

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WILLIAM PRESTON WEST, JR., *et al.*,
Plaintiffs,

v.

BAYER HEALTHCARE PHARMACEUTICALS
INC., *et al.*,
Defendants.

Civil No. 15-1053 (CKK)

MEMORANDUM OPINION

(February 1, 2018)

Plaintiff William Preston West, Jr. alleges that he contracted a severe bacterial infection after using a contaminated alcohol prep pad that was packaged with an injectable medicine produced by Defendant Bayer HealthCare Pharmaceuticals, Inc. (“Bayer”). Plaintiff and his wife, Carolyn Gleason, have filed this lawsuit against Bayer, asserting causes of action for negligence, gross negligence, failure to recall, failure to warn or instruct, strict liability, breach of implied warranty, negligence *per se*, punitive damages and loss of consortium.¹ Presently pending before the Court are Defendant Bayer’s [124] Motion to Exclude the Expert Opinions of Paul Auwaerter, M.D. and Mark Abbruzzese, M.D., and [125] Motion for Summary Judgment. Upon consideration of the pleadings,² the relevant legal authorities, and the record for the

¹ In addition to his claims against Bayer, Plaintiff West also originally asserted a claim against the manufacturers of the alcohol prep pads, Triad Group, Inc., Triad Pharmaceuticals, Inc., and H&P Industries, Inc. (collectively, “Triad”). That claim was resolved through Triad’s bankruptcy. The current action involves only Plaintiffs’ claims against Bayer.

² The Court’s analysis has focused on the following documents:

- Def.’s Mot. to Exclude the Expert Opinions of Paul Auwaerter, M.D. and Mark Abbruzzese, M.D., ECF No. 124 (“Def.’s Mot. to Exclude”);
- Def.’s Mot. for Summary Judgment, ECF No. 125 (“Def.’s MSJ”);
- Pls.’ Opp’n to Def.’s Mot. for Summary Judgment, ECF No. 126 (“Pls.’ Opp’n to MSJ”);

purposes of these motions, the Court will DENY Defendant's Motion to Exclude, and GRANT-IN-PART and DENY-IN-PART Defendant's Motion for Summary Judgment.

Specifically, the Court concludes that the opinions of Plaintiffs' experts are admissible because they have an adequate factual basis and are sufficiently reliable. Defendant's critiques of those opinions bear on their weight, and can be explored through cross-examination, but they do not render those opinions inadmissible. Largely because the Court will allow Plaintiffs to present this expert testimony, summary judgment for Defendant is not appropriate on Plaintiff West's substantive claims. Summary judgment is also not appropriate on Plaintiff Gleason's loss of consortium claim. All parties agree that this claim is derivative of Plaintiff West's substantive claims, which are not being summarily adjudicated. Finally, the Court will grant Defendant summary judgment on Plaintiff's gross negligence and punitive damages claims, because Plaintiffs consent to the dismissal of those claims.

I. BACKGROUND

Although the record before the Court is quite voluminous, the facts of this case are actually fairly straightforward. Plaintiff William P. West has Multiple Sclerosis ("MS"). Plaintiff was prescribed an injectable medicine called Betaseron to treat his MS. Defendant Bayer produces Betaseron. The Betaseron injection kits distributed by Bayer contain alcohol

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- Pls.' Opp'n to Def.'s Mot. to Exclude the Expert Opinions of Paul Auwaerter, M.D. and Mark Abbruzzese, ECF No. 127 ("Pls.' Opp'n to Mot. to Exclude");
 - Def.'s Reply in Support of Mot. to Exclude the Expert Opinions of Paul Auwaerter, M.D. and Mark Abbruzzese, M.D., ECF No. 128 ("Def.'s Reply in Support of Mot. to Exclude");
 - Def.'s Reply in Support of Mot. for Summary Judgment, ECF No. 129 ("Def.'s Reply in Support of MSJ").

The Court has also reviewed all of the evidentiary material attached to these pleadings. In an exercise of its discretion, the Court finds that holding oral argument in this action would not be of assistance in rendering a decision. *See* LCvR 7(f).

prep pads manufactured by Triad Group, Inc., Triad Pharmaceuticals, Inc., and H&P Industries, Inc., (collectively, “Triad”). Plaintiff had been using these kits for several years prior to 2010.³

On the evening of December 29, 2010, after using the provided Triad alcohol prep pads, Plaintiff self-administered his Bayer Betaseron injection. Immediately thereafter, he developed cellulitis in his abdominal wall. Plaintiff West had to be hospitalized for an extended period. During his hospitalization, Plaintiff had a number of cultures taken—some before and some after Plaintiff began receiving antibiotics—but none of those cultures definitively identified the specific bacterial source of Plaintiff’s illness.

While in the hospital, Plaintiff received an e-mail from Bayer. The e-mail stated that “Bayer HealthCare Pharmaceuticals has become aware of a broad United States market recall of alcohol prep pads . . . manufactured by the Triad Group . . . due to potential contamination of these products with the bacteria, *Bacillus cereus* [“*B. cereus*”], that could lead to life-threatening infections.” Pls.’ Ex. 1, ECF No. 127-3, at 1.⁴ The recall warned that “Triad alcohol prep pads packaged for use in the U.S. with Betaseron should not be used by patients.” *Id.* As one might expect, Plaintiff immediately told his treating physician about this potential source of his illness.

Plaintiffs allege in this lawsuit that Plaintiff West’s abdominal wall cellulitis was the result of an infection caused by *B. cereus* bacteria that was present on the Triad alcohol pads in

³ Defendant’s Reply in Support of its Motion for Summary Judgment is largely dedicated to arguing that Plaintiffs’ Statement of Genuine Issues of Material Fact does not comply with Local Civil Rule 7(h). The Court need not engage in an analysis of whether or not Plaintiffs’ Statement was proper. The Court has based the conclusions in this Memorandum Opinion on a careful review of the record and the parties’ briefs, and any dispute about the format of the parties’ statements of fact did not affect those conclusions.

⁴ Many of the exhibits to Plaintiffs’ two opposition briefs (one in opposition to Defendant’s Motion to Exclude, and the other in opposition to Defendant’s Motion for Summary Judgment) are the same. Citations to Plaintiffs’ exhibits in this Memorandum Opinion refer to the exhibits attached to Plaintiffs’ Opposition to Defendant’s Motion to Exclude, ECF No. 127.

the Betaseron injection kit that he used on December 29, 2010. Plaintiffs have proffered two expert witnesses that agree that this is the most likely explanation for Plaintiff's illness. Dr. Mark R. Abbruzzese is an infectious disease specialist licensed to practice in the District of Columbia. *See* Pls.' Ex. 2 (Pls.' Preliminary Expert Witness Designations), ECF No. 127-4, at 5. Dr. Paul G. Auwaerter is a board-certified internal medicine and infectious disease doctor who serves as the Clinical Director of the Division of Infectious Diseases at Johns Hopkins Medicine and is a professor of medicine at Johns Hopkins University School of Medicine. *Id.* at 8. Both experts have lengthy, relevant and impressive backgrounds relating to infectious diseases. *See* Pls.' Ex. 5 (Abbruzzese Curriculum Vitae), ECF No. 127-7; Pls.' Ex. 6 (Auwaerter Curriculum Vitae), ECF No. 127-8.

Dr. Abbruzzese treated Plaintiff during and after his hospitalization, and is expected to testify that, based on his expertise with infectious diseases, and "Plaintiff's clinical history and presentation, including the nature and severity of his infection and its sequelae . . . Plaintiff's abdominal wall cellulitis was caused by *Bacillus cereus*." Pls.' Ex. 2 at 6; Depo. of Dr. Mark Abbruzzese, ECF No. 127-9 ("Abbruzzese Depo."), at 292:21-293:17 (testifying that "with a great deal of certainty, and I'm not sure what the metric is that you need, the answer is, of course" Plaintiff had a *B. cereus* infection). Dr. Abbruzzese initially diagnosed Plaintiff with cellulitis caused by an infection secondary to his self-injection with Betaseron, but did not specify the exact bacteria that caused this condition. *See* Abbruzzese Depo. at 163:4-11. While he was still in the hospital being treated by Dr. Abbruzzese, Plaintiff received the e-mail from Defendant Bayer warning users about the potential *B. cereus* contamination in Triad alcohol prep pads. *Id.* at 38:7-39:6. Plaintiff told Dr. Abbruzzese this information, *id.*, which, in combination with other factors, led Dr. Abbruzzese to conclude that *B. cereus* may have caused Plaintiff's

infection, *see, e.g., id.* at 104:6-105:7, 286:2-290:21. Dr. Abbruzzese noted at the time that a *B. cereus* infection would explain Plaintiff's ailments, *id.* at 207:15-19, and recorded it in his records alongside two questions marks, *id.* at 203:18-22. He testified that he did not confirm Plaintiff had been infected with *B. cereus* with a culture because by the time he learned of the potential contamination, Plaintiff had already received antibiotics that would prevent the bacteria from being cultured. *Id.* at 39:23-40:12. Dr. Abbruzzese did not change Plaintiff's treatment plan when he learned of the potential contamination, because the drug Plaintiff was already prescribed at that point was effective against *B. cereus*. *Id.* 209:18-210:8 (testifying that he did not change Plaintiff's treatment plan after learning about the potential contamination because Plaintiff was already on "Avelox, which kills *Bacillus cereus* historically in the laboratory"). Plaintiff's infection cleared up.

In short, a fair summary of Dr. Abbruzzese's testimony is that he does not have evidence that definitively *proves* that Plaintiff's infection was caused by *B. cereus* (*e.g.*, a culture indicating that the bacteria existed in Plaintiff's system), nor can he definitively and absolutely *prove* that other bacteria (*e.g.*, *streptococcus* or *staphylococcus*) were not the cause. However, based on Plaintiff's symptoms, history and clinical presentation—including the fact that Plaintiff's infection began immediately after he used a Triad alcohol prep pad and injected himself with Betaseron; that Plaintiff had not previously had serious complications from using these pads or injections in the past; and that the one time Plaintiff became infected after using them he was subsequently told that the alcohol prep pads were potentially linked to a *B. cereus* contamination—Dr. Abbruzzese concluded at the time he was treating Plaintiff that *B. cereus* was a possible cause of his patient's condition, and has since concluded that it is more likely than not that *B. cereus* was the culprit.

Dr. Auwaerter's opinion is similar. Dr. Auwaerter is expected to testify that, having reviewed Plaintiff's medical records, Plaintiff's illness was "highly likely due to infection introduced by contaminated alcohol prep pads that failed to cleanse skin surface and introduced high burden of an infectious pathogen that was likely due to *Bacillus* species." Pls.' Ex. 3 (Dr. Auwaerter Expert Report), ECF No. 127-5, at 3; Depo. of Dr. Paul Auwaerter, ECF No. 127-10 ("Auwaerter Depo"), at 207:11-12 ("I would just say more likely than not, *bacillus cereus*"). Dr. Auwaerter's conclusions largely mirror those of Dr. Abbruzzese. To summarize, Dr. Auwaerter concedes that his conclusions are not based on cultures, microbiological data or test results that might conclusively "prove" the cause of Plaintiff's illness, and that it is possible that Plaintiff's symptoms could have been consistent with other types of infections. However, based on a host of factors—including the fact that Plaintiff's clinical presentation, symptoms, and development throughout treatment were consistent with a *B. cereus* infection, the temporal proximity between Plaintiff's self-injection and his illness, the fact that Plaintiff had not had injection-related infections in the past, and the fact that, according to the recall e-mail, the Triad alcohol pad Plaintiff had used immediately prior to his infection may have been contaminated with *B. cereus*—Dr. Auwaerter concluded that *B. cereus* was the most likely cause.

Defendant has moved the Court to exclude the expert testimony of Drs. Abbruzzese and Auwaerter, and has also moved for summary judgment. Both of those motions have been fully briefed and are now ripe for resolution.

II. LEGAL STANDARDS

A. Motion to Exclude Expert Testimony

Federal Rule of Evidence 702 governs the admission of expert testimony. That rule states that: "[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. The trial judge has “considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

The Court’s application of Rule 702 is informed by the Supreme Court’s opinion in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). “Under *Daubert*, the district court is required to address two questions, first whether the expert’s testimony is based on ‘scientific knowledge,’ and second, whether the testimony ‘will assist the trier of fact to understand or determine a fact in issue.’” *Meister v. Med. Eng’g Corp.*, 267 F.3d 1123, 1126 (D.C. Cir. 2001) (quoting *Daubert*, 509 U.S. at 592). “The first inquiry forces the court to focus on ‘principles and methodology, not on the conclusions that they generate,’” and “demands a grounding in the methods and procedures of science, rather than subjective belief or unsupported speculation.” *Id.* at 1127 (quoting *Daubert*, 509 U.S. at 590, 595). “While rejecting a requirement of scientific certainty, the Supreme Court instructed that ‘in order to qualify as “scientific knowledge,” an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—*i.e.*, “good grounds,” based on what is known.’” *Id.* (quoting *Daubert*, 509 U.S. at 590).

In short, the Court is intended to perform a “gatekeeping” role and engage in “a preliminary assessment of whether the reasoning or methodology underlying the testimony is

scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.”” *Ambrosini v. Labarraque*, 101 F.3d 129, 133 (D.C. Cir. 1996) (quoting *Daubert*, 509 U.S. at 592-93). “[T]he proponents of [expert] evidence . . . bear the burden to prove that the expert testimony is reliable by a preponderance of the evidence.” *Arias v. DynCorp*, 928 F. Supp. 2d 10, 17 (D.D.C. 2013).

B. Motion for Summary Judgment

Summary judgment is appropriate where “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The mere existence of *some* factual dispute is insufficient on its own to bar summary judgment; the dispute must pertain to a “material” fact. *Id.* Accordingly, “[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Nor may summary judgment be avoided based on just any disagreement as to the relevant facts; the dispute must be “genuine,” meaning that there must be sufficient admissible evidence for a reasonable trier of fact to find for the non-movant. *Id.*

In order to establish that a fact is or cannot be genuinely disputed, a party must (a) cite to specific parts of the record—including deposition testimony, documentary evidence, affidavits or declarations, or other competent evidence—in support of its position, or (b) demonstrate that the materials relied upon by the opposing party do not actually establish the absence or presence of a genuine dispute. Fed. R. Civ. P. 56(c)(1). Conclusory assertions offered without any factual basis in the record cannot create a genuine dispute sufficient to survive summary judgment. *See Ass’n of Flight Attendants-CWA, AFL-CIO v. Dep’t of Transp.*, 564 F.3d 462, 465-66 (D.C. Cir. 2009). Moreover, where “a party fails to properly support an assertion of fact or fails to properly

address another party's assertion of fact," the district court may "consider the fact undisputed for purposes of the motion." Fed. R. Civ. P. 56(e).

When faced with a motion for summary judgment, the district court may not make credibility determinations or weigh the evidence; instead, the evidence must be analyzed in the light most favorable to the non-movant, with all justifiable inferences drawn in its favor. *Liberty Lobby*, 477 U.S. at 255. If material facts are genuinely in dispute, or undisputed facts are susceptible to divergent yet justifiable inferences, summary judgment is inappropriate. *Moore v. Hartman*, 571 F.3d 62, 66 (D.C. Cir. 2009). In the end, the district court's task is to determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Liberty Lobby*, 477 U.S. at 251-52. In this regard, the non-movant must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Liberty Lobby*, 477 U.S. at 249-50 (internal citations omitted).

III. DISCUSSION

The arguments relating to Defendant's two pending motions overlap considerably. The Court will first address Defendant's motion to exclude Plaintiffs' proffered expert testimony.

The outcome of that motion has a substantial impact on Defendant's motion for summary judgment, which the Court will then address in the latter half of this Memorandum Opinion.

A. Defendant's Motion to Exclude the Expert Opinions of Paul Auwaerter, M.D. and Mark Abbruzzese, M.D.

The Court will deny Defendant's motion to exclude the testimony of Plaintiffs' expert witnesses, Drs. Abbruzzese and Auwaerter.⁵ The parties' dispute with respect to the testimony of these witnesses focuses not on their qualifications or relevance, but on the factual basis and reliability of their opinions. Defendant argues that—for a *wide* variety of reasons—the manner in which Plaintiffs' proffered experts reached their conclusions about the most likely cause of Plaintiff West's illness was so fundamentally flawed and unreliable that a jury cannot be allowed to hear those conclusions at all. The Court disagrees. Despite arguments that may affect the weight of their testimony, both experts' opinions are sufficiently reliable to survive Defendant's *Daubert* challenge.⁶

The Court begins by clarifying the basis of the proffered experts' opinions. Although Defendant attempts to portray Drs. Abbruzzese and Auwaerter's opinions about the likely cause

⁵ The Court has considered the pleadings and the record as a whole and determined that no hearing is necessary to resolve Defendant's motion to exclude the testimony of Plaintiffs' experts. "It is well established that a court is not required to hold an evidentiary hearing regarding the admissibility of expert testimony." *United States v. Jones*, 918 F. Supp. 2d 1, 7 (D.D.C. 2013) (internal quotations and citations omitted).

