

NOT FOR PUBLICATION

[Dkt. Ent. 70]

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

MAUREEN HORAN and DENNIS
VACHON,

Plaintiffs,

v.

DILBET, INC. d/b/a WINDRIFT
HOTEL RESORT,

Defendant.

Civil Action No. 12-2273

OPINION

Appearances

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BUMB, United States District Judge:

This matter comes before the Court upon a motion for summary judgment filed by Defendant Dilbet, Inc. d/b/a the Windrift Hotel Resort ("Windrift") (Dkt. Ent. 70). For the reasons set forth below, the Court denies summary judgment.

I. Factual Background

On July 30, 2010, Plaintiff Maureen Horan (the "Plaintiff") and her husband, Dennis Vachon (collectively, the "Plaintiffs") dined at the Windrift in Avalon, New Jersey. (See Windrift's Statement of Undisputed Material Facts ("WMF"), Dkt. Ent. 70-1, at ¶ 6; Pls.' Resp. ("PR"), Dkt. Ent. 75-1, at ¶ 6.) Around 2:32 p.m., Plaintiff ordered the "Jersey Shore Sampler" and consumed three raw clams that were on the plate. (See WMF ¶ 20; PR ¶ 20.) It is undisputed that these clams had been harvested from Great Bay, New Jersey and delivered to the Windrift that morning from Sea-Lect. (See WMF ¶¶ 39-41; PR ¶¶ 39-41.) On August 1, 2010, Plaintiff began feeling ill and presented twice at the Emergency Room at Holy Spirit Hospital. (See Pls.' Counterstatement of Material Facts ("PMF"), Dkt. Ent. 75-1, at ¶ 10; Windrift's Resp. ("WR"), Dkt. Ent. 77, at ¶ 10.) Plaintiff was subsequently transferred to Hershey Medical Center, where she was diagnosed with a Vibrio vulnificus ("Vibrio" or "VV") sepsis infection and fasciitis. (PMF ¶ 11; WR ¶ 11.) As a result of the infection, Plaintiff underwent an above-the-knee amputation of her left leg and several surgeries upon her arm. (PMF ¶ 12; WR ¶ 12.)

Several months later, one of Plaintiff's physicians expressed concern that Plaintiff may suffer from an iron disorder known as hemochromatosis. Subsequent testing in early 2011 confirmed Plaintiff suffered from hemochromatosis. (PMF

¶¶ 13-14; WR ¶¶ 13-14.) As a result of this diagnosis, Plaintiff's doctors advised her never to eat shellfish again. (WMF ¶ 29; PR ¶ 29.)

The experts agree that *Vibrio* is a naturally-occurring bacteria found in estuaries and sea waters, and resides naturally "in high numbers in filter feeding shellfish such as oysters and clams."¹ (See WMF ¶ 15 (quoting Expert Report of Dr. James D. Oliver, Ex. E to the Declaration of Joseph DeDonato ("DeDonato Decl."), Dkt. Ent. 70-2 (hereinafter, "Oliver Report"), at ¶ 7).) *Vibrio* is only dangerous in raw shellfish; if cooked, there is no risk. (See June 30, 2015 Tr. 18:7-10 (Oliver).) During the Daubert hearing, discussed infra, Dr. Oliver testified that a single piece of raw shellfish "can easily have from a hundred to a hundred thousand [*Vibrio* organisms]" - 100 times the amount of *Vibrio* relied upon as the infective dosage level. (See, e.g., June 30, 2015 Tr. 18:25-19:2, 57:9-10 (Oliver).) The *Vibrio* level naturally present in

¹ Dr. Oliver and Dr. Otwell testified that there are scientists and government regulators who periodically recommend rules to the FDA regarding harvesting of shellfish. (See June 30, 2015 Tr. 27:14-28:1, 137:11-19.) For example, there are rules regarding how quickly shellfish must be refrigerated after harvest, which depend upon the water temperature from which the shellfish was harvested. (Id.) In addition, there are regions designated by states for lawful harvesting of shellfish; these may be closed in the event of contamination or excessive runoff. (Id. at 58:1-11.) Dr. Otwell explained that shellfish must be harvested from "legal" waters and served within 14 days of harvest. (Id. at 137:4-8.)

raw shellfish depends upon many environmental factors such as the season, the coastal area from which the shellfish was harvested, the water temperature, and the salt level. (See id. at 24:5-11, 29:17-23 (Oliver), 101:1-3, 117:19-21 (Costa).) The experts agreed that all molluscan shellfish have the potential for Vibrio if Vibrio exists in the sea water. (See id. at 23:18-25 (Oliver), 117:19-21 (Costa).)

Plaintiffs' expert, Dr. Oliver, opined that although "most people are resistant to infections from [Vibrio], many people are at special risk," including those with hemochromatosis.² (Oliver Report at ¶ 7.) Windrift's expert, Dr. Charles Sanders, opined that hemochromatosis is an inherited condition that results in increased levels of iron stores. (See WMF ¶ 17 (quoting Ex. F to DeDonato Decl. (hereinafter, "Sanders Report") at ¶ 6).) This iron build-up makes the person susceptible to septicemia and pre-disposed to "invasive" Vibrio infections because Vibrio uses the iron stores for bacterial growth; thus people with hemochromatosis, such as Plaintiff, should avoid consumption of raw shellfish. (See id.)

² In fact, Dr. Oliver testified that "the host person has to have some kind of underlying disease" in order to contract an infection and that it is "almost unheard of for a normal healthy person to come [] down with this infection because they don't have these underlying diseases that predispose them to the infection." (June 30, 2015 Tr. 47:3-11.)

Several days after Plaintiffs patronized Windrift, on August 5, 2010, David A. Tormey, Senior Registered Environmental Health Specialist of the Cape May County Board of Health made a routine, unannounced inspection of Defendant Windrift. (PMF ¶ 15; WR ¶ 15.) At the time of this inspection, Tormey was unaware of Plaintiff's infection. Tormey's inspection report did not specifically mention the Windrift's raw bar, nor could Tormey recall during his deposition whether or not the August 5 inspection included an inspection of the raw bar. (See PMF ¶¶ 16-17; WR ¶¶ 16-17.) Nonetheless, Tormey issued a conditional satisfactory rating as a result of his August 5 inspection. (See WMF ¶ 44.)

Upon receiving notification of Plaintiff's infection, however, Tormey returned to the Windrift on August 12, 2010 to inspect the raw bar. (PMF ¶ 18; WR ¶ 18.) This time, Tormey found the following violations:

- The wooden cutting board upon which shellfish was shucked was being cleaned and sanitized only once per week;
- The shucking knife, at best, was being cleaned and sanitized only once daily;
- Two-day oysters and day-old clams were left in the raw bar refrigeration unit and all of the shellfish in that unit measured more than 50 degrees Fahrenheit;
- The employee in charge of the raw bar lacked good hand hygiene, in that gloves were worn for multiple tasks without being changed and without hands being washed; and
- The ice in the display case was contaminated with old shellfish particles and debris.

(PMF ¶ 19; WR ¶ 19.) Windrift denies that these violations actually existed as the raw bar was closed at the time of Tormey's inspection and had not yet been cleaned from the day before. (See WR ¶ 19.) Indeed, Tormey conceded that whether these would be violations when the raw bar was not operational - as it was not at the time of Tormey's inspection - was a "judgment call." (See Ex. M to DeDonato Decl. at 73:5-17.)

Plaintiffs' expert, Dr. Oliver, opined that "any of these critical violations could lead to shellfish that is not merchantable, and which could be dangerous due to an increased Vibrio vulnificus and thus an increase in the risk of harm of a Vibrio vulnificus infection." (PMF ¶ 20 (citing Oliver Report).) Oliver further concluded that these violations would increase the risk of cross-contamination of shellfish, which is minimized by strict adherence to New Jersey sanitary handling practices. (Id.)

