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 case is before the court on Defendant Genzyme Corporation's Motion to Exclude Testimony of Plaintiff Ralph Lowery's Expert Catherine E. Patterson (Doc. # 51) and Defendant's Motion to Exclude Testimony of Plaintiff's Expert Charles Abney (Doc. # 55).[1] The motions are fully briefed (Docs. # 52, 56, 60, 61, 63, 64).[2] After careful review, and for the reasons discussed below, the court concludes that Defendant's Motions (Docs. # 51, 55) are due to be granted.

I. Background

Plaintiff advances six claims in this case based on the allegation that he suffered injuries after Defendant's medical device, Synvisc-One, was injected into his right knee. (*See* Doc. # 35). Plaintiff's device came from Synvisc-One production Lot 7RSL021 ("Lot") that Defendant voluntarily recalled after it discovered that the Lot was contaminated with *Methylobacterium*

[1] This action was filed against Sanofi-Aventis, LLC, Sanofi U.S. Services, LLC, and Genzyme Corporation. (Doc. # 1). Plaintiff amended his complaint and removed as defendants Sanofi-Aventis, LLC and Sanofi U.S. Services, LLC. (Docs. # 34, 35). Genzyme Corporation is the only remaining defendant.

[2] Plaintiff filed a Corrected Response (Doc. # 61) of Plaintiff's original Response in Opposition to Defendant's Motion to Exclude Dr. Catherine E. Patterson (Doc. # 59). Plaintiff also filed a Corrected Response (Doc. # 60) of Plaintiff's original Response in Opposition to Defendant's Motion to Exclude Dr. Charles Abney (Doc. # 58). The court cites to the corrected briefs and exhibits where applicable. But, Plaintiff did not reattach some of the exhibits to the corrected briefs. Thus, where necessary, the court cites to exhibits in the uncorrected filings.

thiocyanatum. (Doc. # 50 at 6). Plaintiff alleges that the contaminant caused septic arthritis (*i.e.*, a joint infection) in his right knee and other injuries resulting from the onset of septic arthritis, including hearing loss, reduced mobility, and a shortened lifespan. (*See* Docs. # 35, 60). He also alleges that the Lot was contaminated because of several deficiencies in Defendant's manufacturing process and that those deficiencies rise to the level of violations of federal requirements.

To establish that the bacteria caused septic arthritis and other injuries, Plaintiff seeks to admit the testimony of Dr. Charles Abney. And, to establish that Defendant's manufacturing processes and facilities violated several federal requirements imposed on Defendant, Plaintiff seeks to admit the testimony of Dr. Catherine E. Patterson. Defendant challenges the admissibility of both witnesses' opinion testimony.

A. Plaintiff's Medical History and the Synvisc-One Injection

Plaintiff is a 70-year-old male with a history of knee problems. (Doc. # 56-3 at 12).[3] On November 1, 2017, Plaintiff visited Dr. Stephen Ikard and reported he was having a pain level of "8/10" and walking with a cane. (Doc. # 56 at 7). Dr. Ikard injected a dose of Synvisc-One from the Lot into Plaintiff's knee to treat his pain associated with osteoarthritis. (Doc. # 50 at 8). Plaintiff experienced pain and swelling in his right knee by the time he returned home. (Doc. # 56 at 7) (citing Doc. # 56-6 at 9). Three days later, Plaintiff went to an emergency room because he continued to experience pain and swelling in his right knee with a pain level of "6/10." (Docs. # 56 at 18; 62 at 9; 62-5). Plaintiff received antibiotics about five hours before Dr. William McKibbin, an orthopedic specialist, operated on his knee. (Doc. # 56 at 3-4, 18). Dr. McKibbin removed fluid from Plaintiff's knee that he described as a "dark yellow thick fluid," sampled

[3] When the court cites to deposition testimony, it references the CM/ECF document and page number but not the specific line reference within the deposition transcript.

cultures, and took a "gram stain" to check for organisms in the fluid. (*Id*. at 18). He also made the initial clinical diagnosis that Plaintiff had septic arthritis. (Doc. # 62-6 at 1). Based on all the facts available to him, Dr. Ikard stated in his deposition 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 statement that "it very possibly could have been infected." (Doc. # 58-3 at 28-29).[4]

The day after his initial treatment and procedure, Plaintiff followed up with Dr. Albert T. White, an infectious disease specialist. (*See* Docs. # 58-17; 60 at 9). Dr. White reviewed Plaintiff's record -- which by then included the negative results on the samples taken during surgery[5] -- and prescribed Vancomycin for six weeks. (Doc. # 56-4 at 18-19). Dr. White's assessment was that Plaintiff "most likely [suffered from] septic arthritis." (Doc. # 58-17 at 5). In February 2018, Plaintiff, again, visited Dr. Ikard. (Doc. # 56 at 8). At this time, Plaintiff stated this his pain was at a level of "4/10." (Doc. # 60-2 at 30). In February 2018, Dr. Ikard noted that "there were some questions whether or not this was actually a pseudoseptic reaction or truly a septic joint" and discussed this possibility with Plaintiff.[6] (*Id*. at 32-33).

At the time Plaintiff received his injection in November 2017, he was also suffering from

[4] 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 records of Dr. Ikard. The two statements referenced above are those most favorable to Plaintiff. Dr. Ikard said other things that are unfavorable to Plaintiff, including that in his opinion Plaintiff's knee "probably was not infected" (*i.e.*, septic arthritis), and "it is more likely than not that he had a pseudoseptic reaction." (Doc. # 62-18 at 33, 38-39). But, even in their most favorable light to Plaintiff, none of Dr. Ikard's statements show that he believed (*i.e.* that it was his opinion) that Plaintiff suffered from septic arthritis caused by Defendant's product. At best, the records and statements indicate uncertainty as to medical causation of Plaintiff's knee issues.

[5] The parties dispute whether the negative test was accurate because of the antibiotics Plaintiff received five hours before Dr. McKibbin collected the samples. (*See* Docs. # 56 at 18; 60 at 22). For the sake of evaluating diagnosis and causation, at least for purposes of this opinion, the court gives Dr. Abney and Plaintiff the benefit of the doubt.

[6] A pseudoseptic reaction is a condition that produces "a reaction in the knee joint after the injection that mimics or appears to be what you would see with an infected joint." (Doc. # 60-2 at 17).

hearing loss and wore hearing aids. (Docs. # 56 at 20; 56-3 at 12). Plaintiff alleges that his Vancomycin antibiotic treatment prescribed by Dr. White following the removal of the fluid from his knee caused additional hearing loss. (Doc. # 56 at 20). Plaintiff visited his primary otolaryngologist (*i.e.*, "ear, nose and throat" (ENT)), Dr. Craig M. Benoit, on May 18, 2018. (Docs. # 56 at 20-21; 56-20 at 3). According to the records from that visit, Plaintiff did not indicate that he was suffering any further hearing loss. (Docs. # 56 at 20-21; 56-20 at 3). On November 19, 2018[7] -- approximately one year after starting his antibiotic treatment -- Plaintiff visited Dr. Lee Loftin, another ENT. (Doc. # 58-20). Dr. Loftin's initial clinical impression was that Plaintiff "appear[ed]" to suffer hearing loss from Vancomycin. (Doc. # 58-8 at 5). Dr. Loftin noted that Plaintiff experienced hearing loss between an audiogram administered in August 2016 and the one he administered in November 2018. (Docs. # 58-8 at 2; 56-22). Dr. Abney testified that there is medical literature concluding that Vancomycin can contribute to hearing loss. (Doc. # 60 at 26). Dr. Abney did not conduct any hearing tests but instead relied on (1) Plaintiff's observations that his hearing loss worsened after starting his Vancomycin treatment and (2) certain clinical impressions. (Docs. # 60 at 25; 60-1 at 23).

B. Expert Testimony of Dr. Charles Abney

Plaintiff retained Dr. Abney -- a medical doctor and attorney -- to offer expert testimony in this case regarding medical causation. Dr. Abney practices in family medicine as a hospitalist. (Doc. # 50-12 at 11). In that role, he "is devoted to adult medical services." (Doc. # 60 at 7). He regularly treats osteoarthritis and often interacts with patients "needing total joint replacement" and refers those patients to an orthopedic surgeon for diagnosis and treatment. (*Id.* at 8). By his estimates, he has seen "at least 150,000 patients as a physician." (*Id.*).

[7] Dr. Loftin stated in his affidavit (Doc. # 56-22) that Plaintiff visited him in October (not November) 2018.

Dr. Abney produced a four-page report in this case opining on issues ranging from infectious disease to orthopedics to otolaryngology. (Doc. # 50-11). Dr. Abney's relevant opinions and conclusions can be summarized as follows:

> [1] Mr. Lowery had septic arthritis of the right knee resulting from intraarticular injection of a contaminated lot of Synvisc One;
>
> [2] given the administration of antibiotics to Mr. Lowery approximately 5 hours before the tissue and synovial samples were taken, these samples would not be reliable sources for microbial culture;
>
> [3] Mr. Lowery suffered aggravated hearing loss from IV Vancomycin use and literature links hearing loss to prolonged Vancomycin use;
>
> [4] Mr. Lowery is no longer a candidate for a total knee replacement because of the septic arthritis;
>
> [5] Mr. Lowery will no longer be able to meaningfully mobilize without a walker and eventually will require a wheelchair; and
>
> [6] limited mobility will reduce Mr. Lowery's lifespan.[8]

(Doc. # 60 at 11) (citing Doc. # 58-14) (formatting modified).

C. Synvisc-One and Lot 7RSL021 Production[9]

Synvisc-One is an FDA-approved Class III medical device that is a gel-like "viscosupplement" injected into a patient's knee to relieve pain. (Doc. # 62-12 at 20). Importantly, and unlike most other consumer products, medical devices are subject to strict regulation enforced by the Food and Drug Administration ("FDA"). New Class III medical devices are approved for public use through the FDA's "premarket approval" ("PMA") process. (Doc. # 50-3 at 11, 15).

