IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
NO. 5:15-CV-63-BO

FRANKLIN LIVESTOCK, INC., J AND K CATTLE, KEVIN VAN BEEK, AND JAY LELOUX, Plaintiffs, v. BOEHRINGER INGELHEIM VETMEDICA, INC., Defendant.	)	**ORDER**

This matter is before the Court on defendant Boehringer Ingelheim Vetmedica Inc.'s motion to dismiss pursuant to Rule 12(b)(6) and 12(c) of the Federal Rules of Civil Procedure. [DE 20]. Plaintiff responded, and a hearing was held on June 16, 2015, in Edenton, North Carolina. Also before the Court are defendant's motion to stay discovery [DE 29] and motion for extension of time to complete discovery [DE 34], which are ripe for ruling. For the reasons stated herein, defendant's motion to dismiss is denied, the motion to stay discovery is denied as moot, and the motion for extension of time to complete discovery is granted.

BACKGROUND

Plaintiffs are commercial cattle farmers who owned cattle that were conditioned on a farm in Franklin County, North Carolina. Beginning in 2010 and through 2013, plaintiffs purchased vaccines which were designed and manufactured by defendant Boehringer Ingelheim Vetmedica Inc. (Boehringer). Each of the vaccines is licensed by the United States Department of Agriculture (USDA) and tested by the Animal and Plant Health Inspection Service (APHIS), an agency within the USDA. After administering the vaccines to their cattle, plaintiff's cattle suffered symptoms of endotoxemia, leading to death or severely reduced performance. Plaintiffs

ultimately lost thousands of cattle and diminished value of thousands of additional cattle. Plaintiffs allege that high levels of endotoxins within the vaccines caused these injuries.

Plaintiffs filed suit in Franklin County Superior Court, alleging breach of express and implied warranties, negligent design and manufacture, failure to warn, failure to comply with the Viruses, Serums, Toxins, and Anti-Toxins Act (VSTAA), codified at 21 U.S.C. §§ 151–159, and unfair and deceptive trade practices. Boehringer removed the case to this Court and filed the instant motion to dismiss.[1]

DISCUSSION

A Rule 12(b)(6) motion to dismiss for failure to state a claim for which relief can be granted challenges the legal sufficiency of a plaintiff's complaint. *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009). When ruling on the motion, the court "must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007)). Although complete and detailed factual allegations are not required, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions . . . ." *Twombly*, 550 U.S. at 555 (citations omitted). "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 *Twombly*, 550 U.S. at 555). Similarly, a court need not accept as true a plaintiff's "unwarranted inferences, unreasonable conclusions, or arguments." *E. Shore Mkts., Inc., v. J.D. Assocs. Ltd.*, 213 F.3d 175, 180 (4th Cir. 2000).

[1] Defendant also asks for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. Defendant argues that Rule 56 governs if the Court considers matters outside the pleadings on a Rule 12(b)(6) motion. While defendant submitted an affidavit [DE 22], the Court declines to consider the affidavit at this time, and will instead allow defendant to present a fully briefed motion for summary judgment following the close of discovery.

I. Preemption

Defendant contends that each of plaintiffs' state law claims is preempted by APHIS's regulations. The affirmative defense of preemption may be resolved on a motion to dismiss, provided the facts necessary to determine the issue clearly appear on the face of the complaint. *Goodman v. Praxair, Inc.*, 494 F.3d 458 (4th Cir. 2007) (en banc); *see also Great-W. Life & Annuity Ins. Co. v. Info. Sys. & Networks Corp.*, 523 F.3d 266, 272 (4th Cir. 2008).

The Supremacy Clause of the United States Constitution "invalidates state laws that interfere with, or are contrary to, federal law." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (internal quotation omitted). Federal law may preempt state law by expressly declaring Congress' intent to do so. *Cox v. Shalala*, 112 F.3d 151, 154 (4th Cir. 1997). It may "occupy the field" by regulating so pervasively that there is no room left for the states to supplement federal law." *Id.* (citing *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). State law also is preempted "to the extent that it actually conflicts with federal law." *Id.* (citing *Pac. Gas & Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n*, 461 U.S. 190, 204 (1983). "Federal regulations have no less pre-emptive effect than federal statutes." *de la Cuesta*, 458 U.S. at 153. Nevertheless, it is the intent of Congress, rather than the agency's interpretation of whether its regulations preempt state law, that controls. *Wyeth v. Levine*, 555 U.S. 555, 576 (2009).

"In 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.'" *Id.* at 565 quoting *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996). This has come to be known as the presumption against preemption. *See,*

e,g., Nat'l City Bank of Ind. v. Turnbaugh, 463 F.3d 325, 330 (4th Cir. 2006). It applies to both federal laws, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 335 (2008), and asserted agency preemption, *Automatic Med. Labs.*, 471 U.S at 715–16, but is "stronger against preemption of state remedies, like tort recoveries, when no federal remedy exists," *College Loan Corp. v. SLM Corp.*, 396 F.3d 588, 597 (4th Cir. 2005). *See also Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir. 1988).

It is clear that Congress intended to create nationally uniform standards for the preparation and sale of animal vaccines via the VSTAA. *See, e.g.,* S. Rep. No. 145 at 339. The VSTAA, however, does not expressly include any intent to preempt state law. Boehringer relies heavily on the fact that APHIS has expressly preempted all state remedies. After the 1985 amendments to the VSTAA which broadened its scope, APHIS declared that "[s]tates are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States." APHIS Final Rule, 57 Fed. Reg. 38,758–38,759 (Aug. 27, 1992).

Boehringer argues that express preemption in the agency context involves a simple analysis of whether the agency intended to preempt state law and whether the act of preemption is within the scope of authority delegated to the agency by Congress. *de la Cuesta*, 458 U.S. at 154. It is true that following the Supreme Court's decision in *de la Cuesta*, a number of courts held that APHIS preempted state law in the field of contamination and dangerousness of animal vaccines. *See, e.g., Lynnbrook Farms v. SmithKline Beecham Corp.*, 79 F.3d 620, 625–26 (7th Cir. 1996); *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050 (8th Cir. 1998); *Cooper v.*

United Vaccines, Inc., 117 F.Supp.2d 864 (E.D. Wis. 2000). All of these cases, however, were decided before the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009).

Wyeth dealt with the Food and Drug Administration's approval of pharmaceutical drug labelling. The preamble to a 2006 FDA regulation governing prescription drug labels asserted that FDA approval of labeling preempted conflicting or contrary state law. *Id.* at 575. The *Wyeth* Court concluded that reviewing courts should not defer "to an agency's *conclusion* that state law is preempted," but instead should conduct their own conflict determination, "relying on the substance of federal law and not on agency proclamations of pre-emption." *Id.* at 576. The weight accorded to an agency's explanation of state law's impact on the federal scheme depends on its "thoroughness, consistency, and persuasiveness." *Id.* at 576–77. The Court ultimately determined that the FDA's proclamation did not merit deference because there was no effort by the agency to create a record showing how it had accommodated conflicting policies, that tort enforcement of non-federal standards burdened commerce, or that imposing damages on a manufacturer was incompatible with the regulatory scheme. *Id.* at 577–79.

Though *Wyeth* did not explicitly overrule *de la Cuesta*, the two decisions espouse opposing principles. While *de la Cuesta* states that an agency's intent to preempt is partially determinative and necessary to a preemption determination, *Wyeth* holds that an agency's intent to preempt is not sufficient. The trend appears to be away from broad presumptions of preemption. *See, e.g., Weyth*, 555 U.S. at 576; *Medtronic v. Lohr*, 518 U.S. 470 (1996). The Court, therefore, will follow *Wyeth*, as the more recent case addressing express preemption.[2]

[2] It appears that the only court to consider whether APHIS preempts state law remedies following *Wyeth* is the District of Wyoming. *Wyoming Premium Farms, LLC v. Pfizer, Inc.*, No. 11-CV-282-J, 2013 WL 1796965 (D.Wy. Apr. 29, 2013). That court distinguished *Wyeth*, finding that APHIS's "regulatory scheme . . . is comprehensive and thorough, has been consistent over an extensive period of time, and may be considered persuasive." *Id.* at 7n.2 The Court did not,

The VSTAA provides no federal remedy, thus the presumption against preemption is strong. This case does not deal with a specific regulation that conflicts with state law, but instead with an agency's proclamation of preemption. The VSTAA, however, does not expressly prohibit state law actions, nor did APHIS explicitly state that it intended to abolish state law remedies in the field of animal vaccine product liability. In fact, when publishing its preemption declaration in 1992, APHIS left in place the labeling regulation prohibiting manufacturers from publishing "disclaimers of merchantability, fitness for the purpose offered, or responsibility for the product," 9 C.F.R. § 112.29, which is an "express recognition that common law remedies are not entirely preempted," *Symens*, 152 F.3d at 1055. Although there are significant difference between the FDCA at issue in *Wyeth* and the VSTAA, *Wyeth* counsels against construing APHIS's preemption proclamation so broadly as to leave plaintiff with no remedy in the instant case. The "purpose of the [VSTAA] is to assure that biologics used in the treatment of animals are pure, safe, potent, and efficacious." 57 Fed. Reg. 38758. "If [the Act] is interpreted to completely insulate manufacturers from liability, it cannot achieve its purposes because manufacturers would have no incentive to maintain quality control after USDA approval." *Gresham v. Boehringer Ingelheim Animal Health, Inc.*, No. 1:95-CV-3376-ODE, 1996 WL 751126, *3 (D.S.D. Oct. 7, 1997).

