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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

OLIVER WIMBUSH, Individually and as Executor of the Estate of Mary Buchanan,
Plaintiff-Appellant,

v.

WYETH; WYETH-AYERST LABS. CO.; WYETH PHARM., INC.; WYETH PHARM.,
Defendants-Appellees.

No. 09-3380

Appeal from the United States District Court
for the Northern District of Ohio at Cleveland.
No. 03-02042—Solomon Oliver, Jr., Chief District Judge.

Argued: January 13, 2010

Decided and Filed: August 18, 2010

Before: MARTIN, BOGGS, and WHITE, Circuit Judges.

COUNSEL

ARGUED: Paul W. Flowers, PAUL W. FLOWERS CO., L.P.A., for Appellant. George E. McDavid, REED SMITH LLP, Princeton, New Jersey, for Appellees. **ON BRIEF:** Paul W. Flowers, PAUL W. FLOWERS CO., L.P.A., Benjamin H. Anderson, ANDERSON LAW OFFICE, L.L.C., Cleveland, Ohio, for Appellant. George E. McDavid, Eric L. Alexander, REED SMITH LLP, Princeton, New Jersey, David R. Cooper, COOPER & WALINSKI, Toledo, Ohio, M. Sean Laane, ARNOLD & PORTER LLP, Washington, D.C., for Appellees.

MARTIN, J., delivered the opinion of the court, in which BOGGS, J., joined. WHITE, J. (pp. 20-22), delivered a separate opinion concurring in part and dissenting in part.

OPINION

BOYCE F. MARTIN, JR., Circuit Judge. Mary Buchanan sued Wyeth, a publicly-held corporation, Wyeth Pharmaceuticals, an unincorporated division of Wyeth, and Wyeth-Ayerst Laboratories Company and Wyeth Pharmaceuticals, Inc., wholly-owned subsidiaries of Wyeth, regarding a diet pill, Redux, that the companies manufactured and sold. Buchanan's claims sound primarily in strict liability and common law negligence. Buchanan appeals the district court's entry of summary judgment for Wyeth on all of her claims. Relatedly, Buchanan requests a finding that the district court abused its discretion in denying her Motion to Alter and Amend Judgment and that the final judgment be reversed.

For the reasons set forth below, we **REVERSE** the judgment of the district court finding that approval of Redux by the Food and Drug Administration (FDA) preempted Buchanan's negligence claims taking issue with Wyeth's actions before FDA approval, as well as the district court's related dismissal of Buchanan's request for punitive damages, and **REMAND** those issues back to the district court. We **AFFIRM** the judgment of the district court on all other claims.

I.

Buchanan alleged that she was prescribed and that she ingested Redux for several months during 1996 and 1997 in order to control her weight. After her November 2001 diagnosis with primary pulmonary hypertension,[1] she filed a complaint against Wyeth in the United States District Court for the Northern District of Ohio on October 2, 2003. She died December 18, 2003, allegedly as a result of having taken Redux.

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[1]Pulmonary hypertension is characterized by an abnormally high blood pressure in the arteries of the lungs, which forces the right side of the heart to work harder than normal. There is no known cure. *See* Pulmonary Hypertension, Medline Plus Medical Encyclopedia, a service of the U.S. National Library of Medicine and the National Institutes of Health, http://www.nlm.nih.gov/medlineplus/ency/article/000112.htm.

Wyeth marketed and sold Redux after its approval by the FDA in April 1996. Redux became available in June 1996 and was taken off the market on September 15, 1997. While Wyeth sold Redux to the public, it provided several warnings regarding the health risks associated with ingesting Redux. In April 1996, Wyeth sent health professionals a letter stating that "a small risk of a serious, potentially life-threatening cardiovascular condition, primary pulmonary hypertension (PPH)" was "associated with the use of all types of prescription weight loss drugs. This risk is . . . about 18 cases per 1,000,000 users per year." On the first Redux label, the warning about PPH was written in all bold typeface and contained the information above.

Wyeth provided a second warning letter to physicians in August 1996, which explained that a final report of clinical studies indicated that the risk of PPH was greater than previously stated and that "the risk of PPH [is] calculated to be about 23 times higher for patients using anorexigens for three or more months compared to non-users." It further warned that "PPH is a serious disorder with an estimated 4-year mortality rate of 45%" and warned doctors that patients experiencing symptoms should immediately discontinue their use of Redux.

New labels were sent to health-care professionals in December 1996 along with a third letter reporting changes made to the label. The letter stated that "Redux . . . increase[s] the risk of developing primary pulminory hypertension, an often fatal disorder." The new labels provided updated information regarding the increased risk of PPH reflected by new studies in boldface capitalized letters.

Buchanan's[2] amended complaint, filed on January 22, 2007, stated claims for: (1) strict product liability encompassing both design defect pursuant to O.R.C. § 2307.75 and failure to warn pursuant to O.R.C. § 2307.76; (2) common-law negligence; and (3) wrongful death pursuant to O.R.C. § 2125.01, *et. seq.* Buchanan also sought economic, non-economic, and punitive damages pursuant to O.R.C. § 2307.80(C). She

[2]This case was originally filed by Mary Buchanan, whose estate, upon her death, was represented first by Romona Longs and then Oliver Wimbush. For consistency purposes, we refer to plaintiff as "Buchanan."

later withdrew her claims for failure to warn, pursuing only a strict product liability design defect claim, negligence claims, and punitive damages.