[8] Opinion [2] referenced in this summary does not support Dr. Abney's conclusion that Plaintiff suffered from septic arthritis because of Defendant's device; rather, it mitigates the fact that the fluid Dr. McKibbin extracted from Plaintiff's knee was negative for microbial growth. (Doc. # 60 at 21-22). Thus, the court gives Dr. Abney the benefit of the doubt and accepts his conclusion that the negative tests are not reliable indicators to rule out septic arthritis.

[9] Defendant produced a detailed report of the processes related to Synvisc-One, which was written by David L. Chesney. (Doc. # 50-3).

The subjects for review in the PMA process include, among other matters, clinical studies and their data related to the device's safety and effectiveness and the processes employed in its manufacture. (*Id.*). On average, approval occurs only after the FDA spends around 1,200 hours reviewing an application. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008) (internal citations omitted).

Once the FDA grants this approval, the manufacturer *cannot* make any "changes in design specifications, manufacturing processes, labeling, or any other attribute[] that would affect safety or effectiveness" without first obtaining FDA approval for such changes. *Frey v. Bayer Corp.*, 2020 WL 5995587, at *1 (M.D. Ga. Oct. 9, 2020) (citing *id*. at 319). It follows that Synvisc-One has design and manufacturing process specifications approved by the FDA in its PMA application and that it cannot deviate from those absent prior FDA approval. The reason that a manufacturer cannot deviate from the approved specifications without prior FDA approval is because the approved specifications "provide a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 317. Incorporated into the manufacturing specifications are the Current Good Manufacturing Practices ("GMPs") that manufactures must comply with -- and cannot deviate from -- in producing these medical devices. 21 C.F.R. § 820.1(a)(1); *see 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)).

Synvisc-One is manufactured using aseptic processing, which means that the processing does not *actively* sterilize; it merely *preserves* the sterile status of a material. (Doc. # 50-3 at 16, 19). To preserve the sterile nature of the device, Defendant manufactures Synvisc-One in "strictly

controlled environments."[10] (Doc. # 50 at 9, ¶ 11) (citing *id*. at 17-19, 24). Water is introduced to the manufacturing process via the Water for Injection ("WFI") system.[11] The PMA specification requires Defendant to test the WFI system daily and before each use of the system. (Doc. # 50-3 at 28). In June and July 2017, Defendant discovered *Methylobacterium thiocyanatum* in the WFI system. (Doc. # 67 at 15).

The final Synvisc-One product is comprised of two components: Hylan A-10 fluid and Hylan B-10 gel.[12] (*Id*.). Both components are subject to "endotoxin, bioburden, and sterility testing" during their respective manufacturing steps. (*Id*.). Although the gel is "terminally sterilized" before being combined with the fluid, the fluid cannot be terminally sterilized. But, it is otherwise filtered for contaminants.[13] (*Id*.).

After producing and testing of the individual components, Defendant combines them during the "bulk" 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 bulk blended product into individual syringes. (*Id*. at 30). These processes are subject to strict "in-process controls," which are laid out in "standard operating procedures [and] 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. #

[10] Controls for aseptic processing include the use of "clean rooms" by controlling personnel movement and using personal protective equipment, air filtering, and specific ventilation to control air movement in the rooms. (Doc. # 50-3 at 26).

[11] The WFI system is not required to be sterile, but there are numerous testing and inspections in place to reduce the risk of contamination. (Doc. # 50-3 at 25, 39-40).

[12] 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).

[13] 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 confirms "the absence of viable organisms." (*Id*.).

50-3 at 30; 50-6 at 51). These tests are required by the procedures in the PMA specifications. (*Id*.). One 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 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.[14] (*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).

The Lot passed both tests: the endotoxin results were below the threshold amount and there was "no growth" in the sterility testing.[15] (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 endotoxin and sterility test. (*Id*.). The results were again within release specifications. (Doc. # 50-1 at 28). Despite these safeguards, the Lot was (at some point) contaminated with a level of *Methylobacterium thiocyanatum* that was "out of the specification for its PMA." (Docs. # 62 at 13, 30, 32; 50-2 at 38-39).

After making this discovery in December 2017, Defendant recalled the Lot. (Doc. # 62-16 at 20-21). Defendant conducted an internal investigation as to the cause of the contamination, and the FDA did a comprehensive review of Defendant's procedures for compliance. (*Id*. at 22-24). The FDA objected to Defendant's procedures in its FDA Form 483 Report ("483 Report"), which stated that Defendant's processes "do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to

[14] 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).

[15] The endotoxin limit is equal to or less than 0.5 eu/ml. Lot 7RSL021 tested at 0.3 eu/ml. (Doc. # 50-1 at 16). The sterility results are binary. (*Id*.). Lot 7RSL021 tested "no growth." (*Id.*).

appropriate standards of identity, strength, quality[,] and purity." (Doc. # 62-3 at 29). The 483 Report did not reference any GMP. (*Id*.).

D. Expert Testimony of Dr. Catherine E. Patterson

To assist the trier of fact in evaluating Defendant's lack of regulatory compliance in the manufacture of the Lot, Plaintiff offers the testimony of Dr. Catherine E. Patterson. (Doc. # 61 at 11). Dr. Patterson has an undergraduate education and a Ph.D. in molecular biology. (*Id*. at 12-13). She also has diverse experience in academia and industry. For example, Dr. Patterson completed a fellowship researching human viruses and was a professor who has researched and taught on the same subject. (Doc. # 62-16 at 3). Her experience includes drug and device product development and evaluating regulatory compliance in manufacturing processes. (*Id*.). She offers the following opinions about Defendant's manufacturing processes and the effects of contamination:

> [1] Synvisc-One Lot 7RSL021 was manufactured in May 2017 and left the New Jersey facility in October 2017 with the microbial contamination *Methylobacterium thiocyanatum*.
>
> [2] Synvisc-One Lot 7RSL021 was not sterile and would be considered adulterated by U.S. FDA regulations when it was distributed by Genzyme in October 2017.
>
> [3] The most probable source of the contamination of Lot 7RSL021 was from the bulk blending process, which occurred during manufacturing of the lot (before distribution). The contamination of Lot 7RSL021 during the bulk blending process would possibly be a manufacturing defect in the manufacture of Synvisc-One, Lot 7RSL021.
>
> [4] The distribution of Lot 7RSL021 by Genzyme put patients, like Mr. Lowery, at risk of serious illness and injury from bacterial contamination, including, but not limited to the risk of septic arthritis.
>
> [5] Genzyme knew or should have known that *Methylobacterium thiocyanatum* would possibly be present in Lot 7RSL021 and possibly other lots of Synvisc-One due to their identification of *Methylobacterium thiocyanatum* in the WFI system during June and July 2017.

> [6] When Genzyme discovered *Methylobacterium thiocyanatum* in the WFI in June and July 2017, Genzyme should have started testing for that specific bacterium, including the lots produced before June 2017, which would have included Lot 7RSL021.
>
> [7] Genzyme violated []GMPs in the production and distribution of Lot 7RSL021 because of the deficiencies in the Ridgefield, New Jersey facility. This was observed in equipment maintenance, risk introduced by procedures, historical documentation of microorganism and endotoxins on personnel and in the facility, and endotoxin testing dilutions that would have provided false negatives.

(*Id*. at 33-34).

II. Standard of Review

Federal Rule of Evidence 702 governs the admissibility of expert testimony. The language of the rule makes clear that before admitting the opinion testimony of an expert, the court must be satisfied that certain conditions are met.

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), the Supreme Court made clear that Rule 702 requires district courts to perform a critical "gatekeeping" function concerning the admissibility of scientific and technical expert testimony. *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc). To perform its role as gatekeeper, a court must "engage in a rigorous three-part inquiry." *Id.* In doing so, a district court must consider whether: "(1) the

expert is *qualified* to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently *reliable* as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony *assists the trier of fact*, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." *Id.* (emphasis added) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). Whether an expert is competent to testify as an expert witness is a matter left to the sound discretion of the court. *See Jack v. Glaxo Wellcome, Inc.*, 239 F. Supp. 2d 1308, 1314 (N.D. Ga. 2002) (citing *Berdeaux v. Gamble Alden Life Ins. Co.*, 528 F.2d 987, 990 (5th Cir. 1976)).[16] Though there is some overlap among them, these three basic requirements -- qualification, reliability, and helpfulness -- are distinct concepts, and a district court must be careful not to conflate them. *Id.*

The proponent of expert testimony always bears the burden to show by a preponderance of the evidence that the requirements of qualification, reliability, and helpfulness are met. *Id*; *Vigneulle for Estate of Vigneulle v. Tahsin Indus. Corp. USA*, 2018 WL 1509435, at *3 (N.D. Ala. Mar. 27, 2018). Expert testimony that is otherwise admissible under Rule 702 and *Daubert* may still be excluded under Rule 403 if it has limited probative value that "is substantially outweighed by its potential to confuse or mislead the jury." *Frazier*, 387 F.3d at 1263; Fed. R. Evid. 403.

III. Analysis

Defendant challenges the admissibility of Plaintiff's medical causation expert, Dr. Abney, and Plaintiff's regulatory expert, Dr. Patterson. After careful review and for the reasons explained below, the court concludes as follows:

(1) Dr. Abney's opinions are inadmissible for three reasons. First Dr. Abney does not have

[16] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir.1981), the en banc Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down before October 1, 1981.

the knowledge, skill, experience, training, or education to proffer his opinions in this case. Second, he did not employ reliable methods in reaching his conclusions. Third, his opinions fail to assist the trier of fact.

(2) Although Dr. Patterson is qualified to offer expert opinion testimony on the regulatory matters in this case, her testimony is otherwise inadmissible for two reasons. First, her conclusions that Defendant's procedures were not in compliance with FDA regulations lack reliable analysis. Second, even if her opinions were based on reliable scientific methods, they go to preempted issues and thus would not assist the trier of act. Thus, Defendant's Motions are due to be granted.