Notably, however, the experts agree that there is no way a restaurant can completely eliminate the risk of infection, even through strict adherence to sanitation regulations. (June 30, 2015 Tr. 41:6-16, 85:20-23 ("Q. Would it then be fair to say that strict compliance with these regulations will not entirely eliminate the risk of illness? Is that true? A. That is correct.") (Oliver), 102:12-19 ("Q. These regulations as they've been promulgated, do they eliminate the risk of harm to a patron

from vibrio? A. They reduce it. Q. Do they eliminate it entirely? A. . . . [I]f a product is served raw, then there is nothing the restaurant can do to completely eliminate that." (emphasis added) (Costa).) With respect to the temperature violation found in the August 12 inspection report, Dr. Oliver explained that Vibrio will not reproduce at temperatures below 45°, but will grow "quite rapidly" at temperatures above 55°. (Id. at 43:14-17 (Oliver).)

According to Oliver, an infective dose of Vibrio is estimated to be between 100 and 300 organisms, which is "likely" the dosage level for an at-risk individual like Plaintiff. (Ex. U to DeDonato Decl. (hereinafter, "Oliver Dep.") at 32:1-23.) As to the scientific source of this purported infective dosage level, Oliver believed it to be "some publication somewhere" by the CDC and/or FDA "that have said [sic] that these are estimates on their part." (Id. at 32:8-11.) When pressed, however, he acknowledged that the infective dose has not been determined from any actual study as "[y]ou can't inject people with VV to find out what caused the death or something. . . . Given that the methodology is not good but **there is no methodology you can use really.**" (Id. at 31:15-25 (emphasis added); see also June 30, 2015 Tr. 30:4-19 ("Nobody can do those studies. . . . There have been estimates. . . . It's not a good

study in a sense, but it's the best we can do.".) He further testified

A. My difficulty in responding [regarding the infective dose] is the **general lack of understanding we have of this disease and the bacteria**. There's something like 15 million Americans that have underlying diseases that should predispose them to *Vulnificus*. Few come down with it. **I don't - we don't understand the variety of the bacterial factors or even host factors that are required. . . .**

Q. How do you explain [Plaintiff] was eating it her whole life and then came down with the infection [sic]?

A. If I knew the answer to that I would publish in the top journals of the world. . . . The kind of thing we study in many laboratories around the world do [sic] but **we don't know the answer yet**. I assume some time we'll find out the combination of bacterial factors, the various virile factors that cells have or things other than being iron overloaded. It has to happen. For all I know you've got to be male, you have to be over 40, you have to be immune-compromised. . . ."

(Oliver Dep. 33:2-34:1 (emphasis added).)³

According to Dr. Oliver, scientists have conducted animal studies involving the injection of mice with varying levels of *Vibrio*, which seems to be a typical method of determining

³ See also June 30, 2015 Tr. 48:19-49:4 (Oliver) ("Q. How can you explain then having this hemochromatosis and having consumed molluscan shellfish all their life, if *vibrio vulnificus* is in every shellfish, why she never got sick before? A. I don't know the answer to that and no expert knows the answer to that. If I did, I would become quite famous. I believe, and I'm not a medical doctor, that even though you genetically have the deficiency to have hemochromatosis, it doesn't mean it's being expressed all through your life. It can become a factor later on in life, like many diseases, in fact. I don't know the specifics on that disease though.").

infective dosage levels for pathogens. (June 30, 2015 Tr. 89:14-90:11 (Oliver).) Although those studies show that mice can contract a Vibrio infection upon injection with "as low as one cell" of Vibrio (Oliver Dep. at 32:1-23; see also June 30, 2015 Tr. 89:17-19 ("And if they had too much iron in the blood, if we injected iron into the blood, then as few as one cell would result ultimately in an infection and death.")), at low dosage amounts of one organism only half of the mice population injected died of an infection, whereas at higher amounts of 300 organisms, all of the population died. (June 30, 2015 Tr. 90:2-5 (Oliver).) Scientists have extrapolated this mouse data to conclude that higher levels of Vibrio increase the risk of infection. (See id. at 51:2-3 ("Based on animal studies, there is a relationship between the number consumed, or the number that you are giving to that animal, and infection."), 90:9-11 (Oliver).) In other words, "the more you increase the number of the vibrios, the greater the risk is going to be." (Id. at 87:2-3 (Oliver).) Dr. Oliver testified that the validity of mice studies can "always" be debated "because they're clearly not the same as a human" and the "numbers are also fluid." (Id. at 31:3-6.) As such, these mice studies are imperfect and the conclusions reached may not accurately reflect the impact of Vibrio on humans. Yet, these imperfect studies, as well as estimates drawn from anecdotal evidence, represent the "best

science available" based upon the experimental limitations scientists face with respect to Vibrio. (Id. at 32:13-20 (Oliver).) "Given the limitations, [the 100-300 organism estimate] is frequently quoted" and reasonably relied upon by experts in the field of Vibrio as the infective dosage level. (Id. at 30:20-31:10 (Oliver).) Notably, state laws and regulations do not prohibit the sale of raw shellfish regardless of the amount of Vibrio contained therein. (June 30, 2015 Tr. 59:18 (Oliver), 118:24-119:2 (Costa).)

The experts testified, however, that there is no scientifically-established connection between the number of shellfish eaten and the likelihood of infection; a single piece of shellfish containing Vibrio may cause an infection. (See id. at 34:18-35:1.) Indeed, Plaintiff consumed only three raw clams but testified that she had eaten shellfish her entire adult life, during which she unknowingly suffered from hemochromatosis, but had never sustained a Vibrio infection prior to this time.⁴ (Ex. G to DeDonato Decl. ("Pl.'s Dep." 21:15-26:25, 33:20-25, 34:1-5.))

⁴ The jury will not be permitted to draw the inference that simply because Plaintiff consumed raw shellfish without sustaining an infection her entire life that these shellfish were defective or that Windrift engaged in any wrong-doing on this occasion. (See June 30, 2015 Tr. 163:6-10.) There is no evidence to support such an inference and, indeed, Plaintiffs' own expert, Dr. Oliver testified that it may be that Plaintiff's genetic condition did not "become a factor" until later in life

Dr. Oliver testified that whether or not a person sustains an infection may also be impacted by the genotype of the Vibrio bacteria - one of which is more virulent than the other - though Oliver could provide no examples of such because the evidence is always destroyed by the person who ate the shellfish. (Oliver Dep. at 34:24-35:8.) Both genotypes occur naturally and may both be present in a piece of shellfish in varying amounts. (See id. at 18:23-19:19; see also June 30, 2015 Tr. 66:17-23 (Oliver).) For example, a raw oyster may contain 300 organisms of Vibrio, but 250 of those are "E" type (the less virulent variety) and only 50 are "C" type. In such a case where the less virulent E type predominate, the consumer may not sustain an infection.⁵ (See June 30, 2015 Tr. 66:17-23 (Oliver).) The record does not indicate which types of Vibrio, or in what quantities, may have been in the raw clams that Plaintiff consumed.

Dr. Oliver also testified that there is no way to determine whether the clams Plaintiff ingested contained an infective dose of Vibrio at harvesting, delivery, preparation, and/or

and this could explain why she did not suffer an infection before this instance. (See June 30, 2015 Tr. 48:19-49:4.) He could provide no definitive answer. (See also id. at 164:1-4 ("[Plaintiff] could have become ill with a number of things that lined up even in the absence of the insanitary conditions.").)

⁵ Dr. Oliver conceded that the infective dosage level of 100-300 organisms was developed before scientists were aware that different genotypes existed. (See June 30, 2015 Tr. 66:24-25.)

consumption. (See, e.g., id. at 41:10-46:6.) Similarly, it cannot be determined to what extent the amount of *Vibrio* in any clam increased, or even whether the amount of *Vibrio* in any clam did increase, at any point prior to Plaintiff's consumption of them. As Dr. Oliver pointed out, clams "typically have a large number of VV in them" from the time of harvest, and "[i]t's not necessary for something else to be around them [for there] to be a large number of VV in the clams." (Id. at 65:17-23.) He conceded that, even if Windrift had followed all of the sanitation regulations, cross-contamination could, and would, still occur simply as a result of shucking two clams in a row. (See, e.g., id. at 47:21-49:25.)

