IN THE CIRCUIT COURT FOR THE SEVENTEENTH JUDICIAL CIRCUIT
IN AND FOR BROWARD COUNTY, FLORIDA
CIVIL DIVISION

ANDERSON MORENO,
a minor, by and through his natural guardians,
ALICIA MORENO and ANDREW MORENO;

Plaintiff,

v.

PHARMATECH, LLC; THE HARVARD DRUG GROUP, L.L.C., individually and d/b/a RUGBY LABORATORIES; and CARDINAL HEALTH, INC.;

Defendants.

Case No.:

Division:

COMPLAINT

Plaintiff, by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants, and alleges as follows:

INTRODUCTION

1. This is an action for damages relating to Defendants' design, manufacture, sale, marketing, advertising, promotion, and distribution of Diocto Liquid (Docusate Sodium) (the "Product") contaminated with *Burkholderia Cepacia*, a rare complex of bacteria. This contamination rendered the Product defective.

2. The defective Product was manufactured for profit and placed into the stream of commerce for sale to the public.

3. The use of Diocto Liquid contaminated with *Burkholderia Cepacia* can result in serious, life-threatening injuries.

4. Plaintiff ingested Diocto Liquid contaminated with *Burkholderia Cepacia*, and as a result suffered injuries.

JURISDICTION AND VENUE

5. This is an individual action brought for damages in excess of $15,000.00, exclusive of interest, costs, and attorneys' fees.

6. This Court has jurisdiction over this action because a substantial part of the events giving rise to this claim arose in Broward County, Florida.

7. Additionally, this Court has jurisdiction over this action because Defendant, PharmaTech LLC is a Florida Limited Liability Company with its principal place of business in Broward County, Florida.

8. Additionally, this Court has jurisdiction over the Defendants because they have conducted business in the State of Florida, have committed a tort in whole or in part in the State of Florida, have substantial and continuing contact with the State of Florida, and derive substantial revenue from goods used and consumed within the State of Florida. The Defendants actively manufacture, sell, market and promote the pharmaceutical product Diocto Liquid to physicians and consumers in this state on a regular and consistent basis.

PARTY PLAINTIFF

9. At all times relevant to this action, Plaintiff, Anderson Moreno, was a minor citizen and resident of the State of Michigan. The minor Plaintiff is represented in this action by his parents, Alicia Moreno and Andrew Moreno, his natural guardians.

10. At all times relevant to this action, Plaintiff, Alicia Moreno, was the mother of Anderson Moreno and a resident of the State of Michigan.

11. At all times relevant to this action, Plaintiff, Andrew Moreno, was the father of Anderson Moreno and a resident of the State of Michigan.

12. Upon information and belief, Plaintiff was administered Diocto Liquid contaminated with *Burkholderia Cepacia* in the State of Michigan on or around May of 2016 upon direction of Plaintiff's physician.

13. As a direct and proximate result of the use of Defendants' Diocto Liquid contaminated with *Burkholderia Cepacia,* Plaintiff suffered serious and dangerous life-threatening injuries including illness, infection, a weakened heart requiring a left ventricular assist device, delayed heart transplant, permanent renal damage, physical pain and mental anguish, diminished enjoyment of life, as well as other severe and personal injuries which are permanent and lasting in nature. In addition, Plaintiff has suffered and incurred damages including expenses for hospitalization and medical treatment, and other economic and non-economic damages. All of Plaintiff's losses are either permanent or continuing in nature, and Plaintiff will suffer the losses in the future.

PARTY DEFENDANTS

14. Defendant, PharmaTech LLC is a Florida Limited Liability Company with a principal place of business at 4131 SW 47th Avenue, Suite #1403, Davie, FL 33314.

15. As part of its business, PharmaTech LLC designs, manufactures, tests, advertises, promotes, markets, sells, and/or distributes Diocto Liquid, including at all times relevant hereto.

16. At all relevant times, PharmaTech LLC has transacted and conducted business in the State of Florida.

17. PharmaTech LLC has derived substantial revenue from goods and products used in the State of Florida.

18. The Harvard Drug Group, L.L.C. is a Michigan Limited Liability Company registered to do business in the State of Florida with a principal place of business at 31778 Enterprise Drive, Lovinia, MI 48150.

19. As part of its business, The Harvard Drug Group, LLC designs, manufactures, tests, advertises, promotes, markets, sells, and/or distributes Diocto Liquid, including at all times relevant hereto.

20. At all relevant times, The Harvard Drug Group, L.L.C. has transacted and conducted business in the State of Florida.

21. The Harvard Drug Group, L.L.C. has derived substantial revenue from goods and products used in the State of Florida.

22. Rugby Laboratories is a fictitious name for The Harvard Drug Group, L.L.C. registered with the Michigan Department of Licensing and Regulatory Affairs.

23. The Harvard Drug Group, L.L.C. is a subsidiary of Cardinal Health, Inc.

24. Cardinal Health, Inc. is an Ohio Corporation with a principal place of business at 7000 Cardinal Place, Dublin, OH 43017.

25. As part of its business, Cardinal Health, Inc. designs, manufactures, tests, advertises, promotes, markets, sells, and/or distributes Diocto Liquid, including at all times relevant hereto.

26. At all relevant times, Cardinal Health, Inc. has transacted and conducted business in the State of Florida.

27. Cardinal Health, Inc. has derived substantial revenue from goods and products used in the State of Florida.

FACTUAL BACKGROUND

28. Diocto Liquid is an over-the-counter stool softener laxative designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed by Defendants.

29. The active ingredient in Diocto Liquid is Docusate Sodium.

30. Defendants misrepresented the Product's safety and efficacy by, *inter alia*, failing to warn that Product was contaminated with *Burkholderia Cepacia*.

31. In June of 2016, the Centers for Disease Control and Prevention ("CDC") reported that it was investigating in collaboration with the US Food and Drug Administration ("FDA") a multistate outbreak of *Burkholderia Cepacia* infections.

32. Between July 5, 2016 and August 9, 2016 the US Food and Drug Administration, Department of Health and Human Services, conducted inspections of PharmaTech LLC where Diocto Liquid is manufactured, and made several observations, as follows:

a. Observation 1: Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established and followed;

b. Observation 2: Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use;

c. Observation 3: Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product;

d. Observation 4: Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing;

e. Observation 5: Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity;

f. Observation 6: The suitability of all testing methods is not verified under actual conditions of use;

g. Observation 7: There is no written testing program designed to assess the stability characteristics of drug products; and

h. Observation 8: A qualified person did not investigate a product complaint that involved a possible failure of a dietary supplement to meet a specification, or other requirement.

33. Samples of Diocto Liquid Lots 20351511, 20351513, and 20351601 tested by the FDA during the July 5, 2016 – August 9, 2016 inspections were positive for *Burkholderia Cepacia*. These lots were manufactured during 2015-2016.

34. A water sample collected by the FDA from PharmaTech LLC's reverse osmosis purified water system, located above a point of use, during the July 5, 2016 – August 9, 2016 inspections tested positive for *Burkholderia Cepacia*.

35. On July 16, 2016, the FDA announced PharmaTech LLC's nationwide recall of all non-expired Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories, and confirmed that Diocto Liquid was contaminated with *Burkholderia Cepacia*, a bacteria linked to an outbreak in five states.

36. On August 9, 2016 the FDA announced that PharmaTech LLC's voluntary recall was being expanded to include all liquid products manufactured by PharmaTech LLC due to possible *Burkholderia Cepacia* contamination.

37. On October 10, 2016 the FDA and CDC announced a direct link between contaminated water at PharmaTech LLC and the multistate *Burkholderia Cepacia* outbreak. The FDA investigation found *Burkholderia Cepacia* in more than ten (10) lots of oral liquid docusate sodium manufactured by PharmaTech LLC, as well as in the water system used to manufacture Diocto Liquid.

38. As of October 12, 2016, the CDC has confirmed sixty (60) cases of *Burkholderia Cepacia* infection in eight states.

39. Plaintiff was administered Diocto Liquid, NDC 0536-0590-85, as the manufacturer intended, for its intended use and in accordance with its label.

40. The Diocto Liquid administered to Plaintiff was contaminated with *Burkholderia Cepacia* and was one of the recalled lots manufactured and distributed by Defendants.

41. Plaintiff's use of the Product was reasonable and foreseeable to the Defendants.

42. The Defendants knew or should have known about the defects in the Product described herein.

43. The defects in the Product existed at the time Defendants parted with the Product.

44. The Product was expected to and did reach the usual consumers, handlers, and persons coming into contact with the Product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.

45. Neither Plaintiff nor Plaintiff's physicians knew at the time Product was ingested by Plaintiff of the existence of the dangers or defects, nor could they have discovered these dangers and defects through the exercise of reasonable care.

46. As a direct and proximate result of the use of Defendants' Diocto Liquid contaminated with *Burkholderia Cepacia,* Plaintiff suffered serious and dangerous life-threatening injuries including illness, infection, a weakened heart requiring a left ventricular assist device, delayed heart transplant, permanent renal damage, physical pain and mental anguish, diminished enjoyment of life, as well as other severe and personal injuries which are permanent and lasting in nature. In addition, Plaintiff has suffered and incurred damages including expenses for hospitalization and medical treatment, and other economic and non-economic damages. All of Plaintiff's losses are either permanent or continuing in nature, and Plaintiff will suffer the losses in the future.

COUNT I
NEGLIGENCE

47. Plaintiff incorporates by reference Paragraphs 1 through 46 previously alleged as though fully set forth herein.

48. At all times material hereto, Defendants had a duty to Plaintiff to exercise reasonable care in designing, manufacturing, testing, advertising, promoting, marketing, selling, and/or distributing Diocto Liquid into the stream of commerce, including a duty

to ensure that the Product would not cause users to suffer unreasonable, dangerous side effects including significantly increased risk of infection.

49. Defendants' negligence includes, but is not limited to, the following:

a. Failing to properly monitor the quality of water used to manufacture the Product so as to prevent contamination by objectionable microorganisms;

b. Failing to ensure that the water used to manufacture the Product was free of objectionable organisms like *Burkholderia Cepacia*;

c. Failing to establish and/or follow policies, procedures and/or standards in the manufacture of the Product designed to prevent objectionable microorganisms in drug products not required to be sterile.

d. Failing to design, manufacture, test, validate, label, market and/or distribute a safe and effective Product in that the Product was contaminated with *Burkholderia Cepacia*, which Defendants knew or should have known posed an unreasonable risk of injury or death to end users, including Plaintiff;

e. Failing to properly test, validate and/or investigate the quality and safety of the Product prior to marketing and sale of same to make sure it was not contaminated with *Burkholderia Cepacia*;

f. Failing to protect Plaintiff from known and/or knowable risks associated with the Product in its adulterated form;

g. Failing to properly design, implement and enforce sufficient post manufacture or post-market monitoring of the Product so as to prevent the Product, in its adulterated form, from reaching end users, like Plaintiff;

h. Failing to stay informed of and up to date with the existing scientific literature related to the safe and proper design, manufacture, testing, validation, labeling, marketing and/or distribution of the Product;

i. Failing to appropriately investigate customer reports and complaints of contaminants in Product prior to Product reaching end users, including Plaintiff, in its adulterated form;

j. Failing to take any meaningful steps to determine the root cause of Defendants' own findings of microbial contamination in Product;

k. Failing to timely act when Defendant knew or should have known that Product had been distributed to end users in an adulterated form;

l. Failing to disclose important material facts related and/or pertaining to the safety of Product to Plaintiff and/or Plaintiff's medical providers and physicians;

m. Failing to disclose that Product was not safe for use as designed and/or intended when Defendants knew or should have known thereof;

n. Defendants failed to disclose that the reprocessing instructions for the Product were inadequate;

o. Failing to disclose or warn that Product was not safe for use on patients with chronic pulmonary disease or compromised immune systems;

p. Any other instances of negligence to be determined through the discovery process; and

q. Any other instances of negligence under the common law and/or applicable statutes, codes and/or regulations.

50. In addition to the above, Defendants breached their duty to Plaintiff by negligently designing, manufacturing, testing, advertising, promoting, marketing, selling, and/or distributing Diocto Liquid, allowing the Product to become contaminated with *Burkholderia Cepacia*, and selling and/or distributing the contaminated Product for individual use.

51. At all relevant times, Defendants knew or should have known that Product was defective and dangerous, and was to be used by Plaintiff and Plaintiff's physicians without further inspection for defects.

52. Despite the Product's defective and dangerous nature, Defendants continued to design, manufacture, test, advertise, promote, market, sell, and/or distribute Diocto Liquid.

53. In so doing, the Defendants failed to act as a reasonable manufacturer, seller, and/or distributer of Product in conscious disregard of the foreseeable harm to and rights and safety of consumers like Plaintiff.

54. As a direct and proximate result of Defendants' negligence as alleged herein, Plaintiff has been damaged and suffered serious and dangerous life-threatening injuries including illness, infection, a weakened heart requiring a left ventricular assist device, delayed heart transplant, permanent renal damage, physical pain and mental anguish, diminished enjoyment of life, as well as other severe and personal injuries which are permanent and lasting in nature. In addition, Plaintiff has suffered and incurred damages including expenses for hospitalization and medical treatment, and other economic and non-economic damages. All of Plaintiff's losses are either permanent or continuing in nature, and Plaintiff will suffer the losses in the future.

COUNT II
STRICT PRODUCTS LIABILITY

55. Plaintiff incorporates by reference Paragraphs 1 through 46 previously alleged as though fully set forth herein.

56. Defendants marketed, advertised, labeled and/or otherwise made public misrepresentation(s) of material fact related and/or pertaining to the safety and/or efficacy of the Product.

57. Plaintiff and Plaintiff's physicians justifiably relied upon the above detailed misrepresentations when purchasing and using Defendants' Product.

58. A defect existed in Defendants' Product at the time Defendants parted possession with the Product. Specifically, the Product was contaminated with *Burkholderia Cepacia* and the Product's foreseeable risks outweighed its benefits.

59. At all relevant times, the Product was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

60. Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Diocto Liquid which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

61. Plaintiff and Plaintiff's physicians could not, by the exercise of reasonable care, have discovered the Product's defects herein mentioned and perceived its danger.

62. As a direct and proximate result of Defendants' defect as alleged herein, Plaintiff has been damaged and suffered serious and dangerous life-threatening injuries including illness, infection, a weakened heart requiring a left ventricular assist device, delayed heart transplant, permanent renal damage, physical pain and mental anguish, diminished enjoyment of life, as well as other severe and personal injuries which are permanent and lasting in nature. In addition, Plaintiff has suffered and incurred damages including expenses for hospitalization and medical treatment, and other economic and non-economic damages. All of Plaintiff's losses are either permanent or continuing in nature, and Plaintiff will suffer the losses in the future.

COUNT III
BREACH OF WARRANTY

63. Plaintiff incorporates by reference Paragraphs 1 through 46 previously alleged as though fully set forth herein.

64. At the time Defendants manufactured, marketed, sold, and distributed Product for use by Plaintiff, Defendants knew of the use for which Product was intended and impliedly warranted the product to be of merchantable quality and safe and reasonably fit for such use.

65. Defendants expressly and impliedly represented and warranted to the users of Product and their physicians, healthcare providers, and/or the FDA that Product was safe and of merchantable quality and reasonably fit for the ordinary purpose for which said product was to be used.

66. These representations and warranties were false, misleading, and inaccurate in that Product was contaminated with *Burkholderia Cepacia* and contained *Burkholderia Cepacia* while being used for its intended purpose, causing injuries to Plaintiff who was a user of the Product.

67. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Product was of merchantable quality and safe and fit for its intended use.

68. Product was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and Product was expected to and did reach users, handlers, and persons coming into contact with Product without substantial change in the condition in which it was sold.

69. As a result of the aforementioned acts and omissions, Defendants breached their warranties.

70. As a direct and proximate result of Defendants' breaches as alleged herein, Plaintiff has been damaged and suffered serious and dangerous life-threatening injuries including illness, infection, a weakened heart requiring a left ventricular assist device, delayed heart transplant, permanent renal damage, physical pain and mental anguish, diminished enjoyment of life, as well as other severe and personal injuries which are permanent and lasting in nature. In addition, Plaintiff has suffered and incurred damages including expenses for hospitalization and medical treatment, and other economic and non-economic damages. All of Plaintiff's losses are either permanent or continuing in nature, and Plaintiff will suffer the losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and causes of action and as follows:

1) Awarding past and future compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2) Awarding past and future economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determine at trial of this action;

3) Prejudgment interest;

4) Post judgment interest;

5) Awarding Plaintiff the costs of these proceedings; and

6) Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues triable by jury.

Dated: September 29, 2017

Respectfully submitted,

/s/ Michael Goetz
Michael Goetz, Esq.
Florida Bar Number 0963984
Joseph T. Waechter, Esq.
Florida Bar Number 0092593
Morgan & Morgan
Complex Litigation Group
201 N. Franklin St., Suite 700
Tampa, FL 33602
MGoetz@forthepeople.com
JWaechter@forthepeople.com
Phone: (813) 223-5505
Fax: (813) 222-4730

The Weinberg Law Firm
Eric H. Weinberg, Esq.
New Jersey Bar Number 001801981
(Pro Hac Pending)
Alan J. Weinberg, Esq.
New Jersey Bar Number 124822015
(Pro Hac Pending)
149 Livingston Ave.
New Brunswick, NJ 08901
ehw@erichweinberg.com
ajw@erichweinberg.com
Phone: (732) 246-7080
Fax: (732) 246-1981

Michael B. Serling, P.C.
Denise J. Grass, Esq.
Florida Bar Number 86934
Eric B. Abramson
Michigan Bar Number P60949
(Pro Hac Pending)
280 N. OId Woodward, Suite 406
Birmingham, MI. 48009
denise.grass@gmail.com
eabramson@serlinglaw.com
Phone: (248) 647-6966
Fax: (248) 647-9630

Attorneys for Plaintiff