A. Dr. Abney's Expert Opinion Testimony is Inadmissible

1. Dr. Abney is Unqualified to Opine on the Issues in this Case

Experts may be qualified to provide opinion testimony in various ways, including training, education, or experience in a given field. *Frazier*, 387 F.3d at 1260-61; Fed. R. Evid. 702. There are no definite guidelines for determining whether an expert is qualified to testify. Rather, the question boils down to whether under the totality of the circumstances, the expert is qualified to testify on a particular scientific or medical issue based upon knowledge, skill, experience, training, or education. In this case, Plaintiff has failed to meet his burden by showing that Dr. Abney is qualified to testify on the medical diagnosis and causation issues in this case regarding infectious disease, orthopedics, and otolaryngology.

Often the issue raised under the qualification prong is not whether the proffered expert is qualified in a general field but whether his training, education, or experience qualify him to render an opinion on a *specific* "issue before the court." *Jones v. Novartis Pharm. Corp.,* 235 F. Supp. 3d 1244, 1251 (N.D. Ala. 2017). Particularly where an expert's qualifications rest on his experience (as opposed to education or training), the expert "must explain *how* that experience leads to the

conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Frazier*, 387 F.3d at 1261 (emphasis in original) (citing Fed. R. Evid. 702). The court cannot simply take the expert's word for it. *Id.*

Many times, an expert's credentials raise credibility issues, but do not affect admissibility. *Maiz v. Virani*, 253 F.3d 641, 666 (11th Cir. 2001); *Rushing v. Kansas City S. Ry. Co.*, 185 F.3d 496, 507 (5th Cir. 1999). Nonetheless, a court must determine whether an expert is "minimally qualified" to testify to the subject matter at issue.[17] *Kilpatrick v. Breg, Inc.*, 2009 WL 2058384, at *3 (S.D. Fla. June 25, 2009). If an expert satisfies that minimal foundation for competency, criticism of that expert's "level of expertise" is a credibility issue reserved for a jury. *Id.* (internal citations omitted); *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006).

a. Dr. Abney is Unqualified to Opine on Plaintiff's Septic Arthritis Diagnosis and the Medical Causation of Plaintiff's Conditions

Defendant argues that Dr. Abney is not qualified to opine on the general effect that the bacteria in the Lot had on the human body, especially in a patient's knee. (Docs. # 56 at 11; 64 at 5). Specifically, Defendant contends that Dr. Abney is not qualified to opine that Plaintiff suffered from septic arthritis because of contaminants in the injection as opposed to a pseudoseptic reaction, a common side effect of Synvisc-One, or from other potential conditions and causes. (Docs. # 56, 62, 64, 67). A diagnosis *and* the causation of that diagnosis are essential to establish medical causation. And, when both are in dispute (like they are here), Plaintiff must have competent expert testimony establishing both. *In re Am. Airlines Flight 331*, 2013 WL 12340397, at *2 (S.D. Fla. Oct. 24, 2013); *Compton v. Bach*, 374 F. Supp. 3d 1296, 1304 (N.D. Ga. 2019); *Banegas v. BP Expl. & Prod., Inc.*, 2019 WL 424683, at *2 (E.D. La. Feb. 4, 2019).

[17] Sometimes it is helpful to think about this question in terms of whether the expert lacks the qualifications necessary to proffer an opinion. An expert is unqualified if he *lacks* expertise on a specific topic at issue in a case. But, mere criticism of his qualifications related to this issue goes to the *degree* of his expertise, not its admissibility.

To qualify as a medical causation expert, there is no *per se* requirement that a witness be the foremost expert in a given field of medicine based on his or her education, as opposed to being qualified based on extensive experience with the relevant medical issues in a case. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999) (emphasis added) (explaining that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized *experience*"); *see, e.g., Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1043 (D. Minn. 2013) (denying motion to exclude physician's testimony on orthopedic issues despite not being an orthopedic surgeon because physician published over "200 peer-reviewed articles" relevant to his opinion). At the same time, a medical doctor is not qualified to opine on all areas of medicine by virtue of having a medical license or practicing in one area of medicine. *See Hendrix v. Evenflo Co.*, 255 F.R.D. 568, 578 (N.D. Fla. 2009), *aff'd sub nom.*, *Hendrix ex rel G.P. v. Evenflo Co.*, 609 F.3d 1183 (11th Cir. 2010). Another district court aptly analogized that "[j]ust as a lawyer is not by general education and experience qualified to give an expert opinion on every subject of the law, so too a scientist or medical doctor is not presumed to have expert knowledge about every conceivable scientific principle or disease." *Whiting v. Bos. Edison Co*., 891 F. Supp. 12, 24 (D. Mass. 1995); *see Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1276, 1281 (N.D. Okla. 2000) (holding that possession of a medical degree and emergency room experience was insufficient to testify to "the advantages of [a] spinal fixation device, the medical causation of spine-related ailments, or the mechanical functioning of an orthopedic implantation device").

In accordance with that line of case law, Dr. Abney is unqualified to testify that Plaintiff *in fact* had septic arthritis because he lacks specialized training, education, and experience regarding that medical issue. Defendant contends that there is "no evidence that Dr. Abney has the [expertise] needed … to reliably assess whether Plaintiff's reaction was septic versus

pseudoseptic." (Doc. # 56 at 11). Specifically, Defendant cites Dr. Abney's admissions that, except during an approximately two-month long rotation during his residency (which was not in orthopedics and was over twenty years ago), he has never administered Synvisc-One, has never performed any orthopedic procedure on a patient's knee, has never completed any training in orthopedics, and has never (at any time) researched or written on the subjects of "treating osteoarthritis, knee replacements, viscosupplement injections, Synvisc-One, knee infections, or pseudoseptic reactions." (*Id.* at 11) (citing Doc. # 56-1 at 11-13). Plaintiff counters these points by noting Dr. Abney's credentials, including his medical degree, his American Medical Association membership, and his license to practice medicine in Alabama. (Doc. # 60 at 8). Plaintiff also relies on Dr. Abney's experience with over 150,000 patients as a "general physician with knowledge in many areas," including experience in practicing adult medicine, treating osteoarthritis, and seeing "5-7 patients per day" related to their joint replacements. (*Id*. at 7-8).

But, whether Plaintiff has osteoarthritis is not what Dr. Abney is offering an opinion about. He is being asked to opine as to whether Plaintiff had a septic infection in his knee and also to rule out a side effect with similar symptoms, among other potential orthopedic conditions and their causes. Plaintiff does not contend that Dr. Abney has relevant experience treating patients with septic arthritis or administering the injection in question. Nor does Plaintiff argue (other than Dr. Abney's reliance on the clinical impressions of Plaintiff's treating physicians and his reading of an article on septic arthritis) that Dr. Abney has any specialized knowledge in treating septic arthritis.[18] (Doc. # 60 at 15). *See Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015) (disqualifying pulmonologist when plaintiff failed to show that expert previously treated patients

[18] Plaintiff cites *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn*., 388 F.3d 976 (6th Cir. 2004) to support his argument that Dr. Abney's methods are sufficient based on his experience despite the fact that he failed to cite "medical literature." But, as already discussed, Plaintiff fails to show that Dr. Abney has experience with the issues in this case.

for a specific respiratory condition at issue); *In re Trasylol Prod. Liab. Litig.*, 2010 WL 4053756, at *4 (S.D. Fla. May 17, 2010) (excluding expert on issue because she never reviewed medical literature on the condition or treated patient with the condition *prior* to being retained as an expert in the case). Although Dr. Abney may be qualified to testify about osteoarthritis and its treatment, Plaintiff has not shown that Dr. Abney is qualified to distinguish between the range of potential diagnoses in this case, which is the specific "issue before the court." *Jones*, 235 F. Supp. 3d at 1251.

Dr. Abney's lack of experience extends beyond the diagnosis of Plaintiff's condition and also affects his ability to assess its cause. In *Harvey v. Novartis Pharm. Corp.*, another judge of this court held that a maxillofacial surgeon, who had "no experience in identifying the specific cause" of the diagnosed condition at issue, was incompetent to opine on the issue of causation. 895 F. Supp. 2d 1206, 1211-12 (N.D. Ala. 2012) (citing *Thomas v. Novartis Pharm. Corp.*, 443 F. App'x. 58, 63 (6th Cir. 2011)). The surgeon, while eminently qualified to testify "within the ordinary expertise of maxillofacial surgeons" and generally knowledgeable of the relationship between the condition and the alleged cause in the case, did not have any practical experience in identifying the cause of the condition at issue in that case. *Id*. That is, mere expertise about treatment of a condition simply does not equate to expertise about what causes that condition. *Id.*

After careful analysis, the court concludes that the distinction drawn in *Harvey* between treating a condition and identifying its underlying cause is persuasive. Indeed, the *Harvey* result is not an outlier. *See Jones*, 235 F. Supp. 3d at 1292 (internal citations omitted) (adopting the reasoning from *Harvey* and holding that treating physician and board-certified orthopedic surgeon was not competent to opine on cause of femur fracture); *Murphy v. Precise*, 2017 WL 1632870, at *4-5, *7 (M.D. Ala. Apr. 28, 2017) (holding board-certified neurologist with extensive training

and experience with treatment and *causes* of strokes was qualified to opine on the effect of epinephrine administration while general practitioner without experience in determining cause of stroke was unqualified); *see also Parmentier v. Novartis Pharm. Corp.*, 2012 WL 2326047, at *4 (E.D. Mo. June 19, 2012) (citing *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000)) ("Diagnosing a condition is quite different from determining causation."); *Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271, 1301 (M.D. Fla. 2009) (holding expert with "general[]" knowledge of diagnosing diabetes was unqualified to offer opinion on the cause of diabetes); *Morin v. United States*, 534 F. Supp. 2d 1179, 1185 (D. Nev. 2005) (holding that physician with experience diagnosing and treating cancer was unqualified to opine on cause of cancer); *Wynacht v. Beckman Instruments, Inc.*, 113 F. Supp. 2d 1205, 1209 (E.D. Tenn. 2000) ("The ability to diagnose medical conditions is not remotely the same, however, as the ability to deduce, delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions."); *Morritt v. Stryker Corp*., 973 F. Supp. 2d 177, 187-88 (E.D.N.Y. 2013) (holding that orthopedic surgeon's expert opinion that product defect caused device to fail was outside of the surgeon's "clinical expertise").

