UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
FORT WAYNE DIVISION

15:23-4 AMH: 19

BERNICE THARP,	
Plaintiff,	
v.	
FRANCK'S LAB, INC., Individually and d/b/a) CASE NO. 1 1 1 3 C V 0 6 1 9
Franck's Compounding Lab and/or Franck's Pharmacy, Inc.;	
WELLS PHARMACY NETWORK, L.L.C.;))
PAUL W. FRANCK, R.Ph.; and)
ANTHONY JAMES CAMPBELL, R.Ph.,	
)
Defendants.	ý .

COMPLAINT FOR DAMAGES

Plaintiff, Bernice Tharp, by counsel, respectfully makes her Complaint for Damages against Franck's Lab, Individually and d/b/a Franck's Compounding Lab and/or Franck's Pharmacy, Inc., Wells Pharmacy Network, L.L.C., Paul W. Franck, R.Ph., and Anthony James Campbell, R.Ph., and alleges and states as follows:

COUNT I JURISDICTION AND VENUE

1. Original jurisdiction exists in this Court pursuant to 28 U.S.C. § 1332 in that there is complete diversity of citizenship between Plaintiff and Defendants, the amount in controversy exceeds \$75,000 exclusive of interests and costs, and there is complete diversity between the parties.

- 2. Venue is proper within this district pursuant to 28 U.S.C. § 1391(b)(2) as a substantial part of the events, acts, or omissions giving rise to the asserted claim took place in this district.
- 3. Plaintiff, Bernice Tharp, is a person of the full age of majority and at all times relevant domiciled in the state of Indiana.
- 4. Defendants, Franck's Lab, Inc., individually and d/b/a Franck's Compounding Lab, and/or Franck's Pharmacy, Inc., are Florida corporations not registered but doing business in the State of Indiana with their principal place of business in Ocala, Florida.
- 5. The Defendant, Wells Pharmacy Network, L.L.C., is a Florida limited liability corporation not registered but doing business in the State of Indiana and is, in whole or in part, a successor in interest to the aforementioned Defendants and, as such, is liable to the Plaintiff for the below listed acts, omissions or strict products liability of its predecessors in interest, as well as liable for the actions of its agents, employees and/or representatives, including but not limited to Anthony James Campbell, R.Ph.
- 6. Defendant, Paul W. Franck, R.Ph., was a principal and shareholder of defendant, Franck's Lab, Inc., and was involved in the management and operations of Franck's Lab, Inc. and directed the manner in which the pharmaceutical products were compounded in the laboratory. Mr. Franck was a licensed pharmacist in Florida engaged in the practice of compounding pharmaceutical products placed in the stream of commerce, distributed and used in Indiana and causing injury to Indiana resident, Bernice Tharp.
- 7. Defendant, Anthony James Campbell, R.Ph., was a lead chemist with Franck's Lab, Inc. with responsibility for overseeing the laboratory operations and assuring compliance with the rules, laws and regulations concerning compounding pharmacies, including the federal

rules and regulations concerning the manufacture, sale and distribution of products, including the one that caused injury to Bernice Tharp.

8. Whenever reference in this Complaint is made to any act of Defendants, such allegation shall be deemed to mean that the officers, directors, members, agents, subsidiaries, affiliates, and employees of the Defendants did or authorized such act or conduct, and did so while acting within the course and scope of their employment.

COUNT II FACTUAL ALLEGATIONS

- 9. Plaintiff incorporates herein by reference paragraphs 1 through 6 of this Complaint for Damages the same as if fully set forth.
- 10. At all times relevant herein, the Defendants were engaged in the business of manufacturing, compounding, labeling, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of Indiana, either directly or indirectly through third parties or related entities, its products, including "Brilliant Blue G" (BBG), which is a dye used by ophthalmologists during eye surgeries.
- 11. At all times relevant to this matter, the Defendants represented that the product was pure, sterile and for the purpose of assisting with cataract surgery.
- 12. On or about November 8, 2011, Bernice Tharp underwent cataract surgery on her right eye in Fort Wayne, Indiana, performed by J. Rex Parent, M.D.
- 13. During the surgery, Brilliant Blue G was administered to Bernice Tharp's right eye.
- 14. The Brilliant Blue G administered to Bernice Tharp's right eye was contaminated with microorganisms which cause endophthalmitis.

