

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
(at Lexington)

ESTELLE WELLS, Executrix of the)
Estate of Larry Wells, et al.,)
)
Plaintiffs,)
)
V.)
)
FRESH FOODS OF WASHINGTON,)
LLC, et al.,)
)
Defendants.)

Civil Action No. 5: 21-269-DCR

**MEMORANDUM OPINION
AND ORDER**

*** **

This matter is pending for consideration of Defendants Fresh Foods of Washington, LLC’s and Sam’s West, Inc.’s motions for judgment on the pleadings and Plaintiff Estelle Wells’ motion to amend her Complaint. Because the plaintiff has shown good cause for amending the Complaint, her motion will be granted. The defendants’ motions for judgment on the pleadings will be denied, as moot.

I. Background

Plaintiff Estelle Wells (“plaintiff” or “Wells”) is the widow of Larry Wells (“Mr. Wells”). Mr. Wells purchased a two-container package of Member’s Mark brand clam chowder at Sam’s West, Inc. (“Sam’s West”), doing business as Sam’s Club, in Lexington, Kentucky on January 19, 2021. The product was manufactured by Defendant Fresh Foods of Washington, LLC (“Fresh Foods”). Mr. Wells consumed the second container of soup on January 30, 2021, and became ill the following day. He went to the University of Kentucky Chandler Medical Center, where his condition rapidly deteriorated.

Mr. Wells' health continued to worsen and by February 2, 2021, a feeding tube was inserted. He was no longer able to use hand gestures or move his lower extremities. Given these symptoms and reported food history, doctors began to suspect botulism poisoning. Serum collected from Mr. Wells on February 3 was confirmed positive for botulinum toxin type A. In conjunction with the CDC, hospital staff administered botulism anti-toxin to Mr. Wells on February 4.

The Lexington-Fayette County Health Department ("LFCHD") interviewed the plaintiff about Mr. Wells' symptoms and the food he consumed two days before his onset of symptoms. The plaintiff retrieved the soup container from the trash and gave it to LFCHD, which sent it to the Division of Laboratory Services ("DLS") for testing on February 4, 2021. On February 9, DLS confirmed the presence of *C. botulinum* toxin type A in the leftover clam chowder collected from the Wells' home.

Mr. Wells' condition continued to deteriorate and he passed away on March 7, 2021. The plaintiff filed this action in her individual capacity and as executrix of Mr. Wells' estate on October 22, 2021, alleging that the defendants were negligent in manufacturing, distributing, marketing, and selling the clam chowder that Mr. Wells consumed ("Count II"). Wells also alleged a strict liability claim against Fresh Foods, asserting that the product was defective and unreasonably dangerous ("Count I").

The defendants filed individual motions for judgment on the pleadings on September 20, 2022, arguing that the negligence claims should be dismissed. [Record Nos. 40, 41] Before briefing of those motions was complete, Wells filed a motion to amend the Complaint, which addressed several of the alleged deficiencies identified in the defendants' motions. The

defendants maintain that the motion to amend should be denied and that their motions for judgment on the pleadings should be granted.

II. Standards of Review

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that, when a party seeks leave of court to file an amended pleading, “[t]he court should freely give leave when justice so requires.” This rule “reinforce[s] the principle that cases should be tried on their merits rather than the technicalities of pleadings.” *Inge v. Rock Fin. Corp.*, 388 F.3d 930, 937 (6th Cir. 2004) (internal quotation marks omitted). Accordingly, the court has broad discretion in considering whether to grant leave to amend. The court may consider factors such as “undue delay, bad faith or dilatory motive on the part of the movant, repeated failures to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of the amendment.” *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Ousley v. CG Consulting, LLC*, 339 F.R.D. 455, 459 (S.D. Ohio 2021)).

Because Wells moved to amend the Complaint after the Court’s April 15, 2022 deadline, she “must meet the higher threshold for modifying a scheduling order found in Rule 16(b).” *Shane v. Bunzl Distrib. USA, Inc.*, 275 F. App’x 535, 536 (6th Cir. 2008); Fed. R. Civ. P. 16(b)(4). This means that the plaintiff must “show good cause under Rule 16(b) for the failure to seek leave to amend prior to the expiration of the deadline before [the Court] will consider whether the amendment is proper under Rule 15(a).” *Hill v. Banks*, 85 F. App’x 432, 433 (6th Cir. 2003). The touchstone of this inquiry is whether the moving party acted diligently in attempting to meet the deadline set forth in the scheduling order. *Permasteelisa CS Corp. v. Airolite Co., LLC*, 2007 WL 1683668, at *2 (S.D. Ohio June 8, 2007); *Synthes USA Sales, Inc. v. Taylor*, 2012 WL 928190, at *2 (M.D. Tenn. Mar. 19, 2012) (“Diligently seeking to

rectify pleading deficiencies—‘as opposed to an effort to add new claims or parties’—even after a deadline has passed can be the basis for allowing amendment of a scheduling order.”).

The standard for ruling on motions to dismiss under Rule 12(b)(6) applies to the defendants’ motions for judgment on the pleadings under Rule 12(c). *See Moderwell v. Cuyahoga Cnty., Ohio*, 997 F.3d 653, 659 (6th Cir. 2021). All well-pleaded allegations of the party opposing the motion are taken as true, and the motion may be granted only if the moving party is nevertheless clearly entitled to judgment. *Id.* “A Rule 12(c) motion ‘is granted when no material issue of fact exists and the party making the motion is entitled to judgment as a matter of law.’” *Id.* (citations omitted).

III. Discussion

Wells seeks to amend four substantive portions of her Complaint. First, she seeks to add new paragraphs 40 through 47 which describe Defendant Fresh Foods’ method for producing the clam chowder at issue. The defendants argue that this amendment should not be allowed, as the proposed allegations are materially the same as those in the original Complaint and are not based on new information uncovered in the discovery process. However, Wells maintains that the allegations are based on discovery received within the last three months, including depositions and documents produced by Fresh Foods.¹ She claims that, through this discovery material, she gained information concerning Fresh Foods’

appreciation of the risk of botulism poisoning associated with the subject clam chowder product, (2) Fresh Foods’ production process for the subject product, including its lone control of continuous refrigeration (including by distributors

¹ Wells reports that she deposed Andrew Hearn, Ph.D., Fresh Foods’ Rule 30(b)(6) representative, on August 4 and October 18, 2022. She also deposed Matthew Monteverde, Fresh Foods’ Director of Culinary research and development department, on October 18, 2022. Notably, the October depositions took place *after* the proposed Amended Complaint was tendered to the Court, on October 10, 2022.

and consumers) as protection against the development of botulism toxins, (3) actions taken, or not taken, to understand the realities and likelihood of consumer handling practices or habits for similar products, and (4) actions taken, or not taken, to ensure that the subject product was formulated in a manner that reduced the risks associated with the subject product as much as possible.

Contrary to the defendants' assertions, Wells maintains that she had no information regarding these topics prior to receipt of this discovery. There is no evidence of undue delay or bad faith on the plaintiff's part in seeking to make the amendments. Further, this is her first motion to amend the Complaint. Additionally, the defendants do not report that they would be prejudiced if the amendments are permitted, let alone explain what type of prejudice would likely occur.

Next, Wells seeks to amend paragraphs 48-55 regarding Sam's West's sale of the clam chowder to Mr. Wells. Specifically, she seeks to allege:

48. Defendant Sam's West, Inc. is a subsidiary of Walmart, Inc., and is a multibillion-dollar food retail company.

49. As a food retail giant, Defendant Sam's West, Inc., was aware of the dangers associated with reduced oxygen packaged food products, such as the subject clam chowder, including the potential for *Clostridium botulinum* Type A toxin to proliferate in such products if not kept under constant refrigeration.

50. Defendant Sam's West, Inc., knew that Defendant Fresh Foods was using the reduced oxygen packaging method to produce Maker's Mark brand clam chowder as an exclusive recipe for Defendant Sam's West, Inc.

51. Defendant Sam's West, Inc., knew the extent of any and all labels present on its Maker's Mark brand clam chowder product sold in its stores in January 2021, and specifically on the subject product.

52. As a food retail giant, Sam's West, Inc., was aware of the potential for the subject product to be improperly stored at some point after its manufacture and before its consumption by Mr. Wells.

53. As a food retail giant and seller of reduced oxygen packaged products, including the subject clam chowder product, Defendant Sam's West, Inc., knew

or should have known about the multiple guidance documents the FDA has issued over the years to ensure consumers are adequately warned about the dangers of failing to refrigerate such products, including the danger posed by *Clostridium botulinum* specifically.