Even if Dr. Abney was qualified to opine on the orthopedic diagnosis in this case (and, to be clear, the court concludes he was not), Plaintiff has failed to show that he is qualified as an expert witness on whether the septic arthritis was caused by *Methylobacterium thiocyanatum* present in Plaintiff's injection. *Harvey*, 895 F. Supp. 2d at 1211. Again, on this point *Harvey* is instructive. Like the maxillofacial surgeon in that case, Dr. Abney lacks the training, experience, and knowledge to identify the root cause of Plaintiff's condition. *Id.* Dr. Abney has not demonstrated that he has an understanding of the bacterium that Plaintiff alleges harmed him and its effect on the human body. (Doc. # 56 at 12). Dr. Abney admitted that before this case he never

heard of (or worked with) *Methylobacterium thiocyanatum*, has never treated or heard of a patient infected by the bacterium, and admitted there was no research he knew of discussing the bacter**ium** causing "an infection in a joint." (Docs. # 56 at 12; 56-1 at 57). In fact, Dr. Abney stated that "*Methylobacterium thiocyanatum* is not a well-documented cause of human infection in the medical literature." (Doc. # 56-1 at 57). And, despite acknowledging that exposure by itself does not "automatically" lead to infection, Dr. Abney does not know the infectious properties of the bacteria, including how much exposure is necessary (or even likely) to lead to an infection. (Docs. # 56 at 12; 60-1 at 57; 56-1 at 58). Dr. Abney also agreed that a full understanding of the "pathogenicity" (*i.e.*, the propensity for causing a disease) of the bacteria in question is "more within the realm of [the] infectious disease specialty." (Docs. # 56 at 12-13; 56-1 at 57).

The absence of Dr. Abney's specialized training in infectious diseases combined with his admission that he has no experience with and no significant knowledge about the effects of *Methylobacterium thiocyanatum* on the human body, leads inexorably to the conclusion that Dr. Abney is unqualified to opine on the underlying cause of Plaintiff's condition. *See Jones*, 235 F. Supp. 3d at 1292 (disallowing testimony of expert who had specialized medical training and general knowledge, but who had no "practical experience" identifying causes of condition).

b. Dr. Abney is Unqualified to Opine on Plaintiff's Fitness for Knee Replacement Surgery or Any Decrease in Plaintiff's Life Expectancy

After careful review, the court concludes that Dr. Abney is not qualified to offer the opinion that Plaintiff is no longer able to receive a total knee replacement because of the septic arthritis allegedly caused by his Synvisc-One injection. Dr. Abney does not have any specialized training or knowledge in orthopedics. (Doc. # 56 at 11). Nor is he qualified based on his experience. Indeed, he admits, in his practice and in general, that when faced with the determination of whether a

patient should receive a knee replacement, he (as a general physician and hospitalist) refers his patients to an orthopedic specialist. (Doc. # 60-1 at 11-12). As Dr. Abney does not (and admits he cannot) make these determinations in his practice, he is also unqualified, due to his lack of experience, to offer this opinion to a jury. *See Avendt v. Covidien Inc.*, 314 F.R.D. 547, 563 (E.D. Mich. 2016) (quoting *Kumho Tire*, 526 U.S. at 152) (explaining that "experience-based testimony" must be based on "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). Dr. Abney does note that his practice includes seeing -- "postoperatively" -- "5-7 patients needing total joint replacements every day." (Docs. # 60 at 7; 60-1 at 12). But, that is of no help to Plaintiff here because that part of his practice is limited to seeing 5-7 "patients that *have had* total joint procedures." (Docs. # 60 at 7; 60-1 at 12) (emphasis added). Simply put, the fact that Dr. Abney regularly evaluates and treats knee replacement patients for conditions *after* they receive knee replacements does not qualify him to evaluate the *ex ante* medical decisions to undergo knee replacement surgery.

Finally, Plaintiff does not argue that Dr. Abney has any experience, knowledge, or training that helps him form qualitative or quantitative opinions on any reduction of Plaintiff's prospective mobility or lifespan. Because the burden lies with Plaintiff to show this, and he has not done so, Dr. Abney is unqualified to offer this opinion.

c. Dr. Abney is Unqualified to Opine on Plaintiff's Hearing Loss

After his injection, Plaintiff intravenously received the antibiotic Vancomycin. (Docs. # 60 at 25; 58-5). Plaintiff alleges that his "pre-existing hearing loss was aggravated by the prolonged use" of that antibiotic. (Doc. # 60 at 25). As already discussed, an expert may be minimally qualified based on his or her experience with a specific issue. Like Dr. Abney's qualifications to opine on septic arthritis, Plaintiff has not made a showing that Dr. Abney has experience

diagnosing hearing loss based on the use of Vancomycin. Dr. Abney does not hold himself out as a hearing expert, admits that an ENT is more qualified to opine on hearing loss, and has never performed "any diagnostic testing" on patients purporting to be suffering from hearing loss induced by Vancomycin. (Docs. # 56 at 22; 56 at 21-22; 60-1 at 66, 69, 73). Rather, Dr. Abney relies on his experience of "suspect[ing] [V]ancomycin-induced hearing loss" and seeing "10-20" patients who self-reported suffering hearing loss after taking Vancomycin (among other medications) in addition to learning "about medication-related hearing loss" in residency and medical school twenty years ago. (Docs. # 60 at 26-27; 56 at 26; 60-1 at 66-67).

As explained further below, when a proffered expert determines causation based on temporal proximity of a "suspected" diagnosis and a "suspected cause," that quite simply is not a reliable foundation for determining medical causation (*i.e.*, the "*post hoc ergo propter hoc* fallacy"). *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1310 (11th Cir. 2014); *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1254 (11th Cir. 2010); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005). If temporal proximity is an unreliable method of determining medical causation, then an expert's experience observing temporal proximity between a condition and its potential cause is an equally unacceptable foundation of expertise. It follows that without reliable experience diagnosing hearing loss and its causes, Dr. Abney cannot "reliably apply his experience to the facts of this case." *McDowell v. Brown*, 392 F.3d 1283, 1297 (11th Cir. 2004); *see Haller*, 598 F. Supp. 2d at 1301; *Seaman v. Seacor Marine L.L.C.*, 326 F. App'x 721, 725 (5th Cir. 2009) (upholding exclusion of oncologist's opinion on cause of patient's cancer as oncologist had treated only three cancer patients); *Harvey*, 895 F. Supp. 2d at 1212. Nor do Dr. Abney's education and residency -- which occurred over twenty years ago and were not in this area of specialty -- qualify him to testify on the causation of hearing loss. *See Precise*, 2017 WL

1632870, at *7 (holding general practitioner unqualified where education was not in area of specialty).

There is an old adage: "Jack of all trades, master of none." (Perhaps in this matter, "Jack of all trades, expert in none" is the way that should read). The court is aware that Dr. Abney has had a long career as a family medicine practitioner and has treated as many as 150,000 patients in his career. (Doc. # 60 at 8, 17). He is truly to be commended for that service. But, the breadth of experience is not what is required under *Daubert*. Rather, the court is concerned only with the specific issues in this case. And, when faced with Defendant's arguments pointing to Dr. Abney's deficiencies in education, experience, and training regarding issues of orthopedics, otolaryngology, and infectious disease, the court concludes Plaintiff failed to show that Dr. Abney has any "practical experience" -- let alone any expertise -- in diagnosing the conditions at issue in this case and their causes. *See Jones*, 235 F. Supp. 3d at 1292.

2. Dr. Abney's Expert Opinion Testimony is Unreliable

Before admitting a qualified expert's testimony, the court must determine that the testimony is (1) based on reliable facts or data; (2) the product of reliable principles and methods; and (3) based on a reliable application of those principles and methods to the facts of the case. Fed. R. Evid. 702. When evaluating expert testimony on scientific matters, courts consider the following factors in making those determinations: "(1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community." *Frazier*, 387 F.3d at 1262.

Courts may also use the same criteria to evaluate the reliability of "non-scientific, experience-based testimony." *Id.* Importantly, "[t]hese factors are illustrative, not exhaustive; not

all of them will apply in every case, and in some cases other factors will be equally important in evaluating the reliability of proffered expert opinion." *Id.* Sometimes these factors "will aid in determining reliability; sometimes other questions may be more useful." *Id.* The bottom line is that trial judges have "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Id.* "Exactly *how* reliability is evaluated may vary from case to case, but what remains constant is the requirement that the trial judge evaluate the reliability of the testimony before allowing its admission at trial." *Id.* (emphasis in original). Ultimately, the court will exclude testimony where it finds that an opinion "is connected to existing data only by the *ipse dixit* [*i.e.*, the unproven statement] of the expert." *McClain*, 401 F.3d at 1244 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997)).