- 15. Approximately one week after the surgery, Bernice Tharp developed endophthalmitis in her right eye.
- 16. Dr. J. Rex Parent diagnosed endophthalmitis in Bernice Tharp's right eye due to the contaminated Brilliant Blue G manufactured and distributed by the Defendants.
- 17. On March 9, 2012, an "Urgent Product Recall" was issued by Defendants concerning defective and contaminated lots of Brilliant Blue G that were manufactured, compounded or otherwise placed into the stream of commerce by Franck's Lab, Inc., individually and d/b/a Franck's Compounding Lab, and/or Franck's Pharmacy, Inc., and compounded by Mr. Franck, Mr. Campbell and/or other employees, agents and representatives of other Defendants.
- 18. On March 19, 2012, the United States Food and Drug Administration issued a recall of all remaining Brilliant Blue G from Defendants because of reports of endophthalmitis in patients who had the dye administered during surgery.
- 19. The investigation by numerous state, county and federal health agencies concluded that the defendants' BBG product was contaminated and that the defendants had violated numerous federal rules and regulations. On July 9, 2012, the United States Food and Drug Administration ("FDA") issued a Warning Letter FLA-12-38, which advised Paul W. Franck and Franck's Lab, Inc., that:
- a. The subject BBG was adulterated within the meaning of Section 501(a)(1) of the Act [21 U.S.C. § 351(a)(1)], it was not sterile, and it was contaminated with filthy, putrid or decomposed substances;

- b. The BBG was adulterated within the meaning of Section 501(c) of the Act [21 U.S.C. § 351(c)] in that its strength differed from, or its purity or quality fell below, that which it was purported to possess;
- c. The BBG and all sterile drugs compounded by the defendants were adulterated under Section 501(a)(2)(A) of the Act [21 U.S.C. § 351(a)(2)(A)] in that they were prepared, packed and stored under unsanitary conditions whereby they may have been contaminated by filth and were not sterile as represented;
- d. The BBG was misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. § 352(a)] because their labeling was false and misleading;
- e. That the FDA found several locations in the firm's laboratory where multiple bacterial and fungal species were identified. These bacterial and fungal species in the laboratory sections which were identified as "clean rooms" made any products compounded in those areas adulterated within the meaning of Section 501(a)(2)(A) of the Act [21 U.S.C. § 351(a)(2)(A)];
- f. The FDA investigators observed numerous instances of unsanitary and inappropriate practices by compounding technicians who left and re-entered clean rooms without changing lab coats, who were touching non-sterile items while wearing their sterile gloves and then returned to compounding activities, etc.; and
- g. The BBG drug products were misbranded insofar as they were labeled as being sterile, and they contained filthy, putrid, or decomposed substances and organisms.
- 20. The defendants knew that failing to follow safe and appropriate compounding practices could result in complications, including fatal ones. In 2009, the defendants compounded cocktails that were given to prized polo horses from the Venezuelan-owned

Lechuza Caracas team in preparation for championship matches near West Palm Beach, Florida.

Twenty-one of these prized polo horses died from errors committed by the defendants in compounding these cocktails.

COUNT III STRICT LIABILITY AGAINST DEFENDANTS

- 21. Plaintiff incorporates herein by reference paragraphs 1 through 20 of this Complaint for Damages the same as if fully set forth.
- 22. The Brilliant Blue G was defective in its compounding and manufacture since it was different from the manufacturer's intended result as set forth on the packaging and related material that accompanied the product, specifically that the product was sterile and free of any contamination. Plaintiff is informed and believes that the batch of the product that included the BBG that was injected into her eye was defective in compounding and manufacture in that it differed from other batches of BBG from these defendants.
- 23. The defect in the compounding and manufacture of the product, specifically the contamination and non-sterile nature of the product, existed in the product when it left the possession of the defendants.
- 24. At the time that Brilliant Blue G was placed into the stream of commerce by Defendants, it contained defects which made the product unreasonably dangerous for its intended use. The defective product contained no warnings that the product was or could be contaminated with filth, foreign matter or organisms.
- 25. Defendants failed to perform adequate testing, failed to have appropriate quality control procedures in place, and failed to follow those quality control procedures which would have shown that the Brilliant Blue G was in an unreasonably defective and dangerous condition.

- 26. Defendants knew or should have known that the Brilliant Blue G was unreasonably defective and dangerous for the use for which it was supplied.
- 27. Defendants failed to inform Bernice Tharp and Dr. J. Rex Parent of the increased risk of using the contaminated Brilliant Blue G, including but not limited to a risk of infections and the risk of endophthalmitis associated with the use of the non-sterile Brilliant Blue G.
- 28. The Brilliant Blue G manufactured, compounded, labeled, distributed, sold, marketed, and/or introduced into interstate commerce by the Defendants lacked proper warnings regarding possible non-sterile conditions, possible inclusion of organisms in the Brilliant Blue G itself, and possible endophthalmitis and other injuries.
- 29. The Brilliant Blue G manufactured, compounded, labeled, distributed, sold, marketed, and/or introduced into interstate commerce by the Defendants was in an unreasonably defective and dangerous condition when it left the Defendants' control and was represented as sterile.
- 30. As a direct and proximate result of the defective and unreasonably dangerous conditions of the Brilliant Blue G, Plaintiff, Bernice Tharp, suffered damages as described in paragraphs 10 through 20 and 58 through 61 in this Complaint for Damages.

COUNT IV NEGLIGENCE OF DEFENDANTS

- 31. Plaintiff incorporates herein by reference paragraphs 1 through 30 of this Complaint for Damages the same as if fully set forth.
- 32. Defendants owed a duty of reasonable care to Plaintiff to design, compound, manufacture, market, sell, and distribute the Brilliant Blue G in a condition that was safe for its intended purpose and consistent with the representation that it was sterile. Defendants were

careless and negligent in their testing, design, manufacturing, compounding, packaging, storing, labeling distributing, selling, marketing, advertising and/or introducing into interstate commerce of Brilliant Blue G.

- 33. Defendants had a duty to exercise reasonable care in the manufacturing, compounding, labeling distributing, selling, marketing, and/or introducing into interstate commerce of Brilliant Blue G, including a duty to assure that Brilliant Blue G did not cause users, including Bernice Tharp, to suffer from unreasonable and dangerous injuries from contamination such as endophthalmitis.
- 34. Defendants failed to exercise reasonable care and/or were reckless in the manufacturing, compounding, labeling, distributing, selling, marketing, and/or introducing into interstate commerce of Brilliant Blue G, in that Defendants knew or should have known that using Brilliant Blue G caused a risk of unreasonable and dangerous injuries from contamination, including endophthalmitis.
- 35. Defendants knew or should have known of the potential for contamination, nonsterile condition and unfit conditions that were present in the compounding facility where the Brilliant Blue G was compounded and failed to ensure that the Brilliant Blue G was compounded in a safe and sterile environment that was free from contamination and safe for its reasonably intended and foreseeable uses prior to sale and distribution.
- 36. Defendants knew or should have known they were violating provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331, by introducing a misbranded and adulterated drug into interstate commerce.

- 37. Defendants also had a duty to warn Bernice Tharp and Dr. J. Rex Parent of potential adverse drug reactions, including the development of endophthalmitis, when Brilliant Blue G was administered into a patient's eye.
- 38. Defendants failed to warn Bernice Tharp and Dr. J. Rex Parent of potential adverse drug reactions, including the development of endophthalmitis and including failing to give a timely and adequate warning that would have attracted the attention of Dr. J. Rex Parent when he administered the defective Brilliant Blue G to Bernice Tharp's right eye on or about November 8, 2011.
- 39. Defendants knew or should have known that consumers, including Bernice Tharp, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care and failure to warn, as set forth above.
- 40. As a direct and proximate result of the defective and unreasonably dangerous conditions of the Brilliant Blue G, Plaintiff, Bernice Tharp, suffered damages as described in paragraphs 10 through 20 and 58 through 61 in this Complaint for Damages.

COUNT V BREACH OF EXPRESS WARRANTY

- 41. Plaintiff incorporates herein by reference paragraphs 1 through 40 of this Complaint for Damages the same as if fully set forth.
- 42. Defendants expressly warranted and represented to physicians and consumers, including Bernice Tharp and Dr. J. Rex Parent, that Brilliant Blue G was safe for its intended use, was well tolerated and sterile.

- 43. The express warranties represented by Defendants were relied upon by Bernice Tharp and Dr. J. Rex Parent and were part of the basis for Dr. J. Rex Parent's administration of Brilliant Blue G into Bernice Tharp's eye.
- 44. The Brilliant Blue G did not conform to the express representations of the Defendants, because it was contaminated with adulterated substances and because it was defective and unreasonably dangerous and caused damage, including endophthalmitis, when administered to Bernice Tharp.
- 45. As a direct and proximate result of the defective and unreasonably dangerous conditions of the Brilliant Blue G, Plaintiff, Bernice Tharp, suffered damages as described in paragraphs 10 through 20 and 58 through 61 in this Complaint for Damages.

COUNT VI BREACH OF IMPLIED WARRANTY

- 46. Plaintiff incorporates herein by reference paragraphs 1 through 45 of this Complaint for Damages the same as if fully set forth.
- 47. At the time that Defendants marketed, sold and distributed Brilliant Blue G,
 Defendants knew of the use for which Brilliant Blue G was intended and impliedly warranted
 Brilliant Blue G to be of merchantable quality, safe and fit for the uses described herein and as
 represented by Defendants.
- 48. Defendants knew or had reason to know that consumers like Bernice Tharp and her physician, Dr. J Rex Parent, would rely on Defendant's judgment and skill in providing Brilliant Blue G for its intended use during surgery.
- 49. Bernice Tharp and Dr. J. Rex Parent relied on Defendants' judgment and skill as to whether Brilliant Blue G was of merchantable quality, safe and fit for intended use.

- 50. Contrary to such implied warranty, Brilliant Blue G was not of merchantable quality or safe or fit for its intended use, because the product was unreasonably dangerous, defective and unfit for the ordinary purpose for which Brilliant Blue G was used due to contaminated ingredients which cause harmful conditions as described herein.
- 51. As a direct and proximate result of the defective and unreasonably dangerous conditions of the Brilliant Blue G, Plaintiff, Bernice Tharp, suffered damages as described in paragraphs 10 through 20 and 58 through 61 in this Complaint for Damages.

<u>COUNT VII</u> FRAUDULENT MISREPRESENTATION

- 52. Plaintiff incorporates herein by reference Paragraphs 1 through 51 of this Complaint for Damages the same as if fully set forth.
- 53. Prior to and at the time Defendants placed the Brilliant Blue G into the stream of commerce, Defendants made false statements of past and existing material facts concerning the quality, reliability, purity, and safety of the Brilliant Blue G with knowledge and/or reckless lack of knowledge of the falsity of those misrepresentations.
- 54. At the times these misrepresentations were made, Defendants knew or should have known that these statements were false and misleading.
- 55. The Defendants made these statements to induce consumers, including Bernice
 Tharp and Dr. J. Rex Parent, to act upon the statement and purchase Brilliant Blue G based upon
 their statements regarding its quality, reliability, purity, and safety.
- 56. Bernice Tharp and Dr. J. Rex Parent relied upon the Defendants' statements and acted upon the statements by administering Brilliant Blue G into Bernice Tharp's eye.

57. As a direct and proximate result of the fraudulent misrepresentations by the Defendants alleged in this Count, Bernice Tharp suffered injuries and damages which are set forth in paragraphs 10 through 20 and 58 through 61 of this Complaint for Damages.

<u>COUNT VIII</u> DAMAGES SUFFERED BY BERNICE THARP

- 58. Plaintiff incorporates herein by reference paragraphs 1 through 57 of this Complaint for Damages the same as if fully set forth.
- 59. As a direct and proximate result of the negligence of the Defendants, Plaintiff
 Bernice Tharp required seven subsequent surgeries and is now legally blind in her right eye. Her
 severe vision loss has impaired her ability to perform her activities of daily living.
- 60. As a direct and proximate result of the negligence of the Defendants, Bernice
 Tharp, in order to treat her injuries and lessen her physical pain and mental anguish, has
 undergone medical treatment and incurred medical expenses. As a result of the negligence of the
 Defendants, Bernice Tharp may also require further medical services in the future.
- 61. As a direct and proximate result of the negligence of the Defendants, Bernice Tharp experienced severe mental and emotional distress, mental anguish, physical pain and suffering, disability, loss of use/function of her body, and loss of enjoyment of life.

COUNT IX PUNITIVE DAMAGES

- 62. Plaintiff incorporates herein by reference paragraphs 1 through 61 of this Complaint for Damages the same as if fully set forth.
- 63. Defendants acted with malice, fraud, gross negligence, recklessness, willful and wanton misconduct, and/or oppressiveness which was not a result of mistake of fact or law,

honest error of judgment, overzealousness, mere negligence, or other human failing, and, therefore, it is in the public's interest that punitive damages be assessed as a result of the Defendants' conduct.

WHEREFORE, Plaintiff, Bernice Tharp, prays for judgment against Defendants, Franck's Lab, Individually and d/b/a Franck's Compounding Lab and/or Franck's Pharmacy, Inc., Wells Pharmacy Network, L.L.C., Paul W. Franck, R.Ph., and Anthony James Campbell, R.Ph., in an amount commensurate with the damages sustained by Bernice Tharp, for punitive damages, for prejudgment interest, for the cost of this action, and for all other just and proper relief.

Respectfully submitted,

CLINE FARRELL CHRISTIE & LEE, P.C.

Kathy A. Lee (Attorney No. 11608-49)

951 North Delaware Street

Indianapolis, IN 46202

Telephone: (317) 488-5500 Facsimile: (317) 488-5510 E-mail: kathy@cfcl-law.com

L-man. Kamy@cici-law

Attorney for Plaintiff

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

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