IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA WESTERN DIVISION No. 5:10-CV-446-D

JAMES F. BENNETT, et al.,)
Plaintiffs,)
v.	ORDER
HOFFMANN-LA ROCHE, INC. and ROCHE LABORATORIES, INC.,)
Defendants.)

On October 19, 2010, James Bennett and Veronica Bennett (collectively "plaintiffs"), as personal representatives for the estate of their son Daniel Bennett, filed this action against Hoffmann-La Roche, Inc. and Roche Laboratories, Inc. (collectively "Roche") [D.E. 1]. Plaintiffs assert four claims under North Carolina law against Roche based on Roche's manufacture and distribution of the anti-malarial medication Lariam. On June 21, 2011, the court entered an order that bifurcated discovery into two phases [D.E. 38]. The first discovery phase dealt solely with the "identification of the brand of anti-malaria medication Daniel Bennett took, if any, in connection with his deployment to Afghanistan and prior to his death." [D.E. 38] 2. Discovery related to this issue concluded on February 28, 2012. See [D.E. 53] 2.

On March 29, 2012, Roche filed a motion for summary judgment pursuant to Federal Rule of Civil Procedure 56 [D.E. 53] and materials in support [D.E. 56–57]. Roche contends that plaintiffs "have failed to produce any admissible evidence that [Daniel Bennett] <u>ingested</u> Lariam, rather than a generic equivalent prior to his death" and thus plaintiffs cannot establish a causal link between Daniel Bennett's death and Lariam. [D.E. 53] 2–3. Plaintiffs responded in opposition [D.E. 59], and Roche replied [D.E. 60]. The court permitted plaintiffs to file a surreply [D.E. 61, 64]. The

court stayed commencement of the second discovery phase pending disposition of Roche's motion for summary judgment. As explained below, the court denies Roche's motion for summary judgment.

I.

In October 2008, before deploying to Afghanistan, members of Daniel Bennett's Marine unit were issued an anti-malarial drug with mefloquine as its active ingredient. See Martin Decl. [D.E. 59-5] ¶ 4. At that time, there were four anti-malarial drugs with mefloquine as the active ingredient—Roche's Lariam and three different manufacturers' generic versions. See DeVenezia-Tobias Aff. [D.E. 56] ¶ 2; [D.E. 57-4]. Lariam doses were packaged in blister packs contained within a white carton. [D.E. 58-2]; [D.E. 58-3]. The Lariam carton also contained "a Medication Guide," "a Package Insert," and "an Information Wallet Card." DeVenezia-Tobias Aff. ¶ 3; see id. Exs. 1–3. The generic version that Sandoz, Inc. manufactured also had doses packaged in blister packs contained within a white carton. [D.E. 60-2] 19–20.

A Marine medical logistics unit ("MEDLOG") was responsible for purchasing medications from outside vendors and supplying those medications to Marine units stationed at Camp Lejeune, North Carolina. Hampden Decl. [D.E. 59-3] ¶2. Records from MEDLOG's outside vendor indicate that from 2005 to 2007, MEDLOG received large numbers of units of both Lariam and the Sandoz generic drug [D.E. 59-4] 1; see Hampden Decl. ¶3. In 2008, shipments of the Sandoz generic grossly outnumbered shipments of Lariam by 1041 units to 3 units. See [D.E. 59-4] 1. MEDLOG procedures called for dispensing medications to a unit "on a first in and first out basis; in other words, the stock of the medicines/drugs which has been in the MEDLOG storeroom the longest is

¹ In 2008, an additional seven units of Lariam were shipped to Camp Lejeune, but the base hospital received this shipment under a separate, non-MEDLOG account. <u>See</u> [D.E. 59-4] 1.

issued to the military unit." Hampden Decl. ¶ 4.

