riegel* and *McMullen*), attempting to advance a fraud-on-the-FDA claim (which, as explained more fully below, would be impliedly preempted under the FDCA) or bringing claims that are unsupportable.

The Internet archive records do not prove as much as Smith & Nephew contends. These records show that the FDA deemed the "progress" of the study adequate, not that the FDA had reviewed whether the study fully complied with the post-approval requirements it set forth in the premarket approval letter. The fact that the FDA received Smith & Nephew's reports on time through January 2011 is also beside the point. The FDA granted premarket approval on Smith & Nephew's BHR on the condition that it would not only submit timely reports and make adequate progress, but that its study would adequately investigate adverse reports and provide analyses of complaints and reported adverse events. *See* Pl.'s Ex. A, dkt. no. 1, at 14. Moreover,

the Lavertys allege that Smith & Nephew delayed reporting adverse events, not that it delayed submitting status reports. Smith & Nephew submitted all but one report to the FDA on time, but this does not prove that Smith & Nephew included all the information it was required to include in those reports, when it was required to include it.

Smith & Nephew insists that *Bausch* is inapplicable to this case because it dealt with manufacturing defect claims and that *McMullen* compels preemption because it dealt with failure-to-warn claims. But neither *Bausch* nor *McMullen* was decided on the basis of the type of state law claim with which it dealt. It is not correct to say that simply because the plaintiffs in this case and *McMullen* both brought failure-to-warn claims against a manufacturer whose Class III device received premarket approval, the two cases are indistinguishable. The court in *McMullen* did not find that all failure-to-warn claims against Class III medical device manufacturers with premarket approval are preempted under section 360k(a). Instead, the court in *McMullen* found state-law failure-to-warn claims preempted insofar as they imposed obligations that were "different from, or in addition to," federal obligations. Likewise, the court in *Bausch* determined that the manufacturing defect claims at issue did not impose requirements that were different from federal requirements, not that manufacturing defect claims are never subject to preemption.

Section 360k does not expressly preempt state law claims alleging harm caused by conduct that violates a federally imposed requirement. That is precisely what the Lavertys have alleged: that Smith & Nephew failed to disclose information relevant to the safety and effectiveness of its device in violation of the rules the FDA set forth as a condition of premarket approval. Because their failure-to-warn claims do not seek to

impose obligations different from or in addition to those imposed through agency action taken pursuant to the MDA, section 360k does not expressly preempt them.

**B. Implied preemption**

The Lavertys have not brought suit under the FDCA; indeed, the FDCA does not provide a private right of action. *See Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharm., Inc.*, 586 F.3d 500, 509 (7th Cir. 2009). Instead, they allege that Smith & Nephew committed the torts of negligence and strict products liability under Illinois law based on a failure-to-warn theory. The Lavertys claim that the FDA imposed reporting obligations on Smith & Nephew by which the company failed to abide. They allege that Smith & Nephew breached its duty to warn, causing Terence's injuries and the loss of consortium Sherry experienced as a result.

Smith & Nephew contends that the Lavertys' claims are not really tort claims based on a failure to warn but rather are claims that seek to enforce the FDA. Accordingly, Smith & Nephew argues that these claims are impliedly preempted under the FDCA in accordance with the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court determined that state-law fraud claims conflicted with federal law because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348 (footnote omitted). Because "[t]he balance sought by the Administration can be skewed by allowing fraud on the FDA claims under state tort law," the Court concluded that the plaintiffs' state-law fraud claims were preempted. *Id.*

As the Lavertys point out in their response memorandum, their claims are different from the claims asserted in *Buckman* in a crucial way. The Lavertys do not claim that Smith & Nephew failed to warn by making material misrepresentations or omissions in their application for premarket approval, but rather that Smith & Nephew failed to satisfy its continuing obligation to properly evaluate adverse reports and disclose them to the FDA. The Lavertys thus have not asserted the sort of fraud-on-the-FDA claims that the Court in *Buckman* ruled were preempted under the FDCA. Rather, they have asserted a traditional tort claim, for which, "as both *Buckman* and *Lohr* make clear, we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Bausch*, 630 F.3d at 557 (quoting *Lohr*, 518 U.S. at 485).