The court reiterates that this analysis is independent of its analysis of experts' qualifications. Indeed, experts without the proper qualifications may still employ proper methods in their conclusions and vice versa. *Id.* at 1261; *see United States v. Bays*, 2014 WL 3764876, at *4 (N.D. Tex. July 31, 2014). The court concludes that even if Dr. Abney were qualified to offer his opinion testimony (and, to be clear, he is not), that testimony is due to be excluded because it is unreliable.

a. Dr. Abney's Opinion that *Methylobacterium Thiocyanatum* in the Lot Caused Plaintiff to Have Septic Arthritis is Unreliable

Because the ultimate issue in this case is whether a contaminant caused Plaintiff's injuries, this is a toxic tort case that requires expert testimony to establish two types of causation: general and specific. General causation is established by an expert "laying a scientific groundwork" that the toxin in question "*can* cause the harm plaintiff alleges."[19] *Chapman*, 766 F.3d at 1303

[19] For general causation, the Eleventh Circuit has divided product liability cases into two categories for *Daubert* purposes: (1) cases where "the medical community generally recognizes the toxicity of the drug or chemical at issue"; and (2) cases where "the medical community does not generally recognize the agent as both toxic and

(emphasis in original). Specific causation requires a court to evaluate whether the expert's methodology reliably concludes that the "substance 'caused the plaintiff's *specific* injury.'" *Id*. (internal citations omitted) (emphasis in original). Plaintiff offers Dr. Abney's testimony to establish specific causation while relying on other evidence for general causation. (*See* Doc. # 60 at 12-14). But, Dr. Abney's medical causation opinion testimony is inadmissible because (1) he failed to conduct or rely on reliable scientific groundwork before arriving at his conclusions regarding Plaintiff's condition; and (2) his specific causation analysis is not the product of reliable methods and analysis.

i. Dr. Abney is Required to Base Specific Causation on Adequate General Causation

Plaintiff does not dispute that Dr. Abney does not offer or rely on general causation testimony. (*See id*.). Rather, he asserts that "with general causation established by [Defendant] itself, Dr. Abney's opinions establish the necessary specific causation" by differential diagnosis. (Doc. # 60 at 14). Defendant argues that Dr. Abney *cannot* establish reliable specific causation because his opinion "is not based on reliable facts or data." (Docs. # 56 at 13-14; 64 at 2-3). Fed. R. Evid. 702; *Frazier*, 387 F.3d at 1262.

causing the injury plaintiff alleges." *McClain*, 401 F.3d at 1239 (emphasis added). In the first category, the court need not engage in an extensive inquiry on general causation because it is beyond doubt that the substance in question can cause the harm alleged. *Id.* The bar to fit into this category is very high. For example, cases that "include toxins like asbestos, which causes asbestosis and mesothelioma; silica, which causes silicosis; []cigarette smoke, which causes cancer"; alcohol, which causes cirrhosis; and arsenic, which causes death are assumed to be established for general causation. *Id*. at 1239, n.5 (explaining that whether caffeine and ephedrine combined significantly increases the likelihood of heart attacks and strokes is not assumed); *see In re Seroquel Prod. Liab. Litig.*, 2009 WL 3806435, at *14 (M.D. Fla. June 23, 2009) (rejecting general cause opinion on whether drug caused diabetes); *In re Denture Cream Prod. Liab. Litig.*, 204 F. Supp. 3d 1348, 1352 (S.D. Fla. 2016) (holding that causation theory related to whether certain levels of zinc in a product led to copper deficiencies and neurological issues was in the second category). Neither party has addressed this issue with respect to *Methylobacterium thiocyanatum*. The court clarifies that it falls within the second category of causation questions. Indeed, as Dr. Abney admitted, the bacteria's likelihood to cause "human infection" is "not well documented." (Doc. # 56-1 at 57).

The Eleventh Circuit and several other courts have excluded specific causation testimony that did not evaluate or rely on admissible general causation. *McClain*, 401 F.3d at 1253 (emphasis added) ("A valid [specific causation analysis], however, only satisfies a *Daubert* analysis if the expert can show the *general* toxicity of the drug by reliable methods."); *see, e.g.*, *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 457-58 (S.D.N.Y. 2016) (emphasis added) (holding that physician's "failure to *offer* or *rely* upon a general causation opinion renders his specific causation opinion … inadmissible"); *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 438 (S.D.N.Y. 2005); *Byrd v. Janssen Pharm., Inc.*, 333 F. Supp. 3d 111, 131 (N.D.N.Y. 2018). The same principle applies here: a physician cannot determine whether bacteria *did* cause a specific injury without an adequate basis for determining that the bacteria *can* cause the specific injury under all the attendant circumstances.

In this case, Dr. Abney must put forth some reliable basis on facts or data for concluding that *Methylobacterium thiocyanatum* could cause the injury before conducting a differential diagnosis concluding it *was* the cause. *See In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 494 (E.D. Pa. 2016) ("[D]ifferential diagnosis assumes that general causation has been established."). This point is readily apparent in the requirement that an expert, in utilizing this approach, must "rule in" possible causes by "scientifically valid methodology" before "ruling out" alternative causes. *Hendrix*, 609 F.3d at 1198; *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (internal quotation marks omitted) ("Where an expert employs differential diagnosis to 'rule out' other potential causes for the injury at issue, he must also 'rule in' the suspected cause, and do so using scientifically valid methodology.'"). Dr. Abney admits that he does not know the propensity of *Methylobacterium thiocyanatum* to cause septic arthritis and (before this case) that he had not heard of *Methylobacterium thiocyanatum*. (Doc. # 56-1 at 58).

He also concedes that exposure does not "automatically" result in an infection.[20] (*Id.*). At the same time, Dr. Abney is aware that a pseudoseptic reaction is a known side effect of Synvisc-One and can cause symptoms like septic arthritis. (Doc. # 50-12 at 84). Nor does Plaintiff argue that Dr. Abney relied on any other expert's reliable general causation evidence. (*See generally* Doc. # 60). *See In re Mirena*, 169 F. Supp. 3d at 457. Thus, without understanding the fundamental scientific properties of *Methylobacterium thiocyanatum* and physiological responses to it, Dr. Abney "ruled out" a pseudoseptic reaction among other conditions (and causes) in his differential diagnosis without properly "ruling in" that *Methylobacterium thiocyanatum* can cause septic arthritis in Plaintiff's circumstances. To put it another way, Dr. Abney's conclusions cannot "overcome the failure of laying [the] scientific groundwork" of general causation. *McClain*, 401 F.3d at 1255. This failure presents substantial concerns about introducing an unacceptable "potential rate of error." *See Frazier*, 387 F.3d at 1262; Fed. R. Evid. 702(b).

ii. Dr. Abney's Differential Diagnosis Fails

An "overwhelming majority of the courts of appeals" have held that differential diagnosis (that is, differential etiology) is reliable for determining medical causation.[21] *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 178 (6th Cir. 2009) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999) (collecting cases)); *Chapman*, 766 F.3d at 1308. There are two steps in a "process of elimination" differential diagnosis: (1) the expert rules in "the possible causes of a condition"; and (2) the expert then arrives at a cause by ruling out the possible causes "one-by-one, leaving only one cause remaining." *Hendrix*, 609 F.3d at 1198; *see Guinn*, 602 F.3d at 1253.

[20] The court notes that there is Eleventh Circuit case law distinguishing *McClain* in situations where *any* level of exposure to a foreign agent would cause the condition. *Taylor v. Mentor Worldwide LLC*, 940 F.3d 582, 595 (11th Cir. 2019) (internal citations omitted). But, no party or expert in this case suggests that any amount of contamination will cause Plaintiff's condition.

[21] For causation purposes, "differential etiology" and "differential diagnosis" are interchangeable even though causation and diagnosis are both at issue on this motion. *McClain*, 602 F.3d at 1253 n.6.

A reliable differential diagnosis need not rule out every conceivable alternative cause. *Guinn*, 602 F.3d at 1253. But, an expert must consider the most relevant potential causes. *Chapman*, 766 F.3d at 1309. As to the acceptable degree of analysis in a reliable differential diagnosis, an expert must provide a "reasonable" explanation for eliminating other causes under the circumstances and cannot "simply" claim that he "performed a differential diagnosis." *McClain*, 401 F.3d at 1253; *Guinn*, 602 F.3d at 1253 (internal citations omitted). Such a "process," that wholly fails to provide a reasonable explanation, is not a method at all but rather a substitution of the expert's own assertion for the scientific method (the "*ipse dixit*"). *McClain*, 401 F.3d at 1242.

Even if Dr. Abney relied on admissible general causation evidence, his specific causation analysis fails. Plaintiff explains Dr. Abney's differential diagnosis this way:

> [he] ruled out: (1) pseudo septic arthritis (initial clinical impressions of physicians was "septic arthritis"); (2) gonococcal (you see that in the young); (3) endocarditis (no history of that); (4) *Methylobacterium thiocyanatum* infection from soil or water (no history of knee trauma); and (5) drug use (no history of that), and Dr. Abney then ruled in septic arthritis caused by *Methylobacterium thiocyanatum*. (PX1, Depo of Abney at 324-25, 327-28).
>
> Dr. Abney *ruled in* septic arthritis from exposure to *Methylobacterium thiocyanatum* because both of Lowery's treating physicians said it was their initial clinical impression, and Mr. Lowery received a shot from a Lot contaminated with the same bacteria. (PX1, Depo of Abney at 324-25, 327-28). Dr. Abney reached this conclusion after ruling out the other possibilities.

(Doc. # 60 at 10). Dr. Abney also relied on "the temporal sequence" between the injection and the onset of symptoms. (*Id*. at 21).

But, in this instance Dr. Abney may not rely on the "temporal proximity between Plaintiff's injection and the onset of his symptoms" to support his opinion that the bacteria in Defendant's device caused septic arthritis. (Docs. # 56 at 17, 64 at 8). As the Eleventh Circuit has said, temporal proximity is not a reliable indicator of causation but "leads to the blunder of the *post hoc ergo propter hoc* fallacy." *Chapman*, 766 F.3d at 1310; *McClain*, 401 F.3d at 1254 (explaining that

"temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation"). This is particularly true where, as here, Dr. Abney admits that the "onset of pain and swelling" could be a sign of septic arthritis or a pseudoseptic reaction.[22] (Doc. # 60 at 15-16) (citing Doc. # 60-1 at 54).

Here, Plaintiff is quick to point out that, in addition to temporal proximity, Dr. Abney has relied on a combination of other factors when making his diagnosis. (*See id*. at 17-18). But, the other factors that Dr. Abney relies on in his differential diagnosis are also not reliable. For example, Dr. Abney ruled out a pseudoseptic reaction based on clinical impressions that indicated that Plaintiff's condition was septic arthritis. (*Id*.) (citing Doc. # 56-1 at 54). Defendant argues that relying on the clinical impression of a treating physician is inappropriate, at least in this context, because it is "nothing more than a parroting" of the treating physician's diagnosis. (Doc. # 64 at 8). The court agrees. Simply relying on what other physicians opined during treatment is not a "technique" that is "generally accepted." *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1372 (N.D. Ga. 2001) ("[C]linical impression is not the sort of scientific methodology that *Daubert* demands."); *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 664 (S.D.N.Y. 2007) (explaining that "in [relying on the opinion of other experts], the expert witness must in the end be giving his own opinion. He cannot simply be a conduit…."); *United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005). This is especially true where, as it occurred in this case, Dr. McKibbin and Dr. Ikard have indicated that their initial impressions were not reliable. (*See* Docs. # 64 at 8; 58-3 at 25, 60-1 at 62-63; 60-2 at 32). Dr. Abney did not even discuss the treating physicians' impressions with them, and he was left to "make assumptions" based on their records without

[22] There is evidence in the record suggesting that the immediacy of the timing between Plaintiff's injection and the onset of symptoms makes it *unlikely* that this injury was septic. (Doc. # 56 at 17) (citing Docs. # 56-3; 56-4). Defendant notes that pseudoseptic and severe inflammatory reactions are "known and labeled" side effects to Synvisc-One. (*Id*. at 18).

knowing if the physicians had Plaintiff's medical records and the knowledge of his injection and the possible side effects or alternative conditions. (Docs. # 56-1 at 7-8, 42-43; 60-1 at 42).

It is also evident that Dr. Abney did not evaluate the merits of the clinical impressions or rely on data or facts collected by the treating physicians. Rather, he simply has passed their opinions along. Indeed, Plaintiff asserts that in "ruling *in* septic arthritis versus pseudo septic reaction, Dr. Abney considered the initial clinical impressions of the orthopedist," which was a diagnosis of "septic arthritis, right knee." (Doc. # 60 at 18). This is particularly problematic because, as previously discussed, Dr. Abney is not qualified to opine on the orthopedic and infectious disease conditions in this case and is otherwise acting as a "mouthpiece of a scientist in a different specialty." *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002); *see Malletier*, 525 F. Supp. 2d at 666 (excluding expert where expert relied on conclusions of regression analysis prepared by another expert for which he was not qualified to conduct); *Sommerfield v. City of Chicago*, 254 F.R.D. 317, 325 (N.D. Ill. 2008) (explaining that "the problem … is that the expert is vouching for the truth of what another expert told him—he is merely that expert's spokesman"); *Abrams v. Ciba Specialty Chemicals Corp.*, 2010 WL 779283, at *4 (S.D. Ala. Mar. 2, 2010) (citing *Dura Auto*, 285 F.3d at 614).

To the extent that Dr. Abney relied on Dr. McKibbin's extraction of a fluid from Plaintiff's knee, Plaintiff cites only to Dr. Abney's testimony that he "found it significant" that Dr. McKibbin "described the … fluid from [Plaintiff's] right knee as 'yellow, thick, [and] dark'" without explaining how that supports a conclusion that Plaintiff suffered from septic arthritis. (Doc. # 60 at 18) (citing Doc. # 60-1 at 84). Notably, as Defendant points out, Dr. Abney's expert report lacks any analysis on why "thick yellow fluid" supports his "*unequivocal* diagnosis of Septic Arthritis." (*See* Doc. # 56-2 at 4) (emphasis added). Stripped to its bare bones, his conclusion is nothing more

than his own assertion. *McClain*, 401 F.3d at 1244. And, such a bare-bones reliance on a treating physician's clinical impressions (and, for that matter, on the presence of a symptom without any analysis as to why that symptom supports ruling out one diagnosis while also ruling in another) is not only an unreliable method to establish causation but also introduces significant room for error.

Further, even if it could be said that Dr. Abney reliably determined that Plaintiff's condition was septic arthritis and not a pseudoseptic reaction (and, it cannot be so said), he did not reliably determine the *cause* of that diagnosis. Indeed, neither of the "clinical impressions" he relies on determined the underlying cause. And, besides the temporal proximity between the contaminated injection and the onset of symptoms (which, again, is not a reliable indicator of this causation), Dr. Abney relied only on the mere fact that Plaintiff "was injected with a syringe … contaminated with *Methylobacterium thiocyanatum*." (Doc. # 60 at 23) (citing Doc. # 60-1 at 87). As previously discussed, he does not have a reliably scientific basis for concluding that the contamination caused the onset of septic arthritis in these circumstances. *See id*. at 1255. His testimony is *not* "the product of reliable principles and methods." Fed. R. Evid. 702(c). Thus, his opinion that Plaintiff's condition was septic arthritis caused by *Methylobacterium thiocyanatum* is inadmissible.

b. Dr. Abney's Opinions on Plaintiff's Hearing Loss, Knee Replacement, and Life Span are Based on Unreliable Methods

Dr. Abney states that Vancomycin prescribed to Plaintiff because of his septic arthritis caused his hearing loss. He says this is so because 10-20 of his other patients reported hearing loss while taking Vancomycin and other similar drugs. But, this is not a reliable method for a few reasons.

Dr. Abney relies on temporal proximity to establish cause and effect. *McClain*, 401 F.3d at 1244. Second, he otherwise passes along Dr. Loftin's clinical impressions, which Dr. Loftin has since indicated were based on incomplete records and were not conclusive "to a reasonable degree

of medical certainty or probability."[23] (Docs. # 60 at 27; 56-22). *See Henderson*, 409 F.3d at 1300; *Dura* Auto, 285 F.3d at 614.

With respect to Dr. Abney's opinion that Plaintiff is not a candidate for knee replacement because of septic arthritis, his methods are again unreliable in reaching that conclusion. He bases his opinion on the "increased risk of a second infection" and the "deposition testimony of Dr. Ikard [,which] decidedly demonstrates that [Plaintiff] no longer is a potential candidate for a … total knee replacement as a result of" contamination from Defendant's product. (Docs. # 60 at 24; 56-2 at 5). Dr. Abney's methods fail for two reasons. First, he does not provide a basis in literature or scientific knowledge other than it "is what [he] see[s]" to support his conclusion that the risk of a second infection removes Plaintiff as a candidate for knee replacement. (Doc. # 56-1 at 78). Second, Dr. Abney attempts to close the analytical gap by repeating the impression of Dr. Ikard and saying that "orthopedic physicians [would be] very hesitant" to do a knee replacement. (*Id.* at 76). *Malletier*, 525 F. Supp. 2d at 664.

For similar reasons, Dr. Abney's opinion that Plaintiff has a reduced life expectancy due to loss of mobility because of the injection is unreliable. Among other things, Dr. Abney admitted that he did not review Plaintiff's post-operative physical therapy records to determine whether his mobility has improved and is not aware of Plaintiff's current mobility. (Doc. # 56-1 at 78-79). This will not suffice. *Turner*, 229 F.3d at 1208 (excluding expert where Defendants showed that expert failed to consider alternative plausible outcome). If Dr. Abney is not even aware of Plaintiff's

[23] Plaintiff and Dr. Abney noted that there is medical literature linking Vancomycin to hearing loss. (Doc. # 60 at 26). However, other than stating that there is an observed association between hearing loss and Vancomycin in the elderly, Plaintiff does not contend how the information in that literature (*e.g.*, how frequently hearing loss occurred as a side effect of Vancomycin) supported Dr. Abney's analysis and conclusion. Thus, because it is unclear how Dr. Abney used the medical literature (that is, if he applied the information at all to this case), the court does not find it probative to the reliability of his opinions. *See, e.g.*, *Nozinich v. Johnson & Johnson, Inc.*, 2011 WL 13124085, at *9 (W.D. Tenn. July 6, 2011) (excluding testimony where expert stated that he relied on medical literature to determine occurrence rate of side effect without explaining analysis).

mobility -- let alone any progression or regression in his mobility following his injection -- it follows that he cannot reliably opine that Plaintiff's lifespan was reduced *because of* the loss of mobility caused by his injection.

Regardless of whether Dr. Abney reliably determined the likelihood of Plaintiff's downstream conditions, Dr. Abney's opinions also fail because he has failed to reliably establish the prerequisite causation related to these conditions: a diagnosis of septic arthritis due to *Methylobacterium thiocyanatum* in his injection. Consequently, all these conditions, at least as related to Defendant's product, are causally related to Plaintiff's alleged injuries *only* if Synvisc-One caused septic arthritis. As this court has said, a "[d]ifferential diagnosis, 'however, will not usually overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug and that it can cause the harm a plaintiff suffered.'" *Jones*, 235 F. Supp. 3d at 1275 (quoting *McClain*, 401 F.3d at 1252).

3. Dr. Abney's Expert Opinion Testimony Fails to Assist the Trier of Fact[24]

An expert's opinion must assist the trier of fact through reliable methods to "understand the evidence or determine a fact in issue." *In re Trasylol Pro. Liab. Lit.*, 709 F. Supp. 2d 1323, 1328 (S.D. Fla 2010) (citing Fed. R. Evid. 702). Expert testimony is helpful to the trier of fact if it "concerns matters that are beyond the understanding of the average lay person." *Id.* Expert opinion generally will not help the trier of fact "when it offers nothing more than what lawyers for the parties can argue in closing arguments." *Frazier*, 387 F.3d at 1262-63. Additionally, expert

[24] The court notes that Plaintiff bears the burden of proving medical causation by a preponderance of the evidence. Thus, an expert's "equivocating" testimony regarding the facts will not assist a jury in reaching a factual determination by a preponderance of the evidence. *Clarke v. Schofield*, 632 F. Supp. 2d 1350, 1370 (M.D. Ga. 2009) (citing *McClain*, 401 F.3d at 1240). Thus, Dr. Ikard's equivocal opinion (parroted here by Dr. Abney) that Plaintiff's knee "very possibly could have been infected" and that a "reasonable physician [could] conclude" that Plaintiff had septic arthritis because of Synvisc-One does not assist the trier of fact and is inadmissible. (Docs. # 62-18 at 71; 58-3 at 28-29). *Id*. (excluding expert that said medical condition "could" occur in the circumstances); *McClain*, 401 F.3d at 1240 (excluding expert testimony with statements that medical condition "may" or "can" occur).

testimony is helpful to the trier of fact only if there is "an appropriate 'fit' with respect to the offered opinion and the facts of the case." *Geyer v. NCL (Bahamas) Ltd.*, 203 F. Supp. 3d 1212, 1215 (S.D. Fla. 2016) (quoting *Daubert*, 509 U.S. at 591); *McDowell*, 392 F.3d at 1299. "For example, there is no fit where a large analytical leap must be made between the facts and the opinion." *McDowell*, 392 F.3d at 1299. Put another way, "expert testimony must be relevant to the task at hand" and must "logically advance[] a *material* aspect of the case." *Id*. at 1298-99 (emphasis added) (internal quotation marks omitted).