In October 2008, Navy Corpsman Sheldon Martin was responsible for issuing and distributing "individual packages of the anti-malarial drug mefloquine to each member" of Daniel Bennett's unit. Martin Decl. [D.E. 59-5] ¶ 4. Martin received the anti-malarial medications for distribution from the MEDLOG supply. Id. ¶ 5. Martin states that "[e]ach individual package of mefloquine consisted of a white box with a blister pack inside the white box; the blister pack contained approximately 25 tablets of mefloquine." Id. ¶ 6. Martin, however, "do[es] not recall what name was on the white box." Id. To receive the anti-malarial medication, the Marines from Bennett's unit came into a room, where Martin instructed them on the medication and each Marine completed a health questionnaire. Id. ¶ 7. Martin then "gave to each Marine, including Daniel Bennett, one package of mefloquine, i.e., one white box containing the blister pack of mefloquine tablets." Id. "At [Martin's] direction, each Marine, including Daniel Bennett, took from his blister pack and ingested one mefloquine tablet at that time." Id. Martin provided final instructions to all of the Marines from Daniel Bennett's unit that they should take one tablet each week before and during their deployment to Afghanistan, and that they should take the medication Martin just issued with them to Afghanistan. Id.

About November 10, 2008, James and Veronica Bennett, along with their son's fiancee, visited Daniel Bennett at Camp Lejeune. See V. Bennett Dep. [57-11] 30. While in Daniel Bennett's barracks room, he opened his closet and "all sorts of stuff fell out," including an object with "silver foil" and "a small white rectangular box." Id. 39-41. At the time, Veronica Bennett was facing the closet about two to three feet away. Id. 47. Beyond observing that the white box was about the same size as the silver object, Veronica Bennett does not recall whether the box had been opened or any markings on the box. Id. 41.

Veronica Bennett asked Daniel Bennett about the silver object that had fallen out. Id. 42. In response, he picked up the object, handed it to Veronica Bennett, and said, "It's Lariam." Id. Veronica Bennett held the silver object and noticed that it looked "like a blister pack that would have medication in it." Id. 43. She does not recall whether any of the medication had been removed from the pack. Id. Before Veronica Bennett responded to Daniel Bennett handing her the blister pack, he also handed her "a package insert." Id. The insert was a "[t]hin, white paper . . . folded very tightly" with "black lettering." Id. 44. To Veronica Bennett, who worked as a nurse, the paper appeared consistent with "the type that normally comes in . . . medication packs." Id. The paper also appeared to have been opened before. Id. She unfolded the insert and noticed the word "Lariam," as well as "the hexagon logo for Roche." Id. 44–45. Veronica Bennett estimated that the entire sequence of events from the items falling out of the closet to Daniel Bennett handing her the silver object and the paper insert occurred in a matter of "seconds." Id. 49.

Daniel Bennett deployed with his unit to Afghanistan a few days after November 10, 2008. See id. 57. On January 11, 2009, while in Afghanistan, he committed suicide with his service-issued sidearm. Autopsy Report. [D.E. 59-6] 1. A toxicology test conducted during the autopsy revealed the presence of mefloquine in his blood. Id. 6. Neither party possesses any medication bottles or packages that were in Daniel Bennett's possession when he died. [D.E. 57-3] 8-9.

Plaintiffs claim that Daniel Bennett ingested Lariam before and during his deployment to Afghanistan and that ingestion of Lariam caused his suicide in January 2009. See Compl. [D.E. 1]. Roche contests liability.

II.

Summary judgment is proper when "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);

Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. Celotex, 477 U.S. at 325. After the moving party has met this burden, the nonmoving party "must come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (emphasis and quotation omitted). A genuine dispute about a material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248. The court views the evidence and the inferences drawn therefrom in the light most favorable to the nonmoving party. Scott v. Harris, 550 U.S. 372, 378 (2007).

Plaintiffs assert four separate claims under North Carolina law against Roche, and each claim sounds in products liability. See N.C. Gen. Stat. § 99B-1(3) (providing that "'[p]roduct liability action' includes any action brought for or on account of . . . death . . . caused by or resulting from the manufacture, construction, design, formulation, . . . preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product"); Stoddard v. Wyeth, Inc., 630 F. Supp. 2d 631, 633 (E.D.N.C. 2009); Moore v. Coachmen Indus., Inc., 129 N.C. App. 389, 397, 499 S.E.2d 772, 777 (1998). In pharmaceutical-based products liability actions, "a brand name pharmaceutical may not be held liable for injuries stemming from the use of another manufacturer's generic bioequivalent." Stoddard, 630 F. Supp. 2d at 634; see Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994). Thus, as part of their causes of action, plaintiffs must prove a causal connection between Roche's Lariam and Daniel Bennett's death. See, e.g., N.C. Gen. Stat. § 99B-1(3) (referencing causation); Ryan v. Eli Lilly & Co., 514 F. Supp. 1004, 1006 (D.S.C. 1981) (construing North Carolina law); Elledge v. Pepsi Cola Bottling Co. of Winston-Salem, 252 N.C. 337, 338, 113 S.E.2d 435, 436 (1960) (per curiam).