Like Dr. Oliver, Plaintiffs' other experts opined that Windrift's food handling practices increased the risk of and/or were a cause of her infection. Mr. Roy Costa opined "within a reasonable degree of scientific probability, poor food handling practices as reported by the Cape May New Jersey Health Department, resulted in a likelihood that increased Vibrio bacteria would be found in clams consumed by Ms. Horan." (Ex. R to DeDonato Decl. (hereinafter, "Costa Report") at 3.) He agreed, however, that even following the letter of the law, there is still potential for cross-contamination or transfer of *Vibrio*. (See June 30, 2015 Tr. 123:8-12.) In addition, Dr. John

Stern concluded that "the violations increased the risk of, and were a cause of her infection." (Ex. S to DeDonato Decl. at 2.)

In response to these opinions, Windrift offered the expert testimony of Dr. W. Steven Otwell. Dr. Otwell agreed that a Vibrio infection is a rare event. As he put it, "it is very rare when all the stars line up that this event [a Vibrio infection] can occur" and when it does, it is "unpredictable." (June 30, 2015 Tr. 135:17-22.) He opined that there is no medical or scientific literature of which he is aware that "establishes the [Vibrio] bacterium has been created, spread or enhanced by insanitary practices." (Ex. T to DeDonato Decl. (hereinafter, "Otwell Report"), at 2.) While he acknowledged that some studies on cross-transfer of other Vibrio species exist, there have been none addressing transfer or cross-contamination of Vibrio Vulnificus.⁶ (See June 30, 2015 Tr. 140:25-141:8.) Specifically, there is no evidence addressing the ability of this particular species of bacteria to survive on surfaces for any particular time or whether it would present a food safety risk. (Id. at 141:11-142:1, 147:10-12.) Dr. Otwell testified that such an absence was significant since, inter alia, Vibrio vulnificus does not act like other bacteria. (Id. at 143:25-144:3 (noting

⁶ Dr. Oliver testified that there are reliable studies of Vibrio Parahaemolyticus ("VP"), "a very close sister" to VV, that deal with cross-contamination. (See June 30, 2015 Tr. 45:4-46:16.)

"distinct differences between [VV and VP] with their thermal lethality, growth rates, ability to survive, even the salinities that they survive at"), 159:7-11.) Dr. Otwell is further unaware of any data that substantiates the degree of probability of transfer or cross-contamination, or the probability of any increased risk. (See id. at 145:2-4.) He concluded that "[t]he claims that there is an 'elevated risk' of Vibrio vulnificus in this case are not documented in the scientific literature that I am aware of and it is an opinion of these three experts not supported by accepted medical or scientific data." (Otwell Report at 2.)

Dr. Otwell also testified that there is no authority establishing an infective dosage level, and that the 100-300 dosage level cited by Dr. Oliver is, at best, "better-than-nothing information" but is based upon extrapolation and estimation. (June 30, 2015 Tr. 138:14-20 (Otwell).) He noted the "general agreement among the prevailing experts now that it takes a very little amount of these vibrio vulnificus to cause the infection." (Id. at 138:1-3.) He further opined that the amount of Vibrio contained in the clams, and which caused Plaintiff's infection, was present in the clams at harvest. (Id. at 136:22-24.) In other words, the "culprit was in the clams" and due to Plaintiff's condition, the source of the clams, and the season in which they were harvested, she would have gotten

ill even if Windrift had not been involved. (Id. at 139:14-17.) In support, Dr. Otwell referred to years of scientific research demonstrating that VV is most problematic from July to September and is found particularly in New England coastal waters, making it highly probable, in his opinion, that the clams Plaintiff consumed contained high levels of Vibrio. (Id. at 139:20-140:5.)

The Amended Complaint alleges causes of action for violation of the New Jersey Products Liability Act ("NJPLA") for sale of a defective product (Count I) and failure to warn (Count II), strict liability (Count III), breach of the implied warranty of merchantability under the Uniform Commercial Code (Count IV), violation of the Adulterated Food Act, N.J.S.A. § 24:5-1 et seq. (Count V), negligence (Count VI), and loss of consortium (Count VII). Many of the other named defendants have been dismissed by consent of the parties or Order of this Court, leaving only Windrift. (See PR ¶ 24; Dkt. Ents. 80, 82.) As part of its motion, Windrift argued that Plaintiffs' experts' opinions are "without adequate foundation, entirely speculative and scientifically unreliable" in violation of the principles set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993), and Federal Rule of Evidence 702. (Def.'s Mot. at 34.) Accordingly, on June 30, 2015, this Court held a

hearing pursuant to Daubert and Rule 702 hearing to address the methodology and reliability of the experts' testimony.

II. Legal Standard

Summary judgment shall be granted if "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). A fact is "material" if it will "affect the outcome of the suit under the governing law" Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute is "genuine" if it could lead a "reasonable jury [to] return a verdict for the nonmoving party." Id. When deciding the existence of a genuine dispute of material fact, a court's role is not to weigh the evidence; all reasonable "inferences, doubts, and issues of credibility should be resolved against the moving party." Meyer v. Riegel Prods. Corp., 720 F.2d 303, 307 n.2 (3d Cir. 1983). However, a mere "scintilla of evidence," without more, will not give rise to a genuine dispute for trial. Anderson, 477 U.S. at 252. Further, a court does not have to adopt the version of facts asserted by the nonmoving party if those facts are "utterly discredited by the record [so] that no reasonable jury" could believe them. Scott v. Harris, 550 U.S. 373, 380 (2007). In the face of such evidence, summary judgment is still appropriate "where the record . . . could not lead a rational trier of fact to find for the nonmoving party"

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

The movant "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986) (quoting Fed. R. Civ. P. 56(c)). Then, "when a properly supported motion for summary judgment [has been] made, the adverse party 'must set forth specific facts showing that there is a genuine issue for trial.'" Anderson, 477 U.S. at 250 (quoting Fed. R. Civ. P. 56(e)). The non-movant's burden is rigorous: it "must point to concrete evidence in the record"; mere allegations, conclusions, conjecture, and speculation will not defeat summary judgment. Orsatti v. N.J. State Police, 71 F.3d 480, 484 (3d Cir. 1995); Jackson v. Danberg, 594 F.3d 210, 227 (3d Cir. 2010) (citing Acumed LLC v. Advanced Surgical Servs., Inc., 561 F.3d 199, 228 (3d Cir. 2009)) ("[S]peculation and conjecture may not defeat summary judgment.").

III. Windrift's Motion for Summary Judgment

As an initial matter, Windrift contends that all of Plaintiffs' causes of action are subsumed within Plaintiffs'

claims under the NJPLA. See, e.g., Tirrell v. Navistar Int'l, Inc., 591 A.2d 643, 647-48 (N.J. Super. Ct. App. Div. 1991). Plaintiffs do not oppose summary judgment as to the non-NJPLA claims. (See generally Opp. & n.1.) In addition, Plaintiffs concede the dismissal of the claim for failure to warn under the NJPLA. (Id.) Accordingly, Windrift's summary judgment motion is granted as unopposed as to these causes of action. The remaining claim against Windrift is the claim for the sale of a defective product under the NJPLA, to which the Court now turns.

Under the NJPLA, a seller of a product

shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or . . . c. was designed in a defective manner.

N.J.S.A. 2A:58C-2. "Although a plaintiff is relieved from proving fault [under the NJPLA,] that plaintiff must nonetheless prove that the product was defective under the common law jurisprudence that was incorporated into the Act." Myrlak v. Port Authority of New York & New Jersey, 723 A.2d 45, 52 (N.J. 1999). "Based on our well-established case law in this area, a plaintiff must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the

plaintiff, a reasonably foreseeable or intended user." Myrlak, 723 A.2d at 52. The existence of a defect may be proven through expert testimony or through circumstantial evidence of a defect. See, e.g., Lauder v. Teaneck Volunteer Ambulance Corps, 845 A.2d 1271, 1277 (N.J. Super. Ct. App. Div. 2004). That an accident occurred resulting in an injury to a plaintiff are not sufficient to demonstrate a defective product. Id.; see also Myrlak, 723 A.2d at 52 ("Proof that a product is not fit for its intended purposes 'requires only proof . . . that something was wrong with the product.' The mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." (citations omitted)).