Wyeth filed three separate motions for partial summary judgment on September 21, 2007: one based on federal preemption; one arguing lack of evidence of proximate causation; and one related to punitive damages. Oral arguments were held on January 17, 2008.

On February 28, 2008, the district court granted summary judgment in favor of Wyeth on all claims. *Longs v. Wyeth (Longs I)*, 536 F. Supp. 2d 843 (N.D. Ohio 2008). The court found that Buchanan's strict liability and negligence claims relating to Wyeth's conduct prior to the FDA's approval of Redux for placement on the market were preempted by the FDA's subsequent approval of the drug and that any post-FDA-approval claims, which were not preempted, failed on their merits. As relevant to this appeal, the court further held that: (1) Buchanan's strict liability design defect claim failed because Buchanan failed to provide evidence refuting Wyeth's showing that the Redux warnings were adequate as a matter of law; (2) Buchanan's negligence claims failed because Buchanan did not provide evidence of proximate causation; and (3) the request for punitive damages was moot because, as a result of the dismissal of all of the substantive claims, Buchanan could not establish liability under any theory for which she could be entitled to any damages, much less punitive damages. As a result of these holdings, the district court dismissed the case.

On March 10, 2008, Buchanan moved to vacate the order and judgment and to alter the judgment. Buchanan argued that: (1) her pre-FDA-approval claims were not preempted in light of the Supreme Court's intervening decision in *Wyeth v. Levine*, __ U.S.__, 129 S. Ct. 1187 (2009); (2) Wyeth bore the burden of proving that its warnings were adequate rather than Buchanan bearing the burden of proving the warnings inadequate; (3) Wyeth did not properly raise the argument that Buchanan lacked evidence showing the inadequacy of Wyeth's warnings with regard to Buchanan's design defect claim; and (4) Wyeth did not properly raise the issue that Buchanan lacked evidence of proximate causation in regard to her negligence claim. The court denied

Buchanan's motion on March 20, 2009. *Longs v. Wyeth (Longs II)*, 621 F. Supp. 2d 504 (N.D. Ohio 2009). Buchanan timely appealed.

II.

Buchanan appeals the district court's summary judgment order as well as the order denying her motion to vacate and alter judgment.

A. Standard of Review

"The Sixth Circuit reviews de novo a district court's grant of summary judgment." *Hamilton v. Starcom Mediavest Group, Inc.*, 522 F.3d 623, 627 (6th Cir. 2008) (citing *Hardesty v. Hamburg Twp.*, 461 F.3d 646, 650 (6th Cir. 2006)). "Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law." *Id.* (citing Fed. R. Civ. P. 56(c)). "The moving party has the initial burden of proving that no genuine issue of material fact exists," *Vaughn v. Lawrenceburg Power Sys.*, 269 F.3d 703, 710 (6th Cir. 2001) (citing *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1477 (6th Cir. 1989)), and the court must draw all reasonable inferences in the light most favorable to the nonmoving party. *Id.* (citing *City Mgmt. Corp. v. U.S. Chemical Co.*, 43 F.3d 244, 250 (6th Cir. 1994)). When a motion for summary judgment is properly made and supported and the nonmoving party fails to respond with a showing sufficient to establish an essential element of its case, summary judgment is appropriate. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *see also Street*, 886 F.2d at 1479-80.

In Ohio, three basic theories of liability exist "under which a claimant may assert a product liability action: (1) under the Ohio Product Liability Act; (2) negligence; and (3) breach of warranty." Christopher M. Ernst, et al., *Baldwin's Ohio Practice, Ohio Tort Law*, § 6.1 (2009). We will address Buchanan's design defect claim under the Ohio Product Liability Act and her common law theories of negligence first, and then address the district court's preemption ruling.

B. Strict Liability Claims

Strict liability for manufacturers and suppliers is codified by the Ohio Products Liability Act, O.R.C. §§ 2307.71-2307.80, effective January 5, 1988. Recent amendments to the Act provide that the legislature intended the Act to abrogate *all* common law product liability causes of action. *See* O.R.C. § 2307.71(B), effective April 7, 2005. Buchanan initially brought strict liability claims for design defect and failure to warn, though she subsequently dropped the failure-to-warn claim. But, dropping the failure-to-warn claim did not render the warnings irrelevant.

According to Ohio law, so long as adequate warning has been provided for a pharmaceutical product, then the manufacturer cannot be strictly liable for design defect under Ohio law, regardless of whether there is a causal connection between the plaintiff's use of the drug and the plaintiff's injury or whether the product was unavoidably dangerous. *Frey v. Novartis Pharm. Corp.*, 642 F. Supp. 2d 787, 794 (S.D. Ohio 2009) (citing *Seley v. G.D. Searle & Co.*, 432 N.E.2d 831 (1981)). This is because the common law "learned intermediary doctrine" is codified in the Act:

> An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

O.R.C. § 2307.76(C); *see also Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006) (explaining that, in a case involving a drug prescribed by a physician, the learned intermediary doctrine provides that the adequacy of a product's warning is based on "whether the doctor, rather than the patient, would reasonably understand the risks").

