IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

LAMONT SINGLETON and JOCELYN WILSON, Administrators of the Estate of ALIVIA SINGLETON, deceased,	)	
Plaintiffs,	)	Civil Action No. 17-921 Senior Judge Nora Barry Fischer
v.	)	
PHARMATECH, LLC[1]; THE HARVARD DRUG GROUP, LLC d/b/a RUGBY LABORATORIES; and BAYSHORE PHARMACEUTICALS, LLC,	)	
Defendants,	)	
v.	)	
BRUCHEM, INC.,	)	
Third-Party Defendant.	)	

MEMORANDUM OPINION

I. INTRODUCTION

Presently before the Court is a Joint Motion for Leave to File Petition for Approval of Wrongful Death and Survival Settlements Under Seal filed by Plaintiffs Lamont Singleton and Jocelyn Wilson, Administrators of the Estate of Alivia Singleton ("A.S." or "decedent"), deceased (collectively "Plaintiffs"), Defendants the Harvard Drug Group, LLC, ("THDG") and Bayshore Pharmaceuticals, LLC, ("Bayshore") (collectively "Defendants"). (Docket No. 440). On receipt, the Court ordered the parties to submit a copy of their proposed petition to the Court for in camera review. (Docket No. 445). Oral argument was held on October 27, 2020. During same, the Court

[1] Defendant PharmaTech, LLC ("PharmaTech") is no longer defending the case. (Docket No. 151). This Court granted Plaintiffs' motion for default against PharmaTech on January 28, 2020. (Docket No. 300).

ordered Plaintiffs' counsel to produce certain information to the Court for a further in camera review. Accordingly, Plaintiffs produced Plaintiff mother's mental and emotional health records and portions of Plaintiffs' depositions where they discuss the toll their child's death took on them. The parties requested the opportunity to file a supplemental brief and the Court granted same. That brief was submitted on November 12, 2020. Having considered the parties' positions, all of the evidence before the Court, and the standard set out in *In re Avandia Marketing, Sales Practices & Products Liability Litigation*, 924 F.3d 662, 673 (3d Cir. 2019), and its progeny, the Court granted the Motion, in part, on November 19, 2020. The Court writes at this time to support its Order and to confirm its ruling approving the referenced settlements.

II. RELEVANT PROCEDURAL BACKGROUND

In this personal injury and product liability action, Plaintiffs claim that their daughter's death was caused by Diocto Liquid,[2] an over-the counter liquid stool softener, that was contaminated with *Burkholderia cepacia* ("*B. cepacia*").[3] (Docket No. 35). Plaintiffs allege that Bayshore manufactured, tested, and supplied/sold the purportedly contaminated Diocto Liquid to THDG which, in turn, distributed, labeled, and sold it. (*Id.*) This case was heavily litigated and culminated in two motions for summary judgment on the issue of product liability being filed. The first was filed by THDG against Plaintiffs. (Docket Nos. 291-94; 319-21; 344-46; 354, 417, 420-21). The second was filed by Third Party Defendant Bruchem, Inc. against THDG. (Docket Nos. 288-90; 311; 324-28; 369-71; 386-88; 417). Prior to the Court rendering a decision on same, the

[2] The parties use "Diocto Liquid," "Colace," "liquid docusate sodium," and "docusate sodium" interchangeably. Additionally, despite "Colace" being the brand name of a THDG product, UPMC Children's uses the phrase "docusate (Colace)," generically to describe any "liquid docusate" and "docusate sodium" medication. (Docket No. 294-23 at 26).

[3] *B. cepacia* is "the name for a group or 'complex' of bacteria." (Docket No. 294-6 at 2). In the hospital setting, *B. cepacia* infections can spread to patients by respiratory secretions and through contact with anything that is contaminated like unwashed hands, water, equipment, medical devices, medicine, and even the hospital room, itself. (Docket Nos. 294-5 at 5-7; 346-1 at 8). Although these infections are most commonly found in cystic fibrosis patients, that is not always the case. (Docket No. 294-5 at 5, 8, 25).

parties notified the Court that both Plaintiffs' claims against THDG and THDG's third party claims against Bruchem had resolved by means of a settlement. (Docket No. 431).

III. RELEVANT FACTUAL BACKGROUND[4]

A. A.S. develops a *B. cepacia* infection

A.S. was born on August 3, 2015 and passed away nine months later on May 4, 2016. (Docket Nos. 35; 294-9 at 4; 346-1 at 44). She was hospitalized on and off throughout her short life.[5] (Docket No. 319 ¶¶ 18-20). On January 10, 2016, she was admitted into the intensive care unit at UPMC Children's Hospital ("UPMC Children's") after exhibiting symptoms of respiratory failure and hypokalemia. (*Id.* ¶ 20; Docket No. 294-9 at 5). She was then placed on respiratory and ventilatory support, on which she remained until her death. (Docket Nos. 294-9 at 6; 319 ¶¶ 20-21).

Two weeks into her stay, she was administered a docusate sodium liquid, which Plaintiffs allege was, at some point, contaminated with *B. cepacia*. (Docket Nos. 35 ¶¶ 1-2; 319 ¶ 22). A.S. received her first dose on January 28, 2016 and was given daily 10 mg doses through April 28, 2016. (Docket Nos. 294-12; 294-14; 319 ¶¶ 22-24). In total, she was administered 181 doses. (Docket No. 319 ¶ 24). A.S.'s medical records do not identify the manufacturer or brand name of this medication. (*Id.* ¶¶ 41, 103).