Here, the Court is faced with a very unique set of facts. Plaintiff admittedly suffered from a medical condition, hemochromatosis, that rendered her highly susceptible to an invasive *Vibrio* infection and, for that reason, unbeknownst to her, she should have avoided consuming raw shellfish, which contains this naturally-occurring bacteria in high levels. Unaware of her genetic condition at the time that she consumed the raw clams served by Windrift, Plaintiff tragically suffered an infection that resulted in the amputation of her leg. This matter is further complicated by the apparent lack of scientific understanding of the *Vibrio* bacteria or the factors that lead to

a Vibrio infection. With this in mind, the Court turns to Windrift's arguments.

A. Clams Containing Vibrio Are Not a Defective Product Per Se

Defendant first contends that clams containing Vibrio, a naturally-occurring bacteria, are not a defective product under the NJPLA as a matter of law. This issue has not been addressed by New Jersey courts, but other jurisdictions that have considered this issue have generally held that a seller is not liable for selling shellfish containing Vibrio because it is a naturally-occurring bacteria that is harmless to most consumers. See, e.g., Simeon v. Doe, 618 So.2d 848, 851 (La. 1993); Woeste v. Washington Platform Saloon & Restaurant, 836 N.E.2d 52 (Ohio Ct. App. 2005); Bergeron v. Pacific Food, Inc., No. CV075001992S, 2011 Conn. Super. LEXIS 366 (Conn. Super. Ct. Feb. 14, 2011).

For example, in Simeon v. Doe, the Supreme Court of Louisiana held that

Based on the record, we are unable to say that raw oysters containing the vibrio vulnificus bacteria are unreasonably dangerous to the ordinary consumer. The evidence is uncontroverted that vibrio vulnificus bacteria in raw oysters poses little, if any, threat to a healthy person. The bacteria is only harmful to those persons with specific underlying disorders such as liver or kidney disease. Seen is this light, the "defect" is really found in the person rather than the product, much in the same way that sugar is harmful only when used by someone with diabetes.

618 So.2d at 851. Accordingly, the Court refused to hold the defendants strictly liable for the sale of raw oysters. Id.; see also Edwards v. Hop Sin, Inc., 140 S.W.3d 13, 16 (Ky. App. 2003) (“We agree with the trial court that the presence of Vibrio bacteria in raw oysters does not constitute either a manufacturing or a design defect. The record indicates that there are no reasonably available alternatives to bacteria-laced oysters. The bacterial presence occurs naturally under commonly occurring conditions and screening is not feasible because current methods of testing for the bacterium destroy the oyster. Furthermore, the bacterium poses little threat of harm to healthy persons. . . . We agree with the trial court that, Vibrio notwithstanding, it is not per se unreasonable to market raw oysters.”).

Similarly, in Woeste v. Washington Platform Saloon & Restaurant, the decedent’s estate sought to hold the defendants liable for the sale of adulterated food in the form of raw oysters containing Vibrio, which caused the decedent’s death. 836 N.E.2d at 73. The decedent suffered from Hepatitis C and cirrhosis of the liver at the time he consumed the oysters. Id. The court determined that

Vibrio is not an added substance. It is a naturally occurring bacteria that is taken in as the oysters filter feed. Because it is naturally occurring, vibrio cannot adulterate the oysters unless the amount of vibrio present in a particular oyster would ordinarily

render it injurious to health. This was not the case here. *Vibrio* has a minimal effect on the general population. At most, it can cause indigestion or diarrhea; it is not commonly injurious to health. *Vibrio* is only deadly to those with weakened immune systems or stomach disorders. Tragically, *Woeste* fell into the latter category. Because the bacteria does not affect the great majority of those who eat raw oysters, we conclude that the oysters in this case were not adulterated.

Woeste, 836 N.E.2d at 76-77.⁷ The court further held that under either the foreign/natural test,⁸ or the reasonable-expectation test,⁹ raw oysters containing *vibrio* are not defective or adulterated. Id. at 79.

More recently, in Bergeron v. Pacific Food, Inc., the decedent consumed at defendant's restaurant raw oysters that were contaminated with *Vibrio*, and died as a result. 2011 Conn. Super. LEXIS 366, at *1. The estate brought an action pursuant to the Connecticut Products Liability Act ("CPLA"), arguing that the raw oysters were defective, and pursuing several theories under the CPLA including strict liability, negligence, breach of

⁷ The plaintiff also brought a common-law negligence claim against the oyster supplier, alleging a violation of the supplier's duty to refrigerate the oysters so as to prevent multiplication of the *Vibrio* bacteria. See Woeste, 836 N.E.2d at 77. The court found no evidence that the supplier failed to refrigerate the oysters and thus dismissed the claim. Id. at 78.

⁸ The foreign/natural test precludes recovery for "injuries caused by a substance that is natural to the food eaten." Id. at 78.

⁹ The reasonable-expectation test considers "whether a consumer would reasonably expect to find the substance in the particular food item being ingested." Id. at 79.

warranty, failure to warn, and misrepresentation. Id. at *2 n.3. Under the CPLA, a product is defective when it is unreasonably dangerous to the consumer, meaning that it is “dangerous beyond that which would be contemplated by the ordinary consumer who purchases it.” Id. at *8. The court found sufficient evidence establishing that raw oysters contaminated with vibrio are not unreasonably dangerous. Id. at *13. The court noted that Vibrio is a naturally-occurring bacteria and cited medical expert testimony acknowledging that “most people can consume raw shellfish without medical problems, whether they have liver dysfunction or not” but liver dysfunction, such as that suffered by the decedent, results in a higher risk of serious illness or death. Id. Thus, the court found no material issue of fact as to whether an oyster containing Vibrio is dangerous beyond the contemplation of an ordinary consumer. Id. at *14.¹⁰

The Court agrees with the reasoning of these other courts and finds that raw clams containing Vibrio are not per se defective products because they are “reasonably fit, suitable or safe” for consumption by an ordinary consumer. See N.J.S.A. 2A:58C-2; New Jersey Model Jury Charge 5.40A. Plaintiffs’ experts agree that Vibrio naturally occurs in “high numbers” in raw shellfish and that raw shellfish, including raw clams,

¹⁰ The Bergeron court permitted the failure to warn claim to proceed.

"typically" contain *Vibrio* in varying and unknown amounts. (See WMF ¶ 15; PR ¶ 15; Oliver Dep. 65:17-18.) Oliver, Plaintiffs' expert, testified that *Vibrio* is neither manmade, nor a mutation; *Vibrio* does not render a clam either contaminated or polluted. (See Oliver Dep. 24:22-25:5, 25:15-20.) As such, raw shellfish consumers must reasonably expect raw clams to contain *Vibrio* in varying amounts. See, e.g., Bergeron, 2011 Conn. Super. LEXIS 366, at *14. Moreover, it is undisputed that the consumption of raw clams containing *Vibrio* is harmless to most individuals and that it is only those consumers suffering from an underlying condition, such as Plaintiff, who are at risk of a serious infection. (See, e.g., June 30, 2015 Tr. 47:3-11 (testifying that "the host person has to have some kind of underlying disease" in order to contract an infection and that it is "almost unheard of for a normal healthy person to come [] down with this infection because they don't have these underlying diseases that predispose them to the infection.").)

