IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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JUDY MARVIN, BEVERLY SCHULTZ,
PATRICIA COLLINS, ROBERT ELICK
and SANDRA CONLEY, individually and
as next friend of the ESTATE OF SHIRLEY JOHNS,

ORDER

Plaintiffs,

v. 15-cv-749-bbc

ZYDUS PHARMACEUTICALS (USA) INC. and
WYETH PHARMACEUTICALS, INC.,

Defendants.

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Plaintiffs in this civil action are suing defendants Zydus Pharmaceuticals (USA) Inc. and Wyeth Pharmaceuticals, Inc. for the wrongful death of Shirley Johns, who died allegedly from injuries incurred when she took a drug commonly known as Amiodarone. Before the court is defendant Zydus Pharmaceuticals (USA) Inc.'s motion to dismiss the complaint against it on the following grounds: (1) plaintiffs' claims are barred by Wisconsin's three-year statute of limitations, Wis. Stat. § 893.54; and (2) plaintiffs do not have a private right of action with respect to their negligence per se claim that defendant Zydus failed to provide a medication guide for the Amiodrone sold to Johns because the Food, Drug and Cosmetic Act, 21 U.S.C. § 337, limits enforcement of its provisions to actions brought by the United States. Dkt. #22.

I am denying defendant Zyfus's motion to dismiss with respect to timeliness because

it is not clear from the complaint that plaintiffs' claims are barred by the statute of limitations. I am reserving ruling on its motion with respect to plaintiffs' negligence per se claim because further briefing from the parties is needed to determine whether such a claim is preempted by § 337 of the Food, Drug and Cosmetic Act.

ALLEGATIONS OF FACT

In resolving a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the court must accept as true all well-pleaded factual allegations in the complaint, Adams v. City of Indianapolis, 742 F.3d 720, 728 (7th Cir. 2014), and view them in the light most favorable to the non-movant, Santiago v. Walls, 599 F.3d 749, 756 (7th Cir. 2010) (quoting Zimmerman v. Tribble, 226 F.3d 568, 571 (7th Cir. 2000)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). For purposes of the present motion, I will accept as true the following allegations of fact from plaintiffs' first amended complaint. Dkt. #16.

Shirley Johns was a 77-year-old resident of Crandon, Wisconsin who had a diagnosis of atrial fibrillation. She died on November 19, 2012, allegedly from Amiodarone-induced lung disease. (Amiodarone has many side effects, the most serious being pulmonary toxicity-lung disease.) Plaintiffs Judy Marvin, Beverly Schultz, Patricia Collins, Robert Elick and Sandra Conley are the children of Shirley Johns; all of them reside in Crandon, Wisconsin. Plaintiff Conley is the next friend of the estate of Shirley Johns.

Defendants Wyeth Pharmaceuticals, Inc. and Zydus Pharmaceuticals (USA) Inc. are New Jersey corporations involved in the distribution, marketing, promotion, sale, labeling and design of amiodarone hydrochloride (or Amiodarone). Wyeth was the initial manufacturer and distributor of Amiodarone in the United States. In 1985, it received approval from the Food and Drug Administration to market and sell Cordarone (its named brand of Amiodarone) as a drug of last resort for patients suffering from recurrent life-threatening ventricular fibrillation and ventricular tachycardia when those conditions would not respond to other available anti-arrhythmic drugs and therapies. On September 16, 2008, Zydus received approval from the Food and Drug Administration to manufacture, market, sell and distribute a generic formulation of Amiodarone. As it does with all generic drug approvals, the Food and Drug Administration required Zydus to provide patients prescribed the drug with approved labels, warnings and medication guides containing the exact same information required of Wyeth as the brand formulation manufacturer.

A medication guide is a "plain English" description of the dangers of a drug. The Food and Drug Administration requires drug manufacturers to issue medication guides with certain prescribed drugs and biological products when the agency determines the information is necessary to prevent serious adverse effects. In that case, patients are to be informed about a known serious side effect or patient adherence to directions for the use of a product are essential to its effectiveness. The agency requires manufacturers of Amiodarone to provide medication guides in lieu of "package inserts" or any other means by which the manufacturers may attempt to warn consumers of the effects of Amiodarone. Regulations

promulgated by the Food and Drug Administration require each manufacturer who ships a container of Amiodarone to provide a sufficient number of medication guides to authorized distributors, packers and dispensers so that every consumer receives a guide with each Amiodarone prescription. 21 C.F.R. § 208.24(b).