Despite the complete primer on the VSTAA and APHIS set forth in the memorandum in support of its motion to dismiss, Boehringer did not undertake the *Wyeth* analysis. It did not discuss whether APHIS analyzed whether tort enforcement of state standards burdened commerce or whether imposing damages on a manufacturer was incompatible with the regulatory scheme. Boehringer does not argue that the USDA discussed any way in which the

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however, address whether APHIS considered the impact of preemption on state common-law remedies, so this Court gives that decision little weight.

existence of state remedies interfered with the agency's regulation, or an instance where the statutory goal of uniformity was placed at risk by state common-law actions. Nor has Boehringer explained whether or how each of plaintiff's claims directly conflicts with a specific federal regulation. In sum, Boehringer merely relies upon the agency's proclamation that its regulations preempt state law. In light of *Wyeth*, this is insufficient, and as Boehringer has not engaged in any further analysis that would lead this Court to conclude that plaintiff's claims are preempted, the Court denies the motion to dismiss.

II. Failure to Comply

Defendant argues that the VSTAA does not include a private cause of action, thus plaintiff's failure to comply claim should be dismissed. Even those cases which have afforded APHIS's regulations broad preemptive effect, however, have held that "state tort claims are available when APHIS regulatory standards are violated or disregarded." *Lynnbrook*, 79 F.3d at 629–30; *Symens*, 152 F.3d at 1055. It is well settled that plaintiffs may bring state law claims that "parallel" federal requirements. *Medtronic*, 518 U.S. at 495; *see also College Loan Corp. v. SLM Corp.*, 396 F.3d 588, 598–99 (4th Cir. 2005). Plaintiff's state tort claim of per se negligence liability falls directly within this line of cases. Therefore, Boehringer's motion to dismiss plaintiff's failure to comply claim is denied.

III. Economic Loss Rule

Boehringer also argues that the negligence and UTDPA claims are barred by the economic loss rule. Though the rule "prohibits recovery for purely economic loss in tort," a claimant may recover in tort "for damages to property other than the product itself, if the losses are attributable to the defective product." *Lord v. Customized Consulting Specialty, Inc.*, 643 S.E.2d 28, 30 (N.C. Ct. App. 2007). To pursue a tort claim stemming from a contract, a plaintiff

must allege both damage to property other than the product and "a duty owed him by [a] defendant separate and distinct from any duty owed under a contract." *Crop Prod. Servs. Inc. v. Ormond*, No. 4:11-CV-41-D, 2012 WL 147950 at *11 (E.D.N.C. Jan. 18, 2012) (internal quotation omitted). Courts apply this exception to the economic loss rule unless the "injury was or should have been reasonably contemplated by the parties to the contract." *Palmetto Linen Serv. v. U.N.X., Inc.*, 205 F.3d 126, 130 (4th Cir. 2000).

Here, plaintiffs allege that they contracted for the purchase of vaccines and that the property damaged was cattle. Their claims that Boehringer violated applicable regulation and industry standards and that the vaccines contained dangerously high levels of endotoxins allege duties separate and distinct from the terms of the contract. Defendant argues that this Court should rely on a case out of the Western District of Michigan that it believes demonstrates that minks' adverse reactions to vaccines was foreseeable. *Theuerkauf v. United Vaccines*, 821 F.Supp 1238, 1242 (W.D.Mich. 1993). The Court is not persuaded that adverse reactions separate and apart from symptoms of the disease the vaccine is intended to prevent are foreseeable. Given that *Theurkauf* is non-precedential, the Court finds that plaintiff has stated a plausible claim for relief.

IV. Other Motions

In April 2015, defendant asked the Court to stay discovery until the Court issued its ruling on the motion to dismiss. [DE 29]. Because this order moots that motion, defendant's motion [DE 29] is denied as moot. Defendant recently requested that this Court extend the discovery response deadline to thirty days after the date of this Order, essentially asking the Court to effectuate the stay requested in its prior motion. [DE 35]. Plaintiff does not oppose the request. Pursuant to Rule 26(c), the court may exercise its discretion to issue a stay of discovery

pending resolution of dispositive motions. *See, e.g., Tilley v. United States*, 270 F.Supp.2d 731, 734 (M.D.N.C. 2003), *aff'd,* 85 F. App'x 333 (4th Cir. 2004), *cert. denied*, 543 U.S. 8198 (2004); *Thigpen v. United States*, 800 F.2d 393, 396–97 (4th Cir. 1986), *overruled on other grounds by Sheridan v. United States*, 487 U.S. 392 (1988). In the interest of efficiency, defendant's motion is granted and the discovery response deadline is extended to thirty days after the date of this Order.

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss [DE 20] is DENIED. Defendant's motion to stay discovery [DE 29] is DENIED AS MOOT. Defendant's motion to extend the discovery deadline [DE 34] is GRANTED, and the deadline for defendant to respond to plaintiff's discovery requests is modified to require defendant to respond within 30 days of the date of this order.

SO ORDERED, this 22 day of June, 2015.

Terrence W. Boyle

TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE