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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

RALPH LOWERY,	}	
	}	
Plaintiff,	}	
	}	
v.	}	**Case No.: 7:18-cv-00376-RDP**
	}	
SANOFI-AVENTIS LLC, et al.,	}	
	}	
Defendants.	}	

MEMORANDUM OPINION

This matter is before the court on Defendant Genzyme Corporation's Motion for Summary Judgment. (Doc. # 49). The Motion has been fully briefed. (Docs. # 50, 62, 67). After careful review, and for the reasons discussed below, the court concludes that Defendant's Motion (Doc. # 49) is due to be granted.

This case presents issues about the admissibility of expert testimony, the causation requirements in a toxic tort case with complicated medical and technical issues, and the limiting effect of federal regulations on state-law claims. In the context of these issues, the court must determine if there is a factual issue to present to a jury for determination. This case also stands as a reminder that although some cases seem viable upon their initial presentment, they can fall apart when the legal standards affecting expert testimony are applied and Congress's policy choices come in to play.

Here, Plaintiff Ralph Lowery, a patient with an arthritic knee, received an injection of a medical device manufactured by Defendant Genzyme Corporation to relieve pain in his knee from arthritis. But, as it turns out, the lot from which that injection was drawn was contaminated with bacteria. Almost immediately after receiving the injection, Plaintiff experienced increased pain in

his arthritic knee. He then filed this action claiming that the device caused him to suffer from septic arthritis. On the surface, this claim may seem meritorious. After all, the device was contaminated with bacteria.

But, that is not the whole story. Plaintiff retained experts, which is necessary in a case like this. It was critical for Plaintiff's experts to be qualified and for them to provide reliable expert opinion testimony on two points: (1) that Plaintiff actually had septic arthritis; and (2) that his septic arthritis was caused by the bacteria in the device injected into his knee. Plaintiff's experts were obliged to analyze these issues with the scientific rigor and reliability required by Federal Rule of Evidence 702. However, as explained below, they failed in both of these tasks. Unfortunately, without that expert testimony, Plaintiff cannot connect the dots necessary to present his case to a jury. That is, Plaintiff cannot show exactly what his condition was, much less that his condition was caused by the bacteria in his injection.

There is another problem. The defective product at issue is a Class III medical device, a product that is heavily regulated in every aspect of its design, manufacture, and sale. In fact, the product is scrutinized so much for safety and effectiveness that, once it is approved by the Food and Drug Administration, no one, especially the manufacturer, can alter the device's design or manufacture unless it receives prior approval from the FDA certifying that the device will remain safe and effective with the proposed changes. To enforce this policy, Congress has prohibited the states (or any other authority) from interfering with the federal regulatory scheme by imposing on device manufacturers requirements that are different from or in addition to the federal requirements. Because that is exactly what Plaintiff seeks to do here -- to impose such different or additional obligations on Defendants -- his claims are preempted.

Although this case started out with promising facts for Plaintiff, for the reasons explained in detail below, the legal and evidentiary standards that must be applied prove to be an insurmountable barrier to his recovery. Defendant is due summary judgment in this case.

I. Factual Background

The facts set out in this opinion are gleaned from the parties' submissions and the court's own examination of the evidentiary record. All reasonable doubts about the facts have been resolved in favor of Plaintiff. *See Info. Sys. & Networks Corp. v. City of Atlanta*, 281 F.3d 1220, 1224 (11th Cir. 2002). These are the "facts" for summary judgment purposes only. They may not be the actual facts that could be established through live testimony at trial. *See Cox v. Adm'r U.S. Steel & Carnegie Pension Fund*, 17 F.3d 1386, 1400 (11th Cir. 1994). For summary judgment purposes, the facts that have been excluded under the court's *Daubert* memorandum opinion are not analyzed. *See Rubens v. Mason*, 387 F.3d 183, 188 (2d Cir. 2004) ("[I]n deciding a motion for summary judgment, a court may rely only on material that would be admissible at trial.").

A. Production of Synvisc-One Lot 7RSL021 and Plaintiff's Contaminated Injection

Defendant manufactures Synvisc-One -- a Class III medical device used to treat "pain [caused by] osteoarthritis (OA) of the knee" -- at its facility in Ridgefield, New Jersey. (Doc. # 50-1 at 11, 13). Devices and drugs do not just enter the market without significant regulatory scrutiny. Under FDA regulations, Medical devices fall into three categories. One of those categories is Class III medical devices. Class III devices are subject to the highest scrutiny. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (citing 21 U.S.C. § 360c(a)(1)(C)). With respect to a Class III device, the Food and Drug Administration ("FDA") embarks on a "premarket approval" ("PMA") process, which includes reviewing its design and specifications, clinical studies and data about its safety

and effectiveness, and the processes employed in its manufacture. (Doc. # 50-3 at 13, 17).

An overview of the manufacturing process is helpful to understand the issues in this case.[1] Although certain steps in the process undergo "terminal sterilization," Defendant manufactures the final Synvisc-One product by "aseptic processing," which means that the processing does not *actively* sterilize but *preserves* the sterile status of a material. (*Id*. at 16, 19). Terminal sterilization "is the final step" in a sterilized process. (Doc. # 50-7 at 19). The difference between an aseptic process and a sterilized process is that an aseptic process "reduces" the "risk of the presence of microorganisms" while a sterilized process produces "the absence of viable organisms." (Doc. # 50-7 at 19). Defendant preserves the sterile environment by manufacturing Synvisc-One in "strictly controlled environments." (Doc. # 50 at 9, ¶ 11) (citing *id*. at 17-19, 24). Controls for aseptic processing include the use of "clean rooms" by controlling personnel movement, using personal protective equipment, air filtering, and specific ventilation to control air movement in the rooms. (Doc. # 50-3 at 26). Water is introduced to the manufacturing process via a Water for Injection ("WFI") system.[2] Synvisc-One's PMA specification requires Defendant to test the WFI system daily and before each use of the system. (*Id*. at 28).

Synvisc-One is comprised of two components: Hylan A-10 fluid and Hylan B-10 gel. (*Id*.). Both components are subject to "endotoxin, bioburden, and sterility testing" during their respective manufacturing processes. (*Id*.). Although Defendant "terminally sterilize[s]" the gel before combining it with the fluid, the fluid cannot be terminally sterilized. But, the fluid is otherwise filtered for contaminants. (*Id*.).

[1] Defendant produced a detailed report of its processes related to Synvisc-One, which was written by David L. Chesney. (Doc. # 50-3). A detailed diagram of the high-level steps and sub-steps in the process can be viewed in Defendant's Investigation Report. (Doc. # 50-1 at 65).

[2] The WFI system itself "is not required to be sterile," and there are numerous testing and inspections in place to reduce the risk of contamination in the WFI system. (Doc. # 50-3 at 27, 41-42).

After Defendant produces and tests the individual components, it combines them during the "bulk blending" step into fifty-liter or one hundred fifty-liter vessels. (*Id*. at 28-29). At this stage, Defendant retains samples of the bulk for future investigations and fills the product into individual syringes. (*Id*. at 30). All these processes are subject to strict "in-process controls" laid out in "standard operating procedures, which are reviewed and approved by the FDA as part of the PMA process." (Docs. # 50-3 at 24, 30; 50-1 at 64, 66).

Defendant then conducts two different tests on the product before distributing it. (Docs. # 50-3 at 30; 50-6 at 51). These tests are required by the procedures in the PMA specifications. (Docs. # 50-3 at 30; 50-6 at 51). The first test is the "sterility test," which detects the presence of microbial growth in the product. (Docs. # 50-7 at 21-22; 50-6 at 45). At the time Defendant made Lot 7RSL021 ("the Lot"), it tested for sterility using a fourteen-day incubation period. (Docs. # 50-3 at 45; 50-7 at 20-21). The second test is an endotoxin test, which requires that endotoxins in the product be below a threshold quantity.[3] (*See* Doc. # 50-1 at 28). Defendant conducted an endotoxin test on the Lot by "pool[ing]" together three separate samples. (Docs. # 50-2 at 42; 50-6 at 75).

Defendant manufactured the Lot on May 23, 2017 and kept samples from the bulk blending step in the event future testing became necessary.[4] (Doc. # 50-3 at 33). The Lot was filled into individual syringes on June 15, 2017, and it entered into its sterility and endotoxin protocols. (*Id*. at 34). The Lot passed both tests: the endotoxin results were below the threshold amount and there

[3] Endotoxins are "pieces of the gram negative cell wall of bacteria." (Doc. # 50-7 at 9). In other words, endotoxin tests look for the "byproducts of bacteria … after the bacteria has died" while sterility tests only for active growth. (Doc. # 50-5 at 23).

[4] The manufacturing process spans months. (Doc. # 50-3 at 41). But, the date of manufacture is when bulk blending occurs. (Doc. # 50-3 at 29).

was "no growth" in the sterility testing.[5] (Doc. # 50-1 at 16). The Lot then went through a second round of testing in September 2017. (Doc. # 50-3 at 34). As part of this "stability testing," Defendant conducted another round of endotoxin testing and sterility testing. (*Id*.). The results were again within release specifications. (Doc. # 50-1 at 28).

On November 1, 2017, Dr. Stephen T. Ikard injected Synvisc-One from the Lot into Plaintiff Ralph Lowery's right knee to treat Plaintiff's knee pain associated with osteoarthritis. (Doc. # 50 at 8, 10; 56 at 3). Plaintiff began experiencing pain and swelling in his right knee by the time he returned home. (Docs. # 56 at 7; 56-6 at 9). Three days later, Plaintiff went to an emergency room because he continued experiencing pain and swelling in his right knee. (Doc. # 62 at 9) (citing Doc. # 62-5). Dr. William McKibbin, an orthopedic specialist, operated on Plaintiff's knee, removed a "dark thick yellow fluid," sampled cultures, and made the initial clinical diagnosis that Plaintiff had septic arthritis. (Docs. # 62-6 at 1; 50-11 at 3). The day after his initial treatment and procedure, Plaintiff followed up with Dr. Albert T. White, an infectious disease specialist. (Docs. # 58-17; 58 at 9). Dr. White's assessment was that it was "most likely septic arthritis." (Doc. # 58-17 at 5). Based on all the facts available to Dr. Ikard, he said that a "reasonable physician [could] conclude" that Plaintiff suffered "septic arthritis from a contaminated lot of Synvisc." (Doc. # 62-18 at 71). He also said in a sworn statement that "it very possibly could have been infected." (Doc. # 58-3 at 28-29).[6]

[5] The endotoxin limit is equal to or less than 0.5 eu/ml. The Lot tested at 0.3 eu/ml. (Doc. # 50-1 at 16). The sterility results are binary. (*Id*.). The Lot tested "no growth." (*Id*.).

[6] As discussed below, Plaintiff states in his brief that Dr. Ikard's testimony, statement, and affidavit establish specific causation. (Doc. # 62 at 36). In his *Daubert* brief, Plaintiff highlights the "inconsistencies" he finds between the three records Dr. Ikard produced. The two statements above are the statements most favorable to Plaintiff. Dr. Ikard said other things not favorable to Plaintiff, including that it was his opinion that Plaintiff's knee "probably was not infected" (*i.e.*, he did not suffer from septic arthritis), and "it is more likely than not that he had a pseudoseptic reaction." (Doc. # 62-18 at 33, 38-39). But, none of Dr. Ikard's statements show that he actually concluded that Plaintiff suffered from septic arthritis caused by Defendant's product.

B. Investigation of The Lot and Findings

On November 10, 2017 -- ten days after Plaintiff's Synvisc-One injection -- Defendant became aware of "a higher number of adverse events" for the Lot. (Doc. # 50-1 at 3). These adverse events triggered an internal investigation. (Doc. # 50-1 at 3). At that time, Defendant retested the retained bulk samples collected from the Lot. (*Id*. at 32-33). Defendant's endotoxin retest failed on November 21, 2017, and the sterility retest showed positive microbial growth on December 5, 2017. (Docs. # 50-1 at 28, 32; 62-10 at 105). On December 8, 2017, Defendant found that the growth was *Methylobacterium thiocyanatum*, and it initiated a voluntary recall of the Lot on December 11, 2017. (Docs. # 50-1 at 12, 32; 62-9 at 1). Obviously, Synvisc-One is manufactured without *Methylobacterium thiocyanatum* so that bacteria is not "a part of the release specification of the product." (Doc. # 50-2 at 38-39).

Defendant conducted an investigation to determine the cause of the recall and produced an Investigation Report. (Docs. # 50 at 12; 50-1). While not an exhaustive list, Defendant investigated the rates of adverse events, previous endotoxin and sterility testing, the manufacturing record and testing data for the Lot, the manufacturing environment, and changes to the manufacturing process from 2016 onward. (Doc. # 50 at 13, ¶ 28) (citing Doc. # 50-1). Defendant concluded that the Lot was uniformly contaminated with *Methylobacterium thiocyanatum*; the contamination was an isolated incident; the root cause was not identified, but it was likely from "incidental … contamination" or from the WFI system; and there were no deviations from manufacturing or testing processes in Synvisc-One's PMA or other federal requirements that would have caused the contamination. (Docs. # 50-1 at 77-78; 50-3 at 38; 50-2 at 72; 62-10). The uniform contamination "could only occur if … the bulk was contaminated." (Docs. # 50-1 at 78; 62-10 at 104-105). The Investigation Report stated that the contamination posed a "high risk" because of the combination

of the frequency of the adverse events and the nature of the events observed. (Doc. # 62-10 at 106-107). However, the report did not identify what condition or harm patients were at a "high risk" for. (*Id*). Defendant's Health Hazard Report indicated that "*Methylobacterium thiocyanatum* … are unusual pathogens that rarely cause human infections …. [But the] [r]isk … includes septic arthritis." (Doc. # 62-17 at 4, 30).

There are three Nonconforming Reports ("NCRs") in Defendant's internal investigation "being associated with the Lot." (Doc. # 62-10 at 45). Although the NCRs were upstream (that is, during the manufacturing of the gel component of Synvisc-One), they did not implicate *Methylobacterium thiocyanatum*, and any gel would have been "sterilized … killing any organisms present" before the bulk blending step. (Docs. # 50-1 at 19-20; 62-12 at 61). Defendant's FDA-approved procedures *allow* for them to retest "retained bulk samples" "in the event of an excursion or NCR … *as necessary*."[7] (Doc. # 62-12 at 17) (emphasis added). In explaining whether there was an excursion or NCR that made testing necessary (pursuant to its own FDA-approved procedures), Robert Darius, Defendant's head of Good Manufacturing Practices ("GMP") compliance, stated that "there wouldn't be a reason to [re]test." (Docs. # 62-12 at 17; 50-1 at 3).

The FDA began a year-long inspection of the Ridgefield facility approximately two weeks after the first adverse events were reported. (Doc. # 50-8). The FDA conducted a comprehensive observation and analysis of the facility, including management oversight, laboratory control systems, production systems, environmental controls, testing procedures, equipment, water systems, and production records. (Doc. # 50 at 14, ¶ 45) (citing Doc. # 50-8).

[7] Plaintiff asks the court to make an unreasonable inference on these facts, but the court will not entertain it. *Pina v. Children's Place*, 740 F.3d 785, 795 (1st Cir. 2014) ("[w]e will not 'draw unreasonable inferences'" of the Rule 56 record). He states that Defendant "violated its own Operating Procedures by *not* testing bulk blending retain samples" and quoted Darius's deposition (Doc. # 62 at 20) (emphasis in original) (citing Doc. # 62-12 at 17). Nothing in the Rule 56 record shows that Defendant was *required* to retest. Indeed, it is unreasonable to say that Defendant violated a rule if Plaintiff cannot show how Defendant was compelled to act differently than it did.

There are two aspects of the FDA's inspection report released on February 27, 2018 that are relevant to this case. First, the FDA found that "this facility is considered to be in a minimally acceptable state of compliance with regards to current [GMPs]." (Doc. # 62-3 at 1). Second, the FDA issued a Form FDA 483 ("483 Report") "for … [a] … deficiency." (*Id.*). The 483 Report explained that Defendant's "[l]aboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality[,] and purity." (Doc. # 62-3 at 29). Specifically, the FDA found that Defendant's "endotoxin results *might be invalid* for the final release and stability studies." (*Id.*) (emphasis added). With respect to accurate endotoxin results, Defendant pooled together samples in such a manner that it "[did] not accurately reflect" the "maximum valid dilution" of the samples. (*Id.* at 30). James Assini, Associate Director of Quality Assurance for Defendant, put it simply by explaining that by "not pooling … [manufacturers] are trying to ensure that a single unit with endotoxin is not diluted to the point where it would not be detected if it were pooled with other samples." (*See* Doc. # 67 at 12) (citing Doc. # 50-7 at 10). Artificially low endotoxin concentrations "can lead to false negative results." (*Id.*). Assini admitted that Defendant's endotoxin testing method "was a misinterpretation" of the "FDA guidance for industry Pyrogen and [E]ndotoxin testing." (Docs. # 62-4 at 29; 62-15; 50-2 at 47).[8] Again, it is undisputed that the Lot was "[u]niformly contaminated." (Doc. # 62 at 9, ¶ 3). If the contamination is uniform, "the testing of one syringe individually or [a] pooled syringe … would have [made] no difference in the results generated."[9] (Doc. # 50-7 at 12).

[8] Plaintiff cites to several other parts of Assini's deposition saying the same thing: that pooling was a practice not recommended by the guidance documents. (Doc. # 62 at 9) (citing Docs. # 62-4 at 10-12, 16-17, 35).

[9] Plaintiff cites to the same page in the deposition and quotes Assini's statement that "[i]f there were one contaminated syringe in the three that were sent for testing, there is the potential that it could have been diluted…." (Doc. # 62 at 17-18) (citing Doc. # 50-7 at 11) (emphasis omitted). Plaintiff also cites Dr. Catherine E. Patterson's testimony in his brief regarding the effects of pooled endotoxin testing. For reasons explained in the court's separate

II. Standard of Review

Under Federal Rule of Civil Procedure 56, summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The party asking for summary judgment always bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of the pleadings or filings which it believes demonstrate the absence of a genuine issue of material fact. *Id.* at 323.

Once the moving party has met its burden with a "properly supported motion for summary judgment," Rule 56 requires the non-moving party to go beyond the pleadings and -- by pointing to affidavits, or depositions, answers to interrogatories, and/or admissions on file -- designate specific facts showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 324; *Gargiulo v. G.M. Sales, Inc.*, 131 F.3d 995, 999 (11th Cir. 1997). As *Anderson* teaches, under Rule 56(c) a plaintiff may not simply rest on his allegations made in the complaint; instead, as the party bearing the burden of proof at trial, he must come forward with at least some evidence to support each element essential to his case at trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

The substantive law will identify which facts are material and which are irrelevant. *See id.* 248. All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. *See Allen v. Bd. of Pub. Educ. for Bibb Cty.*, 495 F.3d 1306, 1314 (11th Cir. 2007); *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir. 1993). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson,*

Memorandum Opinion on the Motion to Exclude Testimony of Dr. Patterson (Doc. # 72), her opinion testimony is due to be excluded. But the court notes that Dr. Patterson "can't make a comment on" whether "the difference between the pooling of the three syringes and the individual syringe testing method, caused a difference in the outcome" in this case. (Doc. # 67 at 12-21) (citing Doc. # 50-4 at 100).

477 U.S. at 248. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. *See id.* at 249.

"[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id*. "Essentially, the inquiry is 'whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Sawyer v. Sw. Airlines Co.*, 243 F. Supp. 2d 1257, 1262 (quoting *id.* at 251-52); *see also LaRoche v. Denny's, Inc.*, 62 F. Supp. 2d 1366, 1371 (S.D. Fla. 1999) ("The law is clear ... that suspicion, perception, opinion, and belief cannot be used to defeat a motion for summary judgment.").

The Eleventh Circuit has interpreted *Celotex* to require that, as to issues on which the nonmovant would bear the burden of proof at trial, a

> moving party is not required to support its motion with affidavits or other similar material negating the opponent's claim in order to discharge this initial responsibility. Instead, the moving party simply may show [ ]—that is, point[ ] out to the district court—that there is an absence of evidence to support the non-moving party's case. Alternatively, the moving party may support its motion for summary judgment with affirmative evidence demonstrating that the non-moving party will be unable to prove its case at trial.

Fitzpatrick, 2 F.3d at 1115 (quoting *U.S. v. Four Parcels of Real Property*, 941 F.2d 1428, 1437 (11th Cir. 1991)). And, where the moving party has met this initial burden by showing that there is an absence of evidence supporting the nonmoving party's case, the nonmoving party must

> respond in one of two ways. First, he or she may show that the record in fact contains supporting evidence, sufficient to withstand a directed verdict motion, which was "overlooked or ignored" by the moving party, who has thus failed to meet the initial burden of showing an absence of evidence. Second, he or she may come forward with additional evidence sufficient to withstand a directed verdict motion at trial based on the alleged evidentiary deficiency.

Id. (internal citations omitted).

The parties have raised two issues for the court to resolve at summary judgment: (1) whether Defendant is entitled to summary judgment as a matter of law because there is not a genuine dispute of material fact; and (2) the scope of preemption with respect to Plaintiff's claims. These two issues are separate but not in complete isolation. Nonetheless, because preemption is a constitutional issue, the court "first analyze[s] whether each claim can stand under state law, and only then decide the preemption questions where necessary." *Godelia v. Doe 1*, 881 F.3d 1309, 1317 (11th Cir. 2018). Thus, the court will address Plaintiff's claims under state law before addressing any preemption issues and address preemption issues only in the alternative.

III. Analysis

Defendant moves for summary judgment under Rule 56, arguing that there is no genuine issue as to any material fact and that it is entitled to judgment as a matter of law on all six of Plaintiff's claims. Specifically, it contends that Plaintiff has failed to establish a *prima facie* case under state law—and, even if the record is sufficient to establish such a case under state law, Plaintiff's claims are barred by federal preemption. After careful review and for the reasons explained below, the court concludes as follows: (1) on this record, there is no genuine dispute of material fact regarding the medical causation of Plaintiff's conditions such and Defendant is entitled to judgment as a matter of law on all six claims for this reason; (2) there is no genuine dispute of material fact that Plaintiff failed to provide the notice required under Alabama law as to Count Four and Count Five; and (3) even if Plaintiff's state-law claims were viable (and, to be clear, they are not), Plaintiff's claims are preempted because they impose requirements in addition to, or different from, those required by the FDA under federal law. Thus, for all these reasons, Defendant's Motion is due to be granted.

A. Plaintiff's Claims Fail Under Alabama Law

Plaintiff asserts six separate claims: (1) Strict Liability[10]; (2) Alabama Extended Manufacturers Liability Doctrine ("AEMLD"); (3) Negligence and Wantonness; (4) Breach of Implied Warranty; (5) Breach of Express Warranty; and (6) Failure to Comply with [GMPs]. (Doc. # 35). Defendant is due summary judgment on Counts One through Five because Plaintiff has failed to establish causation. (*See* Doc. # 72). Count Four and Count Five also fail because Plaintiff did not provide notice to Defendant as required under Alabama law. And, Plaintiff concedes that "Failure to Comply with [GMPs]" is not a "viable cause of action in Alabama," (Doc. # 62 at 33 n.10). Thus, Summary Judgment is due to be granted on the claim made in Count Six. The court addresses these reasons in more detail below.

1. Plaintiff Has Not Established a *Prima Facie* Case on Any of His Claims Because He Has Failed to Establish Medical Causation

Plaintiff's claims under Alabama law asserted in Counts One through Five fail because (1) Plaintiff has not pointed to any Rule 56 evidence that he had septic arthritis and, (2) alternatively, because he has not shown that the *Methylobacterium thiocyanatum* in his injection caused septic arthritis. "An essential element of all product liability cases is expert testimony, passing *Daubert* muster, that a defect was the medical cause of plaintiff's claimed injuries." *McCreless v. Glob. Upholstery Co.*, 500 F. Supp. 2d 1350, 1355 (N.D. Ala. 2007) (internal citations omitted); *Sutherland v. Matrixx Initiatives, Inc.*, 2006 WL 6617000, at *14 (N.D. Ala. Nov. 7, 2006) ("[W]ithout an expert to connect a toxin to an injury, there is no toxic tort."); *Jones v. Novartis*

[10] Technically, Strict Liability is not recognized under Alabama law. Alabama "created the [AEMLD] as a substitute for imposing a strict products liability regime." *Hamby v. Trucking*, 2019 WL 3315202, at *3 (M.D. Ala. July 23, 2019) (dismissing claim for strict liability); *Miller v. Pfizer Inc.*, 2014 WL 2155020, at *2 (N.D. Ala. May 22, 2014) ("Alabama law does not recognize a strict liability cause of action, but instead substitutes the judicially-created AEMLD."); *Griggs v. Combe, Inc.*, 456 So. 2d 790, 792 (Ala. 1984) (explaining that strict liability is "a position expressly rejected" by the Supreme Court of Alabama). Thus, because there is no cognizable strict liability claim, Defendant is due to be granted summary judgment on the claim made in Count One.

Pharm. Corp., 2017 WL 553134, at *6 (N.D. Ala. Feb. 10, 2017) (compiling product liability cases in Alabama and the Eleventh Circuit requiring expert testimony to prove medical causation). Indeed, while expert testimony is not required in every case, the "interaction between a complex and technical medical device and the unique physiological and medical circumstances of the patient in which it is implanted is a subject on which no ordinary juror could rationally be expected to have knowledge." *Hughes v. Stryker Corp.*, 423 F. App'x 878, 879 (11th Cir. 2011). Thus, here, in the absence of viable expert testimony, the jury would be left to "speculate" without adequate guidance as to the cause of the injury. *Id.*; *Jones*, 2017 WL 553134, at *6 (citing *Lowery v. Bisbee*, 623 So. 2d 1047, 1049 (Ala. 1993)).

To be sure, in this context there must be expert testimony supporting two types of causation: general and specific.[11] General causation is established by "laying a scientific groundwork" that the toxin in question "*can* cause the harm plaintiff alleges." *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1303 (11th Cir. 2014) (emphasis in original). Specific causation requires a court to evaluate whether the expert's methodology reliably supports the conclusion that the substance did cause the plaintiff's *specific* injury. *Id*. (internal citations omitted).

a. General Causation

Plaintiff points to Defendant's Health Hazard Evaluation and Investigation Report, Dr. Minerva Perrin's deposition testimony, and Dr. Ikard's deposition testimony to establish general causation. (*See* Doc. # 62 at 35-37). For the reasons explained below, none of these establish general causation.

[11] For a more specific discussion on the requirements to satisfy reliable general causation testimony, see this court's opinion on the *Daubert* issues raised by the parties. (Doc. # 72).

Even if Defendant's documents can be said to be a legally sufficient substitute for expert testimony to establish general causation, the contents of them do not establish it.[12] For example, the Health Hazard Evaluation states that *Methylobacterium* "species are unusual pathogen[s] that rarely cause human infections" but present a "risk of septic arthritis." (Doc. # 62-17). Dr. Perrin repeated the Health Hazard Evaluation's conclusion in her deposition. (*See* Doc. # 62 at 32) (citing Doc. # 62-12 at 38). Of course, a possibility or a risk, by itself, does not reliably establish general causation. *Saldana v. Kmart Corp.*, 260 F.3d 228, 234 (3d Cir. 2001) (holding that a "mere possibility" is insufficient as a matter of law); *In re Lipitor*, 227 F. Supp. 3d at 482 (citing *Reference Manual on Scientific Evidence* 218 (3d ed. 2011)) (explaining that evidence of "increase in … risk … is evidence of association, not causation"). For these same reasons, her deposition testimony and the Health Hazard Evaluation form are insufficient to prove general causation. The same problem exists in relation to Defendant's Investigation Report, which specifies a "high risk" of consequences from contamination without specifying the types of harms or conditions of which patients are at a "high risk" (including septic arthritis). (Doc. # 62-10 at 106-107).

[12] Plaintiff assumes (but does not provide any support for the point) that documents produced in discovery are equivalent to expert testimony and that these documents are sufficient to show general causation as a matter of law. (Doc. # 62 at 10, 35-37). However, as just discussed, Plaintiff is required to present expert testimony establishing causation in a product liability case such as this. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005*); Matrixx Initiatives, Inc.*, 2006 WL 6617000, at *14; *Jones*, 2017 WL 553134, at *6. And, where state law requires expert testimony, "[p]laintiffs' claims would fail if the [p]laintiffs did not offer admissible expert testimony tending to establish general causation." *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 802 (N.D. Ohio 2004). Thus, documents discussing the health risks associated with a particular substance (such as indicated in Defendant's Health Hazard Evaluation and the Investigation Report) are not a substitute for expert testimony as to general causation under the relevant circumstances of this case. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 227 F. Supp. 3d 452, 479 (D.S.C. 2017) (holding that party admissions are insufficient to establish general causation); *In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 498 (E.D. Pa. 2016) (excluding documents by internal doctors on general causation); *In re Mirena IUD Prod. Liab. Litig.*, 202 F. Supp. 3d 304, 315-18 (S.D.N.Y. 2016). Indeed, "a jury exposed to admissions [in the absence of] expert testimony will be without the grounding in science necessary to determine whether, as a scientific matter, the events the plaintiff posits can occur in real life." *In re Mirena*, 202 F. Supp. 3d at 319. This is especially relevant in this case because the jury would be required to make speculative inferences regarding the complex causation relationships between exposure to a contaminant and its effects on the human body. And, it is not the type of "a natural inference that a juror could make through human experience." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1320 (11th Cir. 1999).