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[4] As noted, the referenced settlements occurred while the Court was considering summary judgment motions which were pending. Indeed, the Court had drafted much of its opinion addressing said motions. Hence, the Court looks to its factual determinations as part of its rationale in deciding to grant the parties' joint motion and petition. The factual background derives from the undisputed evidence of record, and the disputed evidence is viewed in the light most favorable to the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor").

To avoid any confusion caused by the duplicative numbering in the parties' dueling concise statements of material facts, the Court cites to Docket No. 319 when it is referring to material facts in THDG's statement that Plaintiffs do not contest and references Docket No. 345 when citing to the material facts in Plaintiffs' statement that THDG does not contest.

[5] A.S. was only 2lbs, 9 oz at birth and had congenital heart defects, a severe intrauterine growth restriction, and a cleft palate. (Docket No. 319 ¶ 17).

A.S. tested negative for *B. cepacia* on February 5, 2016 and again seven days later.[6] (*Id.* ¶ 25). But, on February 20th, she tested positive and was placed on a course of antibiotics. (*Id.* ¶¶ 26, 28). She responded readily to same. (Docket Nos. 294-11 at 12; 319 ¶¶ 28-29). A.S. last tested positive on March 10, 2016. (Docket Nos. 294-15; 319 ¶ 27). For the next forty-nine days, she continued to receive liquid docusate. (Docket No. 319 ¶ 31).

She was ultimately released from the care of UPMC Children's infectious disease specialists on March 22, 2016. (*Id.* ¶ 29). Dr. Marian Michaels, one of those treating physicians, could not specifically recall whether all "antimicrobials" were stopped before A.S. was released from her team's care but it was her recollection that they were not. (Docket No. 294-11 at 12). Although the issue of causation is not before the Court, the parties agree that *B. cepacia* was not present in A.S.'s body at the time of her autopsy. (Docket Nos. 294-16; 319 ¶ 35).

B. Diocto Liquid and labeling practices

PharmaTech manufactured a liquid docusate stool softener called Diocto Liquid. (Docket No. 319 ¶ 1). In 2013, THDG, which owns Rugby Laboratories, contracted with Defendant Bayshore Pharmaceuticals ("Bayshore") to purchase same for resale. (*Id.* ¶ 2; Docket No. 345 ¶ 52). UPMC Children's Inpatient Pharmacy ("Inpatient Pharmacy") did not purchase Diocto Liquid directly from THDG or Bayshore but received its supply from HCP Inventory.[7] (Docket Nos. 294-4; 294-29; 319 ¶¶ 64-70).

Each bottle of Diocto Liquid is numbered with a National Drug Code ("NDC")[8] identifier and is assigned a lot number reflecting the year of manufacture and batch. (Docket Nos. 319 ¶ 6;

[6] A negative culture means that there were no microbes in the cultured sample. (Docket No. 294-11 at 7).
[7] HC Pharmacy Central, Inc. "is the procurement agent for pharmaceuticals and associated products for the hospitals and cancer centers and physician offices that make up the University of Pittsburgh Medical Center, plus two non-UPMC entities." (Docket 321-13 at 4). HC Pharmacy Central, Inc. is owned by UPMC. (*Id.*; Docket Nos. 319 ¶ 84; 321-13 at 3).
[8] The NDC has no bearing on the date of manufacture or expiration date of the medicine. (Docket No. 319 ¶ 5).

321-13 at 3). The first four digits of the NDC is the vendor number. (Docket No. 321-13 at 3). Each bottle is also labeled with a lot number — all Diocto Liquid products have a lot number that begins with the prefix "2035" and bears a four-digit suffix to identify the year and batch number. (Docket No. 319 ¶ 7). Bottles manufactured in the same lot have the same product expiration date. (*Id.* ¶ 55).

HCP Inventory shipped bottles of Diocto Liquid to UPMC Children's on the following dates:[9]

- **January 22, 2015** – 6 Bottles from "NULL" Lot – Exp. 6/16
- **March 18, 2015** – 6 Bottles from "NULL" Lot – Exp. 12/16
- **May 6, 2015** – 6 Bottles from "NULL" Lot – Exp. 1/17
- **July 6, 2015** – 3 Bottles from "NULL" Lot – Exp. 3/17
- **July 23, 2015** – 6 Bottles from "NULL" Lot – Exp. 8/17
- **September 15, 2015** – 8 Bottles from "NULL" Lot – Exp. 8/16
- **November 24, 2015** – 4 Bottles from Lot 20351507 – Exp. 6/17; 6 Bottles from Lot 20351508 – Exp. 7/17
- **November 25, 2015** – 1 Bottle from Lot 20351510 – Exp. 10/17
- **December 23, 2015** – 3 Bottles from Lot 20351510 – Exp. 10/17
- **December 24, 2015** – 1 Bottle from Lot 20351510 – Exp. 10/17
- **January 26, 2016** – 8 Bottles from Lot 20351510 – Exp. 10/17
- **March 30, 2016**[10] – 6 Bottles from Lot 20351513 – Exp. 11/17
- **May 17, 2016**[11] – 6 Bottles from Lot 20351601 – Exp. 1/18

(Docket Nos. 294-4; 294-29; 319 ¶¶ 64-70). Lot number "Null" means that the lot number was not recorded. (Docket No. 294-23 at 21). There are six different expiration dates associated with the six "NULL" lots and as such, it is clear that these bottles were not from the same lot. (*Id.* at 21-22). All of the lots that the Inpatient Pharmacy received expired after A.S.'s death. (Docket Nos. 294-4; 294-23 at 20). The bottle or bottles containing the doses of liquid docusate that were administered to A.S. were not retained. (Docket No. 319 ¶¶ 41, 103).