The parties disagree as to which party carries the burden of proof regarding the adequacy of warnings in a design defect claim under O.R.C. § 2307.75(D). Buchanan contends that, as is the case under the common law, adequacy of warning is an

affirmative defense on which the defendant carries the initial burden of proof and the plaintiff carries only a burden to produce rebutting evidence. Wyeth, on the other hand, claims that the text of section 2307.75(D) makes the inadequacy of warnings an element of the prima facie claim for design defect, so the plaintiff carries the initial burden of proof and the defendant carries only a burden to produce rebutting evidence. After considering the authorities, the district court found that the plaintiff bears the burden of proving inadequate warnings in a design defect claim under the Ohio Products Liability Act. *Longs I*, 536 F. Supp. 2d at 851. We need not pass upon[3] this question as, regardless of whether Buchanan or Wyeth carries an affirmative burden of proof or merely a burden of producing rebutting evidence on the question of warning adequacy, Wyeth has met its burden and Buchanan has not.

Wyeth contended at summary judgment that Buchanan's strict liability design defect claim failed because Wyeth had provided adequate warnings to Buchanan's physician about the risks of Redux as information became available, thus qualifying for protection under O.R.C. § 2307.75(D)'s codification of the learned intermediary doctrine. Wyeth submitted voluminous evidence in support of this argument with its motion for summary judgment. Wyeth presented substantial evidence that it had distributed information regarding risks to doctors, including Buchanan's physician, and that those warnings were adequate to inform a physician of the known risks associated with Redux.

In response, Buchanan did not specifically point to any evidence in the record that would contradict Wyeth's evidence, such as expert reports opining that the warnings were inadequate to inform a physician of the true risks of the drug. As the district court summarized, and as is supported by the record, Buchanan did "not put forward any evidence that Defendants did not take appropriate steps in providing adequate warnings

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[3]Because it is neither necessary for us to decide who has the burden regarding adequacy of warnings under O.R.C. § 2307.75(D), nor was it ultimately necessary for the district court to decide, and because the question presents an important issue of the interpretation of the Ohio code, we believe it to be a question best answered by the Ohio state courts without the weight of a federal decision unnecessarily tilting the scales one way or the other. Accordingly, the portion of *Longs I*, 536 F. Supp. 2d at 851, that holds that the plaintiff bears the burden of proving the inadequacy of a warning under section 2307.759(D) is vacated as moot.

about Redux, that Defendants should have taken Redux off the market sooner, or that Defendants' alleged failure to take Redux off the market sooner proximately caused Buchanan's injury and/or death." *Id.* at 856. Instead, Buchanan argued the law, insisting that adequacy of warning was a jury question because Wyeth bore the burden of proof on the issue.

But this argument misses the point as, even if Buchanan is correct and adequacy of warnings is an affirmative defense for which Wyeth bears the initial and ultimate burden, summary judgment is available on affirmative defenses. *E.g.*, *Thornton v. Fed. Express Corp.*, 530 F.3d 451, 457-58 (6th Cir. 2008). Thus, even under Buchanan's interpretation of section 2307.75(D), Wyeth met its burden at summary judgment of providing evidence that its warnings were adequate, at which point it became Buchanan's burden to point to evidence creating a genuine issue of fact as to the adequacy of the warnings. For whatever reason, Buchanan did not point to any such evidence.[4] When responding to a summary judgment motion with legal argument instead of factual rebuttal, a litigant takes the ever-present risk that she is wrong on the law, leaving her with no factual safety net. Because she failed to point to any evidence creating a factual dispute as to the adequacy of warning, the strict liability design defect claim under the Ohio Products Liability Act fails as a matter of law. Thus, it was proper to grant Wyeth's motion for summary judgment on this claim.

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[4]The most that Buchanan may point to as far as rebutting evidence is a large packet of evidence attached to her response to Wyeth's partial summary judgment motion regarding punitive damages. This evidence was not attached to her brief responding to Wyeth's merits argument, nor was it cross-referenced in that brief. Instead, Buchanan suggests that the fact that the evidence was in the record somewhere is sufficient to create a question of fact and survive summary judgment. This is simply incorrect. Even if the evidence to which Buchanan now refers was sufficient to rebut Wyeth's evidence of adequate warning, it was Buchanan's job to point to the evidence with specificity and particularity in the relevant brief rather than just dropping a pile of paper on the district judge's desk and expecting him to sort it out. As we have previously noted, it is not the district court's duty "to search the entire record to establish that it is bereft of a genuine issue of material fact." *Street*, 886 F.2d at 1480-81. The non-moving party must present affirmative evidence on critical issues sufficient to allow a jury to return a verdict in its favor. *Id.* at 1476-77. Here, as Buchanan did not adequately present evidence demonstrating a genuine issue of material fact as to the issue of adequacy of warning, the district court did not err in granting Wyeth's motion for summary judgment on this issue.