Still, the broader teaching of *Buckman* is that, in light of the absence of a private right of action under the FDCA and the fact that the FDA is empowered to enforce and administer it, a plaintiff may not file a lawsuit to enforce the FDCA. If a plaintiff is harmed by a Class III medical device as a result of the manufacturer's failure to comply with the FDCA or regulations promulgated thereunder, he must do so under state law. Smith & Nephew argues that Illinois does not impose a "duty to report to the FDA" on medical device manufacturers. *See* Def.'s Mem., dkt. no. 22, at 13. Accordingly, Smith & Nephew views the Lavertys' claims as nothing more than a thinly veiled attempt to circumvent preemption and privately enforce the FDCA. Indeed, at least one other district court has so held in a virtually identical case. *See Mink v. Smith & Nephew*, No. 15 C 61210, 2016 WL 1045588, at *10 (S.D. Fla. Mar. 14, 2016).

Smith & Nephew defines too narrowly the duty the Lavertys allege it breached.

*Bausch* is instructive on this point. There, the device manufacturer argued that the plaintiff's manufacturing defect claim was preempted because it was based on the manufactured device being "adulterated" in violation of the MDA, and state tort law did not impose a duty to manufacture a product that was not "adulterated". The Seventh Circuit explained that although "there may not be a 'traditional state tort law' claim for an 'adulterated' product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law." *Bausch*, 630 F.3d at 557. It is true that Illinois does not impose on medical device manufacturers a "duty to report to the FDA" in so many words. But Illinois does recognize a claim for failure to warn predicated on a product manufacturer's failure to disclose known defects. *See Woodill v. Parke Davis & Co.*, 79 Ill. 2d 26, 29, 402 N.E.2d 194, 196 (1980); *Hernandez v. Schering Corp.*, 2011 IL App (1st) 093306 ¶ 38, 958 N.E.2d 447, 455 (2011). This duty is not limited to providing warnings directly to end users, but rather "depends on whether [the defendant] and [the plaintiff] stood in such a relationship to each other that the law imposed upon [the defendant] an obligation of reasonable conduct for the benefit of [the plaintiff." *Solis v. BASF Corp.*, 2012 IL App (1st) 110875 ¶ 64, 979 N.E.2d 419, 441 (2012). The MDA sets standards for what, when, how, and to whom a manufacturer must report; it does not eviscerate the longstanding state-imposed duty to warn simply by redefining the way medical device manufacturers satisfy that obligation.

This is why, contrary to Smith & Nephew's argument, the Lavertys' claims are not like the claims found preempted in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), and *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623

F.3d 1200 (8th Cir. 2010). The claims the Ninth Circuit found preempted in *Stengel* broadly alleged that a medical device manufacturer violated the MDA; they did not "specif[y] . . . a state-law duty that parallels a federal-law duty under the MDA." *Stengel*, 704 F.3d at 1233. The Ninth Circuit went on to say that in light of the clarification it provided in its opinion regarding implied preemption, it was possible that on remand the plaintiffs "could plead non-preempted versions of these claims." *Id.* In *Sprint Fidelis*, the Eighth Circuit found preemption where the plaintiffs alleged violations of the MDA—claims that are clearly preempted under *Buckman* and that are wholly unlike the Lavertys' state-law failure-to-warn claims. *Sprint Fidelis*, 623 F.3d at 1205–06.

The Lavertys' claims more closely resemble non-preempted claims approved by the Ninth and Fifth Circuits. In *Stengel*, the Ninth Circuit declined to find preemption where the plaintiffs asserted a failure-to-warn claim under Arizona law based on the failure to comply with post-approval requirements established by the FDA. The court explained that the plaintiffs' failure-to-warn claim was not preempted, because "Arizona law contemplates a warning to a third party such as the FDA." *Stengel*, 704 F.3d at 1233. Accordingly, the claim rested "on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*." *Id.* Similarly, in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 764, 776 (5th Cir. 2011), the Fifth Circuit found that the MDA neither expressly nor impliedly preempted plaintiffs' failure-to-warn claim under Mississippi law based on post-approval failure to abide by disclosure requirements set by the FDA. As explained above, Illinois has long recognized negligence and strict liability torts arising out of a failure to warn, placing a duty on a product manufacturer not to communicate directly with an end user, but to engage in "reasonable conduct for the benefit" of the

end user. Here, that reasonable conduct includes fully and correctly complying with FDA disclosure requirements. The Lavertys' claims are not impliedly preempted.

The Court recognizes that its conclusion differs from that reached by at least one other district court confronting the same question. *See Mink*, 2016 WL 1045588, at *10. In *Mink*, as here, plaintiffs asserted failure-to-warn claims under state law (in that case, Florida) against Smith & Nephew for allegedly failing to adhere to the post-approval reporting requirements set forth in the premarket approval letter it received for its BHR. The court quoted *Sprint Fidelis* in acknowledging that some state law claims against Class III device manufacturers are not preempted, but that such claims must fit through a "'narrow gap'" by "'suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but . . . not . . . *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*.'" *Id.* at *6 (quoting *Sprint Fidelis*, 623 F.3d at 1204). The court found the plaintiff's claims impliedly preempted, stating:

> Although the allegations note with specificity the provisions violated and the manner in which they were violated, Mink, in substance, alleges that [Smith & Nephew] violated the FDCA and its implementing regulations through these various failures, including failures related to reporting deficiencies, failures concerning manufacture in conformity with the PMA requirements, failure to file adverse incident reports and advise the larger medical community of possible dangers, and other general reporting failures. The mere fact that Mink prefaces all such allegations with the disclaimer that they are brought "only to the extent that they are parallel to and not different from or in addition to the requirements of federal law" does not negate the fact that the allegations are a plain attempt at circumventing 21 U.S.C. § 337[k](a).

*Mink*, 2016 WL 1045588, at *10 (internal citations omitted). The court noted that it was "mildly perplexed as to what manner of claim would make it through the 'narrow gap,' described by the Eighth Circuit in [*Sprint Fidelis*], 623 F.3d at 1204," but that "after

canvassing the binding and persuasive authority submitted in support of [Smith & Nephew's] Motion, it is clear that Mink's claim cannot fit." *Id.* at *11.

This Court respectfully disagrees. The holding in *Mink*, in this Court's view, does not square with *Bausch*, *Stengel*, or *Hughes*, none of which the court in *Mink* addressed. As the Seventh Circuit explained in *Bausch*, "[h]ere, as in *Lohr* and as recognized in *Riegel*, the plaintiff claims breach of a well-recognized duty owed to her under state law." *Bausch*, 630 F.3d at 558. In that case, it was "the duty of a manufacturer to use due care in manufacturing a medical device," *id.*; here, it is the duty of a manufacturer to disclose known defects. Like the plaintiffs in *Bausch*, the Lavertys "may do so as long as [they] can show that [they were] harmed by a violation of applicable federal law." *Id.* For the reasons discussed, the Court concludes that the MDA does not impliedly preempt the Lavertys' failure-to-warn claims.

**Conclusion**

For the foregoing reasons, the Court denies Smith & Nephew's motion for judgment on the pleadings [dkt. no. 21]. The ruling and status hearing set for June 28, 2016 is vacated. Counsel are directed to confer and attempt to agree on a pretrial and discovery schedule. A status report containing the parties' proposal is to be filed by no later than July 22, 2016. The case is set for a status hearing on August 10, 2016 at 8:30 a.m.

MATTHEW F. KENNELLY
United States District Judge

Date: June 23, 2016