Roche contends that plaintiffs have failed to produce sufficient admissible evidence from which a reasonable jury could find the requisite causal link between Daniel Bennett and Lariam as distinct from one of the generic versions of mefloquine. Defs.' Mem. Supp. Summ. J. [D.E. 57] 1–2. Roche argues that no records establish that Lariam was distributed to Daniel Bennett nor have plaintiffs offered sufficient evidence that Daniel Bennett actually ingested Lariam rather than a generic version of mefloquine. See id. 10–14. Furthermore, Roche argues that Veronica Bennett's testimony about what her son told her and about the paper she saw on November 10, 2008, is inadmissible hearsay. See id. 14–18.

When causation is challenged at summary judgment, the Fourth Circuit has "emphasized that proof of causation must be such as to suggest 'probability' rather than mere 'possibility,' . . . to guard against raw speculation by the fact-finder." Sakaria v. Trans World Airlines, 8 F.3d 164, 172–73 (4th Cir. 1993); see Ross v. FDIC, 625 F.3d 808, 817 (4th Cir. 2010). The proof must consist of "fact-specific and not merely speculative evidence establishing the cause of [plaintiff's] injury." Ross, 625 F.3d at 817 (quotations omitted). As with all summary judgment motions, the facts asserted by either party must be based on admissible evidence. Fed. R. Civ. P. 56(c)(1)–(2); see, e.g., Toll Bros., Inc. v. Dryvit Sys., Inc., 432 F.3d 564, 568–69 (4th Cir. 2005); Sakaria, 8 F.3d at 171.

Here, the admissible evidence offered by the parties narrows the possible anti-malarial medications that Daniel Bennett ingested to two: Lariam or the Sandoz-manufactured generic. Both medications are packaged in blister packs contained within a white box. See [D.E. 58-2] 17–20; [D.E. 58-3]; [D.E. 60-2] 19–20. Corpsman Martin distributed to every Marine in Daniel Bennett's unit mefloquine that was packaged in blister packs contained within a white box. See Martin Decl. ¶ 7. Significant quantities of each medication were delivered to MEDLOG at Camp Lejeune from 2005 to 2007. See [D.E. 59-4] 1. Although only three units of Lariam were shipped

to MEDLOG in 2008 compared to 1041 units of the Sandoz generic, see id., that fact is not dispositive because MEDLOG's procedure was to dispense medications that had been in the MEDLOG storeroom the longest. See Hampden Decl. ¶ 4. Corpsman Martin stated that each Marine ingested his first pill in front of Martin. Martin Decl. ¶ 7. Martin then instructed the Marines in Daniel Bennett's unit to take one tablet a week from that same package throughout the deployment to Afghanistan. Id. Daniel Bennett's autopsy revealed mefloquine in his blood. Autopsy Report 6. Viewing the evidence in the light most favorable to plaintiffs, a jury could reasonably infer that Daniel Bennett ingested whatever medication Martin dispensed to him until his death.

The only evidence that plaintiffs offer directly linking Lariam to Daniel Bennett is Veronica Bennett's testimony about the events of November 10, 2008. Roche argues that Veronica Bennett's "testimony as to [Daniel Bennett's] statement 'it's Lariam' is inadmissible hearsay." Defs.' Mem. Supp. Summ. J. 15. Plaintiffs respond that the statement is admissible under the hearsay exception in Federal Rule of Evidence 803(1) for present sense impressions. See Pls.' Mem. Opp'n Summ. J. [D.E. 58] 10.