⁶ Defendant disputes a number of the factual statements in the background section of Plaintiffs' Opposition to Defendant's Motion to Exclude. *See* Def.'s Reply in Support of Mot. to Exclude at 2-3. The Court need not resolve these disputes, as they are irrelevant to the resolution of any motion before the Court. The Court notes in particular that in a footnote in their Opposition brief, Plaintiffs stated that "[t]he contaminated Triad pads were ultimately linked to a number of deaths and many serious injuries throughout the country." Pls.' Opp'n to Mot. to Exclude at 4 n.1. Defendant has pointed out that the exhibit Plaintiffs reference in this footnote does not actually support this assertion, and Plaintiffs have not otherwise provided the Court with support for it. The Court has reviewed this exhibit and agrees with Defendant that it does not support Plaintiffs' statement regarding injuries and deaths. The Court has not considered that statement in reaching the conclusions in this Memorandum Opinion.

of Plaintiff West's illness as being based on nothing more than their "*ipse dixit*," Def.'s Mot. to Exclude at 2, a careful review of the record belies this assertion. As Plaintiffs aptly summarize, Drs. Abbruzzese and Auwaerter's opinions are actually based on "their extensive knowledge of infectious diseases and associated medical literature and scientific knowledge, their clinical experience in treating infectious diseases, the information contained in Mr. West's medical records, the information contained in the recall notice identifying *B. cereus* as the potential contaminant of the Triad alcohol prep pads and the temporal relationship between Mr. West's exposure and symptoms." Pls.' Opp'n to Mot. to Exclude at 7. In other words, Plaintiffs' experts are infectious disease doctors who have applied their education, experience and knowledge of infectious diseases to the information available to them about a patient and, based on that information, have chosen what they believe is the most likely cause of that patient's illness over all other possibilities. This type of medical diagnosis—while obviously not infallible—is a reliable, scientific manner of generating an expert opinion. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (holding that the practice of "identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated" based on, among other things, "physical examinations" and "the taking of medical histories" is a valid foundation for an expert opinion). Indeed, Defendant does not seem to challenge the basic premise that, *as a general matter*, a medical doctor can give an expert opinion of this nature. *See* Def.'s Mot. to Exclude at 7 ("physicians rely upon the clinical presentation coupled with the treating physician's knowledge of likely pathogens.").

Defendant does, however, challenge the manner in which Drs. Abbruzzese and Auwaerter reached their conclusions in this particular case. Defendant does so on a number of grounds, which the Court will now address. First, both doctors testified during their depositions

that they chose *B. cereus* as the most likely cause of Plaintiff West's illness in part because they were informed that Plaintiff had used a Triad alcohol prep pad immediately before the onset of his symptoms, and that, based on a recall notice Plaintiff received via e-mail during his hospital stay, there was a known risk (although not a certainty) that those pads were contaminated with *B. cereus*. Defendant contends that this aspect of their testimony runs afoul of Federal Rule of Evidence 407. Rule 407 states that "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product or its design, or a need for a warning or instruction." Fed. R. Evid. 407. Defendant argues that the recall e-mail Bayer sent Plaintiff was a subsequent remedial measure, and accordingly evidence of the recall is inadmissible. Defendant claims that "Plaintiff's experts cannot rely upon an inadmissible subsequent remedial measure." Def.'s Reply in Support of Mot. to Exclude at 13.

Even assuming that Defendant is correct that the recall is inadmissible at trial, the Court sees nothing problematic with this aspect of the doctors' opinions. In the context of Defendant's motion to exclude expert testimony, Defendant's focus on Rule 407 is misguided, because the *admissibility* of the recall e-mail is irrelevant. Defendant's focus should instead be on Rule 703, which states that "[a]n expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed," and "[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, *they need not be admissible* for the opinion to be admitted." Fed. R. Evid. 703 (emphasis added).

Accordingly, the question before the Court—for the purposes of Defendant's *Daubert* motion—is not whether the information about the possible *B. cereus* contamination in the recall e-mail is admissible. It need not be. Instead, the question is whether infectious disease doctors

diagnosing a patient would consider the information conveyed by that e-mail when rendering a diagnosis. Based on the deposition testimony of both doctors, the Court is satisfied that this is the case. *See, e.g.*, Abbruzzese Depo. at 289:11-18 (testifying that “any reasonable doctor” would want to know this information when treating a patient); *id.* at 296:11-297:2 (in response to question about considering the information in the recall e-mail, testifying that “whenever you have access to new pieces of information, it’s just important that you add it. You can’t ignore it”); *id.* at 300:16-301:2 (“we did get that information. And that’s the point of the whole business. That information is there. And I can’t ignore it as you formulate a true bona fide medical opinion”); Auwaerter Depo. at 180:21-181:1 (indicating that if doctors became aware of the information in the recall notice, *B. cereus* would go to “the top of their list”). Accordingly, even assuming Defendant is correct that Rule 407 renders evidence of the recall e-mail inadmissible, that does not mean that there is anything improper about Plaintiffs’ experts’ partial reliance on information that they learned about through that e-mail. *See Pineda v. Ford Motor Co.*, 520 F.3d 237, 246-47 (3d Cir. 2008) (holding that the district court erred by “conflat[ing] the separate issues of whether [a recall] itself can be admitted into evidence [despite Rule 407] and whether [an expert’s] opinion can be admitted if it is based on a consideration of the [recall]” under the requirements of Rule 703).⁷

Relatedly, Defendant also complains about Drs. Abbruzzese and Auwaerter’s consideration of the potential contamination discussed in the recall e-mail because the doctors

⁷ In a footnote, Defendant states that “Courts have also barred expert testimony that is based on subsequent remedial measures.” Def.’s MSJ at 12 n.8. The Court has reviewed the opinions cited by Defendant. The district court opinions are unpublished orders on motions *in limine* from districts outside of this Circuit, which contain very little analysis at all. To the extent they could be interpreted as reaching conclusions contrary to this Memorandum Opinion, the Court does not find them persuasive. The opinion cited by Defendant from the Fourth Circuit Court of Appeals actually supports the Court’s analysis in this case. In *Wehling v.*

did not themselves conduct investigations to “learn about the details of the recall,” or determine with certainty that “Mr. West’s alcohol pads specifically were *in fact* contaminated.” Def.’s Mot. to Exclude at 1-2 (emphasis added). The Court is not persuaded that these points render the proffered expert opinions inadmissible, although they may be fair game for cross-examination. Based on the depositions of Drs. Abbruzzese and Auwaerter, the Court concludes that doctors in their field would reasonably rely on the information relayed by the recall e-mail as one factor to be considered when formulating a diagnosis, despite the fact that they have not confirmed with one-hundred percent certainty that the particular product their patient had used was in fact contaminated. This aspect of the experts’ methodology does not strike the Court as so unfounded or unreliable that exclusion is necessary. The Court notes that Dr. Auwaerter testified that, given the passage of time (many years), he doubted whether attempting to test Plaintiff’s particular alcohol pads for *B. cereus* would be a fruitful exercise at all. *See* Auwaerter Depo. at 35:23-36:1. Dr. Auwaerter’s doubt is lent some credence by the fact that Defendant itself also retains some Triad pads, and has also opted not to test them. *See* Depo. of Suzanne Bunthuwong, ECF No. 127-12, at 114:12-18. Also, while Dr. Auwaerter may not have determined that Plaintiff West’s prep pads were definitely among those contaminated, he did testify that he concluded Plaintiff’s prep pads were likely to have been contaminated because he reviewed an article that stated that “the majority” of alcohol prep pads involved in the recall had tested positive for contamination. *See* Auwaerter Depo. at 33:16-24; Pls.’ Ex. 9, ECF No. 127-11 at 3 (“*B. cereus* and other *Bacillus* species were consistently cultured from the internal

Sandoz Pharm. Corp., 162 F.3d 1158 (4th Cir. 1998), the court held that an expert’s opinion was not based on valid methodology and reasoning where he based his opinion on a subsequent relabeling of a drug, but only because, in that case, the relabeling was not “the type of subsequent remedial measure reasonably relied upon by experts in the field in forming their opinions or inferences.” *Id.* at *4. In this case, the Court has reached the opposite conclusion.

contents of 8 of the 10 lots of the Triad nonsterile APPs”). Defendant argues that this conclusion “cannot survive scrutiny,” Def.’s Mot. to Exclude at 19, and perhaps the jury will agree. But the Court concludes that such issues go to the weight of the proffered experts’ conclusions, not to their admissibility.

A second overarching argument raised by Defendant is that Plaintiffs’ experts do not have conclusive medical proof that Plaintiff was infected with *B. cereus*, such as “cultures” or “microbiological data.” Although Defendant may inquire about this point during cross-examination, it is not a reason to exclude these witnesses’ testimony altogether. At their depositions, both experts testified that the absence of such evidence is routine and does not mean that Plaintiff did not have a *B. cereus* infection. *See, e.g.*, Auwaerter Depo. at 82:12-22 (testifying that the absence of such evidence “would not be viewed as evidence that it’s not *bacillus cereus* infection” and “would not be unusual”); *id.* at 85:5-11 (testifying that a patient not culturing positive “is not unusual with cellulitis”); *id.* at 86:2-3 (“generally cellulitis often doesn’t have positive cultures”); Abbruzzese Depo. at 72:11-15 (agreeing that “cultures don’t always identify the causative etiologic agent for an infectious cellulitis”); *id.* at 288:15-23 (“culturing is such an imperfect world today . . . culturing isn’t the answer”). According to the doctors, this is especially so for those cultures that were taken after Plaintiff started to receive antibiotics, which can prevent *B. cereus* from growing in a culture. *See, e.g.*, Abbruzzese Depo. at 41:18-42:10. Where two highly experienced and knowledgeable infectious disease doctors opine about the most likely bacterial cause of a patient’s infectious disease based on all of the facts surrounding his history and clinical presentation, those opinions are not subject to exclusion

simply because they are not also confirmed by tests that definitively prove the presence of that bacteria.

Third, Defendant argues that the experts in this case did not rely on scientific or medical literature to support their conclusions. As an initial matter, it is not clear to the Court that Defendant is correct with respect to Dr. Auwaerter. Dr. Auwaerter's report cites two published articles. Pls.' Ex. 3 at 3. Regardless, even accepting Defendant's argument that, for the most part, the experts' conclusions are not based on medical literature, such literature is not necessary to render a medical expert's opinion admissible. Defendant "does not dispute" this point. Def.'s Reply in Support of Mot. to Exclude at 6. This is especially so in a case like this one where, given the apparent rarity of self-injection related infections, *see* Abbruzzese Depo. at 90:13-18 (testifying that a patient-administered self-injection conducted in a sterile fashion has a "real close" to zero percent chance of resulting in an infection); Auwaerter Depo. at 212:4-5 (injection related infections are "something we don't see very commonly"), scientific literature on the topic would reasonably be expected to be limited. *See Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 246 (5th Cir. 2002) (holding that district court erred by excluding expert testimony regarding cause of infection, stating that "[t]he lack of literature on injection-related salmonella infections of the joint does not undermine Dr. Coco's hypothesis," especially because, given the rarity of the infection at issue, "it is difficult to see why a scientist would study this phenomenon."). Like Defendant's other arguments, its argument regarding supporting literature goes to the weight of the experts' opinions, and can be used to probe and critique their testimony at trial, but does not render that testimony inadmissible.

A fourth argument for exclusion raised by Defendant is that neither of Plaintiffs' experts have been able to conclusively rule out every other possible cause of Plaintiff West's symptoms.

The Court rejects this argument as well. Even if the experts were unable to narrow the potential list of causes of Plaintiff's illness to one, this is not fatal to the admissibility of their opinions. Both experts opined that, despite the theoretical possibility that Plaintiff's illness was caused by something else, the culprit was more likely than not *B. cereus*. As both parties agree, "more likely than not" is as certain as an expert needs to be to pass the threshold of admissibility. *See* Def.'s Reply in Support of Mot. to Exclude at 16 ("it is true that Plaintiffs' Experts must offer their opinions to a 'more likely than not' standard to be admissible"); *see also Psychiatric Inst. of Washington v. Allen*, 509 A.2d 619, 624 (D.C. 1986) ("The expert need only state an opinion, based on a reasonable degree of medical certainty, that the defendant's negligence is more likely than anything else to have been the cause (or a cause) of the plaintiff's injuries."). Absolute certainty in a causation opinion is not necessary. *See Mendes-Silva v. United States*, 980 F.2d 1482, 1488 (D.C. Cir. 1993) (holding that the fact "that no scientific evidence exists which *conclusively* establishes [a] causal link" is not a "bar to the admissibility of . . . expert opinion on causation.") (emphasis in original). Stated differently, the fact that other potential causes for Plaintiff's illness cannot be definitively ruled out does not preclude Plaintiffs' experts from testifying about what they conclude is the most likely of the remaining possible causes. *See Bell v. Gonzales*, No. CIV.A. 03-163 (JDB), 2005 WL 3555490, at *17 (D.D.C. Dec. 23, 2005) ("failure to eliminate several possible causes 'goes to the weight rather than the admissibility of [the] testimony.'" (quoting *Ambrosini*, 101 F.3d at 140); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49, 57 (D.D.C. 1997) ("an expert must not eliminate each and every possible alternative cause").

Moreover, it is not as though the experts in this case did not narrow the list of possible causes at all. To the contrary, the list was narrowed considerably. As Defendant notes, cellulitis

“can be caused by a wide variety of bacteria or other agents.” Def.’s Mot. to Exclude at 3 n.2. Defendant has offered two potential bacterial causes other than *B. cereus* that Plaintiffs’ experts concede could potentially have caused Plaintiff West’s illness (*streptococcus* and *staphylococcus*), but it appears that the various other potential causes of cellulitis were ruled out. Within the potential bacterial causes, the doctors chose *B. cereus* and provided reasoning for doing so. Dr. Auwaerter testified—although perhaps not in particularly strong terms—that various aspects of Plaintiff’s symptoms were not consistent with the other potential bacterial causes Defendant has proffered. See Auwaerter Depo. at 157:23 (describing Plaintiff’s symptoms as “relatively inconsistent” with *streptococcus* and *staphylococcus*). And both doctors also considered that Plaintiff had just used Triad alcohol prep pads before contracting his infection, which were potentially contaminated with *B. cereus*, a bacteria that would cause symptoms consistent with Plaintiff’s clinical presentation. Again, the issue of other possible causes can be explored before the jury. The jury can weigh this issue when they consider the import of the experts’ conclusions.

Fifth, Defendant argues that Plaintiffs’ experts based their opinions solely on the temporal proximity between Plaintiff’s use of the Triad alcohol prep pad and the onset of his infection. Defendant argues that “[a]n expert’s opinion that is supported by nothing more than a temporal relationship cannot pass muster under *Daubert*.” Def.’s Mot. to Exclude at 20 (internal quotation omitted). As is hopefully clear by this point in the Court’s Memorandum Opinion, the experts in this case did not rely solely on “temporal proximity.” As described in more detail above, Plaintiffs’ experts have based their opinions on, among other things, Plaintiff’s history, symptoms and the information in the recall e-mail regarding the potential *B. cereus* contamination. To the extent Plaintiffs’ experts also relied on timing as one of the reasons for

their conclusions, this was not improper or, frankly, surprising. *See Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 158 (3d Cir. 1999) (“when the temporal relationship is strong and is part of a standard differential diagnosis, it would fulfill many of the *Daubert*[] factors”); *Arias*, 928 F. Supp. 2d at 21 (“An expert may . . . rely on a temporal relationship between the exposure to a toxin and onset of symptoms to form a specific causation opinion.”). The doctors’ reliance on temporal proximity as one of a constellation of factors they considered when determining causation in this particular case is especially appropriate, given the *extremely* close proximity between the time Plaintiff West used the potentially contaminated Triad alcohol prep pad and the onset of his infection.

Sixth, although Defendant concedes that “a physician may rely on her or his own clinical experience, if relevant and sufficient, as one basis for expert opinion,” Def.’s Reply in Support of Mot. to Exclude at 7, Defendant argues that Drs. Abbruzzese and Auwaerter do not have sufficient clinical experience upon which to base their conclusions. This argument lacks merit. Both doctors are infectious disease specialists with extensive experience with infectious cellulitis—the condition Plaintiff suffered from—in particular. Defendant stresses the doctors’ relative lack of experience treating *B. cereus* strains in particular, especially those in “intact skin” or “soft tissue.” Def.’s Mot. to Exclude at 9, 12. But to require, merely to pass the threshold of *admissibility*, that Plaintiff put forth experts who have extensive experience not just with infectious cellulitis generally, but with the exact bacterial strain and circumstances at issue, is too much. Defendant is free to cross examine Plaintiffs’ witnesses at trial on their clinical experience (*e.g.*, how many patients with the exact same condition as Plaintiff have they treated,

how well they remember those instances, differences between those patients and Mr. West, etc.) but the Court will not prevent these witnesses from testifying altogether on this basis.

Seventh, Defendant argues that Dr. Abbruzzese's conclusion that Plaintiff's illness was most likely caused by *B. cereus* is unreliable because it is "radically different" than his conclusion during his care of Plaintiff—that *B. cereus* was a *possible* cause of that illness. Def.'s Mot. to Exclude at 7; Def.'s Reply in Support of Mot. to Exclude at 9. The Court disagrees that Dr. Abbruzzese's initial opinion and his current opinion are "radically different." Def.'s Reply in Support of Mot. to Exclude at 9. At most, he appears to merely have increased his certainty about the role of *B. cereus* in Plaintiff's illness. Defendant claims that the development of Dr. Abbruzzese's opinion "by definition . . . indicates that he is not using the same level of intellectual rigor in this litigation as he did in practice." Def.'s Mot. to Exclude at 22. This argument simply does not follow. Although Defendant is free to question Dr. Abbruzzese during cross-examination about why he became more certain that *B. cereus* was the culprit in the time between when he made his initial note and when he provided an opinion for this litigation, the Court sees no reason to conclude that his current opinion demonstrates any lack of "intellectual rigor."

Defendant raises various other critiques of Drs. Abbruzzese and Auwaerter's opinions and statements they made during their depositions. The Court has considered all of those critiques and is not persuaded that any of them call for exclusion. Defendant argues that one statement in Dr. Abbruzzese's deposition testimony—that Plaintiff had received antibiotics before certain of his cultures were taken—is factually incorrect. Def.'s Reply in Support of Mot. to Exclude at 3-4. Defendant argues that when asked a particular question about cultures and *B. cereus*, "Dr. Abbruzzese admitted he did not know." *Id.* at 4. Defendant argues that one

statement Dr. Auwaerter made during his deposition is “at odds with what he has published on this very question.” *Id.* And Defendant argues that Dr. Auwaerter and Dr. Abbruzzese may disagree on certain points. Def.’s Mot. to Exclude at 11 n.5. The Court’s answer to all of these arguments is the same: they are possible (and, indeed, fairly traditional) avenues of cross-examination and impeachment and go merely to the weight of the experts’ opinions.

In sum, despite the large volume of arguments raised by Defendant, the Court is not persuaded that the testimony of Drs. Abbruzzese and Auwaerter should be excluded. All of Defendant’s arguments regarding the proffered experts’ testimony go to weight, not admissibility, and should be explored before the jury. To the extent Defendant views this expert testimony as unpersuasive, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596. Defendant’s motion to exclude is DENIED.

B. Defendant’s Motion for Summary Judgment

Defendant’s motion for summary judgment relies on many of the same arguments that underpin its motion to exclude. In large part, this motion will also be denied. However, the Court will grant Defendant’s summary judgment motion to the extent it is not contested. In its motion, Defendant argued that it was entitled to summary judgment on Plaintiff West’s gross negligence and punitive damages claims. Def.’s MSJ at 14-19. Plaintiffs consent to the

dismissal of these claims. Pls.’ Opp’n to MSJ at 7. Accordingly, Defendant is granted summary judgment on these claims, and they are dismissed.⁸

Beyond that, however, the Court is not convinced that summary judgment is appropriate. Defendant’s summary judgment motion presents two arguments: (1) that Plaintiffs have no evidence of causation, which is a required element of all of Plaintiff West’s substantive claims, and (2) that Plaintiff Gleason’s loss of consortium claim must fail because its success depends on the success of Plaintiff West’s claims. The Court will address each in turn.

1. Causation with Respect to Plaintiff West’s Claims

Defendant argues that “Plaintiffs cannot make [the] requisite showing” of causation because “[n]o expert has come forward with a reliable opinion, based on actual evidence, to prove Mr. West had a *B. cereus* induced illness or that Bayer’s injection kit even contained a *B. cereus*-infected alcohol prep pad.” Def.’s. MSJ at 6. It is Defendant’s position that “Plaintiffs’ infectious disease experts have no evidence of causation except for the temporal relationship between Mr. West’s illness and the events that gave rise to the recall of Triad alcohol prep pads,” and “a temporal relationship, without more, is insufficient to prove causation.” *Id.* at 6-7.

The Court disagrees and concludes that there is sufficient evidence of causation in this case to allow it to proceed to trial.⁹ Most importantly, the Court has determined that two expert witnesses will be allowed to opine that, in their medical opinion as infectious disease doctors, the most likely cause of Plaintiff’s illness was an infection of *B. cereus* from his use of Triad alcohol

⁸ Plaintiffs also agree with Defendant that the law of the District of Columbia applies to this matter. Pls.’ Opp’n to MSJ at 7.