In response, Plaintiffs contend that Windrift misunderstands the theory of their case: "Plaintiff's [sic] theory of liability - reduced to its simplest terms - is that the Windrift, through [its] unsanitary food handling procedures, increased the risk of the presence of an infectious dose of Vibrio Vulnificus bacteria in the shellfish consumed by Plaintiff, either by cross-contamination and/or by increasing

the amount of bacteria present.” (Opp. 17.) It is the cross-contamination and/or increased presence of *Vibrio*, and the corresponding increased risk of infection, that constitutes the defect, according to Plaintiffs. (Id.; see also June 30, 2015 Tr. 127:19-129:25.) Thus, Plaintiffs contend it is a jury question whether a consumer should reasonably expect a raw clam to possess an increased risk of harm of a *Vibrio* infection due to a restaurant’s negligent food-handling practices. (See Opp. 21 (citing Clime v. Dewey beach Enters., Inc., 831 F. Supp. 341 (D. Del. 1993)¹¹).

Plaintiffs cite several food poisoning cases in support of their argument that negligent and unsanitary food handling practices are a persuasive and often dispositive factor in determining a restaurant’s liability for serving a defective product and thus this Court must consider evidence of Windrift’s unsanitary practices in assessing whether raw clams containing *Vibrio* constitute a defective product under the NJPLA. In doing so, Plaintiffs draw comparisons between the instant matter and other food poisoning cases involving purportedly “naturally-

¹¹ Clime involved claims for breach of the implied warranty of merchantability under Delaware law for service of raw clams containing *Vibrio* where the court found consumers may not reasonably expect clams to be free of *Vibrio* in levels that may cause illness. 831 F. Supp. at 350. However, it further concluded that, whether a consumer should reasonably expect a raw clam to possess elevated health risks due to allegedly negligent handling was a jury question. Id.

occurring bacteria," such as salmonella and e-coli. For example, in Corbi v. Harrah's Hotel & Casino, No. 08-5875, 2010 U.S. Dist. LEXIS 112041 (D.N.J. Oct. 21, 2010), the plaintiffs filed suit against Harrah's contending they were infected with salmonella after consuming food at the casino and suffered serious injuries. The Court noted that a restaurant is strictly liable for serving adulterated food, but that a plaintiff must still prove causation. Id. at *14-15. Ultimately, the Court denied summary judgment to the defendants, finding a reasonable jury could find the expert testimony persuasive and conclude that eggs consumed at Harrah's caused the plaintiffs' salmonella poisoning. Id. at *17. It further concluded that health inspection reports dating before and after the plaintiffs' visit demonstrated sanitation violations, which also support a causal connection between the food consumed by the plaintiffs at Harrah's and their salmonella poisoning. Id. at *19. Notably, the Court did not address whether food contaminated with salmonella constituted an adulterated or defective product but merely assumed such.

Plaintiffs also cite Koster v. Scotch Associates, 273 N.J. Super. 102 (Law Div. 1993), in which the plaintiffs similarly suffered salmonella poisoning after patronizing the defendant's restaurant. The court determined that the defendant served food that was not reasonably fit, suitable, or safe and that caused

the plaintiffs harm. Id. at *111. It thus granted summary judgment to the plaintiffs on their NJPLA claim.

However, these cases involve contamination with bacteria (salmonella) that is harmful to all individuals, and as a matter of law cannot be reasonably suitable, fit or safe for consumption by any person. Moreover, unlike with *Vibrio*, contamination with salmonella clearly constitutes a deviation in that the mere presence of the bacteria in any concentration is indicative of the negligent conduct of the food handlers. Cf. Langan v. BJ's Wholesale Club, Inc., No. 04-4138, 2006 WL 2524178, at *4 (D.N.J. Aug. 29, 2006) ("Here, the contamination with E. coli created a defect, as this was a deviation from the expected performance standard of the meat."). While salmonella and e-coli, like all bacteria, are "naturally-occurring," as Plaintiffs contend, in that they are not synthetic bacteria, they can only be found in prepared food products when introduced through negligence of food-handlers. (Accord June 30, 2015 Tr. 125:13-22 (Costa).) The same cannot be said here. To the contrary, *Vibrio* occurs in raw shellfish in infective dosage levels (and in high numbers such as 100,000 organisms) without human manipulation or negligent conduct, and is not harmful to the average consumer.

Nonetheless, "[w]hile the Court has held a consumer should reasonably expect a raw clam to pose some health risk, it cannot

hold as a matter of law that such expectation extends to elevated risk levels engendered by the alleged negligence of [Windrift]." Clime, 831 F. Supp. at 350.

B. Plaintiff is a Reasonably Foreseeable Consumer

Defendant also argues that Plaintiff cannot be a "reasonably foreseeable or intended [consumer]" of raw shellfish because she suffers from a genetic condition, hemochromatosis, that makes her 800 times more susceptible to infection and, consequently, should never have consumed the raw clams in the first place. See Myrlak, 723 A.2d at 52 ("Based on our well-established case law in this area, a plaintiff must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, a reasonably foreseeable or intended user."). The evidence is undisputed, however, that Plaintiff was unaware of her condition until long after she contracted the *Vibrio* infection that led to her injuries. The Court cannot hold that this fact bars Plaintiff's claims. Moreover, and contrary to Defendant's assertion, the appropriate inquiry is not whether Plaintiff was an "average consumer" but whether she was a "reasonably foreseeable" consumer of raw shellfish, and the Court finds that she was. It is certainly "reasonably foreseeable" that a person who suffers from an undiagnosed condition that unbeknownst to her renders

her highly-susceptible to a Vibrio infection would nonetheless consume raw shellfish.¹²

C. Causation

In order to prove their claim, Plaintiffs must also demonstrate that the defect proximately caused Plaintiff's injuries. Myrlak, 723 A.2d at 52. Under the New Jersey Model Charges applicable to NJPLA claims:

By proximate cause is meant that the defect in the product was a substantial factor which singly, or in combination with another cause, brought about the accident. Plaintiff need not prove that the very accident which occurred could have been anticipated so long as it was within the realm of foreseeability that some harm could result from the defect in question. **If the product in question, however, does not add to the risk of the occurrence of the particular accident and hence was not a contributing factor in the happening of the accident . . . then plaintiff has failed to establish that a particular product defect was a proximate cause of the accident.**

Model Jury Charge 5.40I (emphasis added).

It is undisputed that Plaintiff suffered a Vibrio infection and that the Vibrio came from the raw clams she consumed at Windrift. (PMF ¶¶ 9-11.) Thus, the raw clams containing Vibrio are certainly a but-for cause of Plaintiff's injuries. The Court is confronted by the unique nature of this case: the mere presence of Vibrio in the clams does not render the clams

¹² New Jersey Model Jury Charge 5.40H provides that "the defect caused injury to a direct or reasonably foreseeable user or to a person who might reasonably be expected to come into contact with the product."

defective because *Vibrio* is both naturally-occurring and harmless to most consumers who, unlike Plaintiff, do not suffer an underlying condition that renders them highly susceptible to a *Vibrio* infection. Plaintiffs' theory, however, is that Windrift's unsanitary practices increased the level of *Vibrio* in the raw clams and, therefore, the risk of harm of an infection, and that it is this increase in the risk of harm that renders the raw clams defective and was a substantial factor in producing Plaintiff's harm.

To establish causation, Plaintiffs rely upon the opinions of Dr. Oliver and Mr. Costa as described above. Dr. Oliver, who has a Ph.D. in biology and has been studying *Vibrio* for nearly 40 years, opined in relevant part that any of the sanitation violations listed in the August 12, 2010 report by the health inspector "could lead to shellfish that is not merchantable, and which could be dangerous due to an increased *Vibrio vulnificus* and thus an increase in the risk of harm of a *Vibrio vulnificus* infection." (PMF ¶ 20.) He concluded that these violations would increase the risk of cross-contamination of shellfish, which is minimized by strict adherence to New Jersey sanitary handling practices. (Id.) According to Dr. Oliver, the alleged violations led to service of contaminated raw clams, "which significantly increased the risk of harm to Mrs. Horan and was a contributing

cause of her Vibrio vulnificus infection." (Oliver Report at ¶ 18.)