[9] The only dates provided in the Inpatient Pharmacy's record of Diocto Liquid orders from 2015 to 2016 are order dates, product expiration dates, and actual shipment dates. (*Id.* ¶ 80).
[10] This shipment was received after A.S. first tested positive for *B. cepacia*. (*Id.* ¶¶ 26, 28).
[11] This shipment was received after A.S. died. (*Id.* ¶ 70).

C. Investigation into the nationwide *B. cepacia* outbreak

After a national cluster[12] of *B. cepacia* infections appeared in 2016, the Center for Disease Control and Prevention ("CDC") and the U.S. Food and Drug Administration ("FDA") began to investigate. (Docket Nos. 294-13; 321-2). In July 2016, PharmaTech issued a voluntary recall for all unexpired lots of Diocto Liquid associated with NDC 0536-0590-85 due to possible contamination. (Docket No. 319 ¶ 13). The FDA then took bottles of Diocto Liquid from PharmaTech's Florida facility in August 2016. (*Id.* ¶ 14). Lots 20351511, 20351513, and 20351601 all tested positive for *B. cepacia*. (*Id.*) The FDA also detected the bacteria in PharmaTech's reverse osmosis purified water system. (*Id.* ¶ 49; Docket No. 294-7 at 2). Although not all lots of Diocto Liquid tested positive for *B. cepacia* (Docket No. 363-1), "Eight FDA samples of the following Lots have been found to contain *B. cepacia*: 20351509, 20351510, 20351511, 20351512, 20351513, and 20351601 and have been classified as Lab Class 3. These lot numbers were manufactured in *sequence chronologically from 10/23/15 through 1/12/16*." (Docket No. 363-2) (emphasis added). In literature unrelated to this investigation, the FDA wrote "microbiological contamination is not evenly dispersed throughout a lot or sample of product and finding a contaminant in one sample and not in another does not discount the findings of the initial sample results." (Docket No. 294-8 at 3).

The FDA determined that the outbreak included serious infections in twelve states with sixty-three confirmed cases and forty-five suspected cases. (Docket No. 345 ¶ 46). From patient cultures, two distinct strains of *B. cepacia* complex were identified. (Docket No. 321-2 at 2). All

[12] "Cluster" is defined as "[a]n amount of illness or case or disease more than what you would expect to see on a usual basis." (Docket No. 321-12 at 5). With respect to a *B. cepacia* outbreak, Lindsey Montoya ("Montoya") of UPMC Children's, explained that more than one case in non-cystic fibrosis patients is uncommon. (*Id.*) Dr. Michael Green ("Green") also of UPMC Children's testified similarly, i.e., a cluster exists when two or more cases appear in people who do not have an obvious predisposing condition. (Docket No. 346-2 at 9).

sixty-three confirmed cases had isolates closely related to one of the two strains. (Docket No. 345 ¶ 44). Those same strains were found in water cultures from PharmaTech. (*Id.*) Moreover, fifty-eight of the sixty-three confirmed patients received liquid docusate bearing Diocto Liquid's NDC. (Docket Nos. 321-2 at 4; 321-9 at 2). The FDA concluded its investigation on October 12, 2016. (Docket No. 321-2 at 6). It found that poor manufacturing practices and contamination of the purified water supply at PharmaTech were the root causes of the docusate contamination. (*Id.*) The CDC found likewise. (Docket No. 345 ¶ 47).

D. Investigation into the cluster at UPMC Children's

UPMC Children's had eight patients develop *B. cepacia* infections in 2016. (Docket No. 346-1 at 45). A.S. was the first patient to test positive on February 20, and four more patients tested positive within two months. (Docket Nos. 294-5 at 9; 321-12 at 5-6, 11). The record is unclear when the three other patients developed their infections. (*Id.*) However, one of the eight children who tested positive was not given Diocto Liquid. (Docket No. 346-2 at 19).

On July 18, 2016, the FDA collected every bottle of Diocto Liquid and PAI brand docusate cups[13] from the Inpatient Pharmacy for testing. (Docket No. 319 ¶ 72). The following items were taken: one open bottle from Lot 20351510; one open bottle from Lot 20351513; six unopened bottles from Lot 20351601; eight unopened packages of ten cups each of PAI brand docusate sodium liquid bearing NDC 0121-0544-10; and twelve cups of PAI brand docusate sodium liquid bearing NDC 0121-0544-10. (*Id.*) After cross referencing the shipping dates for the lots; the collection included: one opened bottle of Diocto Liquid shipped no later than January 26, 2016; one opened bottle shipped on March 30, 2016; and six bottles shipped on May 17, 2016. (*Id.*) Plaintiffs admit that there is no direct evidence confirming whether A.S. received any doses from

[13] To the Court's knowledge, no claim has been brought against PAI or Pharmaceutical Associates. It was not named as a defendant in this case.

the two open Diocto Liquid bottles collected from the Inpatient Pharmacy. (*Id.* ¶ 73).