⁹ Defendant points out that Plaintiffs have not elicited causation opinions from other physicians—Dr. Justin McArthur and Dr. Assil Saleh—who treated Plaintiff West and have been disclosed as experts, Def.’s MSJ at 7 n.3, but this is not surprising given that neither of these doctors are infectious disease specialists, like Drs. Abbruzzese and Auwaerter, *see* Pls.’ Ex. 2 at 2-4, 7.

prep pads. As discussed in more detail above, Dr. Abbruzzese will testify that, based on his expertise with infectious diseases, and “Plaintiff’s clinical history and presentation, including the nature and severity of his infection and its sequelae . . . Plaintiff’s abdominal wall cellulitis was caused by *Bacillus cereus*.” Pls.’ Ex. 2 at 6. Dr. Auwaerter will testify that, having reviewed Plaintiff’s medical records, Plaintiff’s illness was “highly likely due to infection introduced by contaminated alcohol prep pads that failed to cleanse skin surface and introduced high burden of an infectious pathogen that was likely due to *Bacillus* species.” Pls.’ Ex. 3 at 3. The testimony of these experts is sufficient to create a genuine question of material fact about whether or not Plaintiff West’s illness was caused by a *B. cereus* infection due to contaminated Triad alcohol prep pads. *See Ambrosini*, 101 F.3d at 141 (reversing grant of summary judgment because expert testimony on causation provided sufficient evidence to raise a question of material fact regarding causation).

Moreover, Plaintiffs have presented circumstantial evidence of causation. *See Doe v. U.S. Postal Serv.*, 317 F.3d 339, 343 (D.C. Cir. 2003) (“we generally draw no distinction between the probative value of direct and circumstantial evidence.”). There is evidence that Plaintiff had used Betaseron injections and Triad alcohol prep pads for a number of years without incident before this infection. *See, e.g.*, Abbruzzese Depo. at 297:3-10; Auwaerter Depo. at 97:4-15; Pls.’ Ex. 11., ECF No. 127-13. There is evidence that certain Triad alcohol prep pads were discovered to be contaminated with *B. cereus*. *See, e.g.*, Pls.’ Ex. 9 at 3 (“*B. cereus* and other *Bacillus* species were consistently cultured from the internal contents of 8 of the 10 lots of the Triad nonsterile APPs”); Auwaerter Depo. at 33:16-34:11. There is evidence that Plaintiff fell ill immediately after using the Triad alcohol prep pads provided in his Betaseron injection kit on December 29, 2010. *See, e.g.*, Depo. of William P. West, Jr., ECF No. 127-14, at

33:19-35:5. There is evidence that Plaintiff's symptoms were consistent with a *B. cereus* infection. *See, e.g.*, Auwaerter Depo. at 208:2 (testifying that Plaintiff's illness was "very consistent" with a *B. cereus* infection). There is evidence that absent a bacterial contamination, the chances that a patient would become infected from self-injecting Betaseron is very low. *See, e.g.*, Abbruzzese Depo. at 90:13-18; Auwaerter Depo. at 212:4-5. There is evidence that Plaintiff's infection cleared up after receiving medicine that has been proven to kill *B. cereus*. *See, e.g.*, Abbruzzese Depo. at 209:18-210:8. Putting all of these pieces together, viewing the evidence in the light most favorable to Plaintiffs and drawing all reasonable inferences for them, the Court concludes that there is a genuine factual dispute as to whether Plaintiff West contracted a *B. cereus* infection from using a Triad alcohol prep pad. Summary judgment will accordingly be denied.

The Court notes that this conclusion does not rest on the admissibility of the recall e-mail Bayer sent to Plaintiff. The Court assumes for the purposes of this Memorandum Opinion that the recall e-mail was a subsequent remedial measure—a point Plaintiffs do not seem to dispute—and accordingly Plaintiffs will not be able to present that e-mail at trial for the purpose of arguing to the jury that Defendant acted negligently or culpably, that there was a defect in Defendant's product, or that Defendant should have provided a warning or instruction. Fed. R. Evid. 407; *see also Velazquez v. Abbott Labs.*, 901 F. Supp. 2d 279, 291 (D.P.R. 2012) ("Recall notices . . . that are issued after an accident or injury are considered to be subsequent remedial measures under Rule 407.") (collecting cases). But this assumption does not affect the conclusions in this Memorandum Opinion. The only way in which the recall e-mail is relevant to the Court's decision today is that the Court has determined that Plaintiffs' experts may rely on the information conveyed by that recall as one basis of their opinions. As explained above, this

is allowable under the Federal Rules of Evidence regardless of whether the recall e-mail itself is admissible. Whether the e-mail is presented to the jury, what arguments can be made about it, and the potential necessity for an instruction limiting how the jury is to consider it, are all issues that can be resolved at a later point, presumably with motions *in limine* on the eve of trial. These issues do not, however, affect the outcome of Defendant's pending motions.

2. Plaintiff Gleason's Loss of Consortium Claim

Both parties agree that Plaintiff Gleason's loss of consortium claim is derivative of Plaintiff West's substantive claims. Def.'s MSJ at 19; Pls.' Opp'n to MSJ at 28. Because summary judgment is not appropriate with respect to Plaintiff West's claims, it is also inappropriate with respect to Plaintiff Gleason's loss of consortium claim.

IV. CONCLUSION

In sum, the Court will DENY Defendant's motion to exclude Plaintiffs' experts on causation, and will GRANT-IN-PART and DENY-IN-PART Defendant's motion for summary judgment. The Court is satisfied that Drs. Abbruzzese and Auwaerter can provide the jury with reliable scientific opinions about what they, as infectious disease doctors, view as the most likely cause of Plaintiff West's illness. This is so despite their inability to prove their conclusions with one-hundred percent certainty, or to definitively eliminate every other possible explanation. These are issues Defendant can raise on cross-examination, but they are not sufficient grounds to exclude the proffered opinions. In large part because the Court will not exclude this expert testimony, Plaintiffs have enough evidence to survive summary judgment on causation as an element of Plaintiff West's substantive claims. Because these claims survive summary judgment, so does Plaintiff Gleason's loss of consortium claim. The Court will, however, with

Plaintiffs' consent, dismiss Plaintiff West's gross negligence and punitive damages claims. An appropriate Order accompanies this Memorandum Opinion.

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge