

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

MARY LITTLE and)
WILLIE LITTLE,)
)
Plaintiffs)
)
v.)
)
C.B. FLEET COMPANY, INC., and)
fictitious Defendants A, B, C & D,)
being those persons, firms or)
Corporations whose negligence,)
wantonness, fraud, and/or other)
wrongful conduct caused or)
contributed to the Plaintiffs' injuries)
and damages, and whose true names)
and identities are presently unknown)
to Plaintiff, but will be substituted by)
amendment when ascertained,)
)
Defendants.)

CIVIL ACTION NO.:

**COMPLAINT
Parties**

1. Plaintiff, Mary Little, is a resident of Newton County, State of Georgia, and is over the age of 18 years.
2. Plaintiff, Willie Little, is a resident of Newton County, State of Georgia, and is over the age of 18 years.
3. Defendant, C.B. Fleet Company, Inc., is a Virginia corporation whose principal place of business is located in Lynchburg, Virginia. C.B. Fleet Company, Inc., is owned by C.B. Fleet Holding Company, Inc., which is also a Virginia

corporation with its principal place of business located in Lynchburg, Virginia. C.B. Fleet Company, Inc., can be served at its principal place of business, 4615 Murray Place, Lynchburg, Virginia 24506.

4. Fictitious Defendants A, B, C & D, are other legal persons (including retailers, pharmacies, sales representatives and manufacturers) who manufactured, labeled, advertised, marketed, promoted, sold and/or distributed Fleet Phospho-soda in Georgia, or who detailed, discussed with, or provided materials to physicians and healthcare providers in the State of Georgia.

5. Defendant Fleet and Fictitious Defendants A, B, C, & D are hereinafter collectively referred to as “Defendants.”

Factual Allegations

6. This is a civil action seeking damages for the severe personal injuries suffered by plaintiff Mary Little as a direct and proximate result of ingesting Defendants’ over-the-counter product known as Fleet Phospho-soda.

7. At all times relevant hereto, Defendants manufactured, created, designed, tested, labeled, packaged, supplied, marketed, sold, advertised, and/or otherwise distributed in interstate commerce, including within the State of Georgia, an over-the-counter (OTC) product known as Fleet Phospho-soda (also referred herein as “Phospho-soda” or the “Product”) which contained the ingredient sodium phosphate. Defendants promoted, distributed, and/or sold Phospho-soda as a “laxative, for the relief of occasional constipation” and “purgative, for use as part

of a bowel cleansing regimen in preparing for surgery, x-ray, or endoscopic examination.”

8. On or about October 29, 2007, Mary Little, in preparation for a colonoscopy, orally ingested the Phospho-soda without knowledge of the significant health risk it created to consumers, including the risk of permanent kidney damage and renal failure. After using Phospho-soda, Mary Little began to have complications, including, but not limited to, acute renal failure which has caused her to suffer permanent and irreversible kidney damage.

9. As a direct and proximate result of orally ingesting Fleet Phospho-soda and the acts and omissions of Defendants, Mary Little has suffered permanent and devastating injuries, including kidney damage and chronic renal failure. These injuries have caused, and will continue in the future to cause, extensive pain and suffering, emotional distress, and a reduction in her ability to enjoy life.

10. As a result of the injuries caused by the Fleet Phospho-soda, Mary and Willie Little have incurred substantial medical related expenses and will continue to incur substantial medical expenses for the treatment of Mary’s damaged kidneys for their rest of their life.

11. As a direct and proximate result, Willie Little has suffered, and will continue to suffer, the loss of the usual services, society and consortium of his wife, Mary Little.

12. Upon information and belief, prior to the date of Mary Little's injury, Defendants had actual notice of a serious risk of bodily injury and harm to foreseeable users of the Product, including the risk of hyperphosphatemia and nephrocalcinosis and acute, transient, and/or chronic renal failure.

13. Upon information and belief, Defendants warranted the safety of Fleet Phospho-soda to consumers such as Mary Little, who did not know about the serious risk of bodily injury, including the risk of hyperphosphatemia and nephrocalcinosis and acute, transient, and/or chronic renal failure and who would not have used Fleet Phospho-soda had they been properly warned about such dangers.

14. Upon information and belief, Defendants, despite the knowledge of their agents and/or assigns of the dangers associated with the use of Fleet Phospho-soda, failed to timely or adequately warn the public about the risk of renal failure from the use of Fleet Phospho-soda, in violation of established federal regulations, including but not limited to, 21 C.F.R. § 330.10 ("Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs"), which under subpart (a)(4)(v), states as follows:

Labeling shall be clear and truthful in all respects and may not be false and misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.

15. Indeed, no warning at all appeared on the labeling of Fleet Phospho-soda about the risk of renal failure. Upon information and belief, Defendants violated 21 C.F.R. § 369.10 ("Conspicuousness of warning statements"), which states:

Necessary warning statements should appear in the labeling prominently and conspicuously as compared to other words, statements, designs, and devices, and in bold type on clearly contrasting background, in order to comply with the provisions of 502 (c) and (f)(2) of the act. The warning statements should be placed in the labeling in juxtaposition with the directions for use and, in any case, should appear on the label when there is sufficient label space in addition to mandatory label information.

Jurisdiction and Venue

16. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332, in that it is a civil action in which complete diversity of citizenship exists between the Plaintiffs and the Defendants and the amount in controversy exceeds, exclusive of interest and costs, the sum of seventy-five thousand dollars (\$75,000.00).

17. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 (a & c) because the events giving rise to the claims occurred within Newton County, Georgia, which is within the District and because Defendants conduct business within the District.

COUNT I
Strict Liability

18. Plaintiffs incorporate paragraphs 1 through 17 of the Complaint as if set out here in full.

19. Defendant Fleet is strictly liable to Plaintiffs, pursuant to O.C.G.A. § 51-1-11, as follows:

- a. Defendant manufactured the Fleet Phospho-soda that was purchased and used by Mary Little;
- b. Mary Little, used and consumed the Fleet Phospho-soda as directed;
- c. the Fleet Phospho-soda was not merchantable or reasonably suited to the use intended, was unreasonably dangerous, was defective, and did not function or work as intended; and
- d. the Fleet Phospho-soda as sold to or used by Mary Little, was the direct and proximate cause of her chronic renal failure, kidney damage, and other injuries and damages alleged herein.

20. As a direct and proximate result of Defendants' actions or inactions, Mary Little has suffered severe kidney damage causing chronic renal failure, has caused her and will continue to cause her to incur substantial medical costs, has caused her to suffer great pain and mental anguish, and has substantially reduced her life expectancy.

WHEREFORE, Plaintiffs demand compensatory and punitive damages against Defendants in an amount within the jurisdiction of this Court, plus costs.

COUNT II
Negligence

21. Plaintiffs incorporate paragraphs 1 through 20 of the Complaint as if set out here in full.

22. At all relevant times, Defendants had a duty to exercise reasonable care in all aspects of the testing, labeling, marketing, sale, and provision of adequate warnings regarding the use of the Fleet Phospho-soda to insure its safety and to insure that the consuming public, including Mary Little, obtained accurate information and instructions for the safe use of Fleet Phospho-soda.

23. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Fleet Phospho-soda interstate, and Defendants knew or should have known that these products created a high risk of unreasonable, dangerous side effects.

24. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing, and/or sale of Fleet Phospho-soda in the following particulars:

- a. Failing to use due care in the design and manufacture of Fleet Phospho-soda so as to avoid risks to consumers when the Product was taken as intended;
- b. Failing to accompany Fleet Phospho-soda with proper warnings regarding all possible side effects associated with the use of the Product, the comparative severity and duration of such adverse effects, and an accurate reflection of the symptoms, scope, and severity of the side effects;

- c. Failing to provide adequate information to the medical care providers as to the appropriate use of Fleet Phospho-soda;
- d. Failing to warn consumers prior to actively encouraging the sale of the Product orally or in writing about (1) the possibility of renal failure; (2) the possibility of becoming disabled as a result of using the Product; (3) that such side effects may result in chronic renal failure; and (4) that such side effects might result in debilitating, difficult, and painful rehabilitation and a lifetime dependence upon dialysis; and
- e. Failing to adequately test or warn about the possible side effects caused by the use of Fleet Phospho-soda.

25. Upon information and belief, Defendants continued to market Fleet Phospho-soda despite the fact that Defendants knew or should have known that Fleet Phospho-soda caused unreasonable, dangerous side effects, from which many users would be at risk of developing permanent and debilitating injuries.

26. Defendants knew or should have known that consumers, such as Mary Little, would foreseeably suffer severe injury as a result of Defendants' failure to exercise ordinary care as described above.

27. As a direct and proximate result of Defendants' actions or inactions, Mary Little has suffered severe kidney damage causing chronic renal failure, has caused her and will continue to cause her to incur substantial medical costs, has caused her to suffer great pain and mental anguish, and has substantially reduced her life expectancy.

WHEREFORE, Plaintiffs demand compensatory and punitive damages against Defendants in an amount within the jurisdiction of this Court, plus costs.

COUNT III
Breach of Warranty of Merchantability

28. Plaintiffs incorporate paragraphs 1 through 27 of the Complaint as if set out here in full.

29. When Defendants placed Fleet Phospho-soda into the stream of commerce, they knew that the Product would be used as a purgative to cleanse bowels in preparation for surgical procedures, x-rays, and endoscopic exams and impliedly warranted to consumers, including Mary Little, that the use of Fleet Phospho-soda in such a manner was safe and acceptable.

30. Mary Little reasonably relied upon the expertise, skill, judgment, and knowledge of Defendants and upon the implied warranty that Fleet Phospho-soda was of merchantable quality and fit for use as a safe and effective purgative to be used as part of a presurgery bowel cleansing regimen.

31. In fact, Fleet Phospho-soda was not of merchantable quality and was not safe or fit for its intended use because it was unreasonably dangerous and unfit for the ordinary purposes for which it was used (as a purgative), and it caused Mary Little to suffer severe personal injuries and related damages.

32. As a direct and proximate result of the actions and conduct of Defendants as set forth above, Mary Little suffered severe kidney damage causing chronic renal failure, has caused her and will continue to cause her to incur substantial medical costs, has caused her to suffer great pain and mental anguish, and has substantially reduced her life expectancy.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in an amount within the jurisdiction of this Court, plus costs.

COUNT IV
Breach of Express Warranty

33. Plaintiffs incorporate paragraphs 1 through 32 of the Complaint as if set out here in full.

34. At all relative times, Defendants expressly warranted to consumers, including Mary Little, that Fleet Phospho-soda was safe, effective, fit, and proper for its intended use.

35. Defendants expressly warranted Fleet Phospho-soda in such a way as to induce its purchase and use, thereby making an express warranty that it would conform to Defendants' representations.

36. Fleet Phospho-soda did not conform to the express representations made by Defendants in that it was defective, dangerous, not merchantable, and not safe for its intended, ordinary, and foreseeable use and purpose by consumers, including Mary Little.

37. In using Fleet Phospho-soda, Mary Little relied on the skill, judgment, representations, and foregoing express warranties of Defendants. Said warranties and representations were false in that Fleet Phospho-soda was not safe and posed serious side effects, as described above.

38. In breaching this express warranty, Defendants directly and proximately caused or contributed to cause Mary Little to suffer severe kidney

damage resulting in chronic renal failure which has left her permanently dependant upon dialysis, has caused her and will continue to cause her to incur substantial medical costs, has caused her to suffer great pain and mental anguish, and has substantially reduced her life expectancy.

WHEREFORE, Plaintiffs demands compensatory damages against Defendants in an amount within the jurisdiction of this Court, plus costs.

COUNT V
Fraud

39. Plaintiffs incorporate paragraphs 1 through 38 of the Complaint as if set out here in full.

40. Defendants represented to Mary Little that Fleet Phospho-soda could be safely used as a bowel cleanser.

41. Defendants' representations and omissions as alleged above were knowingly and recklessly false and made with the intent to induce Mary Little into using Fleet Phospho-soda.

42. Mary Little believed in and justifiably relied upon said misrepresentations and omissions and was thereby induced into using Fleet Phospho-soda.

43. As a direct and proximate result of Defendants' misrepresentations, Plaintiffs have suffered severe personal injuries and related damages, as described above.

WHEREFORE, Plaintiffs demand compensatory and/or punitive damages against Defendants in an amount within the jurisdiction of this Court, plus costs.

COUNT VI
Fraudulent Suppression

44. Plaintiffs incorporate paragraphs 1 through 43 of the Complaint as if set out here in full.

45. Before Mary Little first used Fleet Phospho-soda, Defendants fraudulently suppressed material information and omitted material facts, as previously set forth herein, to Mary Little, her physicians, and the general public including, but not limited to, the fraudulent suppression of the fact that ingestion of Fleet Phospho-soda causes severe, permanent, and disabling kidney damage. Defendants omitted material facts from its warnings, including the harmful side effects mentioned above in order to induce consumers, including Mary Little, to purchase and/or use this OTC drug.

46. As a proximate result of said fraud and deceit, Mary Little was induced to purchase and use Fleet Phospho-soda. If Mary Little had known of the true facts concealed by Defendant, she would not have used Fleet Phospho-soda as a pre-operative bowel cleanser. The reliance of Mary Little upon Defendants' fraud and deceit was justified because the omissions were conducted by individuals and entities who were in a position to know the true facts and had a duty to disclose the dangers of Fleet Phospho-soda.

47. At the time Defendants concealed the fact that Fleet Phospho-soda was not safe, Defendants were under a duty to accurately communicate this information to Mary Little, her physicians, and other consumers and physicians. Defendants had a duty to disclose said material facts because they were in a superior position to know about this safety information and because the information had a direct impact on the health and safety of Fleet Phospho-soda users like Mary Little.

48. As a direct and proximate result of Defendants' malicious and/or intentional conduct, Defendants caused or contributed to cause Plaintiffs to suffer severe personal injuries and related damages, as described above.

WHEREFORE, Plaintiffs demand compensatory and punitive damages against Defendants in an amount within the jurisdiction of this Court, plus costs.

COUNT VII
Loss of Consortium

49. Plaintiffs incorporate paragraphs 1 through 48 of the Complaint as if set out here in full.

50. Plaintiff, Willie Little, is the lawful spouse of Mary Little and makes a claim for loss of consortium, past, present and future. As a result of the injuries sustained to Mary Little, as alleged above, Willie Little, has suffered, and will continue to suffer, the loss of the usual services, society and consortium of his wife, Mary Little.

WHEREFORE, Plaintiffs demands judgment against Defendants for an amount to compensate them for all injuries and damages complained of herein, punitive damages, fees, costs, and all other elements of compensable damages.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Date: October 26, 2009

Respectfully submitted,

RUSSELL TODD ABNEY

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