Dr. Abney's opinions regarding hearing loss, life span, and knee replacement fail to assist the trier of fact. For reasons previously discussed, there is a "large analytical leap" between the facts in the record and Dr. Abney's opinion. *Id*. Thus, his opinions and the facts do not have the "appropriate fit" to assist the trier of fact. *Geyer*, 203 F. Supp. 3d at 1215. And, without a reliable basis for concluding that Defendant's product caused Plaintiff's reaction, whether Plaintiff is unfit for a knee replacement or has aggravated hearing loss because of his antibiotics cannot be connected to Defendant. Thus, it is no longer an issue in this case and would not assist the trier of fact in resolving any "material aspect of [this] case." *Daubert*, 509 U.S. at 591; *McDowell*, 392 F.3d at 1298-99.

B. Dr. Patterson's Expert Opinion Testimony is Inadmissible

After careful review, the court concludes that Dr. Patterson is qualified to opine as to Defendant's compliance with FDA requirements and the root cause of the contamination of the lot of Synvisc-One at issue in this case. However, she is not qualified to testify about the medical risks posed by *Methylobacterium thiocyanatum*. Dr. Patterson's opinions are also unreliable and fail to assist the trier of fact. For these reasons, her opinions are due to be excluded.

1. Dr. Patterson is Qualified to Opine on Defendant's Compliance with FDA Requirements and the Root Cause of Contamination in the Lot, But Not the Medical Risks of *Methylobacterium Thiocyanatum*

Plaintiff offers Dr. Patterson's testimony to "explain to the jury [Defendant's] lack of regulatory compliance which led to [the] distribution of the contaminated [L]ot." (Doc. # 61 at 8). Because Defendant's challenge is not to the absence of Dr. Patterson's expertise but to the *degree* of expertise, it follows that she is qualified to testify on the regulatory issues in this case. That is, Defendant's challenge goes to the weight the evidence should be given, not its admissibility.

Defendant argues that Dr. Patterson is not qualified to opine on its quality system or "the Synvisc-One aseptic manufacturing process" because she lacks academic, educational, or professional experience "related … to aseptic manufacturing of medical devices." (Doc. # 52 at 7). Defendant cites her lack of employment at a medical device facility or company, lack of employment in aseptic processing, lack of experience at the FDA or conducting an FDA site inspection, and the "little experience" she has "evaluating aseptic manufacturing processes" as deficient to offer her conclusions. (*Id*. at 7-8). But, that argument is off the mark.

Dr. Patterson's experiences go directly to the *specific* issues in this case that she offers testimony for and thus she is qualified to testify on these issues. She has extensive education in microbiology and relevant experience advising drug and medical device companies on FDA regulatory compliance. (Doc. # 61 at 13-14). Dr. Patterson's experience includes analyzing "product contamination and [its sources]," as well as advising medical device companies on meeting product specifications, quality system compliance, and manufacturing and testing procedure compliance. (Docs. # 61 at 13-14; 50-4 at 15). *See Jones,* 235 F. Supp. 3d at 1259 (holding regulatory consultant competent to testify on compliance with FDA regulations based on experience advising clients on product design, investigations, and other FDA requirements).

Finally, with respect to Defendant's issue with Dr. Patterson's inexperience as the "primary" decision-maker in her consultant role, that objection goes to the level of Dr. Patterson's expertise, which is a credibility determination left to the jury. The court finds that Plaintiff has shown that Dr. Patterson is qualified to opine on Defendant's compliance with FDA regulations and the source of the contamination in this case. *Kilpatrick*, 2009 WL 2058384, at *3; *GEICO Gen. Ins. Co.*, 447 F.3d at 1100.

Plaintiff also offers Dr. Patterson's opinion that "[t]he distribution of Lot 7RSL021 … put patients, like Mr. Lowery, at risk of serious illness and injury from bacterial contamination, including, but not limited to the risk of septic arthritis." (Doc. # 62-16 at 33). There is no *per se* requirement that a witness be a medical doctor to provide medical opinions. *See, e.g., In re Stand 'N Seal Prod. Liab. Litig.*, 623 F. Supp. 2d 1355, 1376 (N.D. Ga. 2009). But, by Dr. Patterson's own admission, she is "not a medical doctor, so [she does not] have medical opinions to offer." (Doc. # 50-4 at 7). The court gives this admission alone great weight and finds that she is unqualified to opine on the medical hazards of the contaminant at issue in this case. *See Thorn v. Novartis Pharm. Corp.*, 2013 WL 11451758, at *1 (E.D. Tenn. June 26, 2013) (excluding testimony of expert who admitted he is not qualified on the topic). The point is as tautological as it is true: if Dr. Abney, who is a medical doctor, is unqualified to offer opinion testimony on *medical* causation, that is even more so the case with Dr. Patterson.

2. Dr. Patterson's Opinions are Unreliable

Plaintiff presents Dr. Patterson as an expert witness to "explain to the jury [Defendant's] lack of regulatory compliance which led to [Defendant's] distribution of the contaminated [L]ot." (Doc. # 61 at 8). There are, however, significant "analytical gaps" between Dr. Patterson's conclusions and the facts on which she bases her opinions.

a. Source of Lot 7RSL021 Contamination

Plaintiff concedes that Dr. Patterson is not offering an opinion of how the Lot became contaminated. (*Id*. at 18). Yet, confusingly, Plaintiff continues to argue in his brief that Dr. Patterson should be permitted to testify that an "equipment maintenance issue" related to the bulk blending step (or alternatively "operator failures") caused contamination of the Lot. (*Id*. at 19-20). As Defendant points out, during

> her deposition, Dr. Patterson was directly asked: 'Are you offering any opinion … as to how the [bacteria] actually got into [the Lot]?' to which Dr. Patterson stated, 'No, I'm not offering an opinion on how it got into there.' Dr. Patterson also agreed that she was 'not offering an opinion as to how the [bacteria] got into the facility and then connecting the dots for how it actually got into the [L]ot in question.'

(Doc. # 52 at 11) (quoting Doc. # 50-4 at 8) (emphasis omitted). Indeed, when pressed whether she had evidence such that she could conclude what action by Defendant caused the contamination, she said that "I can't confirm that it came from" the issues she identified as posing a contamination risk. (Doc. # 50-4 at 110-11). Because she will not be offering testimony as to the cause of the contamination, Dr. Patterson cannot testify as to the deficiencies that Plaintiff alleges resulted in the bacterium making its way into the Lot.[25]

b. Dr. Patterson's Regulatory Compliance Opinions Do Not Analyze Defendant's Practices Under Applicable Federal Requirements and Defendant's FDA-approved Standard Operating Procedures

Dr. Patterson offers three opinions regarding Defendant's regulatory and procedural failures: (1) "Synvisc-One Lot 7RSL021 was not sterile and would be considered adulterated by U.S. FDA regulations"; (2) Defendant "violated []GMPs in the production and distribution of the Lot because of the deficiencies … observed in equipment maintenance, risk introduced by

[25] This does not mean that Plaintiff has failed to establish that the Lot was contaminated—Defendant does not dispute that. (Doc. # 50 at 12).

procedures, historical documentation of microorganism and endotoxins on personnel and in the facility, and endotoxin testing dilutions that would have provided false negatives"; (3) Defendant "should have started testing" the Lot when it discovered bacteria "in the WFI system in July 2017 [because it was required to as a condition of its PMA approval]." (Doc. # 62-16 at 33-34). All of these opinions are unreliable because Dr. Patterson does not connect her criticisms of Defendant's procedures to any specific binding federal requirement or the facts in this case. The problem lies in her analysis.

In explaining her methodology, Dr. Patterson relies on "findings of the FDA," the "regulatory framework," "industry standards," the "[CFR], FDA [guidance documents], scientific literature, safety database assessments," and her "experience as a professionally trained scientist and her experience in the medical device and pharmaceutical industry." (*Id*. at 6, 8, 17). *See* 21 C.F.R. § 820.1 (stating that GMP "requirements are set forth in" this regulation). Despite her statement that her methods analyze the GMPs and other federal requirements, Dr. Patterson has failed to explain which GMPs that Defendant has violated, let alone how Defendant's conduct or processes violate them. Dr. Patterson opines in her report that Defendant, in manufacturing Synvisc-One, has violated "specific rules and regulations established according to the … GMPs" and cites to 21 C.F.R. § 820. (*Id*. at 30). But, section 820 is comprised of over thirty subsections and is the entire universe of GMPs for the device manufacturing process, including record keeping, management responsibilities, design controls, quality audits, device packaging, device labeling, and quality systems. (Doc. # 63 at 5). Thus, without any analysis connecting the facts to the conclusions in her report, her opinions amount to little more than her personal beliefs.[26] *See*

[26] Dr. Patterson makes similar conclusory statements in other places in her analysis. For example, she states that "these are rules, regulations, FDA guidances, and standards that [Defendant] violated by distributing a contaminated lot of Synvisc-One in 2017 (7RSL021)." (Doc. # 62-12 at 30). Nowhere does she cite a single federal regulation that binds Defendant. (*Id*.).

McClain, 401 F.3d at 1242.

This same analysis applies to her conclusion that the Lot was not "sterile" and "would be considered adulterated by the FDA" under 21 C.F.R. § 820 and 21 U.S.C. § 351.[27] (Doc. # 61 at 22) (citing Doc. # 59-9 at 33). Like section 820, 21 U.S.C. § 351 has ten subsections and many more subparts, including statutory requirements for drugs, devices, and manufacturing techniques that would render a device (or a drug) "adulterated." Dr. Patterson does not connect the fact that the Lot was not "sterile" to her conclusion that it "would be considered adulterated by the FDA" when it was distributed to any provision of section 351 or the GMPs.[28] "[W]here Dr. [Patterson] states that [Defendant] violated … regulation[s] with some specific action, she fails to explain why that regulation was violated." *In re Trasylol*, 709 F. Supp. 2d at 1349 (excluding expert opinion where the expert "referenced" *specific* FDA requirements but "failed to explain why" those requirements were violated).

With respect to guidance documents or other supporting materials, Dr. Patterson makes an impermissible logical jump and contends that Defendant's deficiencies in those documents are themselves violations of the GMPs. As discussed in detail in the court's memorandum opinion on summary judgment (entered contemporaneously with this opinion), the guidance documents are

[27] Plaintiff repeats Dr. Patterson's conclusory statement in his brief: "Dr Patterson stated that the release of a contaminated lot of Synvisc One violated 21 [C.F.R. §] 820 and 21 [U.S.C. §] 351 because it was not considered sterile when released and would have been considered adulterated by FDA." (Doc. # 61 at 22).

[28] While inapposite for purposes of the reliability of Dr. Patterson's report, the court reviewed Plaintiff's brief opposing summary judgment to see if he specified what provision of section 351 Dr. Patterson's testimony supports. In this brief, Plaintiff stated that "the failure to comply with any applicable provision of this part [of the regulations] renders a device adulterated under section 501(h) of the act." (Doc. # 62 at 27) (citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010)). Under § 501(h) (amended as 21 U.S.C. § 351(h)), a product 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 [GMPs]." 21 U.S.C § 351(h); *See United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1285 (D.P.R. 1992). Because Dr. Patterson, as previously discussed, has failed to establish that Defendant violated any specific GMP, her opinion testimony does not support a finding that the lot was "adulterated" under 21 U.S.C. § 351(h) if that was her conclusion (which, to be sure, is unclear).

not binding rules or regulations but recommended procedures. (Doc. # 73 at 31-32). For example, she states that "repeated deficiencies … in the 483s … demonstrate there was a lack of attention to the standard GMPs for sterile injectable products." (Doc. # 62-16 at 31). She does not analyze how the deficiencies listed in the 483 Report violate any part of section 820.[29] This is particularly problematic where the same 483 Report said that Defendant's facility "is considered to be in a minimally acceptable state of compliance with regards to current [GMP]," and Dr. Patterson acknowledged this very point in her report. (Docs. # 62-3 at 1; 62-16 at 33).

The same lack of analysis exists for Dr. Patterson's list of problems related to equipment maintenance, procedures, and historical manufacturing deficiencies where she lists her criticisms and cites generally to an FDA guidance document. (*See* Doc. # 61 at 21-22). For example, she states that "quick movements of personnel were noted … [and can be] sources o[f] manufacturing contaminants" while generally citing the Guidance on Aseptic Processing. (Doc. # 62-16 at 31). There remains a significant "analytical gap" between the facts related to Defendant's practices and Dr. Patterson's conclusion that Defendant violated GMPs. Without this analysis, her opinions amount to little more than her personal beliefs. *See McClain*, 401 F.3d at 1242.

Finally, Dr. Patterson states that Defendant "should have known that *Methylobacterium thiocyanatum* would possibly be present in [the Lot]" because of the identification of the bacterium discovered in the WFI system and should have started testing for that specific bacterium upon that discovery. (Doc. # 62-16 at 33-34). But, Dr. Patterson points to no evidence that Defendant, even if it did know that the bacterium could be present in the Lot, was compelled to do additional testing under the circumstances. To the contrary, Dr. Patterson stated in her deposition that she had no

[29] To the extent that the 483 Form identifies procedures for testing that "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**[,]**" that GMP is located in 21 C.F.R. § 211.160, which is the GMPs for drugs, *not* medical devices. (Doc. # 73).

testimony to offer that "[Defendant] skipped a test that [was] supposed to be performed pursuant to the SOPs." (Doc. # 50-4 at 29). The only other support for her statement is her conclusory testimony that Defendant's violated GMPs based on the 483 Report and "[their] own documentation," but that statement has been proffered without explanation.[30] (Doc. # 61 at 24) (citing Doc. # 59-8 at 123). Again, her conclusion is nothing more than stating her beliefs. *See McClain*, 401 F.3d at 1242.

The deficiencies in Dr. Patterson's report are not trivial: complying with FDA regulations is no small task. Indeed, Dr. Patterson's professional work (based on her advanced education and training) involves helping companies comply with these requirements. So, it is imperative that her analysis be conducted in such a manner that a jury with no experience or knowledge in regulatory compliance can determine the basis of her conclusions and weigh the credibility of her testimony. But, where her analysis jumps from her observations of Defendant's practices to conclusions as to its compliance without specifying which provision Defendant failed to comply with (let alone how it failed to do so), a jury would be left to perform guesswork. The importance of Dr. Patterson being able to properly connect her analysis to specific GMPs is of heightened importance here because preemption requires that liability be based solely on federal requirements, not the personal feelings of an expert. Even if her testimony were admissible, because it is not closely tied to federal requirements and has significant potential to mislead a jury, it should otherwise be excluded under Rule 403. *See Frazier*, 387 F.3d at 1263.

[30] She also states in her report that "[Defendant] should have known … that a product being manufactured with a water line that has been contaminated would probably be contaminated" while citing a quality standard (USP 1231). Again, however, she does not connect this to any binding requirement on Defendant. (Doc. # 62-12 at 30).

c. Dr. Patterson's Opinions on False Negative Results and Health Hazards are Merely Her Own Assertions[31]

Dr. Patterson offers her opinion that the pooling of three test samples resulted in "endotoxin testing dilutions that would have provided false negative" results for release specification. (Doc. # 62-16 at 34). As Plaintiff summarizes, "[a]ccording to Dr. Patterson, if [Defendant] had tested individual samples from different parts of the manufacturing process, there is a chance that the endotoxin test would have been positive for *Methylobacterium thiocyanatum*." (Doc. # 61 at 27). Plaintiff's counsel asked Dr. Patterson, "*could* the use of deficient tests identified by the FDA have led to false negatives for Lot 7RSL021?" (Doc. # 59-8 at 121) (emphasis added). She responded: "Based on the data we've seen, yes. We've not been provided evidence otherwise." (*Id*.).

Viewing this proffered opinion testimony in a light most favorable to Plaintiff, Dr. Patterson's analysis fails to adequately show that the deficient testing *caused* a false negative endotoxin test for the Lot. And, when Defendant pushed Dr. Patterson about the evidentiary basis for her opinion that pooling altered the outcome in this case, she said she did not have "any proof that … the difference between the pooling of the three syringes and the individual syringe testing method [] caused a difference in the outcome." (*Id.* at 99). Just because the FDA found that the test could be invalid is not a sufficient basis to show that it *was* invalid under the facts of this case, especially where Dr. Patterson admitted that she did not have evidence showing that the testing methods would have produced a false negative for the Lot. (*Id*.). Plaintiff also adds that Dr. Patterson knew that it was a false negative because "we know … it's contaminated." (*Id*. at 91). This statement does not support the inference that the different testing proposed would have altered the results such that the product would not have been distributed. As the Eleventh Circuit has held,

[31] Dr. Patterson offers the opinion that "Synvisc-One Lot 7RSL021 was manufactured in May 2017 and left the New Jersey facility in October 2017 with the microbial contamination *Methylobacterium thiocyanatum*." (Doc. # 62-12 at 33-34). Defendant does not dispute this fact.

conclusions that are "connected to existing data only by the [unproven statement] of the expert" are inadmissible. *Chapman*, 766 F.3d at 1305.

Finally, Dr. Patterson does not offer any reliable medical causation testimony. By Dr. Patterson's own admission, she "[does not] have any medical opinions to offer." (Doc. # 50-4 at 7). And, as previously discussed, it is important that an expert develop and analyze a cause-and-effect relationship between a toxin and a condition. *Chapman*, 766 F.3d at 1307; *see Sutherland v. Matrixx Initiatives, Inc.*, 2006 WL 6617000, at *11 (N.D. Ala. Nov. 7, 2006) (citing *McClain*, 401 F.3d at 1241). Dr. Patterson did not perform any analysis to support her conclusory statement in her report that the contamination put patients like Plaintiff at risk. (Doc. # 62-16 at 33).

3. Dr. Patterson's Opinions Fail to Assist the Trier of Fact

"[E]xpert testimony must be relevant to the task at hand" and must "logically advance[] a *material* aspect of the case." *McDowell*, 392 F.3d at 1298-99 (internal quotation marks omitted) (emphasis added). As discussed in detail in the court's memorandum opinion on summary judgment (Doc. # 73), Title 21 U.S.C. § 360k(a) severely limits a plaintiff's theories of liability on his state law claims to those that are premised on violations of binding federal regulations. *Riegel*, 552 U.S. at 328; *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1326 (11th Cir. 2017). That statutory scheme similarly places limits on the relevance of testimony supporting his claims and theories of liability.

Dr. Patterson's opinion testimony that Defendant should have conducted additional testing does not assist the trier of fact in this case for two reasons. First, Dr. Patterson's opinion that Defendant should have implemented different testing methods that are not compelled by a federal law goes, at best, to a theory of liability that is preempted and, for that reason, cannot be an issue put to the jury at trial. *Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any

issue in the case is not relevant and, ergo, non-helpful."); *Mink*, 860 F.3d at 1326. Further, even if Defendant *could* have implemented those procedures, under section 360k(a), Plaintiff cannot make it "obligatory" by holding Defendant liable for failing to do so. *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)).

This same analysis applies to Dr. Patterson's other criticisms of Defendant's facilities and manufacturing practices. Her lack of support, in evidence or logic, connecting Defendant's actions to binding federal requirements would leave it to the fact-finder to bridge the gap in her analysis (and, furthermore, would otherwise be directed to issues preempted by federal law). And, even if Dr. Patterson could connect Defendant's other manufacturing practices to a GMP violation, she has failed to establish that the GMP violation caused Plaintiff's injury. *Mink*, 860 F.3d at 1326.

Second, Dr. Patterson's conclusion that the deficient tests "could" have led to false negatives shows the "equivocal" nature of her opinion and would not assist the jury in finding causation by a preponderance of the evidence. (Doc. # 59-8 at 121). *Clarke*, 632 F. Supp. 2d at 1370 (internal citations omitted); *McClain*, 401 F.3d at 1240.

IV. Conclusion

For all the foregoing reasons, the court concludes that Defendant's Motions (Doc. # 51, 55) are 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