C. Negligence Claims

Because Buchanan dismissed her failure-to-warn claims and cannot show that Wyeth is strictly liable for defective design under the Act, her only remaining claims are for negligence and for punitive damages.

1. State Law Abrogation

We first address whether Buchanan may bring her claims under common law negligence theories at all or whether Ohio has abrogated by statute all common law products liability claims. The Ohio Products Liability Act defines a statutory product liability claim. O.R.C. § 2307.71(M). In addressing whether passage of the Act abrogated common law negligence claims, the Ohio Supreme Court in *Carrel v. Allied Prod. Corp.*, 677 N.E.2d 795 (Ohio 1997), held that "in the absence of language clearly showing the intention to supersede the common law, the existing common law is not affected by the statute . . ." and that, therefore, the statute did not abolish "common-law actions sounding in negligence." *Id.* at 798-99. In an amendment to the Act effective April 7, 2005, however, the Ohio General Assembly explicitly eliminated "all common law product liability claims or causes of action." O.R.C. § 2307.71(B). Buchanan's claims were brought prior to the passage of this amendment, so her common law negligence claims would be abrogated only if the amendment applied retroactively. *See Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 920 (N.D. Ohio 2009).

Since the amendment came into effect, at least three decisions of the Ohio Court of Appeals have held that the amendment is not retroactive, meaning that Buchanan's claims would not be abrogated. *See Doty v. Fellhauer Elec., Inc.*, 888 N.E.2d 1138, 1142 (Ohio Ct. App. 2008); *Luthman v. Minster Supply Co.*, No. 2-06-43, 2008 WL 169999, at *3 (Ohio Ct. App. Jan. 22, 2008) (unpublished); *Hertzfeld v. Hayward Pool Prods., Inc.*, No. L-07-1168, 2007 WL 4563446, at *9 (Ohio. Ct. App. Dec. 31, 2007) (unpublished) (all holding that the amendments applied only prospectively and did not apply retroactively). The *Doty* court also noted that "statutory-construction rules dictate that a statute is presumed to be prospective" and that, although the amendment "clearly

states the intent to abrogate all common-law product-liability claims, it does not provide that causes of action accruing prior to the effective date would be subject to the amendment." *Doty*, 888 N.E.2d at 1142. The court therefore held that the amendment did not apply retroactively. *Id.*

Buchanan filed her original complaint in 2003, well after the Act was enacted but before the 2005 amendment expressly abrogated all common law product liability claims. Thus, her negligence claims survive the enactment of the Ohio Products Liability Act and the 2005 amendment and are not abrogated.[5]

2. Merits of the Negligence Claim

The nature of Buchanan's negligence claim is unclear. Her Amended Complaint states that Wyeth had a duty

> to manufacture, promote, and sell only safe drugs, and the duty to investigate and disclose material facts about risks associated with their drugs. Defendants breached their duty by . . . putting Redux on the market in 1996, when Defendants knew the active ingredient in th[is] drug[], namely, dexfenfluramine, was unreasonably dangerous. Defendants further breached their duty by . . . failing to update the drug['s] labels, failing to adequately monitor the effects of the drug[], failing to make timely . . . warning to the medical profession, failing to timely and accurately report to the FDA all adverse drug experience

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[5]This finding conflicts with a previous Sixth Circuit ruling on this issue. We previously "applied OPLA to product liability negligence claims [arising before the 2005 amendment of OPLA] and [have] therefore implicitly concluded that common law negligence claims have been preempted by OPLA." *Tompkin v. Am. Brands*, 219 F.3d 566, 575 (2000) (citing *Amendola v. R.J. Reynolds Tobacco Co.*, No. 98-4506, 1999 WL 1111515 , at *2 (6th Cir. Nov. 24, 1999)) (holding that a plaintiff's negligent misrepresentation and negligent infliction of emotional distress claims are governed by the Ohio Products Liability Act).

Typically, "[w]ithout taking a case en banc, a panel cannot reconsider a prior published case that interpreted state law, absent an indication by the state courts that they would have decided the prior case differently." *Rutherford v. Columbia Gas*, 575 F.3d 616, 619 (6th Cir. 2009) (internal citations, quotations, brackets omitted). Plainly stated, we are "bound by a prior published case that interpreted Ohio law unless Ohio law has measurably changed in the meantime." *Id.* (brakets omitted). Although the district court's order in this case was issued prior to the Ohio Court of Apeals's decision in *Doty*, and thus the court did not have the benefit of the only published state appellate court case, we "must give an intervening state decision its full force and effect, despite the fact that the decision was unavailable to the district court at the time it rendered its decision." *Chandler v. Specialty Tires of Am. (Tenn.) Inc.*, 283 F.3d 818, 823 (6th Cir. 2002) (quoting *Siegler v. IBM H08 Mktg., Inc.*, 249 F.3d 509, 518 (6th Cir. 2001)). We therefore find that, although the Ohio Supreme Court has not yet spoken on the issue, the Ohio appellate courts' decisions provide the best indication of how the Ohio Supreme Court would rule on this issue and thus present such a measurable change in state law that reconsideration of our precedents is justified. Thus, *Tompkin* and *Amendola* are overruled to the extent that they provide that Ohio common law negligence claims arising prior to the 2005 amendment of the Ohio Products Liability Act are abrogated by the Act.

> information obtained, and concealing and misrepresenting the results of studies to physicians and to the public.

Longs I, 536 F. Supp. at 854 (reproducing Buchanan's Amended Complaint verbatim). The district court noted that at oral argument Buchanan characterized her negligence claim as attacking (1) Wyeth's alleged failure to investigate, prior to FDA approval, the early warning signs that led to the drug being taken off the market and (2) Wyeth's failure to take the drug off the market sooner. *Id.* at 855. We take this to mean that Buchanan's negligence claims may be divided into two general categories: (1) claims regarding Wyeth's acts and omissions, prior to the FDA's approval, in bringing the drug to market and (2) claims regarding Wyeth's acts and omissions subsequent to the FDA's approval of Redux.

We will address the post-FDA-approval negligence claims first. As characterized by Buchanan and the district court, the post-approval negligence claims are either a general negligence claim or a design defect claim. Whatever the label, the claim focuses on Wyeth's actions after the drug went to market, primarily Wyeth's failure to take the drug off of the market sooner. Wyeth moved for summary judgment on the basis that Buchanan could not show that Wyeth's actions or omissions after FDA approval caused any of her injuries. Specifically, Wyeth contended that it had updated its warnings about the risks of Redux as information became available and that it removed Redux from the market as soon as it became aware of the extent of the risk, and it submitted a substantial amount of evidence in support of this position.

But, just as she did with regard to Wyeth's request for summary judgment on the strict liability design defect claim, Buchanan did not highlight any evidence in the record that would contradict the evidence submitted by Wyeth. Instead, Buchanan again argued the law, insisting that the warnings were irrelevant because Wyeth should have known that the drug was so dangerous that no warning could make the drug acceptable. Critically, Buchanan did not point to any facts or evidence in the record that would reveal *why* Wyeth should have known any of this. The district court found that Buchanan failed to present evidence demonstrating proximate cause between Wyeth's

alleged negligence after the FDA approved Redux and Buchanan's injury or death sufficient to survive a motion for summary judgment. We agree, for principally the same reasons as we agreed that summary judgment was proper on the strict liability design defect claim. When Buchanan failed to point to any actual evidence in a particularized manner, she failed to meet her burden under Rule 56. Accordingly, we affirm the entry of summary judgment for Wyeth on the post-FDA-approval negligence claims.

3. Federal Preemption

However, Buchanan's failure to provide evidence of proximate causation for negligence occurring after the distribution of Redux does not dispose of her claims that Wyeth was negligent for bringing Redux to market at all. Doctor notification of potential harms necessarily does not factor into a claim of negligence for bringing a drug to market in the first place.[6] Buchanan argues:

> the theory of causation supporting the remaining negligent introduction and failure to withdraw theories set forth in Count II was completely different. Had Defendants heeded the persistent and near unanimous consensus of authority and either refrained from seeking approval of the diet medication or at least terminating production by the Fall of 1996, the Decedent never would have been exposed to Redux at all.

(Appellant Br. at 59.) Thus, we must address the district court's finding that the FDA's approval of Redux preempted all state law claims based on Wyeth's actions before that approval.

The district court found that Buchanan's pre-approval negligence claims were preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 391 *et seq.*, which is enforced by the FDA, 21 U.S.C. § 393(b). The district court concluded that:

> the FDA is responsible for regulating which drugs are on the market and the warnings such drugs must provide. As such, Plaintiff's strict liability

[6]This discussion assumes the viability of such a claim under the Ohio common law. We do not address whether such a claim actually exists; instead, we address only whether FDA approval would preempt such a claim if it does exist.

> and negligence claims that Redux was an "unreasonably dangerous" drug for which no warning would have been adequate directly conflicts with the FDA's authority to determine which drugs are sufficiently safe and effective to be marketed. Although Plaintiff asserts that she alleges only that *Defendants* should not have marketed Redux, and that she does not argue that *the FDA* did anything wrong, the court finds that her claim that Redux should never have been placed on the market interferes with the FDA's objectives. Consequently, all claims relating to pre-FDA approval are preempted by the FDA.

Longs I, 536 F. Supp. 2d at 847 (emphasis in original).

As the district court framed it, the issue is whether a state-court finding that a manufacturer was negligent in bringing the drug to market conflicts or is inconsistent with the FDA's subsequent approval of that drug for the market. Determining whether this is so requires some degree of understanding of the FDA approval process. A recent Fifth Circuit case summarized the FDA's role in approving new drugs:

> All prescription drugs marketed in this country must first receive FDA approval. Manufacturers of new drugs must submit a new drug application (NDA) to the FDA that demonstrates the drug's effectiveness and safety for its intended use. The 1962 Food, Drug and Cosmetics Act (FDCA) established this avenue for pioneer drugs, with the core objective of ensuring that drugs are both safe and effective; the FDA has codified the NDA regulations at 21 C.F.R. Part 314. New drug approval requires, among other deliverables, the results of successful clinical trials and labeling that accurately portrays the benefits and risks of the drug, as indicated by those trials and other data.

Demahy v. Actavis, Inc., No. 08-31204, 2010 WL 46513, at *2 (5th Cir. Jan. 8, 2010) (internal footnotes omitted). With this basic understanding of FDA drug approval in mind, we turn to federal preemption.

Federal preemption draws its force from the Supremacy Clause of the United States Constitution. U.S. Const. art. 6, cl. 2. "Here, as in every preemption case, '[t]he purpose of Congress is the ultimate touchstone." *Demahy*, 2010 WL 46513, at *3 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (plurality)). "[I]n all preemption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, 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." *Levine*, 129 S. Ct. at 1194-95 (internal quotation marks and ellipses omitted). "Although there is a presumption under the Supremacy Clause that Congress did not intend to preempt state law, 'an assumption of non-preemption is not triggered when the State regulates in an area where there has been a history of significant federal presence.'" *R.R. Ventures, Inc. v. Surface Transp. Bd.*, 299 F.3d 523, 562 (6th Cir. 2002) (quoting *United States v. Locke*, 529 U.S. 89, 108 (2000)). The analysis of whether the presumption of non-preemption applies "accounts for the historic presence of state law but does not rely on the absence of federal regulation." *Levine*, 129 S. Ct. at 1195 n.3.

Here, Buchanan is entitled to the presumption that Congress did not intend to preempt state law because hers are claims under "preexisting state products liability law." *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2006) (stating that "state-based tort liability falls squarely within [a state's] prerogative to regulate matters of health and safety, which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest.") (internal quotation marks and brackets omitted) (*aff'd Warner-Lambert Co., LLC v. Kent*, 522 U.S. 440 (2008) (per curiam) (4-4 decision)). Although "[i]t is not a valid argument against preemption to say that the state seeks to impose greater obligations than Congress did," *Smith v. Provident Bank*, 170 F.3d 609, 613 (6th Cir. 1999), "[w]here possible, a court should try to reconcile federal law and state law." *Rollins v. Wilson County Gov't*, 154 F.3d 626, 629 (6th Cir. 1998).

Keeping in mind that we operate under a presumption against preemption in this case, we turn to the substance of federal preemption. "In general, a federal law may preempt a state law in any of the following three scenarios. First, a federal statute may expressly preempt the state law. Second, a federal law may impliedly preempt a state law. Third, preemption results from an actual conflict between a federal and a state law." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965 (6th Cir. 2004) (citations omitted). Wyeth argues, and the district court based its holding on, the third type of preemption, conflict preemption.

Conflict preemption refers to circumstances "where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *State Farm Bank v. Reardon*, 539 F.3d 336, 342 (6th Cir. 2008). Conflict preemption analysis "should be narrow and precise, 'to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role.'" *Downhour v. Somani*, 85 F.3d 261, 266 (6th Cir. 1996) (quoting *Nw. Cent. Pipeline Corp. v. State Corp. Comm'n*, 489 U.S. 493, 515 (1989)). The Supreme Court has described impossibility preemption as a "demanding defense." *Levine*, 129 S. Ct. at 1199.

In this case, as a general proposition, we can discern no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs. This is not to say that such a physical impossibility could never exist, for instance if a state duty required that the manufacturer do something that the FDA forbade or vice versa. But such a situation would, we think, be the exception to the rule. Thus, we are not persuaded that it is always impossible to comply with both state law duties and FDA regulations in the process leading up to FDA approval.

The only remaining rationale to support conflict preemption, therefore, is that allowing state tort lawsuits would stand as an obstacle to the accomplishment of the statute. The district court quoted the FDCA to find that the purpose of the FDA is to:

> (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
> (2) with respect to such products, protect the public health by ensuring that–
> . . . .
> (B) human . . . drugs are safe and effective; . . . .

Longs I, 536 F. Supp. 2d at 847 (quoting 21 U.S.C. § 393(b)). The district court then determined that permitting common-law negligence claims regarding a drug manufacturer's pre-approval conduct would conflict with this function of the FDA.

However, we cannot agree with the district court's conclusion as, not only is there a presumption against preemption, but the case law supports the conclusion that Congress did not intend to preempt state tort law claims when it passed the FDCA. Part of the *Desiano* analysis is applicable here:

> Significantly, all of the claims advanced by Appellants in this case are premised on traditional duties between a product manufacturer and . . . consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency. As a result, were we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers. We see no reason, nor can we identify any precedent, to justify such a result.

Desiano, 467 F.3d at 94-95. Simply because tort liability "parallel[s] federal safety requirements" does not mean that liability is preempted. *Id.* at 95. Allowing a state tort claim under the instant circumstances would not "interfere[] with the methods by which the federal statute was designed to reach its goal." *Verizon North, Inc. v. Strand*, 309 F.3d 935, 940 (6th Cir. 2002) (internal brackets omitted) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 103 (1992)). Wyeth defends the district court's preemption finding by citing two Supreme Court cases for the principle that "[s]tate tort law disrupts the federal scheme . . .", but these cases are distinguishable.

In *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), the Court found that the plaintiffs' tort suit that "would have required manufacturers of all similar cars to install airbags rather than other passive restraint systems, such as automatic belts or passive interiors" would have presented an obstacle "to the variety and mix of devices that the federal regulation sought" and "to the gradual passive restraint phase-in that the federal regulation deliberately imposed." *Id.* at 881. Such conflicts do not exist here because the state duty urged by Buchanan does not create an obstacle to following the federal regulatory scheme.

Wyeth also cites *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). That case addressed the Medical Device Act, which expressly preempts state requirements

"'different from, or in addition to, any requirement applicable . . . to the device' under federal law." *Riegel*, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)). There is no similar express preemption provision for drugs under the FDCA. Indeed, in the 1962 amendments to the FDCA, Congress expressly limited the preemptive effect of the statute by stating:

> Nothing in the amendments made by this Act to the Federal Food, Drug and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.

Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87781, ¶ 202, 76 Stat. 780, 793 (1962); *see also Levine*, 129 S. Ct. at 1195-96 ("As it enlarged the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness, and reliability of drugs,' Congress took care to preserve state law.") (internal citations omitted).

The Supreme Court also observed that "[i]n keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation." *Levine*, 129 S. Ct. at 1202. The Court further stated:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, *see* § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), Congress has not enacted such a provision for prescription drugs. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. As Justice O'Connor explained in her opinion for a unanimous Court: "The case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them."

Levine, 129 S. Ct. at 1200 (internal citation and footnote omitted).[7] Moreover, even before the Supreme Court's clarification in *Levine*, we previously found that the FDCA did not preempt pre-approval design defect claims. *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993). Finally, we are aware of no federal appeals court decision since *Levine* concluding that FDA regulation preempts any aspect of state tort law, though we admit that, until today, there is also no post-*Levine* court of appeals authority for the proposition that the *Levine* rationale extends beyond the realm of failure-to-warn claims to apply to all pre-approval state law claims.

For these reasons, we hold that the district court erred in granting summary judgment to Wyeth on preemption grounds on Buchanan's pre-approval common law negligence claims. In so holding, however, we do not pass upon whether there may be alternative bases for adjudicating these claims short of trial. Neither the parties nor the district court have asserted any such alternative, so the issue is not before us. We hold merely that FDA approval does not automatically preempt state law tort claims for negligence, and we remand for such further proceedings as may be appropriate under the facts and circumstances. Moreover, because we remand for further proceedings on the

[7]Both the district court, *Longs II*, 621 F. Supp. 2d at 508-09, and Wyeth seek to distinguish *Levine* from the present case on the basis that *Levine* involved a state law inadequate warning claim whereas the instant case involves a state law negligent-bringing-to-market claim. It is indeed true that the question presented in *Levine* dealt solely with state tort inadequate warning claims versus FDA-approved labels, *Levine*, 129 S. Ct. at 1193, whereas this case pits state tort negligent-bringing-to-market claims against FDA approval to market. However, we find this to be a distinction without a difference, as the rationale in *Levine* applies with equal force to this claim as it did to the inadequate warning claim. Just as state tort law on adequacy of warnings can be seen as "complementary," *id.* at 1201, to the FDA's labeling regulation, so too can state law duties regarding the decision to bring a product to market be seen as complementary to the FDA's function of approving a drug for market. This makes sense, as whether the FDA approves a drug for market depends, in very large part, upon the results of the manufacturer's investigation and testing prior to seeking FDA approval. *Demahy*, 2010 WL 46513, at *2. If the manufacturer is negligent in this investigation, then the entire FDA approval process is tainted from the outset. And it is in this way that Buchanan's pre-approval negligence theory varies from a fraud-on-the-FDA claim. Finally, the overwhelming take-away from the *Levine* majority opinion is that state tort law has historically played a substantial role in the regulation of drug manufacturers and that Congress has never indicated an intent to change this role. Thus, while *Levine* did leave open the possibility that there may be some state law claims that would conflict with the FDA's regulatory authority and function, the claim at issue in *Levine* was not one of them. We do not believe that Buchanan's pre-approval negligence claims are, either.

common law pre-approval claims, the district court's mootness ruling as to punitive damages must also be reversed and remanded.[8]

III.

For the reasons set forth above, we **REVERSE** the judgment of the district court as to the pre-FDA-approval negligence claims and punitive damages and **REMAND** those issues to the district court for further proceedings; we **AFFIRM** the judgment of the district court on all other claims. Moreover, we **VACATE AS MOOT** the portion of *Longs I*, 536 F. Supp. 2d at 851, that holds that the plaintiff bears the burden of proving the inadequacy of a warning under section 2307.759(D).

[8]Because we conclude that the district court erred in granting summary judgment on the pre-FDA-approval negligence claims but affirm summary judgment on all other claims, we do not address Buchanan's appeal of the court's order denying the subsequent motion to vacate and amend judgment.