Finally, as a last-ditch effort, Plaintiff cites a single statement by counsel that Dr. Ikard assented to in his deposition: "a reasonable physician [could] conclude that this was … septic arthritis from a contaminated lot of Synvisc." (Doc. # 62 at 36) (citing Doc. # 62-18 at 71). This conclusory statement does not lay "any scientific groundwork" for the conclusion that *Methylobacterium thiocyanatum* causes septic arthritis. *McClain*, 401 F.3d at 1252.

b. Specific Causation

Even if Plaintiff could establish general causation, he is also required to establish specific causation. This is an even more significant undertaking in this case, and one that Plaintiff has been unable to accomplish. Plaintiff relies on the opinions and statements of two physicians for specific causation: Dr. Abney and Dr. Ikard. As discussed in detail in the court's memorandum opinion and order (Doc. # 72), Dr. Abney's opinion that Plaintiff suffered from septic arthritis because of *Methylobacterium thiocyanatum* in the Lot is inadmissible.

Contrary to what Plaintiff represents as a "fact," Dr. Ikard's testimony does not establish a genuine dispute as to whether *Methylobacterium thiocyanatum* caused septic arthritis in Plaintiff's right knee. Dr. Ikard's most favorable statement for Plaintiff is that his (Plaintiff's) knee "very possibly could have been infected." (Doc. # 58-3 at 28-29). Dr. Ikard also said that a "reasonable physician" *could* conclude that plaintiff's condition was septic arthritis caused by the contaminated Lot and that "[Defendant's] medical device *could have* played a role." (Doc. # 62-18 at 71; 58-3 at 21-22, 29) (emphasis added). But, as already discussed, Dr. Ikard's statement that *it was possible* Plaintiff suffered from septic arthritis does not indicate that *it is* Dr. Ikard's medical opinion that Plaintiff had septic arthritis, much less what caused it. (Doc. # 58-3 at 28-29). *Saldana*, 260 F.3d at 234 (3d Cir. 2001); *Tidwell v. Upjohn Co.*, 626 So. 2d 1297, 1301 (Ala. 1993) ("On issues of medical causation a showing of probable cause, rather than possible cause, must be

made."). Nor does Dr. Ikard's statement that a "reasonable physician" could conclude Plaintiff suffered from septic arthritis indicate what Dr. Ikard's medical opinion about Plaintiff's condition actually was. Viewing the Rule 56 record most favorably to Plaintiff, and despite what Plaintiff argues in his *Daubert* brief as to Dr. Ikard "inexplicably" reversing course, nothing supports the assertion that Dr. Ikard concluded that Plaintiff suffered septic arthritis because of Defendant's product—let alone that he conducted an analysis that would withstand *Daubert* scrutiny. (*See* Doc. # 58 at 13).

Further, to the extent that Plaintiff relies solely on Dr. Ikard's clinical impression during Plaintiff's treatment to establish specific causation, a treating physician's testimony is limited to his factual observations and is not expert causation evidence. *United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005); *Rondini v. Bunn*, 2020 WL 136858, at *3 (N.D. Ala. Jan. 13, 2020). Thus, Plaintiff's claims necessarily fail under state law. Defendant's motion for summary judgment is due to be granted as to all of Plaintiff's claims.

2. Breach of Express and Implied Warranties

Plaintiff's warranty claims fail because Plaintiff has not provided the notice of a breach of warranty to Defendant that is required under Alabama law. In a personal injury case, as the Eleventh Circuit has noted, "[t]he Alabama courts have held that notice of breach is a condition precedent to bringing a breach of warranty action …, which *mus*t be affirmatively pleaded in the complaint." *Hart v. Yamaha-Parts Distributors, Inc.*, 787 F.2d 1468, 1474 (11th Cir. 1986) (emphasis added) (citing *Parker v. Bell Ford, Inc.*, 425 So. 2d 1101, 1102 (Ala. 1983), *Lindsey v. International Shoe Co.*, 233 So. 2d 507, 509 (Ala. Civ. App. 1970) ("the giving of notice must be affirmatively pleaded in the complaint")); *Smith v. Apple, Inc.*, 2009 WL 3958096, at *2 (N.D. Ala. Nov. 4, 2009) (reasoning that "general awareness of defects" was insufficient to satisfy notice

requirement where plaintiff failed to plead notice in complaint). Plaintiff has neither alleged nor shown that it provided Defendant with the required notice. (*See* Doc. # 35 at ¶ 30).

Plaintiff argues that the notice requirement for a breach of warranty claim was eliminated by the Supreme Court of Alabama in *Simmons v. Clemco Indus.*, 368 So. 2d 509, 514 (Ala. 1979). This argument fails for two reasons. First, a reading of *Simmons* does not support that broad assertion. *Simmons* only eliminated the notice requirement for warranty "beneficiaries," not "buyers." *Id.*; *see Hart,* 787 F.2d at 1474 (recognizing that *Simmons* distinguishes buyers from beneficiaries in the notice statute); *see, e.g., Hobbs v. Gen. Motors Corp.*, 134 F. Supp. 2d 1277, 1283 (M.D. Ala. 2001) (citing *Simmons*, 368 So. 2d at 509) ("There are Alabama cases which have abrogated the notice requirement for bringing warranty claims" for warranty beneficiaries bringing personal injury claims); *Apple*, 2009 WL 3958096, at *2. And, Plaintiff does not argue that he is a warranty beneficiary (as opposed to a buyer) in these circumstances, so *Simmons* does not apply here. Second, this court is compelled to apply *Hart* (decided seven years after *Simmons*) because this court is bound to follow Eleventh Circuit precedent, even in cases applying state law. *Palmer & Cay, Inc. v. Marsh & McLennan Companies, Inc.*, 404 F.3d 1297, 1307 n.15 (11th Cir. 2005). Plaintiff has not cited (nor is this court aware of) any case law from the Supreme Court of Alabama or the Eleventh Circuit overruling *Hart* or calling *Hart* into question.[13] Finally, there is no fact in the Rule 56 record regarding an express warranty—Plaintiff does not even mention his claim for express warranty anywhere in his brief. (Doc. # 62). *See* Fed. R. Civ. Pro. 56(c). Thus, Defendant

[13] In *Palmer*, the court declined to deviate from older Eleventh Circuit precedent despite a subsequent Georgia Court of Appeals case questioning the validity of the Eleventh Circuit's application of Georgia law. *Palmer & Cay*, 404 F.3d at 1307 n.15. In reaching its decision, the court held that it was bound by its prior precedent unless the "Supreme Court, or, on matters of Georgia state law, the Georgia Supreme Court" (and not an intermediate state appellate court) overrules the circuit's prior decision. *Id*. (citing *United States v. Chubbuck*, 252 F.3d 1300, 1305 n.7 (11th Cir. 2001) (internal citations omitted) ("[W]e are not at liberty to disregard binding case law that is so closely on point and has been only weakened, rather than directly overruled, by the Supreme Court.")).

is due summary judgment on Plaintiff's claims for Breach of Implied Warranty and Breach of Express Warranty.[14]

The court separately addresses the question of causation related to Plaintiff's Breach of Implied and Breach of Express Warranty claims. Plaintiff argues that "the importance of the implied warranty claims cannot be overstated. ... [I]t does not require expert testimony to prove it." (Doc. # 62 at 34). Plaintiff is correct that he does not have to present expert testimony to prove Defendant's *breach* of the warranty. *See Tucker v. Gen. Motors Corp.*, 769 So. 2d 895, 899 (Ala. Civ. App. 1998). However, the same cannot be said in relationship to the *causation* of the medical damages he alleges. *See* Ala. Code § 7-2-314, cmt. 13. Regardless of the cause of action asserted, whether a defective product caused a plaintiff's alleged injuries is "an essential element of all product liability cases." *Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291, 1295 (N.D. Ala. 2003) (citing *Tidwell*, 626 So. 2d at 1299); *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 522 (11th Cir. 2007) (discussing damages in Breach of Warranty case). And, Plaintiff has not alleged (let alone presented sufficient Rule 56 evidence of) any damages resulting from problems with Synvisc-One. (*See* Docs. # 35, 62). It follows that Defendant is due summary judgment on Plaintiff's claims for Breach of Implied Warranty and Breach of Express Warranty.[15]

[14] Alabama law treats express warranties and implied warranties the same for notice requirements. *Apple*, 2009 WL 3958096, at *1 ("There is no distinction between implied warranties and express warranties insofar as [the notice] precondition is concerned.").

[15] The parties have not addressed the point that a Breach of Implied Warranty claim under Alabama Law does not cover "safety warranties" as opposed to "product effectiveness" warranties. *See Houston v. Bayer Healthcare Pharm., Inc.*, 16 F. Supp. 3d 1341, 1347 (N.D. Ala. 2014). Similarly, the court will not discuss this issue other than to say that it has serious doubts that Plaintiff's injuries could be addressed by a breach of implied warranty claim, which is limited to "commercial fitness." *Id*. Rather, it is well established that "any unreasonable danger of the product must be addressed by the AEMLD." *Id*.; *see Shell v. Union Oil Co.*, 489 So. 2d 569 (Ala. 1986); *Spain v. Brown & Williamson Tobacco Corp.*, 872 So. 2d 101 (Ala. 2003).

B. In the Alternative, Plaintiff's State-law Claims are Preempted[16]

In the alternative to its state-law arguments, Defendant asserts preemption defenses to Plaintiff's claims. (Doc. # 50 at 19-33). The court will address these defenses with a full view of Eleventh Circuit case law as its guide. After careful review, and taking fully into account Eleventh Circuit precedent, the court concludes that Defendant is due summary judgment on all counts for an alternate reason: even if his state-law claims were viable, they are preempted by federal law.

1. The Court's Preemption Approach

Preemption finds its authority in the Supremacy Clause. U.S. Const. Art. VI, cl. 2. The court treads lightly here. The Eleventh Circuit has said that "*[w]e* must first analyze whether each claim can stand under state law, and only then decide the preemption questions where necessary." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1328 (11th Cir. 2017) (emphasis added); *see Godelia*, 881 F.3d at 1317; *Sharp v. St. Jude Med., S.C., Inc.*, 2020 WL 7647511, at *1 n.2 (11th Cir. Dec. 23, 2020).

In the context of this case, the Eleventh Circuit case law presents an interesting fork in the road. Although it makes sense for a court of appeals to wade into the question of preemption *only* if a plaintiff's claims fail under state law, a district court, when called upon to rule on a motion to dismiss or a motion for summary judgment, finds itself in a different position.[17] Where a defendant

[16] In his brief, Plaintiff concedes that because Failure to Comply with GMPs is not a "viable cause of action in Alabama," Count Six "would be preempted." (Doc. # 62 at 33 n.10).