54. As a food retail giant, Sam's West, Inc., knew that the subject product's labeling did not warn consumers of the dangers posed by *Clostridium botulinum*.

55. As a food retail giant, Sam's West, Inc., knew that the subject product's preparation instructions were insufficient to guarantee the elimination of any *Clostridium botulinum* Type A toxin that may have formed in the product before consumption.

These proposed amendments appear to be in response to the defendants' argument that the negligence claim against Sam's West should be dismissed pursuant to Kentucky's Middleman Statute, which is designed to "protect middlemen who merely sell another manufacturer's products." *Long v. Juice Box Vapor Co.*, 2019 WL 908241, at *1 (W.D. Ky. Feb. 22, 2019) (quoting *Parker v. Henry A. Petter Supply Co.*, 165 S.W.3d 474, 477 (Ky. Ct. App. 2005)). This statute protects a retailer from liability when the manufacturer is subject to the court's jurisdiction; the product is sold in its original condition or in the same condition in which it was received by the middleman; the middleman did not breach an express warranty; and the middleman did not have reason to know that the product was unreasonably dangerous. *Id.* (citing KRS § 411.340).

The defendants' response in opposition to the motion to amend raises scattered futility arguments, but none in direct reference to application of the Middleman Statute. At this stage of litigation, the amended allegations are sufficient to overcome the defendant's motion for judgment on the pleadings. Kentucky courts have not defined the type of allegations necessary to overcome the protections of the Middleman Statute, but

Kentucky courts would undoubtedly require that to maintain a non-frivolous action against a retailer . . . , Plaintiff state something more than that the seller bore the same knowledge as the buyer. A contrary finding would render the statute's language superfluous; virtually any retailer under any circumstances could be subject to suit and liability by merely selling an item. At the very least, Plaintiffs must allege some more specific or special knowledge of dangerousness to avoid the protections afforded by KRS 411.340.

Weixler v. Paris Co., 2003 WL 10550, at *2 (W.D. Ky. Jan. 2, 2003).

Wells alleges that, “as a food retail giant,” Sam’s West had special knowledge of the “dangers associated with reduced oxygen packaged food products . . . including the potential for *Clostridium botulinum* Type A toxin to proliferate in such products if not kept under constant refrigeration.” [Record No. 52-1, ¶ 49] While this allegation is tenuous, the plaintiff is entitled to pursue discovery on the topic.

In *Parker v. Henry A. Petter Supply Co.*, Leon Parker brought a products liability action against a number of companies he alleged supplied asbestos products to his employer. 165 S.W.3d 474 (Ky. Ct. App. 2005). The circuit court granted summary judgment in favor of defendants Henry A. Petter Supply Company and Hannan Supply Company, concluding that as wholesale distributors, they were subject to the protection of Kentucky’s Middleman Statute. Parker argued on appeal that the Middleman Statute did not apply because these defendants knew or should have known that the products were defective and unreasonably dangerous at the time of Parker’s exposure. *Id.* at 476-77.

The Kentucky Court of Appeals reversed, noting that the plaintiff had provided evidence showing that “the medical and scientific community was aware of defects as early as the time that Parker was exposed to asbestos products.” *Id.* at 478. Parker’s expert witness was expected to testify regarding what was known in the medical and lay literature that was available to everyone, including suppliers. The Court of Appeals concluded that summary

judgment was premature and that, at the very least, Parker should have been permitted to explore discovery on the issue.

The Court is unpersuaded by Sam's West's argument that "food retail giant" is an unduly inflammatory term as used in this context. While a party may not present evidence or advise the jury of the financial condition of another party, there is nothing to suggest that including this language in the Amended Complaint is scandalous or argumentative. *See, e.g., Wedgewood Ltd. P'Ship I v. Twp. Of Liberty, Ohio*, 610 F.3d 340, 344 (6th Cir. 2010) (referring to Wal-Mart Supercenter as a retail giant); *In re Synchrony Fin. Secs. Lit.*, 450 F. Supp. 3d 127, 132 (D. Conn. 2020) (rev'd in part, on other grounds) (referring to Sam's Club as a retail giant).

Likewise, the Court rejects the defendants' assertion that Wells knew or should have known each of these facts at the time she filed her original Complaint. As previously discussed, Wells recently deposed witnesses from Fresh Foods through whom she learned about Fresh Foods' reduced-oxygen production practices, which form the basis of several of these allegations.

Wells also seeks to amend paragraphs 75 and 76, which provide:

75. Defendants had a duty to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage labeling, and sale of their food products including, but not limited to, the Federal Food, Drug, and Cosmetics Act, which bans the manufacture, sale, and distribution of any "adulterated" food, including specifically, but not exclusively, 21 CFR § 123.6 and 123.7(a). Defendants breached this duty.

76. Mr. Wells is among the class of persons designed to be protected by the statutory and regulatory provisions pertaining to Defendants' manufacture, distribution, storage, labeling, and sale of their food.

Title 21 of the Code of Federal Regulations, sections 123.6 and 123.7(a), sets out certain obligations the FDA imposes on fish-product manufacturers to conduct hazard analyses and to take corrective actions should deviations occur. The defendants contend that these proposed amendments should be denied as futile because no private right of action exists under either of these provisions or the FDCA. *Ross v. Sioux Honey Ass'n Co-op*, 2013 WL 146367 (N.D. Cal. Jan. 14, 2013).

It is true that the FDCA and its implementing regulations do not create private rights of action. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Any negligence *per se* claim based on the defendants' purported violation of these regulations necessarily fails. *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 681 (W.D. Ky. 2013) (citing *St. Luke Hosp., Inc. v. Straub*, 354 S.W.3d 529, 534 (Ky. 2011)). However, these regulations may be relevant with respect to determining the applicable standard of care for the plaintiff's negligence claims. *See id.* n.11; *T&M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526 (Ky. 2006) (federal statute was relevant to the duty of care under state law for a federally-licensed gun dealer that sold a gun to an 18-year old); *McCarty v. Precision*, 2006 WL 2644921, at *1 (M.D. Fla. Sept. 14, 2006) (FAA rules and regulations may be relevant in defining duty of care in products liability/negligence case involving airplane crash). Further, Wells' motion to add the provisions was triggered by the defendants' argument that her Complaint should be dismissed pursuant to Rule 8(a) because she failed to identify which specific provision of the FDCA the defendants allegedly breached.

Finally, Wells seeks to amend the Complaint to allege that the Food and Drug Administration has issued numerous guidance documents regarding proper food product labeling and manufacturing with specific reference to the danger posed by *Clostridium*

botulinum. Wells also provides hyperlinks to the articles, which were published in 1997, 2007, 2013, and 2018. Wells seeks to add a new paragraph 14, which alleges that, ““per this FDA guidance, ‘refrigeration below 38°F (3.33°C) can prevent growth of all strains of *C. Botulinum*, but because temperatures above this are commonly employed for refrigeration, temperature should not be relied on as the only control.’” [Record No. 52-1, pp. 4-5]

The defendants oppose these proposed additions for various reasons. First, they contend they are not factual allegations but, instead, are statements of opinion. While such amendments would be futile if the Complaint *only* consisted of conclusions and opinions, the defendants have not identified any harm in allowing the addition of these allegations as background material. The defendants point out that all of these items were within the plaintiff’s knowledge or possession at the time the original Complaint was filed. It is true that these documents were in existence at the time the original Complaint was filed. But it is possible that the plaintiff was not aware of their potential relevance until reviewing the recent discovery regarding Fresh Foods’ alleged production practices.

Based on the preceding analysis, the plaintiff will be permitted to amend her Complaint as requested. An amended complaint typically renders pending motions moot. *Dumphord v. Gabriel*, 2021 WL 3572658, at *3 n.4 (E.D. Ky. Aug. 12, 2021) (citing *Yates v. Applied Performance Techs., Inc.*, 205 F.R.D. 497, 499 (S.D. Ohio 2002)). Accordingly, and for the other reasons discussed herein, the defendants’ motions for judgment on the pleadings will be denied.

IV. Conclusion

Based on the foregoing analysis, it is hereby

ORDERED as follows:

1. The plaintiff's motion to amend her Complaint [Record No. 54] is **GRANTED**.
2. The Clerk of the Court is directed to docket the proposed Amended Complaint tendered at Record No. 51-1.
3. Defendant Sam's West, Inc.'s motion for judgment on the pleadings [Record No. 40] is **DENIED** as moot.
4. Defendant Fresh Foods of Washington, LLC's motion for judgment on the pleadings [Record No. 41] is **DENIED** as moot.

Dated: November 29, 2022.



A handwritten signature in black ink, appearing to read "Danny C. Reeves".

Danny C. Reeves, Chief Judge
United States District Court
Eastern District of Kentucky