UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

ALBION RANCH 2006, LLC, an Idaho limited liability company, Plaintiff, v. ZOETIS INC., a Delaware corporation; and ZOETIS US LLC, a Delaware limited liability company, Defendants.	Case No. 1:22-cv-00530-BLW MEMORANDUM DECISION AND ORDER

INTRODUCTION

Before the Court is Defendants Zoetis Inc. and Zoetis US LLC's (collectively "Zoetis") motion to dismiss (Dkt. 2). The Court held oral argument on May 11, 2023, and now issues its decision. For the reasons explained below, the Court will grant the motion, but with leave to amend.

BACKGROUND

This case involves the unfortunate circumstances of the loss of a significant number of calves, which Albion alleges was caused by the vaccination of its pregnant heifers with a vaccine manufactured by Zoetis and approved by the United States Department of Agriculture (USDA). Specifically, Albion alleges that

on November 15, 2019, it vaccinated its herd of 214 pregnant first-calf heifers with Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine ("Bovi-Shield") it purchased from a company located in Burley, Idaho. *Plf.'s Resps.* at 2, Dkt. 14. Bovi-Shield is one variety of a USDA-approved vaccine that Zoetis develops, manufactures, and sells. *See Def.'s Br.* at 1, Dkt. 3.

In late December 2019, Albion alleges it first discovered an aborted calve in its pasture. *Plf.'s Resps.* at 2, Dkt. 14. The following day, Albion discovered 15 additional aborted calves. Albion alleges that after deciding to send two of the aborted calves off to obtain diagnostic testing and autopsies, it received the results of the autopsies confirming that a single nucleotide polymorphism analysis affirmatively identified Zoetis's virus technology of Bovi-Shield in the aborted calves. *Id.*

On December 6, 2022, Albion filed suit against Zoetis in the Fifth Judicial District of the State of Idaho, raising five causes of action: (1) Breach of Express Warranty; (2) Breach of Implied Warranties; (3) Breach of Contract; (4) Joint and Several Liability; and (5) Negligence. *See Compl.*, Dkt. 1-1. Zoetis then timely removed this matter to federal court based on diversity jurisdiction. *See Notice of Removal*, Dkt. 1.

Following removal, Zoetis filed a motion to dismiss the complaint under

Federal Rule of Civil Procedure 12(b)(6). *See Def.'s Br.* at 1, Dkt. 2-1. Zoetis argues that the preemption doctrine precludes the entirety of Albion's claims, that Albion's claims for negligence and "joint and several liability" are barred by the economic loss doctrine, and that it cannot be liable for Albion's misuse of the vaccine. *See id.* After setting forth the legal standard governing Zoetis's motion, the Court will address each argument in turn.

LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While a complaint attacked by a Rule 12(b)(6) motion to dismiss "does not need detailed factual allegations," it must set forth "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*. at 555. To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Id*. at 570. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to reasonably infer that the defendant is liable for the alleged misconduct. *Id*. at 556. The plausibility standard is not akin to a "probability requirement," but

it asks for more than a sheer possibility that a defendant has acted unlawfully. *Id.* Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* at 557.

The Supreme Court identified two "working principles" that underlie *Twombly* in *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). First, the court need not accept as true, legal conclusions that are couched as factual allegations. *Id.* Rule 8 does not "unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 678–79. Second, to survive a motion to dismiss, a complaint must state a plausible claim for relief. *Id.* at 679. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.*

The Ninth Circuit has held that "in dismissals for failure to state a claim, a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Cook, Perkiss and Liehe, Inc. v. N. California Collection Serv. Inc.*, 911 F.2d 242, 247 (9th Cir. 1990).

ANALYSIS

1. Federal Preemption

The crux of Zoetis's motion to dismiss is that Albion's state law claims are preempted by the Viruses, Serums, Toxins, and Analogous Products Act ("VSTA") and the Animal and Plant Health Inspection Service's ("APHIS") promulgation of regulations. As discussed below, the Court agrees.

A. Preemption framework

The Supremacy Clause of the Constitution of the United States dictates that federal law is "the supreme Law of the land." U.S. Const. art. VI, cl. 2. Accordingly, state law is preempted when it conflicts with federal law. "Preemption of state law, by operation of the Supremacy Clause, can occur in one of several ways: express, field, or conflict preemption." *Cohen v. Apple Inc.*, 46 F.4th 1012, 1027 (9th Cir. 2022), *cert. denied*, 143 S. Ct. 2513 (2023) (citations omitted). Express preemption "arises when the text of a federal statute explicitly manifests Congress's intent to displace state law." *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1022 (9th Cir. 2013) (quoting *United States v. Alabama*, 691 F.3d 1269, 1281 (11th Cir.2012). Field and conflict preemption, however, are types of implied preemption. *Ass'n des Éleveurs de Canards et d'Oies du Quebec v. Bonta*, 33 F.4th 1107, 1114 (9th Cir. 2022). "Field preemption prohibits state regulation of conduct in a field that Congress, acting within its proper authority, has determined

must be regulated by its exclusive governance." *Id.* (internal quotations and citations omitted). Conflict preemption occurs when it is impossible to comply with both state and federal requirements or when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *MetroPCS California, LLC v. Picker*, 970 F.3d 1106, 1117-18 (9th Cir. 2020) (quoting *Williamson v. Gen. Dynamics Corp.*, 208 F.3d 1144, 1149 (9th Cir. 2000)).

It is well settled that "[s]tate law can be preempted by constitutional text, by federal statute, or by a federal regulation." *MetroPCS*, 970 F.3d at 1117 (citing *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)). Thus, Congress can either preempt state law by its own act, or by expressly or impliedly delegating that authority to a federal agency. *See Behrens v. United Vaccines, Inc., a div. of Harlan Sprague Dawley, Inc.*, 189 F. Supp. 2d 945, 951 (D. Minn. 2002) (citing *City of New York v. F.C.C.*, 486 U.S. 57, 63-64, (1988). In deciding whether agency regulation has a preemptive force, a reviewing court does not focus on Congress's intent to supersede state law. Rather, the proper inquiry is whether the power to preempt falls within the scope of the agency's delegated authority and, if so, whether the agency intended to preempt state law. *Cohen*, 46 F.4th at 1028; *MetroPCS*, 970 F.3d at 1117.

B. Statutory structure

The Court will begin with a brief overview of the statutory and regulatory framework at issue. Currently, the federal government regulates animal biologics, including vaccines, through VSTA. *See* 21 U.S.C. §§ 151-159; *see also de Maio Farms v. Hereford Veterinary Supply, Inc.*, No. 2:14-CV-00233-J, 2015 WL 12731758, at *4 (N.D. Tex. Mar. 4, 2015).[1] VSTA was first enacted in 1913 and then amended in 1985 to place the regulation of both intrastate and interstate vaccines within the ambit of federal control. *See* 21 U.S.C. § 151. This change reflected the Congressional findings that federal regulation was "necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce." *Lynnbrook Farms v. Smithkline Beecham Corp.*, 79 F.3d 620, 625 (7th Cir. 1996) (quoting 21 U.S.C. § 159).

VSTA authorizes the United States Department of Agriculture ("USDA") to "make and promulgate from time to time such rules and regulations as may be

[1] As discussed below, the issue before the Court is less focused on the actual application of preemption but on whether the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009) sufficiently changed the preemption landscape, rendering the weight of authority obsolete. Thus, the Court has only provided a brief overview of the federal regulatory scheme. However, more detailed explanations are readily available and have been relied on by the Court. *See, e.g., de Maio Farms*, at *4; *Wyoming Premium Farms, LLC v. Pfizer, Inc.*, No. 11-CV-282-J, 2013 WL 1796965, at *3 (D. Wyo. Apr. 29, 2013).

necessary to prevent the preparation [and] sale . . . of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals . . . .” *Id.* (quoting 21 U.S.C. § 154). USDA, in turn, delegated the responsibility and authority of administering VSTA to APHIS. *See* 9 C.F.R. § 101.2. In accordance with that responsibility, APHIS “promulgated an extensive regulatory scheme governing the design, manufacture, distribution, testing, and labeling of animal vaccines.” *Lynnbrook*, 79 F.3d at 624 (citing 9 C.F.R. §§ 101-24); *see also Wyoming Premium*, 2013 WL 1796965, at *3.

In 1992, APHIS published a Final Rule, which “amend[ed] the regulations pertaining to restrictions which may be imposed by States on the distribution and use of veterinary biological products.” *de Maio Farms*, 2015 WL 12731758, at *4 (quoting 57 Fed. Reg. 38758). Included in the Final Rule, 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.” *Franklin Livestock, Inc. v. Boehringer Ingelheim Vetmedica, Inc.*, 113 F. Supp. 3d 834, 838 (E.D.N.C. 2015) (quoting 57 Fed. Reg. 38758). However, APHIS’s preemption declaration was not included in the actual text of the Final

Rule but was instead inserted into an introductory "Background" section. *de Maio Farms*, 2015 WL 12731758, at *4.

C. Scope of preemption

The Seventh Circuit's decision in *Lynnbrook* is generally viewed as the leading case regarding the preemptive effect of APHIS's federal regulations. *See, e.g.*, *de Maio Farms*, 2015 WL 12731758, at *5 (relying on the *Lynnbrook* test to determine whether state law claims are preempted); *Cooper v. United Vaccines, Inc.*, 117 F. Supp. 2d 864, 869 (E.D. Wis. 2000) ("*Lynnbrook Farms* . . . remains the leading circuit court decision on the preemptive effect of federal regulations governing animal vaccines."). Relying on *City of New York v. F.C.C.*, 486 U.S. 57, 63 (1988) and *Fidelity Federal Savings and Loan Assoc. v. de la Cuesta*, 458 U.S. 141, 152-54 (1982), the Seventh Circuit adopted a three-part test to assess the preemptive effect of the APHIS regulations:

> First, [the court] must ascertain whether the power to preempt is within the authority delegated to the USDA and APHIS by Congress and is a rational exercise of that authority. If so, [the court] must then ask whether APHIS intended its regulations to preempt state common law claims. Finally, if APHIS did seek to preempt state common law, [the court] considers whether the regulations preempt the specific causes of action[ ] asserted by [the plaintiff].

Id. at 624.

Regarding the first question, the Seventh Circuit found that APHIS acted

rationally and within the scope of the authority granted to it by Congress in issuing its declaration of preemption, which stated:

> *[W]here safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field.* This includes, but is not limited to the regulation of labeling. Under VSTA, Congress clearly intended that there be national uniformity in the regulation of these products.
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> *APHIS ... does not agree that States should be allowed to add various restrictions* ... based upon a need to protect domestic animals or the public health, interests or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.
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> *States 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.* Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.

Id. at 625 (quoting 57 Fed. Reg. 38758, 38759 (August 27, 1992)) (emphasis original). In reaching that decision, the Seventh Circuit noted that, through the 1985 amendments to VSTA, Congress expressly granted to the USDA and APHIS "broad regulatory power to promulgate and enforce 'such rules and regulations as may be necessary' to prevent the production and sale of any 'worthless,

contaminated, dangerous or harmful' animal vaccines." *Id.* (quoting 21 U.S.C. § 154). This broad grant was made in direct response to prior judicial decisions "that the scope of VSTA, and hence the application of APHIS regulations, was limited to products made and sold in interstate commerce[,]" *Id.* The VSTA amendments statutorily reversed those prior decisions, and thereby placed both interstate and intrastate vaccines squarely within the ambit of federal control. *Id.* That background and the legislative history supporting the VSTA amendments "evidences an unquestionable congressional intent to create national, uniform standards for the preparation and sale of animal vaccines." *Id.* (citing S. Rep. No. 145 at 339). The court then concluded that "[g]iven these powers and responsibilities, APHIS was acting rationally, and well within its congressionally delegated discretion, in creating a complex statutory scheme governing the safety, efficacy, purity, and potency of animal vaccines and in pronouncing this scheme to be the exclusive law in the area." *Id.*

Regarding the second question, the court found APHIS intended to preempt state law, including common law claims, involving the safety, efficacy, potency, or purity of animal vaccines that impose requirements in addition to, or different from, the federal standards and regulations. *Id.* at 630. The court reasoned that "APHIS'[s] preemption statement is clear and comprehensive[,]" and "in an effort

to fulfill its mandate to create a national, uniform system of regulations, APHIS announced it intended to 'occupy the field' concerning 'the safety, efficacy, purity and potency of biological products.'" *Id.* at 627 (quoting 57 Fed. Reg. 38759 (August 27, 1992)). Importantly, to achieve that purpose, APHIS unambiguously stated 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." *Id.*

The court further explained that the language APHIS chose to use in the declaration mirrors that of federal statutes, which had been held to preempt both state regulations and common law damages. *Id.* at 127-128. The court finally noted that its interpretation was supported by the APHIS Acting Administrator's 1995 letter, which was the only official APHIS statement explaining its intent regarding preemption. *Id.* at 128. That letter stated that "promulgating the rule was, and continues to be, to preempt States from imposing requirements either through statutes, regulations, *or other means* that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product." *Id.* at 629 (emphasis original). However, "[w]e did not intend to preempt common law actions for damages *arising from noncompliance with USDA regulatory standard*s." *Id.* (emphasis original). The court explained that the phrase "or other

means" clearly encompasses common law claims. *See id.*

Finally, the court examined each of the plaintiff's claims and determined that they clearly involved the safety and efficacy of the vaccine at issue in the claims raised by the *Lynnbrook* plaintiffs. *Id.* at 630. The Court thus found that each of the plaintiff's claims were preempted. *Id.*

Since the Seventh Circuit decided *Lynnbrook*, the federal and state courts have consistently reached the same conclusion – VSTA, through APHIS's regulations, preempts state law claims that relate to the safety, purity, potency, or efficacy of animal vaccines, and seek to impose requirements that are additional to, or different from, those federal requirements.[2] Albion argues, however, that the

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[2] *See, e.g., Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050, 1056 (8th Cir. 1998) ("Plaintiffs' broadly pleaded claims are preempted to the extent that they rely upon "liability-creating-premises" that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, purity, or labeling of SBC's licensed vaccines."); *Cooper*, 117 F.Supp.2d at 871 ("State common law claims are preempted if they are in tension with this regulatory scheme, *i.e.*, if their enforcement would impose different or additional requirements concerning the safety or efficacy of vaccines."); *Gresham v. Boehringer Ingelheim Animal Health, Inc.*, No. CIV.1:95-CV-3376-ODE, 1996 WL 751126, at *2 (N.D. Ga. Aug. 7, 1996) ("courts uniformly have interpreted this language to mean that VSTA preempts all state common law actions relating to the safety, purity, potency or efficacy of vaccines which would impose additional or different requirements from those imposed by the USDA."); *Murphy v. SmithKline Beecham Animal Health Group*, 898 F.Supp. 811, 817 (D. Kan. 1995) ("We agree with this line of authority, and hold that APHIS intended to pre-empt state common law as well as state statutes."); *Brandt v. Marshall Animal Clinic*, 540 N.W.2d 870, 878 (Minn. App.1995) ("We find, in sum, that the Inspection Service has effectively regulated commerce in animal vaccines such as to preempt all state law requirements, including state law damages actions, different from or in addition to those imposed by the Inspection Service regarding the safety, efficacy, purity, potency or labeling of animal vaccines.").

legal landscape has substantially changed since *Lynnbrook* was decided. Specifically, Albion points to the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), as requiring a different result. Thus, the Court must consider whether the Supreme Court's decision in *Wyeth* requires an abandonment of the analysis conducted and conclusion reached by the Seventh Circuit in *Lynnbrook*. As discussed below, the Court concludes that while *Wyeth* does require a re-calibration of the *Lynnbrook* analysis, the end result is the same – the APHIS regulations preempt the Plaintiff's claims.

Turning to *Wyeth*, we begin by observing that the Supreme Court was addressing the preemptive effect of a different set of federal regulations promulgated by the Food and Drug Administration (FDA). *Wyeth*, 555 U.S. at 559-60. There, the FDA's preemption declaration was not included in the text of an FDA regulation, but rather was included in the preamble of the 2006 FDA Final Rule. *Id.* at 575-76. After acknowledging that it is proper to give "some weight to an agency's views about the impact of tort law on federal objectives" and that federal agencies "have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," the Court explained that the "weight we accord the

agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness." *Id.* at 576-77 (internal quotation marks omitted).

Under that standard, the Supreme Court held that the FDA's 2006 preamble did "not merit deference[.]" *Id.* at 577. The Court explained that the preemption statement was "inherently suspect" because the States and other interested parties were not provided notice or an opportunity to comment on the preemption question, it was at odds with congressional intent, and "it reverse[d] the FDA's own longstanding position without providing a reasoned explanation[.]" *Id.* at 577-578. For those reasons, the Court held that the plaintiff's state law claim was not preempted because it was not persuaded that the claim obstructed federal regulation. *Id.* at 581.

Here, the Court finds that *Wyeth*'s holding cannot be extended to this case. Although APHIS's declaration of preemption, like the FDA's, was not included within the actual text of a regulation, the similarities end there.

First, APHIS's declaration is not "inherently suspect" because, unlike the FDA declaration, APHIS's assertion of preemption was made after providing interested parties with notice and an opportunity to comment on the scope of preemption. *See de Maio Farms* 2015 WL 12731758, at *8. Even though APHIS's

declaration of preemption was not included in APHIS's Proposed Rule, but was only added later in the "Background" section, "a significant portion of the Proposed Rule was devoted to articulating a narrow [local disease] exception to the general rule that APHIS's regulations preempt state laws relating to the safety, efficacy, potency, or purity of animal biologics." *Id.* Borrowing from an old adage, the focus on the limited exception proves the rule of APHIS preemption.

Moreover, the public apparently recognized the intended preemptive effect and utilized the opportunity to comment. Out of seventeen comments received in response to APHIS's Proposed Rule, seven specifically addressed the preemptive scope of the regulations. Those comments argued that "States should have the authority to add to Federal restrictions, as appropriate, based on a need to protect animal or human health and safety so long as such restrictions do not lessen the effect of Federal regulations." *Id.* (citing 57 Fed. Reg. 38758, 38758-9). The Court's concern in *Wyeth*, that the FDA's assertion of preemption was not subject to public notice and comment, simply does not apply to the APHIS's declaration of preemption at issue here.

Second, there is no evidence that APHIS's declaration conflicted with congressional intent. Unlike Congress's intent to preserve state law by amending the FDCA to add a savings clause, "numerous federal courts have found that

APHIS'[s] declaration of preemption was entirely consistent with congressional intent, because Congress delegated to APHIS the responsibility to establish a national, uniform regulatory scheme for animal biologics[.]" *Id.* at *9 (citing *Symens*, 152 F.3d at 1054 and *Wyoming Premium*, 2013 WL 1796965, at *7). Additionally, Congress showed no intent to preserve state law by adding a savings clause to VSTA.

Third, in contrast to the FDA, "APHIS has never disclaimed an intent to preempt and has instead remained consistent and unwavering in its position that the regulations it promulgated under VSTA preempt state law." *Id.*; *see also Wyoming Premium*, 2013 WL 1796965, at *7 ("There is no indication that [APHIS'] position regarding preemption of state law in the area of veterinary biological products has ever been otherwise."). As mentioned, APHIS's Proposed Rule articulated a narrow "local disease" exception to a generally applicable preemption rule. *Id.* Thus, even before issuing its preemption declaration, APHIS demonstrated its intention to preempt most state law. Moreover, after the declaration was issued, APHIS's Acting Administrator wrote a letter explaining that the intent in "promulgating the rule was, and continues to be, to preempt States from imposing requirements . . . that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product.'"

Lynnbrook, 79 F.3d at 629. Simply put, unlike the FDA, APHIS's regulatory scheme "is comprehensive and thorough, has been consistent over an extensive period of time, and may be considered persuasive." *Wyoming Premium*, 2013 WL 1796965, at *7.

Moreover, Albion's claim that the pre-*Wy*eth cases "are largely outdated and inapposite" is not supported by recent Ninth Circuit decisions. In *Cohen v. Apple Inc.*, 46 F.4th 1012, 1028 (9th Cir. 2022), the Ninth Circuit recently addressed a similar objection to reliance on the "decades-old cases" of *de la Cuesta* and *City of New York*. The Court squarely rejected that argument, unequivocally stating that "the Supreme Court has never overruled either case, and they remain good law." *Id.* It then clarified that the Ninth Circuit has continued to cite those cases for the standard governing agency preemption, which closely aligns with the standards announced in *Lynnbrook*.[3] *Id.* (citing *MetroPCS*, 970 F.3d at 1117 and *Barrientos v. 1801–1825 Morton LLC*, 583 F.3d 1197, 1208 (9th Cir. 2009)).

Accordingly, like many other courts before, this Court finds that Congress delegated APHIS the authority to preempt state law through the 1985 Amendments to VSTA. Further, APHIS's declaration of preemption was a rational exercise of

[3] *Compare Cohen*, 46 F.4th at 1028, *with Lynnbrook*, 79 F.3d at 623–24, *and de Maio Farms*, 2015 WL 12731758, at *2-3.

that power and clearly shows that it intended to preempt most, but not all, state law claims. *See de Maio Farms*, 2015 WL 12731758, at *6 ("Indeed, all the federal courts that have considered this issue reached the same conclusion.") (citing seven different federal decisions). Therefore, the Court joins the vast majority of other courts which have considered the issue, in concluding that "[i]n the context of VSTA, state law claims will be preempted if they (1) relate to the safety, purity, potency, or efficacy of animal vaccines, and (2) seek to impose state law requirements that are additional to, or different from, federal requirements in [that] area." *Id.* at *12. With the scope of preemption set, the Court must now look to Albion's state causes of action to determine which claims are preempted.

D. Application to Albion's claims

Neither party engaged in a careful, claim-by-claim analysis of the complaint. Zoetis generally argues that Albion's claims are preempted because "[t]he gravamen of the Complaint is that this USDA-authorized vaccine is not safe and effective but, rather, harmful and dangerous[.]" *Def.'s Br.* at 10, Dkt. 2-1. Albion does not address its specific allegations in a comprehensive fashion, but argues generally that state law claims based on "merchantability, fitness for a particular purpose, and the like" are not preempted by VSTA. *Plf.'s Resp.* at 11, Dkt. 3.

Whether a claim involving an animal biologic is preempted is not based

solely on the categorization of the claim but rather on the actual allegations in the complaint. *See Symens*, 152 F.3d at 1056 (The preemption issue "require[s] a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope[.]"). Specifically, the Court must ask whether Albion's claims allege noncompliance with federal standards and whether they impose different or additional requirements above those in APHIS's regulations. *See de Maio Farms*, 2015 WL 12731758, at *12 ("[t]he key inquiry for each cause of action is whether the legal duty that is the predicate of the common law damages action constitutes a requirement which is different from, or in addition to, those imposed by USDA") (quoting *Murphy* 898 F. Supp. at 817).

While the allegations in Albion's complaint are sparse, they are undeniably related to the safety, purity, potency, or efficacy of Zoetis's USDA-approved vaccine, Bovi-Shield. The core of each product liability claim is that Bovi-Shield was not safe for its intended use. In doing so, Albion does not allege any violations of regulatory standards, nor does Albion clarify what exactly made the vaccine unsafe. Instead, each of Albion's claims appears to allege that despite meeting those regulatory standards, Bovi-Shield remained unsafe for public use. *See, e.g.*, *Compl.* ¶ 10, Dkt. 1-1.

With so little information, the only reasonable reading is that for Albion to prevail on its product liability claims, standards above or different from the federal regulations must apply. Further, Albion does attempt to show how the claims, *as alleged in the complaint*, might fall outside the scope of preemption.

On the other hand, Albion has made express warranty claims that are arguably not preempted. Courts have found that in some, but not all, situations express warranty claims based on an agent's representation may avoid preemption. *Compare de Maio Farms*, 2015 WL 12731758, at *14 ("because Plaintiff's express warranty claims do not impose state law requirements on the Defendants, but instead represent requirements voluntarily imposed by the Defendants upon themselves, those claims are not preempted by federal law."), *and Behrens*, 189 F. Supp. 2d at 965 (finding that defendant's promotional representations made by a sales representative that the product was 95 percent effective was not preempted because the warrantor imposed a new requirement, not that state), *with Wyoming Premium*, No. 2013 WL 1796965, at *9 (finding that plaintiff's express warranty claim is preempted by federal law because the representations did not significantly deviate from APHIS's and had already been declared safe and effective), *and Cooper*, 117 F. Supp. at 872 (finding that statements made by the defendant's representative regarding the high "field effectiveness" of the vaccine were

preempted because they were not "substantially different from those in the company's approved labeling and packaging and would require the jury to find the vaccine was ineffective to return a verdict."). The problem is that Albion's complaint does not clarify what representations were made or how they created requirements greater than those imposed by federal regulation. While plaintiff's counsel alluded to agent representations during oral argument, the complaint does not allege that any verbal representations were made, let alone how they would create an express warranty which exceeded regulatory standards. *See Compl.* ¶ 24, Dkt. 1-1. The Court will refrain from issuing an advisory opinion on what statements might provide an avenue to a non-preempted claim.

While the Court acknowledges that certain state law claims may be able to survive preemption, Albion's complaint, as it stands, fails to plausibly allege such circumstances. Accordingly, the Court will grant Zoetis's motion to dismiss each of Albion's claims. However, the Court cannot rule out the possibility that the deficiencies in the complaint could be cured by the inclusion of additional allegations. Therefore, it will grant Albion leave to amend.

ORDER

IT IS ORDERED that:

1. Defendant's Motion to Dismiss (Dkt. 2) is **GRANTED**.

2. Plaintiff shall have thirty days to amend its Complaint (Dkt. 1-1) to state sufficient facts supporting its claim for relief in accordance with this decision.

DATED: September 29, 2023

B. Lynn Winmill
U.S. District Court Judge