Mr. Costa, who has a Master of Health Science Management and is a registered sanitarian in public health and food safety, detailed the New Jersey sanitation regulations and how Windrift allegedly violated those regulations. He opined that failure to follow the regulations concerning, e.g., proper treatment of ice in the raw bar, and proper sanitation of utensils and cutting boards probably resulted in cross-contamination of the raw shellfish served at Windrift. (See Costa Report at ¶¶ 1-6.) With respect to refrigeration temperatures, Mr. Costa noted that "[t]he greater the number of Vibrio bacteria, the higher the likelihood that ingestion will lead to infection in a host, and the more severe the infection." (Id. at ¶ 3.) He thus concluded that, "within a reasonable degree of scientific probability, poor food handling practices . . . resulted in a likelihood that increased Vibrio bacteria would be found in clams consumed by Ms. Horan." (Id. at ¶ 6.)

1. Admissibility of Plaintiffs' Experts

Defendant argues that the opinions of Plaintiffs' liability experts, Dr. Oliver and Mr. Costa, on the issues of product defect, breach of duty, and causation should be precluded as they are "without adequate foundation, entirely speculative[,] and scientifically unreliable." (Def.'s Br. 34.) Specifically,

Defendant challenges the opinions on grounds that there is no scientific evidence supporting a connection between Windrift's alleged insanitary practices and any risk of a *Vibrio* infection. Further, Defendant contends that the experts' opinions are speculation because they acknowledge that there is no evidence of what levels of *Vibrio* were in the clams consumed by Plaintiff from the time of harvest to consumption. Because the Court believed it was necessary to determine the admissibility of the experts' testimony prior to resolution of Windrift's motion, it held a hearing pursuant to Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Federal Rule of Evidence 702 provides:

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.

In Daubert, the Supreme Court held that under Rule 702, district courts must act as "gatekeepers" to ensure that expert testimony is reliable, relevant, and helpful to the jury. 509 U.S. at 591, 597. The Supreme Court further noted that

the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies

to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. But, 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.

509 U.S. at 590 (internal citations omitted). Accordingly, when faced with scientific testimony, the trial judge must determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails 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." Id. at 592-93. As applied by the Third Circuit, Daubert requires a three-part analysis of (1) the expert's qualifications; (2) the reliability of the opinion; and (3) whether the opinion would inform the trier of fact in resolution of the factual disputes. Milanowicz v. The Raymond Corp., 148 F. Supp. 2d 525, 530-31 (D.N.J. 2001) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1994), cert. den'd 513 U.S. 1190 (1995)). The proponent of the expert testimony bears the burden of showing by a preponderance of the evidence that the testimony satisfies the requirements of Rule

702. Oddi v. Ford Motor Co., 234 F.3d 136, 144 (3d Cir. 2000), cert. den'd 532 U.S. 921 (2001). Here, Defendant challenges only the reliability of Dr. Oliver's and Mr. Costa's opinions.

In order for an expert's opinion to be reliable, the expert must have "good grounds" for his belief. The opinion must be based on the "methods and procedures of science" and not merely on "subjective belief or unsupported speculation." Paoli, 35 F.3d at 742 (quoting Daubert, 509 U.S. at 589). "If the underlying data are so lacking in probative force and reliability that no reasonable expert could base an opinion on them, an opinion which rests entirely upon them must be excluded." Lithuanian Commerce Corp., Ltd. v. Sara Lee Hosiery, 179 F.R.D. 450, 457 (D.N.J. 1998) (quoting Paoli, 35 F.3d at 748). In conducting the reliability analysis, courts consider the following factors:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Milanowicz, 148 F. Supp. 2d at 531.

Applying these principles, the Court finds that the reports and testimony of Plaintiffs' experts are sufficiently reliable

and supported by scientifically-accepted methodologies in the area of Vibrio. As set forth above, Dr. Oliver and Mr. Costa opine that Vibrio was created, spread, or enhanced by the alleged insanitary practices of the Windrift, and that these practices increased the risk of harm to Plaintiff. (See Oliver Report & Costa Report.) Both parties' experts agree that Vibrio is a naturally-occurring bacteria that is present in varying levels in shellfish, including at levels sufficient to cause infection in highly susceptible consumers such as Plaintiff. (See, e.g., June 30, 2015 Tr. 18:25-19:2, 57:9-10 (Oliver) (testifying that a single piece of shellfish may include 100,000 Vibrio organisms).) In addition, Vibrio is undetectable to the layperson in any amount, and can only be detected through means of a culture that completely destroys the raw shellfish. (See Oliver Dep. 51:16-21.) Moreover, as addressed at length above, Vibrio can be harmlessly digested by most individuals. Only those with certain underlying conditions (such as Plaintiff's hemochromatosis) are at special risk of developing an infection, which is oftentimes fatal. (See Oliver Report at ¶¶ 8-10; see also June 30, 2015 Tr. 47:3-11.) Dr. Oliver explained that "[f]or the above persons in a risk group[, such as those with hemochromatosis], Vibrio vulnificus is one of the most invasive and rapidly fatal human pathogens known." (Oliver Report at ¶ 8.7); see also Vibrio vulnificus Fact Sheet for Health Care

Providers, available at http://www.issc.org/client_resources/education/vvfactsheet.pdf (recording 50% fatality rate for high-risk individuals) (cited in Oliver Report at ¶ 7).

Relying upon the August 12 inspection report, both Dr. Oliver and Mr. Costa opined that any one of the violations could potentially result in an increased level of Vibrio. For instance, Dr. Oliver explained that Vibrio reproduces in a logarithmic fashion above 55°, and thus within an hour the number of Vibrio bacteria can multiply rapidly from 100 to 1,600 organisms. (June 30, 2015 Tr. 39:15-21.) The August 12 inspection report cites Windrift for maintaining shellfish at temperatures of "50F+", which drawing all inferences in favor of Plaintiffs could mean that the temperatures in the raw bar refrigerator exceeded 55°, providing fertile ground for Vibrio reproduction even though the clams were indisputably delivered just that morning. (See Ex. Q to DeDonato Decl.)

Moreover, Dr. Oliver explained that in shucking clams, mantle fluid containing Vibrio may be transferred to the cutting board and, once subject to ambient temperatures, begin to rapidly multiply. (See June 30, 2015 Tr. 39:7-12 ("The longer the period between the initial contamination of the cutting board and the secondary contact with something else. At room temperature you have significant growth of the bacterium to a much higher level than it started at and therefore much greater

chance of contaminating the second item with the large number of bacteria." (Oliver).) The room-temperature Vibrio on the cutting board could then be transferred to clams subsequently shucked on the cutting board or using the same utensil. (Id.) Mr. Costa testified that, in general, sanitation regulations requiring periodic sanitation of cutting boards and utensils exist to prevent high levels of bacteria from accumulating on surfaces that come in contact with food. (Id. at 102:20-104:5; see also id. at 51:23-52:2 (Oliver).) In this way, cross-transfer of bacteria is minimized. (See id. at 105:7-17, 109:5-24 (discussing buildup of bacteria that may occur in absence of sanitation regulations requiring periodic sanitation) (Costa).) Thus, while the experts agree that even under the sanitation guidelines in place, cross-transfer of Vibrio may occur simply by virtue of shucking multiple clams in a row, requirements that cutting boards be sanitized or refrigeration temperatures be maintained may minimize the growth of the bacteria and thus the level of any Vibrio transfer. (See id. at 40:18-22 (noting if you clean and sanitize, you reduce the Vibrio level back down to zero) (Oliver); see also id. at 106:5-9 (testifying that "within a reasonable degree of probability" VV can be cross-contaminated) (Costa).) Yet, as noted, the August 12 inspection report lists temperature violations, as well as violations of

regulations addressing sanitation of cutting boards and utensils.