1. *Deposition testimony of Lindsey Montoya, UPMC Children's lead investigator*

After four non-cystic fibrosis patients developed *B. cepacia* infections in a short period of time at the hospital, UPMC Children's decided to open its own investigation.[14] (Docket No. 346-1 at 5). Montoya, a Senior Infection Preventionist,[15] was appointed as lead and tasked with determining whether anything at the hospital caused the cluster. (Docket Nos. 321-12 at 3; 345 ¶ 3). She gathered information about the medications administered to the patients and reviewed each patient's chart. (Docket Nos. 321-12 at 4; 345 ¶ 39). She quickly ruled out the possibility that the cause was shared ventilator machines, nurses, or other staff. (Docket No. 321-12 at 4). She did not, however, culture any of the hospital's equipment because the local health department told her not to do so. (Docket No. 294-5 at 14-15).

Montoya asserts that a break in the investigation came, "[o]nce the [Diocto Liquid] was implicated [by the CDC] and we knew the patients had the product and that they got *B. cepacia* after [being administered] the product[. Then,] we were comfortable saying that that was the likely cause. And that kind of concluded our investigation."[16] (Docket No. 321-12 at 8-9); *see* (Docket

[14] It bears mentioning that at the time of A.S.'s infection, there were no cystic fibrosis inpatients at UPMC Children's. (Docket No. 294-5 at 24-25). There likely were cystic fibrosis patients receiving treatment at the hospital's clinic, yet Montoya never inquired from the clinic whether any patients there developed a *B. cepacia* infection. (*Id.*)

[15] As a Senior Infection Preventionist, she reviewed "the microbiology from all the patients that are in-house" and determined whether an infection could have been 'acquired here at the hospital.'" (Docket Nos. 321-12 at 3; 345 ¶ 1).

[16] As part of the CDC's investigation into the nationwide outbreak,

> [d]ata collection was conducted using a standardized line list. Information about medical devices; procedures; products used for respiratory, oral, and skin care[;] and intranasal, inhaled, and oral medications was collected. Product information, such as brand and manufacturer, was not always available for respiratory, oral, and skin care products that were thought to have been administered to patients because these types of products are often not charged to patients and their use is often not documented in the medical record. Medication administration and pharmacy records were used to compare the [NDC] of medications.

(Docket No. 345 ¶ 25).

No. 345 ¶ 17). In the same vein, it is her position that when one bottle from a lot tests positive, every bottle in that lot is presumed contaminated. (Docket No. 346-1 at 34). She did concede, "You won't know unless you, actually, test every bottle." (*Id.*)

When asked how she determined who received the allegedly contaminated medication, she responded, "Basically, [the] pharmacy ran their own numbers and said here is a line list of all the patients who would have received [d]ocusate sodium during that time." (Docket No. 294-5 at 11). As previously stated, although many of the patients in the cluster received Diocto Liquid, not all did, and not all who received the drug developed an infection. (*Id.* at 11-12, 15, 28; Docket No. 345 ¶ 10). Furthermore, of the patients who tested positive, not all were exposed to the same strains of bacteria that the CDC identified. (Docket No. 346-1). Because UPMC Children's did not retain A.S.'s positive specimen or the bottles of docusate liquid administered to her, Montoya explained that the hospital is unable to determine whether A.S.'s infection was due to one of the two strains that were identified by the CDC. (Docket Nos. 294-17 at 7; 319 ¶¶ 42-44; 346-1 at 41).

Montoya likewise testified that UPMC Children's could not identify the lot numbers associated with the doses of Diocto Liquid administered to patients and could only hypothesize as to what lot and bottle A.S. received. (Docket No. 319 ¶¶ 37-38, 46). She explained that the hospital does not record lot numbers in patients' electronic medical records because doing so is "too time consuming." (*Id.* ¶¶ 37, 47; Docket No. 294-5 at 12). She added that there is no evidence to confirm that A.S. received any doses from the two open Diocto Liquid bottles, associated with Lots 20351513 and 20351510, that the FDA retrieved from the Inpatient Pharmacy in July 2016. (Docket No. 319 ¶¶ 73-74). Yet, Montoya believes that A.S. was infected by contaminated liquid docusate because her antibiotic sensitivities were the same as the other patients in the hospital's

cluster. (Docket Nos. 321-12 at 8; 345 ¶ 16).

Although her medication administration record lists "docusate (Colace)" as the drug she received, Montoya stated it would not necessarily have been the case that Colace was the brand A.S. was administered.[17] (Docket No. 294-23 at 9-10, 26). Also complicating matters is the fact that docusate sodium is commonly administered at UPMC Children's and the Inpatient Pharmacy likely has "a lot of bottles open at once." (Docket Nos. 294-5 at 23-24; 319 ¶ 86). Nonetheless, Montoya testified that it was the hospital's practice to use bottles of medicine to completion and to dispose of them properly once they expired. (Docket No. 294-5 at 15). Despite Montoya claiming that *B. cepacia* infections were uncommon outside of cystic fibrosis patients, another cluster of infections appeared at UPMC Children's in 2018. (Docket Nos. 345 ¶ 9; 346-1 at 9-10). It was her opinion that those infections stemmed from contaminated water certain patients received while treating at a different facility.[18] (Docket No. 346-1 at 9-10).

2. *Deposition testimony of Dr. Michael Green ("Dr. Green")*

Dr. Green is the Medical Director of Infection Prevention at UPMC Children's and assisted Montoya in her investigation by reviewing her work product. (Docket Nos. 319 ¶ 40; 346-2 at 8). He testified that *B. cepacia* is not commonly found in hospitals. (Docket No. 346-2 at 7). In fact, he could not remember hearing of any non-cystic fibrosis patient developing a *B. cepacia* infection at UPMC Children's before the cluster appeared in 2016. (*Id.* at 5). For purposes of the hospital's investigation, the investigatory team considered all non-cystic fibrosis patients who had a positive culture during the relevant period to be part of the cluster. (*Id.* at 9). He also revealed that of the

[17] Jeffrey Bruggeman of UPMC Children's agreed that references to "docusate (Colace)" in A.S.'s medical records did not identify the supplier or manufacturer of the liquid docusate product. (Docket No. 319 ¶ 106); *see infra* Section D.3.

[18] Montoya never mentioned the name of the facility to which she was referring. (Docket No. 346-1 at 9-10). She simply testified that contaminated faucet water was given to certain patients before they were transferred to UPMC Children's. (Docket No. 346-1 at 9-10). UPMC Children's, in turn, treated the patients for the infection. (*Id.*)

first five cases that appeared at the hospital, three of the cases matched strain B, one did not match either strain (but that patient did not receive Liquid Docusate), and A.S.'s sample was never tested. (*Id.* at 19, 21).

He admitted that there were problems linking A.S. to the national outbreak. (Docket Nos. 321-2; 346-2; 350). First, the hospital does not know the lot number for any of the liquid docusate administered to A.S. (Docket No. 346-2 at 17). Second, pulsed-field gel electrophoresis testing[19] was not performed on any of the isolates taken from A.S. and as such, it is unclear whether the strain of *B. cepacia* with which she was infected is one of the two linked to the nationwide outbreak. (Docket Nos. 321-2 at 3; 350-2 at 12). A.S.'s isolate was not preserved because UPMC Children's only holds isolates for five days unless there is a concern at that time. (Docket No. 346-2). Third, as for susceptibility testing, he cautioned, "One can sometimes compare the antibiotic susceptibility profile between different isolates of the same organism. And you could say, are they the same or different? And that is a potential linkage" but it is not a definitive link. (Docket No. 346-2 at 13).

3. *Deposition testimony of Jeffrey Bruggeman ("Bruggeman")*

Bruggeman was the Manager, Pharmacy Technical at the Inpatient Pharmacy during the period of time in question and is now a manager at UPMC's Procurement Pharmacy. (Docket Nos. 319 ¶ 84; 321-13 at 3). Bruggeman was deposed as UPMC Children's FED. R. CIV. P. 30(b)(6) witness.[20] (Docket No. 321-13 at 3). As noted above, HC Pharmacy Central, Inc. is the procurement agent for pharmaceuticals and associated products for the hospitals and the offices that make up the UPMC network. (Docket No. 345 ¶¶ 27- 28).

[19] Pulsed-field gel electrophoresis or PFGE can be used to identify links between outbreaks by looking at isolates obtained from cultures. (Docket Nos. 321-2 at 3; 350-2 at 12).
[20] The areas of inquiry of his deposition are not included as part of the record. (Docket Nos. 294-23l; 321-13; 346-9).

He collected the liquid docusate invoices for UPMC Children's investigation. (Docket No. 294 at 12). Per Plaintiffs' subpoena in this litigation, he searched for the NDCs associated with THDG and Pharmaceutical Associates to determine which liquid docusate products UPMC Children's purchased in 2015 and 2016. (*Id.* at 12-13; Docket Nos. 319 ¶ 95; 345 ¶ 32). He did not search for "docusate," "sodium docusate," or any other brand name for liquid docusate because he only remembered ordering brands of liquid docusate associated with THDG and Pharmaceutical Associates. (*Id.* ¶ 96; Docket No. 346-9 at 17-18).

He testified that the records he compiled reflected only the formal orders for docusate sodium that the Inpatient Pharmacy placed with HC Pharmacy and did not necessarily represent what was received, possessed, or administered at UPMC Children's. (Docket No. 319 ¶ 98). To this end, the Inpatient Pharmacy sometimes loans or borrows medications from the outpatient side of UPMC Children's as well as from other facilities within the UPMC system – a practice that is not recorded anywhere. (*Id.* ¶ 88). For that reason, any of the Diocto Liquid bottles reflected on the Inpatient Pharmacy's packing slips may have been transferred out of the Inpatient Pharmacy to other UPMC entities with no record of such activity. (*Id.* ¶ 91). Complicating matters is the fact that Bruggeman did not know what brands of liquid docusate other UPMC pharmacies bought during the relevant time. (*Id.* ¶ 89). He also could not rule out the possibility that there may have been inadvertent redactions in the list of orders he compiled. (Docket No. 356-9 at 16-17).

The Inpatient Pharmacy does not track the date when a particular bottle of Diocto Liquid – or any medication, for that matter – is opened, administered to patients, or emptied. (Docket No. 319 ¶ 81). And bottles of Diocto Liquid can sit on the Inpatient Pharmacy's shelves for many months before being opened, but they are discarded when they expire. (*Id.* ¶ 92). Bottles of Diocto Liquid are also shared among patients and are never checked out from the Inpatient Pharmacy.

(*Id.* ¶ 93).

At times, the Inpatient Pharmacy has had multiple bottles of Diocto Liquid open at the same time. (*Id.* ¶ 83). While the general practice is for UPMC Children's to administer doses from bottles in the order that they are received, Bruggeman admitted that "in some instances, [the] general practice [wasn't] followed exactly." (*Id.* ¶ 84) (alteration in original). In addition, sometimes new bottles are ordered before the stock on hand is depleted to ensure that the Inpatient Pharmacy does not experience a shortage. (*Id.* ¶ 87).

Based on his knowledge of the Inpatient Pharmacy, he agreed that it was likely that the only docusate on hand in January was Lot 20351510. (Docket No. 321-13 at 9). When an order was placed on March 30, 2016, he opined that the Inpatient Pharmacy should have used up most of its Lot 20351510 product. (Docket No. 349-9 at 7). He agreed, however, that the general practice was not followed here because a bottle from Lot 20351510 was seized by the FDA on July 18, 2016, despite the fact that UPMC Children's had a policy that medications could only remain opened for thirty days. (Docket No. 346-9 at 21-27).

[redacted]

[redacted]

[redacted]

[redacted]

IV. OVERVIEW OF THE ARGUMENTS

The parties assert six reasons why their Petition for Approval of Wrongful Death and Survival Settlements should be sealed. (Docket No. 440). First, the Court is only required to approve the settlement because Pennsylvania law so requires. (*Id.*) Second, this lawsuit involves private and not public parties. (*Id.*) Third, this case concerns the death of a minor and, as such, intimate details of the minor's health and biographical information would become publicly available. (*Id.*) Fourth, Defendants are presently defending similar claims in Florida state court and the disclosure of the terms of the settlement would be unduly prejudicial to Defendants. (*Id.*) Fifth, this case is subject to a protective order. (*Id.*) Sixth and finally, any relevant information which is of public concern in this case is already available to the public via the online docket. (*Id.*) In the alternative, given the ongoing Florida litigation, the parties argue that they should be allowed to file their Petition under seal until the conclusion of the Florida litigation. (*Id.*)

V. LEGAL STANDARD

Although the Court has already written previously on *Avandia* in this case,[21] the Court reiterates that a party seeking the closure of a hearing or the sealing of part of the judicial record "'bears the burden of showing that the material is the kind of information that courts will protect" and that "disclosure will work a clearly defined and serious injury to the party seeking closure.'" *Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.*, Civ. A. No. 16-1669, 2013 WL 1336204 at *4 (W.D. Pa. Mar. 29, 2013) (quoting *In re Cendant Corp.*, 260 F.3d 183, 194 (3d Cir. 2001 (emphasis added)). Recently, the United States Court of Appeals for the Third Circuit in *In re Avandia Marketing, Sales Practices & Products Liability Litigation*, stressed that "the common law presumes that the public has a right of access to judicial materials." 924 F.3d at 672. This is because public access "promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court." *Id.* (quoting *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988)).

> The party seeking to overcome the presumption of access bears the burden of showing "that the interest in secrecy outweighs the presumption." *Bank of Am.*, 800 F.2d at 344. The movant must show "that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted). The "strong presumption of openness does not permit the routine closing of judicial records to the public." *Id.* (internal quotation marks omitted).
>
> To overcome that strong presumption, the District Court must articulate "the compelling, countervailing interests to be protected," make "specific findings on the record concerning the effects of disclosure," and "provide[ ] an opportunity for interested third parties to be heard." *In re Cendant Corp.*, 260 F.3d at 194 (emphasis omitted). "In delineating the injury to be prevented, specificity is essential." *Id.* "Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Id.* "[C]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants." *Leucadia, Inc. v. Applied*

[21] This Court issued numerous rulings vis-à-vis *Avandia* in the context of protective orders and motions to seal. (*See, e.g.,* Docket Nos. 302, 310, 348, 352; 360).

> *Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993). To that end, the District Court must "conduct[ ] a document-by-document review" of the contents of the challenged documents. *Id.*

Id. at 672-73.

Recognizing parallels to the instant case, the Court finds *DePari v. Runyon*, Civ. A. No. 3:17-CV-00755, 2019 WL 3387662 (M.D. Pa. July 26, 2019), persuasive. In *DePari*, Shirley DePari, filed a wrongful death and survival action following the motor vehicle accident death of Lugi DePari. *Id.* at *1. The parties ultimately settled; however, after the settlement was reached, a nonparty to the original action, Christine Rutkowski, filed a motion to intervene seeking to unseal five documents that had been filed under seal with the court. *Id.* at *1, *5. Ms. Rutkowski sought access to the following: order approving settlement, the petition for approval of settlement and allocation of settlement proceeds; praecipe to supplement exhibits on petition, statement of legal and factual jurisdiction, and joint amendment to the petition. *Id.* at *5. The settling parties opposed the motion arguing that there were four pending matters in Pennsylvania state courts arising from the same litigation and DePari was a named defendant in each of those actions. *Id.* at *7. After weighing the *Avandia* factors, the *DePari* court found that "the balance tips in favor of temporary non-disclosure of the redacted items . . . *while the Pennsylvania state court actions remain pending*." *Id.* at *7 (emphasis added). The *DePari* court explained settlement amounts and identifying features that could lead to the ascertainment of such amounts should remain redacted and specifically noted that the disclosure of such information "could serve to prejudice the plaintiff in potential settlement negotiations in the state court actions where she is a named defendant." *Id.*

VI. ANALYSIS

The Court affirms its findings of fact and makes additional findings of fact which support its decisions to first approve the settlements under Pennsylvania law and following *Avandia*,

temporarily seal the petition for approval of settlements and corresponding order while the parallel litigation involving THDG and Bayshore is ongoing. *See In re Avandia Marketing, Sales Practices & Products Liability Litigation*, 924 F.3d 662; (Docket No. 450). The Court emphasizes that the temporary sealing authorized here is necessitated by the procedural requirements under Pennsylvania law requiring court approval of the settlement involving the estate combined with our District's policies on electronic filing mandating that motions be filed on CM/ECF. *See* LCvR 5.5. As noted, the motions arose in the context of a wrongful death and survival action following the death of a minor, who has a surviving twin sister. (Docket No. 35). The Court is mindful of its duties to protect minors. *See Peronis v. United States*, Civ. A. No. 16-1389, Docket No. 229; *see also* LCvR 5.2(D)(1). A.S. spent much of her short life in and out of the hospital due to a number of debilitating conditions including: congenital heart defects; a severe intrauterine growth restriction; feeding issues; a cleft palate; and the need for oxygen administration. (Docket No. 319 ¶ 17). Despite same, at the time of her death, she appeared to be progressing per her parents. (Docket No. 451). Accordingly , privacy and confidentiality rights of both the parents and children are at play.

A.S.'s repeated and lengthy hospitalizations resulted in enormous medical bills. (*Id.*) Fortunately, her father had insurance through his employer. (*Id.*) The bills were paid but ultimately resulted in a very large lien in this case which counsel were able to successfully negotiate. (*Id.*)

The parent-plaintiff depositions, parts of which were supplied to the Court, demonstrate the mental and emotional strain these facts and circumstances placed on them. In camera, the Court reviewed the health care provider records of the plaintiff mother. (*See* Docket No. 447).

[redacted]

[redacted]

In this Court's estimation, the details underlying the conclusions made by the Court here should remain private and confidential for a number of reasons including the potential for resurrecting feelings and emotions on the part of both plaintiffs and their surviving minor daughter and potentially renewing family strife. 42 PA. CONS. STAT. ANN. § 5944 (Pennsylvania's psychiatrist-patient privilege statute); FED. R. EVID. 501 (explaining "in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision"); *Henkel v. Gilmore*, Civ. A. No. 15-CV-477, 2015 WL 5472891, at *6 (W.D. Pa. Sept. 17, 2015). Yet, these facts demonstrate to the Court the real suffering experienced by the plaintiffs particularly the plaintiff mother and factored into the Court's decision to accept these settlements as fair and reasonable.

The Court is mindful that liability was strenuously contested. To that end, the Court acknowledges the decedent's conditions which may have shortened her young life. (Docket No. 319 ¶ 17). The Court also finds that issues related to product identification, which was not decided at the summary judgment stage, and causation were likely to be repeatedly challenged given the factual background of this case as outlined above and other facts yet to be explored as expert discovery has not taken place. (*See* Docket Nos. 288, 291). Importantly, UPMC Children's could not definitively identify the lot numbers associated with the doses of Diocto Liquid that were

administered, and its witnesses could only hypothesize as to the lot and bottle number(s). (Docket Nos. 319 ¶ 81; 346-2 at 17). Dr. Green testified that testing was not performed on any of the isolates taken from A.S. nor was her isolate preserved for later testing. (Docket No. 350-2 at 12). The Pharmacy Manager stated that the Inpatient Pharmacy loaned or borrowed medications from the outpatient side. (Docket No. 318 ¶ 88). The Inpatient Pharmacy does not track medications and multiple bottles of medication can be open at any one time despite its policy of using up stock before moving on to newly delivered medication. (Docket Nos. 319 ¶ 81; 346-9 at 21-27). Finally, the evidence reflects that another *B. cepacia* infection outbreak appeared at UPMC Children's in 2018. (Docket Nos. 345 ¶ 9; 346-1 at 9-10). These facts likewise support compromise in this case.

The Court also finds compelling the fact that PharmaTech, the manufacturer, recalled the product at issue in July of 2016 and is no longer in business.[22] (Docket Nos. 319 ¶ 13; 440 ¶ 19). Consequently, the expiration date of any liquid docusate that it manufactured has long since passed. (Docket Nos. 294-4; 294-23 at 20). As such, to the extent that one could argue that public concerns counter confidentiality in this matter, it would appear that the risk posed by PharmaTech's product was made known through agency action and the potential for additional harm has been extinguished with its demise. *See id.*; (Docket No. 345 ¶ 47). In addition, PharmaTech had limited insurance coverage for this and similar claims pending in the state of Florida. That coverage has been the subject of an Interpleader action there.[23] *See Lloyd's of London v. PharmaTech, LLC, et al.*, 8:18 – cv – 02550 – WFJ – AAS (M.D. Fla.).

The present defendants were in the supply chain and under Pennsylvania law faced

[22] The Court's analysis on this point is bolstered by Plaintiffs' counsel's recent filing wherein they detail PharmaTech's dire financial straits representing that PharmaTech has been unable to pay its debts or obligations and Raidel Figureroa is now the subject of a criminal investigation. (Docket No. 459).
[23] A settlement was reached in Interpleader action on December 16, 2020. (*See* Docket No. 454).

potential liability for their roles. (Docket No. 35).[24] All counsel informed the Court that continued litigation would have been extensive and time consuming as expert disclosures; depositions; and *Daubert* challenges were yet to occur. (Docket Nos. 304; 392). Pretrial proceedings would likewise have been extensive given the number of documents produced by the parties; the legal issues surrounding the FDA and CDC investigations as well as the fact that PharmaTech was no longer defending the case against it. Moreover, the COVID-19 pandemic and the restrictions placed on court proceedings would have made trial unlikely any sooner than mid-2022. *See* October 30, 2020 Administrative Order, Misc. No. 2:20-mc-394-MRH.