After receiving approval from the Food and Drug Administration, Wyeth, Zydus and other companies sought to increase sales of Amiodarone for the "off-label" use as a "first-line anti-arrhythmic medication," or a drug of first choice in treating non-life threatening heart ailments. ("Off label" uses are those not yet approved by the Food and Drug Administration.) Although pharmaceutical companies may disseminate certain information about off-label uses, they must adhere to strict requirements. For instance, a manufacturer must submit an application to the Food and Drug Administration seeking approval of the drug for off-label use, provide its marketing materials to the Food and Drug Administration prior to dissemination, distribute the materials in unabridged form and include disclosures that the materials pertain to an unapproved use of the drug and, if the Food and Drug Administration deems it appropriate, provide "additional objective and scientifically sound information . . . necessary to provide objectivity and balance." 21 U.S.C. § 360aaa. A drug manufacturer's dissemination of information in violation of any of these provisions qualifies as a violation of the Federal Food, Drug and Cosmetic Act and regulations promulgated under it. Zydus did not adhere to these requirements.

Dr. Richard A. Reinhart prescribed Shirley Johns a 90-day course of 200mg Amiodarone tablets for treatment of atrial fibrillation, an off-label use of the drug. Shirley

Johns filled the prescription at a pharmacy and ingested the Amiodarone according to instructions. In the spring of 2012, Johns began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, depression, impaired vision and stomach, leg and chest pain. Johns asked Dr. Reinhart about the effects of Amiodarone and underwent tests for pulmonary toxicity, but Dr. Reinhart told her that her lungs looked perfect. Later it was determined that a mistake had been made in reading those tests. Johns died on November 19, 2012.

The bottles of Amiodarone that Shirley Johns received were each marked with "MANUFACTURER ZYDUS PHARM," identifying the bottles as manufactured, marketed and distributed by defendant Zydus. Defendant failed to provide up-to-date warning labels or the medication guides required by the Food and Drug Administration to any of the pharmacies from which Johns obtained Amiodarone.

Plaintiffs filed their complaint in this action on November 20, 2015.

OPINION

A. Statute of Limitations

Defendant Zydus has moved to dismiss the wrongful death claims against it on statute of limitations grounds. "[B]ecause the period of limitations is an affirmative defense," the Court of Appeals for the Seventh Circuit has held that "it is rarely a good reason to dismiss under [Fed. R. Civ. P.] 12(b)(6)." Reiser v. Residential Funding Corp., 380 F.3d 1027, 1030 (7th Cir. 2004). See also Clark v. City of Braidwood, 318 F.3d 764, 767 (7th Cir. 2003)

(plaintiff is not required to allege facts that negate affirmative defenses in his complaint). However, dismissal under Rule 12(b)(6) on statute of limitations grounds is "appropriate where 'the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense, such as when a complaint plainly reveals that an action is untimely under the governing statute of limitations.'" Andonissamy v. Hewlett–Packard Co., 547 F.3d 841, 847 (7th Cir. 2008).

In Wisconsin, actions to "recover damages for death caused by the wrongful act, neglect or default of another" must be commenced within three years of the date of death or "on the date the injury is discovered or with reasonable diligence should be discovered by the wrongful death beneficiary, whichever occurs first." Wis. Stat. § 893.54; Christ v. Exxon Mobil Corp., 2015 WI 58, ¶ 47, 362 Wis. 2d 668, 691, 866 N.W.2d 602, 613 (internal quotations omitted) (holding that discovery rule permits survival and wrongful death claims to accrue after date of decedent's death). In Christ, the Wisconsin Supreme Court explained that

> In the absence of a legislatively created rule to the contrary, these claims accrue when there is a "claim capable of present enforcement, a suable party against whom it may be enforced, and a party who has a present right to enforce it." Employers Insurance of Wausau, 154 Wis. 2d 199, 231, 453 N.W.2d 856, 869 (1990) (citation omitted). These criteria are not met "until the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, not only the fact of injury but also that the injury was probably caused by the defendant's conduct or product." Borello v. U.S. Oil Company, 130 Wis. 2d 397, 411, 388 N.W.2d 140, 146 (1986).

Christ, 2015 WI 58, ¶ 75.