As Windrift's expert, Dr. Otwell, points out, however, Plaintiffs' experts initially failed to identify any scientific literature supporting a connection between insanitary food-handling practices and the likelihood of contracting a *Vibrio* infection. When queried whether he was aware of any literature that addresses whether unsanitary practices create or enhance the risk of a *Vibrio* infection, Dr. Oliver could identify none. (See Oliver Dep. 71:23-72:4.) Instead, both Dr. Oliver and Mr. Costa appeared to rely merely upon the fact that the health codes exist in order to minimize contamination and the transmission of foodborne illnesses generally. (See, e.g., Oliver Dep. ("Q. . . . [A]re you aware of any literature that speaks of unsanitary practices at a restaurant either creating or enhancing the risk of *Vibrio*? A. I am not familiar with that. That's not an area I would normally read but, to my knowledge, **all the food safety procedures that are adopted by States are based on those kind of findings.**" (emphasis added)); Costa Report at ¶ 3 ("Temperature abuse of potentially hazardous foods, such as raw shellfish, has historically been a leading cause of foodborne illness at the restaurant level. Great care must be taken to avoid this food safety hazard.")) During the Daubert hearing, however, Dr. Oliver cited studies regarding

cross-contamination with VP, a close relative of VV. (June 30, 2015 Tr. 45:13-46:16.) He explained that scientists could rely upon these VP studies due to the similarities between VP and VV. (Id. at 45:24-46:4; see also 13:14-24. But see id. at 15:15-24 (explaining that VV carries a 50% fatality rate while VP is rarely fatal).) Dr. Otwell challenges Dr. Oliver's reliance upon these VP studies as they do not address the specific bacteria at issue here (VV), and are thus of minimal use in supporting a connection between insanitary practices and higher levels of Vibrio. (See, e.g., June 30, 2015 Tr. 140:25-141:8, 141:11-142:1, 143:25-144:3, 147:10-12.) In particular, Dr. Otwell described "distinct differences between [VV and VP] with their thermal lethality, growth rates, ability to survive, even the salinities that they survive at," all of which would impact the applicability of these studies' conclusions to VV and consequently, the validity of Plaintiffs' experts' reliance on them. (See id.) But this is a factor to be considered by the jury in its estimation of the weight to be given to the expert testimony; it does not necessarily undermine the reliability of Plaintiffs' experts' conclusions.

Dr. Oliver also testified that higher levels of Vibrio increase a susceptible individual's risk of infection. Dr. Oliver testified that the level at which a person will sustain a Vibrio infection is 100-300 Vibrio organisms, which is an

estimation based upon scientific studies conducted after people contracted a Vibrio infection¹³ as well as analysis of data obtained through studies of mice. (June 30, 2015 Tr. 89:14-90:11 (Oliver).) As Dr. Oliver conceded, however, this purported infective dosage level is based in large part upon speculation because **"there is no methodology you can use really"** for determining what level of bacteria causes an infection. (Oliver Dep. at 31:11-25 (emphasis added).) Because researchers cannot simply inject people to determine the infective dosage levels, they must resort to animal studies. (Id.) Dr. Oliver testified those animal studies indicate that mice can contract a fatal Vibrio infection after being dosed with only one cell of Vibrio bacteria. (See id. at 32:6-17; see also id. at 34:18-35:1 (the amount of seafood consumed may not impact whether an infection is sustained).) But, at higher dosage levels, more mice sustain a fatal Vibrio infection and, when dosed with 300 organisms, all of the mice in the study died. (June 30, 2015 Tr. 90:2-11 (Oliver).) From this study, scientists have concluded that higher levels of Vibrio increase the risk of infection. (Id. at 87:2-3, 90:2-11, 51:2-3 (Oliver).) This data has then been extrapolated to humans. Moreover, Dr. Oliver candidly admitted

¹³ Specifically, Dr. Oliver described a case in which a woman purchased and consumed oysters in her home, after which she developed a Vibrio infection. (June 30, 2015 Tr. 30:4-19.) The remaining oysters in the batch were tested and the data obtained was used to calculate the infected dosage rate. (Id.)

that the infective dosage level of 100-300 organisms upon which he relied was not only an estimate, but that he could not even state with certainty whether that infective dose applied to healthy individuals or to those pre-disposed to a Vibrio infection due to an underlying disease, such as Plaintiff. (Oliver Dep. 31:15-25, 32:1-23.) Despite the recognized "limitations" of this experimental data, the experts agreed that this infective dosage level is generally accepted and relied upon by experts in the field. (Id. at 30:20-31:10, 32:13-20 (Oliver), 138:14-20 (Otwell) (agreeing information is considered "better-than-nothing").)

Windrift also argues that Plaintiffs' experts' conclusions that Windrift's purportedly insanitary practices increased Plaintiff's risk of harm are based upon speculation because there is no evidence regarding the Vibrio levels in the clams at any point from harvest forward. The Court disagrees in part. As the above explanation conveys, the experts' opinions are drawn from what little scientific data and research may be available regarding the nature and behavior of Vibrio and its close relatives (i.e., VP). Dr. Oliver explained that it is "extrapolating what we think would potentially happen because of failure to follow the regulations to decrease the risk." (June 30, 2015 Tr. 69:9-11.) In other words, it is extrapolation of the available scientific data found in the literature, which

concludes that a failure to follow sanitation regulations is "likely to increase the number of bacteria [] and, therefore, the risk." (See id. at 70:1-8 (Oliver); see also id. at 55:13-18 ("A. All those regulations are based on the premise that following them will minimize the public health hazard. To not follow them implies that there will be an increased risk. We don't know what that risk is. We don't know what the number of bacteria that were there. But not following any of those regulations would increase the risk of infection.")) That Plaintiffs' experts remain unable to quantify the amount of the increase does not render their opinions so speculative as to be inadmissible. Cf. Lithuanian Commerce Corp., 179 F.R.D. at 457 ("In fact, far from precluding the exclusion of evidence, where evidence 'is too 'speculative' as a matter of law . . . Daubert and the Federal Rules of Evidence require that a district court be willing and able to do just that.'" (quoting Target Market Publishing, Inc. v. ADVO, Inc., 136 F.3d 1139, 1143 (7th Cir. 1998))). Accordingly, the Court finds that the expert testimony is sufficiently reliable to be permitted under Daubert and Rule 702.

2. There is Sufficient Evidence to Deny Summary Judgment

There are two reasonable causation inferences to be drawn from the evidentiary record. First, the "culprit was in the

clams" before the Windrift encountered the product, and thus the jury could conclude that Windrift did not proximately cause Plaintiff's injuries. (See June 30, 2015 Tr. 139:14-17.) Second, if the jury accepts the premise that the August 12 sanitation violations also occurred on July 30 - an issue in dispute - and the jury determines that it was likely the clams contained *Vibrio* in an amount less than the infective dosage - an issue that depends on various factors, see supra, then the jury could infer that the insanitary conditions increased Plaintiff's risk of infection.

As to the first inference, Dr. Otwell testified that it is "scientifically probable" that Plaintiff would have sustained the infection regardless of Windrift's involvement.¹⁴ (June 30, 2015 Tr. 151:8-9, 139:11-17.) According to Plaintiffs' own expert, Dr. Oliver, all shellfish contains *Vibrio* in "high numbers" that can "easily" exceed the infective dosage level of 100-300 organisms. (See WMF ¶ 15; June 30, 2015 Tr. 18:7-10, 18:25-19:2, 57:9-10 (Oliver).) Moreover, the experts agree that *Vibrio* infections "primarily" occur between May and October

¹⁴ Dr. Otwell's testimony was quite persuasive. In so saying, the Court recognizes that its role for purposes of this motion for summary judgment is not to weigh the evidence and that all reasonable "inferences, doubts, and issues of credibility should be resolved against the moving party." Meyer, 720 F.2d at 307 n.2. It has faithfully applied this standard and denies the instant motion, in part, because the expert testimony and reasonable inferences to be drawn therefrom demonstrate a dispute that must be resolved by the jury.

(Oliver Report at ¶ 8), and that *Vibrio* is commonly found in those clams harvested from the Northeastern United States, as were the clams Plaintiff consumed on July 30 (id.; see also WMF ¶ 40 (clams were harvested from Great Bay, New Jersey)). Dr. Otwell further testified that *Vibrio* levels are the "most problematic" from July through September - the precise time in which Plaintiff consumed the clams - due to water temperature. (See June 30, 2015 Tr. 140:2-3.)