[17] It is undisputed that Eleventh Circuit case law addresses -- and requires district courts to address -- the merits of a plaintiff's state-law claims before addressing whether those claims are preempted. *Godelia*, 881 F.3d at 1317; *see Sharp*, 2020 WL 7647511, at *1 n.2. But, if the court were writing on a clean slate, it wonders if the order of operation for a district court facing a motion to dismiss or a motion for summary judgment may be different. In most instances, a court addresses choice of law principles first before wading into the merits of the claims. That is, the court may need to first address preemption as a choice-of-law principle because preemption "tells the court which law should be referred to in order to determine the plaintiff's right to relief." *Grun v. Pneumo-Abex Corp.*, 1992 WL 86066, at *1 (N.D. Ill. Apr. 22, 1992) (citing *La Freniere v. Gen. Elec. Co.*, 572 F. Supp. 857, 860 (N.D.N.Y. 1983)). Applying this principle to the preemption issues presented in this case, it may be advisable to first determine the extent to which federal law precludes state law as applied to Plaintiff's claims and allegations. Second, the court may analyze the surviving claims under the applicable state law to determine if there remains any dispute for trial. But, the

raises an *alternative* ground for summary judgment (such as here, preemption), it would be a disservice to the parties (not to mention the court, as a matter of judicial economy) not to address all alternative grounds for its ruling. For example, if the district court did not address in the alternative a meritorious preemption argument and the court of appeals ultimately disagreed with its conclusion that the state-law claims were inviable, the case would have to be remanded for further briefing and a ruling on the preemption defense. If faced with a meritorious preemption argument on remand, the district court would grant summary judgment, and there would likely be a second appeal. This piecemeal litigation approach would cause further delay and expense in resolving the case and be inconsistent with Rule 1, which requires that the "rules govern[ing] … in all civil actions … be construed, administered, and employed by the court and the parties to secure the *just, speedy, and inexpensive determination* of every action and proceeding." Fed. R. Civ. P. 1 (emphasis added). Rather, this court believes that presenting and ruling on both issues (at least in the alternative) is the prudent way to proceed.

The court is aware of the admonition by the panel in *Sharp* that indicates that "it was inappropriate for the district court to reach preemption after finding that the state law claims were not viable." *Sharp*, 2020 WL 7647511, at *1 n.2. But, the court is not bound by *Sharp*, an unpublished decision. And, with respect, *Sharp* does not take into account either the practicalities of district court practice (noted above) or the mandate of Rule 1 (also discussed above). *Sharp* actually goes a step further than the precedential opinions in this area, which indicate "we" -- that is, the Eleventh Circuit -- should not address preemption if state law claims are determined to be inviable. *Mink*, 860 F.3d at 1328; *Godelia*, 881 F.3d at 1317. But, in the vast majority of appeals,

counterweight to all this is that preemption finds its moorings in the Supremacy Clause. So, notwithstanding what may be the logical approach, the court proceeds as the Eleventh Circuit instructs and addresses the validity of Plaintiff's preempted claims under state law. *See Sharp*, 2020 WL 7647511, at *1 n.2.

a circuit court need not concern itself with the practical effects of correction of any purported errors it may make (due to the limited prospect of Supreme Court review). Indeed, very few circuit decisions are reviewed en banc or by the Supreme Court.

Further, the Eleventh Circuit's decision in *Sharp* actually proves this point. Although the Eleventh Circuit reversed and remanded the case because the district court erred in determining that the plaintiff failed to state a claim under state law, the Eleventh Circuit also noted that the district court's preemption analysis was incorrect and provided guidance on this issue for remand. *Sharp*, 2020 WL 7647511, at *1 n.2. As it turns out, if the district court had remained silent on the alternative argument, it may have taken the same erroneous preemption approach on remand. And, that may have, in turn, necessitated a second appeal, a second reversal, and a second remand. With these pragmatic concerns in mind, this court proceeds (albeit with some trepidation) to analyze Defendant's preemption defense as an alternative ground for granting summary judgment.

2. The FDA Regulatory Scheme and Preemption

Congress passed the Medical Device Amendments ("MDA") of 1976 to the Federal Food, Drug, and Cosmetic Act ("FDCA") giving the FDA regulatory authority over medical devices. *Riegel*, 552 U.S. at 316 (citing 21 U.S.C. § 360(c)). Under this authority, the FDA approves a medical device for entry into the market by evaluating the device's effectiveness and safety. *Mink*, 860 F.3d at 1325.

The approval process for medical devices is rigorous and requires the FDA to spend (on average) over 1,200 hours reviewing each application. *Riegel*, 552 U.S. at 317-18 (internal citations omitted). Unsurprisingly then, an application includes large amounts of data on the effectiveness and safety of the device under review, descriptions of facilities, manufacturing specifications, processes for device production, and proposed product labeling. *Id.*; 21 U.S.C. §

360e(c). Based on this data, and only after weighing the health benefits of the device's use against the risks of injury associated with the device, and only after concluding that "there is a reasonable assurance" of the device's "safety and effectiveness," may the FDA grant PMA. *Riegel*, 552 U.S. at 318-19 (citing 21 U.S.C. §§ 360c, 360e(d)). After the FDA grants PMA, the applicant may not make any changes to "design specifications, manufacturing processes, labeling, or any other attribute" that would "affect [its] safety or effectiveness" without first obtaining FDA approval. *Id.* at 319; *Mink*, 860 F.3d at 1325 (citing 21 U.S.C. § 360e(d)(5)(A)(i)).

The court begins its analysis by examining the scope of preemption. As already discussed, a Class III device is subject to "rigorous" scrutiny before the FDA approves it for commercial use. *Riegel*, 552 U.S. at 312, 316. Congress, recognizing that a manufacturer cannot deviate from requirements in the PMA and MDA, enacted an express preemption provision that applies to Class III devices after their approval:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is *different from, or in addition to,* any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). Preemption goes beyond state regulatory enforcement and includes state common law or statutory liability. The reason for preempting state-law claims is simple: if a state imposes liability on a manufacturer for producing a medical device in a manner different from what is required under the device's PMA (*i.e.*, requiring a manufacturer to meet additional requirements), then that could upset the FDA's "cost-benefit analysis" that a device, approved only after weighing the "probable benefit to health from the use of the device against any probable risk of injury or illness from such use," provides a "reasonable assurance" of "safety

and effectiveness." *Riegel*, 552 U.S. at 318-19, 325.

However, this express preemption provision does not preempt state-law claims "premised on a violation of the FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 312. Unsurprisingly, these state-law claims are called "parallel claims." *Mink*, 860 F.3d at 1325-26 (internal citations omitted). When analyzing a claim for express preemption, the issue is whether a plaintiff's theories of liability and the facts supporting his or her cause of action, if enforced, would hold a defendant liable for violating requirements that are beyond the FDA's. *See Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713, at *3 (N.D. Tex. Aug. 13, 2008). Parallel claims may be based on *any* requirement, including device-specific requirements in the PMA and the generally-applicable GMPs. *Mink*, 860 F.3d at 1331.

There is also an implied preemption provision stating that "all such proceedings for the enforcement, or to restrain violations, of this chapter *shall be by and in the name of* the United States." 21 U.S.C. § 337(a) (emphasis added); *Mink*, 552 U.S. at 1327. Implied preemption requires that the "MDA [is] … enforced exclusively by the Federal Government." 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (citing 21 U.S.C. § 337(a)). Thus, private litigants are not "authorized to file suit for noncompliance with the medical device provisions." *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009) (quoting *Buckman*, 531 U.S. at 349 n.4), *aff'd*, 623 F.3d 1200, 1205 (8th Cir. 2010). In other words, private litigants cannot "seek to privately enforce a duty owed to the FDA." *Mink*, 860 F.3d at 1320.

These two preemption provisions, when considered together, leave only a narrow gap for a private litigant to bring a state-law claim related to medical devices. Indeed, the Eleventh Circuit has defined this "narrow gap":

> To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption). Putting these ideas into practice, … a plaintiff may proceed on her claim so long as she claims the 'breach of a well-recognized duty owed to her under state law' *and* so 'long as she can show that she was harmed by a violation of applicable federal law.'

Mink, 552 U.S. at 1327 (emphasis added) (internal citations omitted) (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)).

Not only must the claim be premised on a duty equivalent to one required by the FDA and cognizable under state law, but the claim must also be connected to the alleged injury. *Kubicki on behalf of Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 172 (D.D.C. 2018); *see id.* at 1331 (citing *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011)).

Once a defendant invokes preemption under the MDA, the burden falls on the plaintiff to show that his claims are not preempted. *Kubicki*, 293 F. Supp. 3d at 172. This is, by necessity, a high burden. The plaintiff must "set forth [evidence] pointing to *specific* PMA requirements that have been violated" and that those violations caused the plaintiff's injury. *Wolicki-Gables*, 634 F.3d at 1301 (emphasis added) (internal citations omitted); *Godelia*, 881 F.3d at 1319-20. In other words, if a plaintiff simply claims that a defendant violated a federal regulation without identifying (1) the specific facts showing *how* a defendant violated either a PMA specification or a specific GMP and (2) the specific facts showing that the violation caused the injury at issue, then that plaintiff fails to adequately assert a parallel claim. *Wolicki-Gables*, 634 F.3d at 1301 (internal citations omitted).

Here, the court concludes that regardless of whether Plaintiff has met his burden to establish that his claims are premised on binding federal requirements (and, to be clear, the court doubts that he has), all his claims are preempted because there is insufficient Rule 56 evidence that Defendant's product caused Plaintiff's injuries. *Kubicki*, 293 F. Supp. 3d at 172; *Wolicki-Gables*,

634 F.3d at 1301. Thus, Plaintiff's claims are preempted.

3. Parallel Claims and Additional Requirements

There is a two-step inquiry for determining whether a claim is parallel or expressly preempted:

> First, a court must determine whether the Federal Government has established requirements applicable to the device. If so, [second] the court must then determine whether the plaintiff's common-law claims are based upon state law requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to the safety and effectiveness.[18]

Mink, 552 U.S. at 1326. The second step is that which is central to Defendant's summary judgment motion. Analyzing whether Plaintiff's claims are expressly preempted under section 360k(a) requires the court to examine the scope of federal requirements applicable to Synvisc-One.

There are two types of requirements applicable to all medical devices. *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 178 (N.D.N.Y. 2014). First, "[PMA] ... imposes 'requirements' under the MDA" that are "specific to individual devices." *Wolicki-Gables*, 634 F.3d at 1301 (quoting *Riegel*, 552 U.S. at 323). Second**,** as already discussed, there are GMPs that manufacturers are required to comply with, and they must not deviate from them. 21 C.F.R. § 820.1(a)(1); *see Marmol v. St. Jude Med. Ctr*., 132 F. Supp. 3d 1359, 1363 (M.D. Fla. 2015); *Herrnandez v. Stryker Corp.*, 2014 WL 7044171, at *3 (W.D. Wash. Dec. 11, 2014) (citing *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278-79 (E.D.N.Y. 2009)). In other words, medical device manufacturers are bound by both device-specific requirements in its PMA *and* generally-applicable requirements of the GMP promulgated in the various parts of 21 C.F.R. § 820. *Godelia*, 881 F.3d at 1318.

[18] The first step is not at issue in this case because Synvisc-One is a type III device that is indisputably subject to FDA requirements. *Riegel*, 552 U.S. at 323.

Even though GMPs are requirements, Defendant argues that Plaintiff's claims fail because GMPs are "overarching objectives that apply to all manufacturers" and do not support a parallel claim. (Doc. # 50 at 29). Defendant is correct that many courts have indicated that "manufacturing processes" (*i.e.*, GMPs) are "intentionally vague and open ended" such that an allegation that a GMP has been violated cannot support a parallel claim. *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009); *see Wolicki-Gables*, 634 F.3d at 1301; *Sprint Fidelis*, 592 F. Supp. 2d at 1157; *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008). The main problem with Defendant's argument is that the Eleventh Circuit disagrees with it. Our circuit has said that "[t]he fact that [GMPs] are not device-specific is of no moment" and that GMPs may support a parallel claim because Section 360k(a) refers to "any requirement." *Godelia*, 881 F.3d at 1320; *Mink*, 860 F.3d at 1331 n.3 (citing *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440-41 (6th Cir. 2010)); *Rowe*, 297 F. Supp. 3d at 1299 (recognizing that the Eleventh Circuit has stepped back from *Wolicki-Gables*, at least with respect to a GMP not supporting a parallel claim) and stating "the holdings in *Mink* and *Godelia* are directly at odds with *Wolicki-Gables*"). Indeed, this narrower interpretation of preemption is consistent with *Riegel*, where the Supreme Court said that state-law claims are parallel if they are "premised on a violation of FDA regulations" without distinguishing between PMA specifications and GMPs. *Riegel*, 552 U.S. at 330; *see Steiden v. Genzyme Biosurgery*, 2012 WL 2923225, at *4 (W.D. Ky. July 18, 2012) ("We emphasize the phrase 'any requirement.' And federal law is clear: for … Class III medical devices … [GMPs] … are legally binding requirements….").

Although preemption does not uniformly prohibit a plaintiff from relying on general requirements, establishing a parallel claim in that context is still a high bar. To assert a parallel claim, a plaintiff must "set forth" evidence of "*specific* violations" of "*specific* regulations."

Godelia, 881 F.3d at 1319-20 (distinguishing the holding in *Wolicki* from case where plaintiff connected "the violation of the specific federal regulations" to his claim) (emphasis added) (internal citations omitted); *see Wolicki-Gables*, 634 F.3d at 1301; *Mink*, 860 F.3d at 1331. Importantly, not only must a plaintiff show that a federal requirement has been violated but he must also "causally connect the simultaneous violations of federal and state law **…** to the alleged injury."[19] *Kubicki*, 293 F. Supp. 3d at 172; *see Mink*, 860 F.3d at 1331 (citing *Wolicki-Gables*, 634 F.3d at 1301-02); *Barnes v. Howmedica Osteonics Corp.*, 2010 WL 11565343, at *11 (N.D. Ala. Dec. 14, 2010) (granting summary judgment for defendant because plaintiff could not "demonstrate that the injury …. [he] sustained resulted from the federal violations"). And, once a defendant raises a preemption defense, the burden is on the plaintiff to show that his or her claims are parallel. *Kubicki*, 293 F. Supp. 3d at 172. Whether a claim is preempted is a "question of law, which may be decided on summary judgment." *Barnes*, 2010 WL 11565343, at *2 (internal citations omitted).

Thus, a plaintiff who simply claims that a defendant violated a federal regulation, without identifying the specific facts showing (1) *how* the defendant violated either a PMA specification or a specific GMP and (2) that the violation caused an injury, fails to adequately assert a parallel claim. *Godelia*, 881 F.3d at 1319-20; *Wolicki-Gables*, 634 F.3d at 1301 (internal citations omitted). A plaintiff must show that the claim is *"genuinely* equivalent." *Wolicki-Gables*, 634 F.3d at 1300 (emphasis in original) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)). A claim is genuinely equivalent only if the defendant "could [not] be held liable under the state law without having violated federal law." *Id*. In other words, a plaintiff "cannot simply incant the magic words [that Defendant] violated FDA regulations in order to avoid preemption." *Id*. This is

[19] As previously noted, Plaintiff has not put forth sufficient Rule 56 evidence on the issue of medical causation.

important, because without specifically establishing a "federal-requirement baseline," there is a high risk that a claim untethered to the established baseline would operate to "demand[] … more of the manufacturer than the federal law requires." *Kubicki*, 293 F. Supp. 3d at 180.

4. Plaintiff's Claims are Preempted

Defendant argues that Plaintiff's state-law claims are preempted by federal law. Defendant is correct for two reasons.

First, despite Plaintiff characterizing his claims as premised on "[Defendant's violation] of the relevant federal requirements," there is nothing in the Rule 56 record connecting Defendant's conduct to any specific binding regulation. Specifically, with one exception,[20] Plaintiff relies only on sources, such as the FDA *guidance* documents, regulations applicable *only* to pharmaceuticals, and the criticisms of Plaintiff's excluded regulatory expert. None of these bind Defendant with respect to any federal requirement for Synvisc-One. To allow Plaintiff to assert his state-law claims based solely on these sources would impose requirements on Defendant that are "in addition to" or "different from" requirements imposed by federal law. Indeed, Plaintiff highlights the problems with his claims by stating in his *Daubert* brief that observations of the facility and processes were "consistent with the minimal state of compliance of the facility." (Doc. # 59 at 31).

Second, even if there were Rule 56 evidence that Defendant has violated a federal requirement (and, to be clear, there is not), all of Plaintiff's claims are preempted because there is no evidence that Defendant's alleged conduct actually caused Plaintiff's injury. Thus, for all these reasons**,** Defendant's Motion is due to be granted.

[20] Plaintiff has presented summary judgment evidence that the contamination in the Lot constitutes a violation of Synvisc-One's PMA specification in violation of a federal requirement imposed by the Federal Food, Drug, and Cosmetic Act. But, as explained below, that claim is preempted.

a. Negligence, Wantonness, and AEMLD

Plaintiff asserts a Negligence and Wantonness claim for failure to exercise due care by not complying with several federal requirements.[21] (*See* Doc. # 62 at 20-21, 23). Under Alabama law, a violation of a federal requirement supports a negligence *per se* claim. *Allen v. Delchamps, Inc.*, 624 So. 2d 1065, 1067 (Ala. 1993) (holding that plaintiff had adequately stated a parallel negligence claim based on sale of food with substance in violation of FDA requirement). Such a claim is not impliedly preempted because it does not seek to privately enforce a duty owed to the FDA. And, a negligence claim premised on manufacturing defects is not expressly preempted *if* the defects are a result of violations of federal requirements. *Godelia*, 881 F.3d at 1319.

Plaintiff also asserts a claim under the AEMLD. To establish an AEMLD violation, a plaintiff must show:

> (1) he suffered injury or damage[] to himself or his property by one who sells a product in a defective condition unreasonably dangerous to the plaintiff as the ultimate user or consumer, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Casrell v. Altec Indus., Inc., 335 So. 2d 128, 132 (Ala. 1976); *see Heard v. FCA US, LLC*, 2020 WL 1285743, at *2 (N.D. Ala. Mar. 16, 2020) (internal citations omitted). Importantly, while this is not a "no fault regime," a manufacturer is deemed to be have "conducted himself unreasonably in placing a product on the market which will cause harm." *Atkins v. Am. Motors Corp.*, 335 So. 2d 134, 139-140 (Ala. 1976). A plaintiff has established a *prima facie* AEMLD claim if there is

[21] Plaintiff asserts claims for negligence and wantonness in the same count. (Doc. # 35). Although wantonness and negligence are qualitatively different, for ease of reference, in its analysis the court treats them as one cause of action -- a singular claim sounding in negligence. Negligence and wantonness are separate cognizable claims from an AEMLD claim. (Doc. # 62 at 28). *Tillman v. R.J. Reynolds Tobacco Co.*, 871 So. 2d 28, 35 (Ala. 2003); *see Spain v. Brown & Williamson Tobacco Corp.*, 363 F.3d 1183, 1189 (11th Cir. 2004) (applying the court's decision in *Tillman*).

evidence from which a fact finder could infer that plaintiff's injuries were caused by a defective product. *Rudd v. Gen. Motors Corp.*, 127 F. Supp. 2d 1330, 1345 (M.D. Ala. 2001) (Internal citations omitted). A product may be defective because of a manufacturing defect, which occurs when a product deviates from its intended design.[22] *McDaniel v. Mylan, Inc.*, 2019 WL 11638407, at *6 (N.D. Ala. Dec. 16, 2019); *Schwartz v. Volvo N. Am. Corp.*, 554 So. 2d 927, 941 n.5 (Ala. 1989).