Defendant argues that plaintiffs' claims are barred by the statute of limitations

because they filed their complaint three years and one day after the date of Shirley Johns's death. It contends that plaintiffs' claims accrued no later than the date of Johns's death because it is clear from the facts of the complaint that Johns had reason to believe before she died that Amiodarone was causing her adverse effects. In support of its contention, defendant cites plaintiffs' allegations that Johns asked her doctor about the side effects of Amiodarone and was tested for lung toxicity. However, as plaintiffs argue, it is not when Johns discovered the cause of her injuries that matters for the purposes of the statute of limitations. According to Christ, plaintiffs' claims accrue on the date that they (the wrongful death beneficiaries) discovered or with reasonable diligence should have discovered the cause of Johns's injuries.

The first amended complaint alleges no information about when plaintiffs discovered the cause of Johns' death. Defendant points out that plaintiffs allege that Johns's symptoms were serious enough to elicit worry [in] those around her" and forced her to depend "on the charity of others," dkt. #16 at ¶¶ 18-23 and 102, and argues that the most plausible scenario is that Johns's children were the ones to worry and about and tend to Johns's needs. However, this is only speculation. Further, even if plaintiffs were the ones worrying about Johns's symptoms and tending to her needs, they did not necessarily have reason to know the cause of her symptoms. Because it is impossible to determine at this stage of the proceedings when plaintiffs' claims accrued under the statute of limitations, defendant's motion to dismiss will be denied.

B. Medication Guides

Defendant argues that plaintiffs' claims that it failed to provide medication guides for the Amiodarone it manufactured must be dismissed because the duty to provide medication guides to pharmacies arises under federal law, 21C.F.R. § 208.24(b), and the Food, Drug and Cosmetics Act does not allow private litigants to enforce its provisions. 21 U.S.C. § 337(a) (enforcement proceedings "shall be by and in the name of the United States"). See also Buckman Co. v. Plaintiff's' Legal Committee, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with [its] provisions."). However, as plaintiffs contend, they are not attempting to enforce federal regulations; they are relying on them to establish the standard of care for their claim that defendant was negligent per se in failing to provide medication guides for Amiodarone. Schmitz v. Canadian Pacific Railroad Co., 454 F.3d 678, 682 (7th Cir. 2006) (citing Restatement (Second) of Torts § 286) ("In a typical negligence per se case, a violation of a statute can be a basis for liability when the statute is intended to protect against the specific type of harm sustained by the plaintiff."); Kurer v. Parke, Davis & Co., 2004 WI App 74, ¶ 20, 272 Wis. 2d 390, 405, 679 N.W.2d 867, 874 ("In Wisconsin, violations of FDA regulations may constitute negligence per se.").

In Kurer, the Wisconsin court of appeals considered whether a drug manufacturer could be found negligent for failure to warn of a rare medication side effect; the plaintiffs' claims included negligence per se and common law negligence. 2004 WI App 74, ¶¶ 1-2.

The specific question in Kurer was whether the failure to include additional warnings was a cause of the patient's injury when she disregarded specific statements in the warning directing her to seek medical attention for the symptoms she exhibited. Michaels v. Mr. Heater, Inc., 411 F. Supp. 2d 992, 1006 (W.D. Wis. 2006) (finding same). The court noted that Food and Drug Administration regulations concerning prescription drug labeling standards could establish the standard of care for negligence per se in Wisconsin and explained that compliance with the regulations generally would foreclose a claim of negligence per se. Kurer, 2004 WI app 74, at ¶¶ 19-24 (citing Lukaszewicz v. Ortho Pharmaceuticals Corp., 510 F. Supp. 961, 964 (E.D. Wis. 1981), amended, 532 F. Supp. 211 (E.D. Wis. 1981)). In addition, the court held that "it is a 'well-established rule that the enactment of safety statutes or legislation giving a commission jurisdiction over a certain activity does not abolish the duty arising under common-law negligence.'" Id. at ¶ 20. It explained the Wisconsin Supreme Court has found that "a safety statute merely establishes a minimum standard of care and the conduct, even though sanctioned or in conformity with the statute, is not thereby necessarily relieved of conforming to the common-law requirements of ordinary care." Id. (quoting Hoffmann v. Wisconsin Electric Power Co., 2003 WI 64, ¶ 12, 262 Wis.2d 264, 664 N.W.2d 55).

In its reply brief, defendant discounts Kurer as a non-binding state appellate opinion "of dubious validity" after the decision in PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011), in which the U.S. Supreme Court held that the Food, Drug and Cosmetic Act preempted a state law requiring generic drug companies to update and improve a warning label that had

been approved previously by the Food and Drug Administration. In PLIVA, the Supreme Court reasoned that "[i]f the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law" requiring that generic drug labels exactly match those of their brand-name counterparts. Id. at 618. The Court was concerned primarily with the fact that state law imposed a greater duty on drug manufacturers than that required under federal law. Id. Although PLIVA seems to cast doubt on the continuing validity of Kurer's holding with respect to common law negligence, it is not clear that the Court's ruling with respect to preemption has any effect on whether a regulation promulgated under the Food, Drug and Cosmetic Act may supply the standard of care for a state law negligence per se claim. Unlike in PLIVA, plaintiffs are not attempting to subject defendant to additional state law requirements that conflict with the requirements of the Food, Drug and Cosmetic Act; they merely seek to hold defendant liable for negligence under state law for the same conduct that violated the federal regulations.

Defendant contends that this court has rejected plaintiffs' argument concerning negligence per se in an earlier decision. In Cali v. Danek Medicine, Inc., 24 F. Supp. 2d 941, 953-54 (W.D. Wis. 1998), Judge Shabaz held that basing a claim of negligence per se on the violation of an Food, Drug and Cosmetic Act regulation is not actionable under Wisconsin law. Judge Shabaz found that "[f]or the violation of a safety statute to constitute negligence per se [in Wisconsin], a plaintiff must show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the person injured was within the class of persons sought to be protected; and (3) there is some expression of legislative intent that the statute become a

basis for the imposition for civil liability." Id. (quoting Tatur v. Solsrud, 174 Wis. 2d 735, 743, 498 N.W.2d 232 (Wis. 1993)). Judge Shabaz concluded that the third element was absent because "[t]here is no explicit private right of action and no suggestion that the act creates an implied private right of action." Id. at 954 (citing limitation in 21 U.S.C. § 337 that only United States may bring enforcement proceedings under Act).

Plaintiffs have not had an opportunity to respond to defendant's arguments with respect to Kurer or Cali. A review of relevant case law shows that courts have reached different conclusions about whether negligence per se claims based on violations of the Food, Drug and Cosmetic Act should be permitted. Howard v. Zimmer, Inc., 2013 OK 17, ¶¶ 24-31, 299 P.3d 463, 470-73 (summarizing cases). At least a few courts in the Seventh Circuit who have addressed the issue have not found the reasoning in Cali to be persuasive and have allowed negligence per se claims to proceed in certain cases. Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 875-76 (E.D. Wis. 1999) (relying on Medtronic v. Lohr, 518 U.S. 470, 495 (1996), for view that nothing in preemption provision of Medical Device Amendments Act, 21 U.S.C. § 360(k), prohibits states from providing damages remedy for violations of common-law duties when those duties parallel federal requirements); Menges v. Depuy Motech, Inc., 61 F. Supp. 2d 817, 829 (N.D. Ind. 1999) (plaintiff could assert negligence per se claim based on alleged violations of Act). The Supreme Court and the Court of Appeals for the Seventh Circuit also have discussed whether the Food, Drug and Cosmetic Act preempted state law claims in certain circumstances. E.g., Riegel v. Medtronic, Inc., 552 U.S. 312 (2008); Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir.1997). However, many

of these cases address the effect of the preemption provision in the Medical Device Amendments to the Act, 21 U.S.C. § 360(k), and not the enforcement limitation in § 337. (Congress declined to enact a preemption provision for prescription drugs. Wyeth v. Levine, 555 U.S. 555, 567 (2009).) Because the parties have not had the opportunity to fully brief this issue and there appears to be some disagreement among courts, I am asking the parties for supplemental briefing.

Plaintiffs shall have until May 10, 2016 to provide additional legal argument on whether the limitation on enforcement actions in 21 U.S.C. § 337 prohibits them from basing a negligence per se claim on defendant's alleged violation of the federal medication guide provisions in 21 C.F.R. § 208.24(b). Defendant shall have until May 17, 2016 to respond.

ORDER

IT IS ORDERED that defendant Zydus Pharmaceuticals (USA), Inc.'s motion to dismiss the first amended complaint, dkt. #22, is DENIED with respect to the statute of limitations. The ruling on defendant's motion with respect to plaintiffs' medication guide claims is RESERVED. Plaintiffs shall have until May 10, 2016 to provide additional legal argument on whether the limitation on enforcement actions in 21 U.S.C. § 337 prohibits plaintiffs from basing a negligence per se claim on defendant's alleged violation of the federal

medication guide provisions in 21 C.F.R. § 208.24(b). Defendant shall have until May 17, 2016 to respond.

Entered this 28th day of April, 2016.

BY THE COURT:

/s/

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BARBARA B. CRABB
District Judge