The settlement releases entered into by the parties were achieved at arm's length after negotiation by experienced counsel. (*See* Docket No. 440). Given the backdrop of Plaintiffs' claims and their strong desire to resolve the lawsuit without further litigation, they agreed to accept the material term of confidentiality proposed by the Defendants as part of the settlement agreement. (*See id.*)

In this Court's estimation, Defendants sought the confidentiality provision for important reasons in that revealing the settlement amounts publicly at this time would prejudice them in ongoing litigation in Florida involving the same or similar product(s) and any settlement discussions regarding those matters. This Court has been kept apprised of those cases which involve state law and different claims; parties; counsel; and damages. (Docket Nos. 367; 408; 413; 428; 432; 444; 450). At least one of those cases has been mediated and negotiations continue. In light of same along with the other facts outlined herein upon which the Court relies, the rationale employed in *DePari* is convincing to this Court to seal for a limited period of time so as not to

[24] Under Pennsylvania law, distributors can be found liable in strict liability. *Bernard v. Air Vent, Inc.*, Civ. A. No. 17-2361, 2019 WL 144852, at *4 (M.D. Pa. Jan. 9, 2019) (citing *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 384 (Pa. 2014)).

cause prejudice to the defendants in this action as to their ongoing efforts to resolve the cases pending in Florida. Further, Plaintiffs agreed to confidentiality given their own concerns for privacy and confidentiality which are justified by the facts before the Court. Hence, the Court issued its order on November 19, 2020 (Docket No. 45), upholding the parties' request for confidentiality yet ordering counsel to apprise the Court of the status of the Florida cases by May 3, 2021, at which time the Court will revisit continued confidentiality and the sealing of the Petition for Approval of Wrongful Death and Survival Settlements.

As required by *Avandia*, this Court has conducted a document-by-document review concerning the petition, attachments, and order which have been sealed at Docket Nos. 451 and 452. Once, again, the Court recognizes that the sealing authorized here is temporary and extends only during the pendency of the parallel litigation against THDG and Bayshore in Florida.

With respect to the Petition, itself, the Court notes that in many ways it parallels the separately filed Petition brought by Plaintiffs on December 18, 2020 (Docket No. 451), concerning the resolution of the claims against PharmaTech and its insurer, Lloyd's of London, with the only differences between the documents being the amounts of the settlements with THDG and Bayshore, and resolution of the medical lien. The document, however, shall remain under seal for the reasons set out above. Exhibit A to the Petition is the grant of letters issued by the Orphan's Court. Since this document does not contain settlement amounts and is available publicly, it will now be unsealed by the Court. Exhibit B is a letter from Optum regarding the resolution of the UnitedHealth Care Lien which contains repeated references to the sealed amounts. This exhibit shall remain under seal. Exhibit C is a document from the PA Department of Revenue that shows allocation of 80% survival and 20% to wrongful death without mentioning the amounts of the settlement. Accordingly, this exhibit shall be unsealed. Finally, Exhibit D is the proposed Order

which was adopted and entered by the Court separately at Docket No. 452. Both contain the sealed settlement amounts and should remain under seal like the Petition as outlined below.

As a final matter, "the strong common law presumption of access must be balanced against the factors militating against access. The burden is on the party who seeks to overcome the presumption of access to show that the interest in secrecy outweighs the presumption." *DePari*, 2019 WL 3387662, at *7. While the plaintiffs involved in the Florida cases have not sought to intervene in this case to access the settlement information, the Court agrees that the parties have met their burden to justify the temporary sealing because revealing the settlement information in this case publicly could place THDG and Bayshore at a significant disadvantage in both the litigation of the Florida cases and any negotiations toward a resolution of those matters. *See DePari*, 2019 WL 3387662, at *6-7. The general public's interest in immediate disclosure of the settlement information does not outweigh the potential prejudice to Defendants. Rather, it is this Court's opinion that the timely resolution of this matter via the present settlement between the parties strongly outweighs the interest in public disclosure, at this time, of the amounts of the settlement Plaintiffs achieved vis-à-vis THDG and Bayshore. It is this Court's duty to "secure the just, speedy, and inexpensive determination of every action and proceeding," FED. R. CIV. P. 1, and approving settlements achieved through the type of arm's length negotiations at issue here is wholly consistent with those goals. See W.D. Pa., ADR, available at: https://www.pawd.uscourts.gov/alternative-dispute-resolution ("Often a quicker resolution and/or resolution designed by the parties is more important and satisfying than any remedy a court may order").

After careful consideration of all of the factors under *Avandia* and the standard of common law access, the Court finds that the temporary sealing of the settlement amounts and the Petition,

Ex. B, Ex. D, (Docket Nos. 451, 451-2, 451-4), and the Order (Docket No. 452) is appropriate while the Florida litigation remains pending. *See DePari* at *7.

VII. CONCLUSION

Based on these facts as well as counsel's arguments, the Court found the settlements documented in the Petition to be fair and reasonable. The Court also found the basis to grant, in part, the parties' Joint Motion for Leave to File Petition for Approval of Wrongful Death and Survival Settlements under Seal found at Docket No. 450.

/s Nora Barry Fischer
Nora Barry Fischer
Senior United States District Judge

Dated: December 30, 2020

cc/ecf: All counsel of record