CONCURRING IN PART AND DISSENTING IN PART

HELENE N. WHITE, Circuit Judge, concurring in part and dissenting in part. I join the majority opinion except Part II(C)(2) and the related portion of Part III, from which I respectfully dissent. I would reverse the summary dismissal of claims based on Wyeth's alleged negligence in failing to adequately investigate adverse reports regarding Redux after FDA approval, and in failing to timely remove Redux from the market, and remand such claims to the district court for further proceedings. Although I agree with the majority that Buchanan failed to present evidence in support of these claims, my review of the record convinces me that this is because Wyeth's motions for summary judgment did not attack the factual support for these claims.

Buchanan's Amended Complaint included claims that Wyeth was negligent in "failing to adequately monitor the effects of the drug[] . . . failing to timely and accurately report to the FDA all adverse drug experience information obtained, and concealing and misrepresenting the results of studies to physicians and the public." Wyeth brought three motions for summary judgment. The only motion potentially related to the post-FDA-approval negligence claims was Wyeth's Motion for Summary Judgment Based on Lack of Evidence of Proximate Causation. Wyeth included two arguments in that motion. The majority of the brief was dedicated to Wyeth's argument that Buchanan's "failure to warn" claim is barred by the "learned intermediary" doctrine. Wyeth's second argument was that Buchanan's "design defect" claim under the OPLA is barred because Wyeth had provided a statutorily sufficient "adequate warning" under Ohio Rev. Code Ann. § 2307.75(D), and that even if the warnings were inadequate, Buchanan had not "established that any such claimed inadequacy proximately caused her physician to prescribe the drug to her." These arguments were not addressed to Buchanan's allegations that Wyeth is responsible for "[n]egligence in failing to investigate adverse reaction reports and in other conduct below the industry standard of

care . . . leading to Wyeth's failure to withdraw Redux from the market before December 1996."[1]

In its order granting summary judgment, the district court identified two negligence claims, general negligence and negligent design. In granting summary judgment to Wyeth on all negligence claims, the district court cited Wyeth's evidence regarding the warnings it sent to physicians, and specifically to Dr. Erokwu, and faulted Buchanan for not submitting evidence that Wyeth should have taken Redux off the market sooner. Although that failure was justifiably regarded as fatal to the design-defect claims based on inadequate warnings (which were directly addressed by Wyeth's summary judgment motion), it should not have been regarded as fatal to the general negligence claims alleging failure to adequately investigate and/or to take Redux off the market sooner.

In effect, the district court granted summary judgment on these claims *sua sponte*. Although this is permitted, it is disfavored. *Saxe v. Dlusky*, 162 F. App'x 430, 432 (6th Cir. 2006) ("Sua sponte grants of summary judgment are disfavored.") (citing *Employers Ins. of Wausau v. Petroleum Specialties, Inc.*, 69 F.3d 98, 105 (6th Cir. 1995)); *Chance v. Mahoning County*, 105 F. App'x 644, 649 (6th Cir. 2004) (noting that grants of summary judgment *sua sponte* are discouraged in the Sixth Circuit). If a district court is to do so, the losing party must be "on notice that she ha[s] to come forward with all of her evidence." *Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986).

"Notice and opportunity are determined from the totality of the proceedings below, including whether any party filed a motion for summary judgment on the claim and whether the losing party addressed the claim in its arguments." *Aubin Indus., Inc. v. Smith*, 321 F. App'x 422, 423 (6th Cir. 2008). In this instance, Buchanan did not have notice that she had to present her evidence as to the post-FDA approval failure to investigate/failure to remove from the market negligence claims because Wyeth's motion did not address these claims. *See Black Shield Police Ass'n v. City of Cleveland*, 838

[1]As the district court noted, much confusion could have been avoided if Buchanan had been clearer in identifying and distinguishing her claims.

F.2d 470, at *3 (6th Cir. 1988) (unpublished table decision); *see also Shelby County Health Care Corp. v. S. Council Indus. Workers Health & Welfare Trust Fund*, 203 F.3d 926, 931 (6th Cir. 2000) ("[W]e have held that Fed. R. Civ. P. 56(c) mandates that the losing party must 'be afforded notice and reasonable opportunity to respond to all the issues to be considered by the court.'"). As a result, Buchanan had "no reason to believe that [her] cause of action was in danger of being dismissed." *Moisenko v. Volkswagenwerk Aktiengesellschaft*, 198 F.3d 246, at *5 (6th Cir. 1999) (unpublished table decision).

Further, the dismissal of the post-FDA approval negligence claims prejudiced Buchanan because it foreclosed a potential avenue of relief. *See Yahon v. Gregory*, 737 F.2d 547, 552 (6th Cir. 1984) (appellant of *sua sponte* entry of summary judgment must show prejudice); *see also Moisenko*, 198 F.3d at *5 ("This Court has held that 'not having an opportunity to respond constitutes prejudice,' as a plaintiff is entitled to be informed of the deficiencies in his case 'in order that he might respond to the district court's proposal to grant summary judgment with whatever arguments and evidence in the record that he could muster.'" (quoting *Yashon*, 737 F.2d at 552)). Buchanan had no notice that the district court was contemplating granting summary judgment on the post-FDA-approval general negligence claims, and therefore should not be penalized for failing to address that point.[2]

[2]To be clear, I would not hold that summary judgment on this claim is inappropriate, only that the issue should be squarely addressed by the parties before the district court rules on it.