Rule 803(1) provides that "[a] statement describing or explaining an event or condition, made while or immediately after the declarant perceived it" is not excluded by the hearsay rule. The criteria of "subject matter, perception, and time" must be satisfied for the exception to apply. United States v. Portsmouth Paving Corp., 694 F.2d 312, 323 (4th Cir. 1982). As for subject matter, Daniel Bennett's statement explained an object that had fallen out of his closet a few seconds earlier. The fact that several objects unexpectedly fell out of his closet when he opened the door would qualify as "an event." See id. (determining that a telephone call was an event); see also Makuc v. Am. Honda Motor Co., 835 F.2d 389, 391–92 (1st Cir. 1987). As for perception, Daniel Bennett

perceived that objects had just fallen out of his closet when he opened the door. As for timing, Daniel Bennett identified the silver object that had fallen out of the closet within seconds of it falling and immediately after Veronica Bennett asked about it. A statement's contemporaneity (or nearly so) to the event is a key guarantee of the statement's reliability. See, e.g., United States v. Green, 556 F.3d 151, 155–56 (3d Cir. 2009); Portsmouth Paving Corp., 694 F.2d at 323; see also Fed. R. Evid. 803 advisory committee's note (recognizing "that in many, if not most, instances precise contemporaneity is not possible and hence a slight lapse is allowable"). Veronica Bennett's testimony that the sequence of events was measured in seconds establishes the necessary time window for the statement to fit within the exception. See V. Bennett Dep. 49; Portsmouth Paving Corp., 694 F.2d at 323 (determining that a statement made "[w]ithin a matter of no more than a few seconds [after the event] . . . falls squarely within the time strictures of Rule 803(1)"). Thus, Daniel Bennett's statement that the silver object was Lariam is admissible as a present sense impression under Rule 803(1).

Roche also argues that Veronica Bennett's statements about the paper that Daniel Bennett handed her immediately after saying the silver object was Lariam are inadmissible hearsay. See Defs.' Mem. Supp. Summ. J. 16–17. Roche additionally contends that the statements are barred under the best evidence rule. See Fed. R. Evid. 1002. Plaintiffs respond that the statements are not hearsay because they are offered not to prove the contents of the paper but to identify an item in Daniel Bennett's possession. See Pls.' Mem. Opp'n Summ. J. 12.

"Words in their visible embodiment in written form amount to identifying characteristics of any physical object on which they appear." 4 Christopher B. Mueller & Laird C. Kirkpatrick, Federal Evidence, § 8:21, at 129 (3d ed. 2007). Correspondingly, statements that identify an object based on words or symbols that appear on the object are not hearsay merely because the means of

identification is written. See, e.g., Commonwealth v. Harvey, 446 Pa. Super. 395, 401–02, 666 A.2d 1108, 1111–12 (1995) (concluding that testimony about a brand name written on a label was not hearsay because it was offered only to prove the brand affiliation not the contents of a container). To the extent plaintiffs offer Veronica Bennett's statements to identify a paper in Daniel Bennett's possession, the statements are not hearsay and are admissible. See, e.g., United States v. Buchanan, 604 F.3d 517, 521–22 (8th Cir. 2010). To the extent the best evidence rule applies, the paper appears to have been lost or destroyed, but not in bad faith. Thus, Veronica Bennett's testimony may substitute. See Fed. R. Evid. 1004(a), 1007.

Next, Roche argues that Veronica Bennett must be mistaken about what she saw on the paper. See Defs.' Reply [D.E. 60] 7–8. That argument goes to her credibility, which the court does not address at summary judgment. See, e.g., Summerlin v. Edgar, 809 F.2d 1034, 1039 (4th Cir. 1987).

Drawing all reasonable inferences in plaintiffs' favor, Veronica Bennett's testimony that Daniel Bennett identified a silver object that fell out of his closet as Lariam and that he possessed a paper bearing the name Lariam and the Roche logo provides sufficient evidence to bridge the gap between the white box of medication dispensed to Daniel Bennett by Corpsman Martin and Lariam.

See, e.g., Ross, 625 F.3d at 817. Whether a jury will find by a preponderance that Daniel Bennett received and ingested Roche's Lariam is a question for another day. Accordingly, Roche's motion for summary judgment is denied.

Ш.

In sum, Roche's motion for summary judgment as to product identification [D.E. 53] is DENIED. The parties are DIRECTED to file a proposed timeline for the second phase of discovery no later than April 9, 2013.

SO ORDERED. This 22 day of March 2013.

JAMES C. DEVER III Chief United States District Judge