b. FDA Guidance Documents

Plaintiff argues that Defendant violated a federal requirement because Defendant did not comply with FDA guidance documents, including the Guidance on Aseptic Processing (Doc. # 62-14) and the FDA Guidance on Endotoxin Testing (Doc. # 62-15). (Doc. # 62 at 13-15). However, unlike federally-imposed obligations such as GMPs, guidance documents are not binding requirements. *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 961 (D. Minn. 2009); *BBK Tobacco & Foods, LLP v. U.S. Food & Drug Admin*., 672 F. Supp. 2d 969, 975 (D. Ariz. 2009) (holding that FDA guidance documents are not "final agency" actions and thus "do not provide any legal basis from which the FDA can institute civil or criminal legal proceedings"); *Vanda Pharm., Inc. v. Food & Drug Admin.*, 436 F. Supp. 3d 256, 270 (D.D.C. 2020) (holding that guidance documents were not binding where they were not published in CFR and were labeled as "recommendation"). The FDA makes this clear. The guidance documents state in bold letters at the top of each page that they "contain[] nonbinding recommendation[s]" and are limited to the FDA's "current thinking on this topic." (Docs. # 62-15; 62-14). The guidance documents also state that a manufacturer "can use an alternative approach if the approach satisfies the requirements of

[22] Defendant argues that Plaintiff must show that a "safer, practical, alternative" design existed at the time of manufacturer. (Doc. # 50 at 24). That is true for a design defect, but Plaintiff has not asserted such a claim. (Doc. # 62 at 28).

the applicable statutes and regulations." (Docs. # 62-15 at 5; 62-14 at 5). That is not to say that the guidance documents are irrelevant. *See Howard,* 382 F. App'x at 441 (using guidance documents to understand scope of GMPs plaintiff specifically identified and presented at summary judgment). But, because guidance documents are not binding requirements, mere deviation from their practices will not support a parallel claim.

c. Endotoxin Testing Methods[23]

Plaintiff alleges that Defendant violated federal requirements because of what he argues are deficient endotoxin testing methods. (Doc. # 62 at 14-15). Specifically, he alleges Defendant breached its duty to exercise due care by conducting endotoxin testing in a manner noted as deficient in the FDA's 483 Report and by violating the "FDA's GMP Guidance on Endotoxin Testing," which "could lead to false negative test results." (Doc. # 62 at 22).

The 483 Report makes clear that Defendant's endotoxin testing methods "do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." (Doc. # 62 at 13-14). Specifically, the FDA flagged Defendant's testing of "pooled sample[s] (three units)," which may dilute samples to the point that the endotoxin test "results might be invalid for the final release and stability studies." (Docs. # 62 at 16; 62-3 at 29-30). Plaintiff asserts that Defendant was required to test each syringe individually. (Doc. # 62 at 15). Assini agreed that Defendant's practices were a result of a "misinterpretation of the guidance" and that a GMP requires "scientifically sound and appropriate specifications." (*Id*. at 18) (emphasis omitted).

[23] Plaintiff supports his argument that Defendant's endotoxin methods violated GMPs with Dr. Patterson's opinions. Because her testimony is not admissible for this purpose as discussed in the court's *Daubert* memorandum opinion (Doc. # 72), the court does not consider her testimony for establishing a dispute of fact regarding a parallel claim.

However, nothing in the Rule 56 record -- including the 483 Report and Assini's testimony -- cites a single *specific* GMP that the allegedly deficient endotoxin testing violated. Yet, that is precisely what the Eleventh Circuit requires to state a claim. *Godelia*, 881 F.3d at 1319-20 (emphasis added) ("This case is different [than *Wolicki-Gables*]. [Plaintiff] alleged the violation of the *specific federal regulations* identified in the FDA Warning Letter."); *Mink v. Smith & Nephew, Inc.*, 169 F. Supp. 3d 1321, 1325 (S.D. Fla. 2016), *aff'd in part, rev'd in part and remanded*, 860 F.3d 1319 (11th Cir. 2017) (plaintiff connected defendant's conduct to how it violated 21 C.F.R. §§ 814.80, 814.82, 814.84, 820.30, 820.80, 820.100, and 820.198); *cf. Wolicki-Gables*, 634 F.3d at 1301 (failing to allege specific violations of PMA or GMP). In this case, Plaintiff attempts to support his claim that Defendant failed to exercise due care by presenting evidence that Defendant pooled the syringes in endotoxin testing, but he has failed to establish that Defendant was compelled by any federal regulations to perform individual testing. *Sprint Fidelis*, 592 F. Supp. 2d at 1158 (explaining that plaintiff's claim failed under preemption where plaintiff did not "point to something in [GMPs] precluding [defendant's conduct]"). Thus, this theory would add to or modify the federal requirement placed upon Defendant in its handling and distribution of this Class III device. Plaintiff cannot rely on this theory to support his negligence claim because nothing in the Rule 56 record establishes that this duty parallels a federal requirement.

The 483 Report and the guidance documents are of no moment, at least in the context of this case. There is only one deficiency purportedly linked to a GMP in the 483 Report: "laboratory controls do not include … scientifically sound and appropriate specifications and test procedures." (Doc. # 62 at 13-14) (citing Doc. # 62-3 at 79). This purported deficiency relates to the requirement codified in 21 C.F.R. § 211.160(b), a GMP applicable to "pharmaceuticals," not medical devices. That distinction is important because the preemption statute precludes any requirement different from, or in addition to, "requirement applicable…to the *device*." 21 U.S.C. § 360k(a) (emphasis

added). The FDA promulgated separate GMPs for medical devices (21 C.F.R. § 820) and for drugs (21 C.F.R § 211). Indeed, the FDA defines pharmaceuticals and medical devices differently in the MDA. *See* 21 U.S.C. §§ 321(g)(1), 321(h); *Genus Med. Techs., LLC v. United States Food & Drug Admin.*, 427 F. Supp. 3d 74, 84 (D.D.C. 2019) (explaining that the MDA allows for hybrid drug/devices but only when there are "drug" components and "device" components to a medical product); *Tarallo v. Searle Pharm., Inc.*, 704 F. Supp. 653, 655 (D.S.C. 1988) (explaining that drugs and devices, by definition, are "mutually exclusive"). Not only are certain medical devices (and pharmaceuticals) defined differently, but they are regulated differently. *Prevor v. United States Food & Drug Admin.*, 67 F. Supp. 3d 125, 129 (D.D.C. 2014) (stating that drugs and devices are separately regulated). Even the guidance document on aseptic processing says that the guidance is relevant to "specification sections of … 210 and 211 … which address [GMPs] for *drugs*." (Doc. # 62-14 at 6) (emphasis added). Notably, Plaintiff has not responded to Defendant's argument that the requirements in Section 211 are inapplicable to medical devices. (*See* Docs. # 50 at 24 n.76; 62).

Plaintiff also contends (without support) that because Defendant "was incorrectly pooling the syringe …. instead of testing individual syringes … [it] violated [the] FDA's *GMP* Guidance for Endotoxin Testing" (*i.e.*, the GMP itself). (Doc. # 62 at 15) (emphasis added). However, as just noted, deviation from a guidance document by itself is not a violation of a GMP, and Plaintiff has not connected any such purported deviation to any specific binding requirement.

Finally, even if Defendant's endotoxin testing deficiencies were connected to a federal requirement (and, to be clear, they are not), nothing in the Rule 56 record establishes that the testing methods caused Plaintiff any injury. Despite the 483 Report stating that pooled testing results "might be invalid," Plaintiff admits that the Lot was "uniformly contaminated." (Doc. # 62 at 9, ¶ 3). The fact that the results *might* be invalid establishes only a speculative possibility—and "speculation cannot create a genuine dispute of material fact." *Espinoza v. Target Corp.*, 2021 WL 164507, at *5 (11th Cir.

Jan. 19, 2021). The speculative nature of this evidence is highlighted by the fact that there is *no dispute* that testing individual samples in a *uniformly contaminated* Lot "would have made no difference in the results." (Docs. # 50-7 at 12; 62 at 9, ¶ 3). In other words, there may be a dispute that the testing methods were a deficient practice, but Plaintiff has put forth no Rule 56 evidence that, but for the deficiency, the test results would have been different such that Plaintiff would have never received a contaminated injection from the Lot. For example, even if the Lot's endotoxin results were false negatives, Plaintiff has failed to establish the more fundamental proposition that Defendant's device caused his injury. Without a "link[]" between the alleged deficient endotoxin method and "the injury alleged," Plaintiff's claims are preempted. *See Mink*, 552 U.S. at 1326.

d. Additional Product Testing

Plaintiff also contends that Defendant's lack of additional testing was a violation of federal requirements. (Doc. # 62 at 20). But, Plaintiff's position does not find support in the Rule 56 record. Although he cites to Darius's deposition testimony for the proposition that Defendant "violated [its] own [FDA-approved] [o]perating [p]rocedures by *not* testing retained bulk blending sample" (*id*.) (citing Doc. # 62-12 at 18) (emphasis in original), Darius testified that Defendant's procedure included testing for "additional retained samples" that "*can* be tested as necessary."[24] (*Id*. at 18) (emphasis added). Plaintiff argues that three NCRs, one of which identified *Methylobacterium thiocyanatum* in the WFI system, made this testing necessary.[25] (*Id.* at 20, 34).

[24] On the same CM/ECF page where Plaintiff cites Darius's deposition to support that Defendant violated their procedures by not doing bulk testing on the retained samples, Darius clarified that because "[the Lot] passed all full release testing … there would be … no reason to do testing of the retained samples." (Doc. # 62-12 at 18).

[25] The parties dispute the source of the contamination in the WFI system relevant to the NCRs. Specifically, Plaintiff asserts that the bacteria recovered in NCR 318729 was found "in the water." (Doc. # 62 at 34). And, Defendant asserts that the only evidence in the record is that bacteria was observed "on the outside of water ports connected to the WFI system." (Doc. # 67 at 15). However, this dispute over where in the WFI system the contamination was located does not present a genuine issue of material fact because is it undisputed that the process at issue in NCR 318729 was a process for the Hylan B-10 gel, which is terminally sterilized. (Doc. # 67 at 14-15). Thus, any contamination in the WFI system at that time (regardless of the source) would not have survived into the bulk blend.

But, other than Plaintiff's conclusory assertion that Defendant was compelled to perform this testing, nothing in the Rule 56 record supports a reasonable inference that retesting was "necessary" in the circumstances based on any PMA or FDA requirement. This asserted "fact," at best, is "speculative" and "suspicious;" therefore, it cannot defeat summary judgment. *Espinoza*, 2021 WL 164507, at *5; *LaRoche*, 62 F. Supp. 2d at 1371.

Plaintiff argues that Defendant was not prohibited from conducting additional testing and therefore could have prevented the release of the contaminated Lot. (Doc. # 62 at 34). But, this is of no moment because "[w]here a federal requirement permits a course of conduct and [a] state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *Sprint Fidelis*, 623 F.3d at 1205 (internal citations omitted).

e. Adulteration and Contamination

In supporting his AEMLD and negligence claims, Plaintiff argues that the product was sold in a defective condition that was unreasonably dangerous because it was sold with *Methylobacterium thiocyanatum* and not according to PMA specifications, "rendering it unfit for human consumption."[26] (Doc. # 62 at 30). And, consequently Plaintiff argues, Defendant released

[26] Plaintiff argues in the preceding page in his brief that Defendant violated multiple "duties created by the AEMLD" because they "violated industry standards, including" (1) violating the FDCA, § 331 and § 351; (2) violating the []GMPs; (3) violating the FDA's GMP Guidance on Aseptic Manufacturing; (4) violating the FDA's GMP Guidance on Endotoxin Testing; and (5) violating Genzyme's own [standard operating procedures] for additional testing of bulk retain samples before release where there were three NCR's associated with the Lot. (Doc. # 62 at 29). As related to a manufacturing defect, AEMLD liability is premised on the defective condition of the product, not the due care exercised by the defendant in manufacturing the product. Indeed, the advantage of bringing an AEMLD claim (as opposed to a negligence claim) is that fault is established by producing and selling a defective product. *Atkins v. Am. Motors Corp.*, 335 So. 2d 134, 139-140 (Ala. 1976). Further, Plaintiff argues that industry standards can be considered for determining if a product is defective, but that legal principle is narrower than he suggests. In the case Plaintiff cites, *General Motors Corp. v. Edwards*, 482 So. 2d 1176, 1198 (Ala. 1985), the industry standards at issue were *design* standards in a design defect case, not the manufacturing standards plaintiff argues are at issue here. Allowing Plaintiff to proceed on conduct that does not satisfy his state-law claims as a matter of law is prohibited by the implied preemption provision. 21 U.S.C. § 331(a). Thus, the only industry standard at issue is whether Plaintiff's Synvisc-One injection was in a defective condition unreasonably dangerous to him because of the *Methylobacterium thiocyanatum* contamination.

the Lot in an "adulterated" condition, in violation of 21 U.S.C. §§ 331(a), 331(g), 351(h). (Doc. # 62 at 15, 20, 30).

The term "adulteration" is defined by statute. Section 351(h) states that a device is adulterated: "If it is a device *and* the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements …." 21 U.S.C. § 351(h); *see* 21 C.F.R. § 820.1(c)). The plain reading of this provision is that a device is adulterated only if it is a medical device (as opposed to a drug or other products), and its method, controls, or facilities for manufacture (among others) are violating applicable requirements, such as the GMPs.[27] *Sprint Fidelis*, 592 F. Supp. 2d at 1162; *see Cline v. Advanced Neuromodulation Sys., Inc.*, 921 F. Supp. 2d 1374, 1381 (N.D. Ga. 2012) (evaluating allegations of GMP violations as sufficient as a matter of law to render the device "adulterated within the meaning of … 351(h)); *Herrnandez*, 2014 WL 7044171, at *6; *Roberts v. Stryker Corp.*, 2014 WL 12911070, at *2, *8 (W.D. Ky. Aug. 7, 2014) (explaining that violations of 21 C.F.R. § 820 are applicable requirements under 21 U.S.C. § 351(h)). Because Plaintiff has not presented Rule 56 evidence that the medical device reached Plaintiff in a contaminated state not in conformity with a GMP applicable to a method used in, or the facilities or controls used for, its manufacture, packing, storage, or installation, Plaintiff has failed to show that his injection was "adulterated" under 21 U.S.C. § 351(h).[28]

[27] Plaintiff citing 21 U.S.C. § 331(a) and the Guidance on Aseptic Processing is off the mark because it similarly prohibits actions related to "adulterated products," which, as discussed here, is a defined term by law. *See* 21 U.S.C. § 351(h); 21 C.F.R. § 820.1(c).

[28] The *only* specific GMP identified anywhere in the Rule 56 evidence is 21 C.F.R. § 820.140: "Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling." (*See* Docs. # 35 at 3; 60 at 16). But, the construction of section 820.140 (and its application here) is at best unclear. For example, the majority of a Sixth Circuit panel held in an unpublished opinion that a GMP with similar language to section 820.140 *requires* a manufacturer to "ensure … actual removal" of the material in question from the final product. *Howard*, 382 F. App'x at 440-41 (citing 21 C.F.R. § 820.70(h)). The dissent disagreed, and opined that the GMP requires only "procedures" for removal, not

Having said all that, the court readily acknowledges that whether Defendant released the Lot with a level of *Methylobacterium thiocyanatum* that was "out of the specification for its PMA" is at least a disputed fact. (Docs. # 62 at 13, 30, 32; 50-2 at 38-39). In *Wolicki-Gables*, the Eleventh Circuit said that "to properly allege parallel claims," a plaintiff must "set forth facts pointing to specific PMA requirements that have been violated." *Wolicki-Gables*, 634 F.3d at 1301; *Godelia*, 881 F.3d at 1319-20. As recently as three months ago, the Eleventh Circuit stated that a manufacturing defect claim premised on deviations from "consistent insulation diameters" in the PMA specification presents a sufficient parallel claim. *Sharp*, 2020 WL 7647511, at *2. As a condition of premarket approval of Defendant's device, it cannot "make, without FDA permission, changes in *design specifications*." *Riegel*, 552 U.S. at 319. Thus, establishing the elements of his AEMLD claim that the Lot was "in a defective condition unreasonably dangerous," or that Defendant was negligent *per se*, based on Defendant's failure to comply with the design specifications approved in the PMA, of which "*Methylobacterium* is not a part of," is not an additional requirement but a "duty … parallel to the federal requirement." (Doc. # 62-13 at 39). *Mink*, 860 F.3d at 1330. Nonetheless, this point is more academic than consequential here because Plaintiff's claims fail under both state law and preemption principles due to a lack of medical causation.

f. Breach of Implied Warranty

In Alabama, there is an implied warranty attached to a sale of goods promising that "the goods shall be fit for their ordinary purposes for which such goods are used." *Grubbs v. Medtronic*,

"procedures [for removal] and … outcomes." *Id.* at 443 (Guy, J., dissenting). Plaintiff does not argue that the court should construe section 820.140 like the Sixth Circuit majority in *Howard* construed section 820.70(h). And, even if the court were to construe 820.140 so broadly, Plaintiff's claim would be still be preempted because there is no evidence in the record that the contamination actually caused Plaintiff's injuries. *See Kubicki*, 293 F. Supp. 3d at 172.

Inc., 2019 WL 3288263, at *4 (N.D. Ala. July 22, 2019). A breach of implied warranty claim requires that a plaintiff show "the existence of the implied warranty, a breach of that warranty; and damages proximately resulting from that breach." *Wilson v. Kidde Prod. Ltd*, 2012 WL 3542210, at *8 (N.D. Ala. Aug. 14, 2012). Plaintiff brings a breach of implied warranty claim alleging that his Synvisc-One injection was "not fit for its intended purpose or use" making it "unmerchantable" for several reasons, including Defendant's testing deficiencies and because the injection was contaminated with *Methylobacterium thiocyanatum*. (Docs. # 35 at 5; 62 at 32-34).

This court has recognized that a breach of implied warranty claim is not preempted as long the breach of the implied warranty is supported by a failure to conform to applicable federal requirements. *Grubbs*, 2019 WL 3288263, at *4. As previously discussed, there is no Rule 56 evidence indicating that Defendant violated any federal requirement with respect to testing procedures. For that reason, testing deficiencies cannot support a parallel claim that Plaintiff's injection was unfit for its intended purpose.

There mere fact of contamination does not allow this claim to survive summary judgment. In *Grubbs*, the plaintiff brought a claim for breach of an implied warranty asserting the condition of the product, which was alleged to have been manufactured in violation of a federal requirement, rendered it unfit for its intended purpose. *Id*. The court held that this claim was not preempted *because* the claim was supported by Defendant's violation of a federal requirement. *Id*. Similarly here, Plaintiff alleges that the product was contaminated in violation of its PMA specification. However (and again), there is simply no Rule 56 record evidence establishing that the contamination caused Plaintiff's condition. *See Wolicki-Gables*, 634 F.3d at 1301-02. Without evidence of causation, this claim is preempted.

g. Breach of Express Warranty

Under Alabama law, an express warranty exists where the seller of a good makes "[a]ny affirmation of fact or promise made … which relates to the goods and becomes part of the basis of the bargain ...." *Grubbs*, 2019 WL 3288263, at *4. Plaintiff argues that, although Defendant warranted that the Synvisc-One injection would "provide long-term relief" for arthritis, he suffered "adverse reactions." (Doc. # 35). There is nothing in the Rule 56 record establishing that Plaintiff's claim for a breach of express warranty parallels any federal requirement for "performances" or that there would not be an "adverse reaction." And, without Rule 56 evidence of a federal requirement that his injection would provide him "long-term relief" or that he would not suffer any "adverse reaction," a state-law claim premised on the device's performance would impose an additional requirement. Thus, his Breach of Express Warranty claim is preempted.

IV. Conclusion

For all the foregoing reasons, the court concludes that Defendant's Motion for Summary Judgment (Doc. # 49) is due to be granted. An Order consistent with this Memorandum Opinion will be entered.

DONE and **ORDERED** this March 9, 2021.

R. DAVID PROCTOR
UNITED STATES DISTRICT JUDGE