Significantly, while she did not know it at the time, Plaintiff's hemochromatosis rendered her highly susceptible to a *Vibrio* infection. Dr. Oliver characterized her risk of developing a *Vibrio* infection as 800 times greater because of her illness. (See Oliver Dep. 58:7-10.) Plaintiff's experts further acknowledged that it is possible Plaintiff could have developed this infection without any action on the part of Windrift. (See June 30, 2015 Tr. 70:9-15 (Oliver); accord id. at 120:19-121:1 (Costa).)

Tellingly, Dr. Oliver - who has 40 years' experience studying *Vibrio* - testified that so little is known about the *Vibrio* bacteria or why it causes infection, and for all he - a veritable authority on *Vibrio* - knows, a whole host of factors may be required to result in an infection: "For all I know you've got to be male, you have to be over 40, you have to be immune-compromised." (Oliver Dep. at 33:25-34:1.) When asked to

explain how Plaintiff had been able to consume raw shellfish her entire life without experiencing any illness or infection,¹⁵ yet suddenly developed an invasive Vibrio infection after consuming three clams, Dr. Oliver could provide no answer: "If I knew the answer to that I would publish in the top journals of the world. . . . I assume some time we'll find out the combination of bacterial factors, the various virile factors that cells have or things other than being iron overloaded."¹⁶ (Id. at 33:21-24.) Experts for both sides agree that Vibrio infections are rare and no one knows why they occur in particular individuals or at particular times in a person's life. (See, e.g., June 30, 2015 Tr. 46:17-21, 77:7-15 ("It's such a rare event that we don't know all the conditions that lead to the infection. As an example, she had eaten shellfish many times before with no consequence, probably when she had hemochromatosis then too, and we don't know why she didn't. That's a typical scenario of

¹⁵ Plaintiff testified that prior to her infection and diagnosis with hemochromatosis, a genetic condition, Plaintiff had consumed raw seafood her entire adult life without experiencing any illness or infection (WMF ¶¶ 21-24; PR ¶¶ 21-24); raw oysters were her "big love" (WMF ¶ 22; PR ¶ 22).

¹⁶ As previously indicated, the jury will not be permitted to draw the inference that because Plaintiff had never suffered a Vibrio infection before despite her life-long consumption of raw shellfish, this somehow demonstrates that it is Windrift's negligent food-handling practices that caused her infection on this occasion. There is no evidence to support such an inference and, indeed, Plaintiffs' own experts dispute it. (See, e.g., June 30, 2015 Tr. 46:17-21, 77:7-15 (Oliver).)

people who are susceptible, still [sic] eat many, many times and they have no consequence, and then eat one time and die. But we don't know what the combination is that results in that.") (Oliver).) Indeed, Dr. Otwell explained that nearly 20-30 million people suffer from a health condition that predisposes them to a Vibrio infection, yet the experts agree that fewer than 100 cases are reported each year. (See June 30, 2015 Tr. 135:7-16.) This scarcity of cases seems to be because, as Dr. Otwell put it, the stars must align to create, in essence, the perfect storm for an infection to develop. (See CITE.) What is known is that Plaintiff's condition rendered her highly susceptible and, for this reason, she has now been instructed by her doctors never to eat shellfish again.

In the final analysis, a jury may find the testimony of Dr. Otwell to be persuasive and credible and may conclude that "the culprit was in the clams" due to the season, the harvesting location, and Plaintiff's extreme susceptibility to a Vibrio infection. As Dr. Otwell put it, "it's hard for people to comprehend the fact that something that could cause this could be allowed to be consumed, but if it's harvested from legal waters and it's served within 14 days through all the channels of distribution and control, then it's legal." (June 30, 2015 Tr. 137:4-8 (Otwell).)

However, if the jury believes that the clams contained either no *Vibrio* or *Vibrio* below the infective dosage level prior to their arrival at Windrift, and if the jury finds that the sanitation violations found on August 12 likely occurred on July 30 during Plaintiffs' visit, then it may rely upon the testimony of Plaintiffs' experts to conclude that Windrift's sanitation violations increased the level of *Vibrio* and therefore Plaintiff's risk of infection. In order to reach this conclusion, the jury must first determine that the clams contained either no *Vibrio* or an amount below the infective dosage level of 100-300 organisms. While it is undisputed that there are no tests of the *Vibrio* content of these clams at any point, the experts testified to certain factors that impact *Vibrio* levels in shellfish. For example, Plaintiffs' expert, Dr. Oliver, testified that "if *vibrio vulnificus* exists in the water, then yes, you will find them [in shellfish]," and "in temperate waters you will always find vibrios in molluscan shellfish [e.g., clams, oysters, scallops, and mussels]." (June 30, 2015 Tr. 23:20-25.) As noted above, the level of *Vibrio* also depends on the water temperature and "the warmer it is the greater the risk there is of having an increase in the level of vibrios in the shellfish." (Id. at 24:7-10, 27:24-28:1 (Oliver).) However, the levels of *Vibrio* in seawater varies from nondetectable to 100 organisms/milliliter, or higher if the

temperature is warmer or the water is full of nutrients. (See id. 29:1-16 (Oliver).) Further, as Dr. Oliver testified, Vibrio occurs primarily in clams from the Northeastern and Mid-Atlantic United States and that infections occur primarily in susceptible individuals above the age of 40¹⁷ who consume raw shellfish between May and October. (Oliver Report ¶¶ 8, 11.) Although the testimony by Plaintiffs' expert seems to support the conclusion that the "culprit was in the clams" at the time of harvest, as Defendant argues, there are material disputes, i.e., the temperature of the water and presence of nutrients, supra, to put before a jury to resolve.

If the jury concludes that the clams contained Vibrio in an amount less than the infective dosage level, then it may turn to the question of the impact of Windrift's conduct on the level of Vibrio in the clams and hence Plaintiff's risk of infection.¹⁸ As discussed at length above, Plaintiffs' experts testified that violation of the sanitation regulations could increase the amount of Vibrio that may be transferred to other shellfish. For example, Dr. Oliver testified that permitting the clams to be stored in the raw bar refrigerator at temperatures above 55°

¹⁷ Plaintiff was born April 24, 1951 (Pl.'s Dep. 6:18-20), making her approximately 59 years old at the time she suffered the Vibrio infection.

¹⁸ If the jury concludes that the clams contained an infective dosage level, then the conduct of the Windrift becomes irrelevant for causation purposes.

could cause the *Vibrio* levels in the clams to multiply. In addition, Dr. Oliver and Mr. Costa testified that failing to properly sanitize the cutting board or shucking utensil every four hours (as required by law) could result in a buildup of *Vibrio*, which could then be transferred into clams shucked on that cutting board. Dr. Oliver testified that scientists have extrapolated data from studies conducted on mice to conclude that at higher dosages of *Vibrio*, a human consumer is at a greater risk of developing a *Vibrio* infection. (June 30, 2015 Tr. 90:2-11 (Oliver).) Should the jury choose to credit this testimony, it could reasonably infer that Windrift's sanitation violations increased the risk that Plaintiff would suffer an infection and thus conclude that Windrift's food-handling practices proximately caused Plaintiff's injuries. Cf. Model Jury Charge 5.40I ("If the product in question, however, does not add to the risk of the occurrence of the particular accident and hence was not a contributing factor in the happening of the accident . . . then plaintiff has failed to establish that a particular product defect was a proximate cause of the accident.").

Accordingly, while the evidence is slim, Plaintiffs have proffered sufficient evidence to create a dispute of fact as to whether Windrift's purported insanitary practices increased the risk of infection and proximately caused Plaintiffs' injuries.

IV. Conclusion

In sum, Plaintiffs have proffered minimal - but sufficient - evidence to demonstrate a genuine dispute of material fact. Fed. R. Civ. P. 56(a). As such, summary judgment is denied.

Dated: August 25, 2015

s/Renée Marie Bumb
RENÉE MARIE BUMB
UNITED STATES DISTRICT JUDGE