FELDMAN SHEPHERD WOHLGELERNTER TANNER WEINSTOCK & DODIG, LLP
By: Mark W. Tanner
Identification No.: 58738
1845 Walnut Street, 21st Floor
Philadelphia, PA 19103
(215) 567-8300

Attorneys for Plaintiffs

SAMUEL WONIEWALA
5542 Pentridge Street
Philadelphia, PA 19143
Plaintiff,

v.

MERCK & CO., INC.,
One Merck Drive
Whitehouse Station, NJ 08889-0100
and
SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.
Three Connell Drive
Berkeley Heights, NJ 07922
and
BRAINTREE LABORATORIES, INC.
60 Columbian Street West
PO Box 850929
Braintree, MA 02185-0929
and
BAYER CORPORATION
100 Bayer Road
Pittsburgh, PA 15205-9741
Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

APRIL TERM, 2015

NO.

JURY TRIAL DEMANDED

Complaint

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
One Reading Center
Philadelphia, Pennsylvania 19107
Telephone: 215-238-6333 TTY: 215-451-6197

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguien-tes, usted tiene viente (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparesencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decidir a favor del demandanre y requiere que usted cumpla con todas las provisiones de esta demande. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.
LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFFICIENTE DE PAGAR RAL SERVCIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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Filadelfia, Pennsylvania 19107
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I. The Parties

1. Plaintiff, Samuel Woniewala, is an adult individual and a citizen of the Commonwealth of Pennsylvania, residing therein at 5542 Pentridge Street, Philadelphia, PA 19143.

2. Defendant, Merck & Co., Inc., is a corporation formed under the laws of New Jersey, with a principal place of business in New Jersey, located at One Merck Drive, Whitehouse Station, NJ 08889-0100.

3. Defendant Schering-Plough Healthcare Products, Inc. is a corporation organized under the laws of New Jersey with a principal place of business therein at Three Connell Drive, Berkeley Heights, NJ 07922.

4. Defendant Braintree Laboratories, Inc., is a Massachusetts corporation with a principal place of business located therein at 60 Columbian Street West, PO Box 850929, Braintree, MA 02185-0929.

5. Defendant Bayer Corporation is an Indiana corporation with a principal place of business in Pennsylvania, located therein at 100 Bayer Road, Pittsburgh, PA 15205-9741.

6. The defendants, jointly and severally, worked over many years to manufacture, market and sell an over-the-counter laxative known as MiraLax® and/or its active ingredient polyethylene glycol 3350 (PEG-3350).

7. The defendants further acted jointly, severally, and at times in concert, to promote the safety and efficacy of MiraLax® and/orPEG-3350, and to support its widespread marketing and use.

8. Plaintiff, Samuel Woniewala, was prescribed MiraLax®, an over-the-counter product, and took it under the careful supervision of his primary care physician as well as his

nephrologist. As a direct and proximate result of the Plaintiff's use of this over-the-counter product, MiraLax®, the Plaintiff sustained an acute kidney injury identified as oxalate nephropathy and, as a consequence, he will require ongoing treatment and dialysis, a possible kidney transplant, and/or this acute kidney injury will prove fatal to the Plaintiff.

9. At all times relevant and material hereto, the defendants knew, or in the exercise of reasonable diligence and investigation should have known, that this over-the-counter laxative was capable of causing this type of nephropathy in the Plaintiff and others who were similarly situated, and defendants failed to take the necessary steps to warn Plaintiff and Plaintiff's healthcare providers concerning this risk, and further failed to design, manufacture, distribute and sell their product in such a fashion as to avoid posing this deadly and unnecessary risk to Plaintiff and others who were similarly situated.

II. FACTUAL ALLEGATIONS

10. In 1999, defendant Braintree Laboratories introduced MiraLax® (polyethylene glycol 3350. NF powder for solution) as a prescription laxative.

11. In 2006, MiraLax® was approved by the United States Food and Drug Admistration as an over-the-counter drug, and was marketed by defendant Merck & Co., Inc.

12. MiraLax® is a registered trademark of Merck & Co., Inc.

13. Defendant, Schering-Plough Healthcare Products, Inc. manufactured MiraLax® and, on November 4, 2009, merged with defendant Merck & Co., Inc.

14. Upon information and belief, in May of 2014, defendant Bayer Corporation signed an agreement to purchase Merck's consumer care business, including the rights to market and sell MiraLax®, and on October 1, 2014 that sale was finalized.

15. Upon information and belief, defendant Bayer Corporation's purchase of this business included a purchase of some or all the liabilities of the defendant Merck, including some or all of the liability arising from the circumstances set forth herein.

16. Between 2006 and today, the defendants have advertised MiraLax® by describing it and marketing it as follows:

> MiraLax® contains polyethylene glycol 3350, which is a completely different way to treat occasional constipation. It activates water to work in three way – hydrating, easing and softening – to unblock your system naturally. Nothing works better than MiraLax® laxative to relieve constipation and soften stool with no harsh side-effects (excluding other polyethylene glycol 3350 laxatives).

See www.miralax.com/miralax/why-miralax/how-miralax-works.jspa

17. Additionally, defendants advertised:

> There are no harsh side-effects such as cramps, gas, bloating, or sudden urgency caused by MiraLax®, only gentle, predictable relief from constipation. When using this product you may have loose, watery or more frequent stools.

See www.miralax.com/miralax/faq/index.jspa

18. In the labeling information that accompanies MiraLax®, there has never been any warning of the risk of oxalate nephropathy.

19. The labeling information associated with MiraLax® states in pertinent part:

> Do not use this product if you have kidney disease, **except** under the advice and supervision of a doctor. (emphasis supplied).

20. At all times relevant and material hereto, Plaintiff Samuel Woniewala had chronic kidney disease.

21. At all times relevant and material hereto, Plaintiff used MiraLax® under the advice and supervision of both his primary care physician and his nephrologist.

22. The defendants have never identified the risk of oxalate nephropathy as being associated with the use of MiraLax®.

23. Neither Plaintiff's primary care physician, nor Plaintiff's nephrologist was aware, nor reasonably could they have been aware, that the use of MiraLax® by Plaintiff Woniewala would or could result in oxalate nephropathy.

24. By way of background, Plaintiff Samuel Woniewala, had been diagnosed with chronic kidney disease, Stage III, with stable creatinine values (a standard measure of kidney function) over a period of years.

25. In 2009, Mr. Woniewala was experiencing problems with constipation, and his primary care physician, who was aware of his history of chronic kidney disease, and who was monitoring his creatinine levels, prescribed the use of over-the-counter MiraLax® in an effort to treat his constipation.

26. On July 10, 2009, Mr. Woniewala' s creatinine level was 1.47 (normal 0.5-1.3).

27. At or about the same time, Plaintiff Samuel Woniewala was treating with a nephrologist at the Hospital of the University of Pennsylvania, who was likewise monitoring his stable chronic kidney disease. This specialist also received copies of Mr. Woniewala's laboratory studies, and in September of 2009, noted that his creatinine was 1.3.

28. Both Mr. Woniewala's primary care physician, and his nephrologist, continued to prescribe and recommend MiraLax® to be taken as needed for chronic constipation, and Plaintiff used MiraLax® at the advice of, and under the supervision of, his physicians.

29. Plaintiff, Mr. Woniewala followed his doctors' instructions and took the MiraLax® as directed.

30. This practice continued throughout 2010 and Mr. Woniewala's creatinine levels were tested and documented as follows:

Date	Creatinine Level
2/16/10	**1.81**
8/20/10	**1.73**
9/10/10	**1.37**
10/16/10	**1.36**
10/18/10	**1.5**
10/26/10	**1.31**
11/1/10	**1.4**
12/2/10	**1.75**

31. In 2011, Plaintiff continued to experience problems with constipation, and his nephrologist again prescribed over-the-counter MiraLax® to treat this constipation.

32. Plaintiff continued to use MiraLax® under his doctors' advice and supervision.

33. On August 31, 2011, Mr. Woniewala's creatinine was 1.67.

34. In December of 2011 Mr. Woniewala saw his nephrologist who again recognized his ongoing constipation complaints and prescribed and recommended over-the-counter MiraLax®.

35. Mr. Woniewala continued to follow his doctors' advice, and utilized the MiraLax® under his doctors' advice and supervision to treat his constipation.

36. In 2012, Mr. Woniewala's creatinine levels were reported as follows:

Date	Creatinine Level
1/30/12	**1.42**
6/11/12	**1.71**

37. Again in March 2012, Mr. Woniewala's nephrologist noted his chronic constipation continued to prescribe and recommend MiraLax®.

38. Mr. Woniewala continued to take MiraLax® as instructed under his doctor's advice and supervision.

39. Mr. Woniewala's chronic constipation continued into 2013, and again at his physicians'' prescription and recommendation, he continued to take MiraLax® to treat this condition.

40. Beginning in February 2013, Mr. Woniewala noted some left-sided abdominal flank pain, and on March 15, 2013, he presented to his primary care physician complaining of that pain. It was again noted that he had been experiencing longstanding constipation, and that he continued to take MiraLax® to treat this constipation.

41. On May 6, 2013 Plaintiff was admitted to Mercy Hospital in Philadelphia complaining of malaise, nausea, worsening lower extremity edema and abdominal pain.

42. Upon admission, Plaintiff's creatinine was measured at 8.3.

43. Between May 6 and May 13, 2013, while an inpatient at Mercy Hospital, Plaintiff's creatinine continued to range between 7.4 and 8.3, and on May 13, 2013, he was transferred to the Hospital of the University of Pennsylvania.

44. Plaintiff's creatinine level at admission the Hospital of the University of Pennsylvania was 7.68.

45. Plaintiff Samuel Woniewala was diagnosed as suffering from an acute on chronic kidney injury, and it was noted during his admission that he had been taking MiraLax® daily to treat his constipation.

46. Plaintiff continued to experience constipation while an inpatient at the Hospital of the University of Pennsylvania where he was being treated for his acute on chronic kidney injury, and during that admission his healthcare providers continued to prescribe MiraLax® and administer MiraLax® to him in an effort to treat that constipation.

47. Initially, the etiology of Plaintiff's acute kidney injury remained unclear despite a variety of testing conducted at the direction of his nephrologist.

48. In June of 2013 a renal biopsy was performed, and the biopsy specimens were submitted to the Mayo Clinic for examination.

49. These biopsy specimens were examined at the Mayo Clinic, and it was reported that the specimens demonstrated oxalate nephropathy with a fair amount of chronicity.

50. This oxalate nephropathy was caused by PEG-3350, the active ingredient in MiraLax®.

51. During the years that they prescribed and recommended Miralax® to the Plaintiff, the Plaintiff's healthcare providers had no way of knowing that Miralax® was capable of causing oxalate nephropathy in a patient such as the Plaintiff. If they had known this information, they would not have recommended that the Plaintiff use Miralax® to treat his constipation.

52. At all times relevant and material hereto, the defendants manufactured, marketed, sold and advertised Miralax®, without sufficiently investigating the effect of Miralax® on kidney function, and/or without acknowledging this deadly side-effect.

53. Although the labeling information which the defendants supplied with MiraLax® stated "Do not use this product if you have kidney disease, **except** under the advice and supervision of a doctor" (emphasis supplied), in truth, no healthcare provider could reasonably provide adequate advice or supervision to patients taking MiraLax®, insofar as the defendants had failed to identify or disclose to the healthcare community that MiraLax®was capable of causing oxalate nephropathy.

54. The failure of the defendants to identify this specific and life-threatening risk in patients who have kidney disease renders the aforementioned language in their labeling meaningless, as the healthcare community was not sufficiently informed so as to be able to properly advise or supervise the use of this product in patients.

55. Plaintiff, Samuel Woniewala first had reason to believe that his acute kidney injury was due to oxalate nephropathy caused by the active ingredient of MiraLax®, polyethylene glycol 3350, at some point following June 19, 2013, after he learned of the biopsy results.

56. Moreover, at all times relevant and material hereto, the defendants were aware, and/or in the exercise of reasonable diligence should have been aware, that there was significant and widespread use of the product MiraLax® within the population of patients who had some level of kidney disease.

57. In fact, the defendants were aware that the United States Food and Drug Administration had received in excess of 30 adverse event reports involving consumers who were taking MiraLax® and sustained some form of serious kidney injury. By way of example,

the defendants were aware of adverse event reports concerning patients taking MiraLax®, including:

- Renal failure suffered by a 5 year old boy in 2002;
- Renal failure suffered by a 5 year old boy in 2003;
- Acute renal failure suffered by an 83 year old female in 2007;
- Renal disorder suffered by a 71 year old male in 2007;
- Renal failure suffered by a 74 year old male in 2008;
- Renal disorder suffered by a 71 year old male in 2008;
- Renal failure suffered by a 65 year old female in 2008;
- Renal impairment suffered by a 56 year old female in 2010;
- Kidney enlargement suffered by a 4 year old female in 2011;
- Renal failure suffered by a female in 2012;
- Renal impairment suffered by a female in 2013;
- Renal failure and death of an 86 year old male in 2013;
- Acute renal failure of a 69 year old male in 2013.

58. Similarly, the defendants were aware or should have been aware that there were adverse events reported to the United States Food and Drug Administration involving polyethylene glycol 3350, which reported kidney injuries and complications. These events include but are not limited to:

- Acute renal failure in a 95 year old female in 2001;
- Renal impairment in an 80 year old female in 2003;
- Renal failure in a 5 year old male in 2003;
- Acute renal failure in a 73 year old male in 2004;

- Acute renal failure in an 87 year old male in 2005;
- Renal disorder in a 1 year old female in 2005;
- Acute renal failure in an 84 year old male in 2006;
- Acute renal failure in a 68 year old female in 2006;
- Decreased creatinine clearance in a 90 year old female in 2006;
- Renal failure in a 70 year old male in 2007;
- Acute renal failure in an 84 year old female in 2008;
- Renal failure in an 84 year old female in 2008;
- Renal failure in a 65 year old female in 2008;
- Renal failure in a 70 year old female in 2008;
- Acute renal failure in a 73 year old male in 2009;
- Acute renal failure in a 75 year old male in 2009;
- Acute renal failure in an 87 year old female in 2010;
- Renal impairment in a 56 year old female in 2010;
- Renal disorder in a 74 year old female in 2011;
- Abnormal renal function in a 63 year old female in 2011;
- Acute renal failure in an 84 year old female in 2012;
- Renal failure in an 80 year old male in 2012;
- Renal failure in a 62 year old female in 2012;
- Acute renal failure in a 68 year old female in 2012;
- Renal failure in a 14 year old male in 2012;
- Acute renal failure in an 86 year old female in 2014; and
- Renal failure in a 66 year old female in 2014.

59. Despite continued reports of adverse events involving kidney injuries to consumers, the defendants failed to take reasonable steps to investigate these adverse reports and to investigate the overall nephrotoxicity of MiraLax®, and/or its active ingredient, PEG-3550.

60. Additionally, the defendants were aware, or in the exercise of reasonable diligence should have been aware, that there was widespread use of this product on a long-term basis in patients who were suffering from chronic constipation.

61. Similarly, the defendants were aware, or in the exercise of reasonable diligence should have been aware, that the medical community regarded this over-the-counter laxative as safe and effective, even when used over long periods of time and when used by patients who had some level of kidney disease.

62. Notwithstanding this awareness, the defendants never made any reasonable effort to educate the medical community and/or the patient population of the specific and deadly risk of oxalate nephropathy that was posed by this product.

Count I – Negligence (Against all Defendants)

63. Plaintiff incorporates by reference each and every paragraph of this Complaint as though the same were set forth fully herein at length.

64. At all times relevant and material hereto, the defendants, and each of them, had a duty to exercise reasonable care in the research, development, testing for safety, formulation, manufacture, hiring of and use of qualified scientific or medical personnel, labeling, packaging, promotion, advertising, marketing, distribution, sale and otherwise releasing into the stream of commerce MiraLax® and/or its active ingredient, PEG-3350.

65. Defendants, and each of them, breached their duty of reasonable care to the Plaintiff in that they negligently designed, developed, manufactured, tested, inspected, packaged,

promoted, marketed, distributed, labeled and/or sold MiraLax®. Specifically, defendants failed to exercise reasonable care in ways described throughout this Complaint and which included but were not limited to, the following:

a. failing to properly study the effects of MiraLax® on patients who had stable chronic kidney disease;

b. failing to properly study the effects of long-term use of MiraLax®;

c. failure to properly review and investigate reports of kidney injury sustained by patients on MiraLax®;

d. failing to exercise the degree of vigilance in manufacturing, selling, marketing and advertising their product which is commensurate with the harm that is likely to result from their relaxed vigilance;

e. failing to ensure that their warnings and labeling information remain adequate in the face of increasing reports and information pertaining to kidney injuries associated with this drug;

f. failing to adequately advise the medical community of the hazards and risks associated the use of the product MiraLax® and/or PEG-3350;

g. failing to acknowledge the shortcomings of their research and studies concerning the use of this product in patients who have some level of kidney disease;

h. failing to provide the consumer with sufficient information so as to allow the consumer to make reasonable choices concerning the use of this product in patients with chronic stable kidney disease; ‘

i. failing to provide the medical community with sufficient information to allow them to safely advise patients, recommend MiraLax®, supervise the condition of patients taking MiraLax®, and/or recommend reasonable alternatives to patients who have stable chronic kidney disease;

j. failing to reasonably investigate information about the risk of oxalate nephropathy in patients;

k. by unduly promoting the drug and the use of this over-the-counter medication to a degree that effectively negated any relevant warnings;

l. failing to adequately warn of the risks presented by this drug in users who have underlying kidney disease;

m. misrepresenting that MiraLax® was safe for use, under the advice and supervision of a physician, for patients with kidney disease;

n. failing to perform appropriate premarket testing of MiraLax®;

o. failing to perform appropriate post-market testing of MiraLax®;

p. failing to perform appropriate post-market surveillance of MiraLax®;

q. negligently permitting free ethylene glycol to contaminate their product;

r. failing to adequately test and exert sufficient quality control measures so as to prevent the contamination of their produce with free ethylene glycol;

s. failing to properly warn and advise that use of this product can result in the deposit of ethylene glycol crystals in the kidneys resulting in oxylate nephropathy.

66. Defendants, individually and together, knew or in the exercise of reasonable diligence should have known that consumers, such as the Plaintiff herein, would foreseeably suffer injury as a result of the defendants' failure to exercise reasonable and ordinary care.

67. As a direct and proximate result of the defendants' carelessness and negligence, and due to the unreasonably dangerous and defective characteristics of MiraLax®, Plaintiff suffered severe and permanent injuries.

68. As a direct and proximate result of the conduct of the defendants as set forth throughout this Complaint, the Plaintiff has lost kidney function, and will be required to endure significant pain, pain and suffering and will require ongoing medical treatment indefinitely into the future.

69. As a direct and proximate result of the defendants' conduct as set forth more fully herein, Plaintiff has incurred and will incur significant expenses for medical care and treatment, has suffered and will suffer lost wages and lost earnings and earning capacity, and has suffered and will suffer from physical, emotional and mental pain and anguish. Plaintiff further has suffered and will suffer a loss of an ability to enjoy life's pleasures.

WHEREFORE, Plaintiff demands judgment against defendants, jointly and severally, together with interests, costs of suit and all other such relief as may be provided by law in an amount in excess of the jurisdictional limits of the Court for arbitration.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT
(Against All Defendants)

70. Plaintiff hereby incorporates by reference each and every paragraph of this Complaint as though the same were set forth more fully herein at length.

71. At all times relevant and material hereto, the defendants, and each of them, were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling, directly and indirectly, the laxative MiraLax®, which is defective and unreasonably dangerous to users and/or consumers, including the Plaintiff.

72. At all times relevant and material hereto, MiraLax® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by the respective defendants in a defective and unreasonably dangerous condition in ways which included, but were not limited to one or more of the following:

a. this medication is unreasonably dangerous to users with kidney disease. Instead of issuing a blanket warning against its use in patients who had kidney disease, defendants expressly and implicitly warranted that it could safely be used in patients with kidney disease, provided it was used under the "advice and supervision" of a physician. In point-of-fact, there was no advice or supervision of a physician which was capable of rendering the use of this product safe when used in patients who have kidney disease.

b. this drug poses an undisclosed risk of oxalate nephropathy, which was not made known to consumers, to the medical profession, nor was it indicated in the labeling or warnings which accompanied the medication.

c. the medication was insufficiently tested, in that there was insufficient studies in long-term follow-up to determine the effects of this drug when taken by patients with kidney disease;

d. in patients who have kidney disease, the drug causes harmful side-effects that outweigh any potential utility;

e. in patients with kidney disease, the drug was more dangerous than other laxatives which were available on the market;

f. the drug was not accompanied by adequate labeling or instructions for use to fully apprise the public and consumers, including the Plaintiff, of the potential risks and serious side-effects associated with its use.

73. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of the true potential risk of harm would have concluded that MiraLax® should not have been marketed in the condition that it was marketed.

74. There existed safer alternative designs, but defendants, and each of them, chose to market a more dangerous design, so as to sell their drug to the largest possible market at the greatest profitability.

75. At all times relevant hereto, defendants, and each of them, knew that MiraLax® would be purchased and utilized by a population of people who had underlying kidney disease, and whose physicians were unaware of the propensity of MiraLax® to cause oxalate nephropathy in such patients. Nonetheless, defendants represented that it could be safely used by such patients when used under the advice and supervision of physicians.

76. Defendants, and each of them, knew or should have known of the defective nature of MiraLax® but continued to research, develop, design, test, manufacture, package, formulate, inspect, label, distribute, market, promote, sell and otherwise release this product into the stream of commerce so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by this product, including serious kidney damage in the form of oxalate nephropathy.

77. At all times relevant and material hereto, Plaintiff used MiraLax® for its intended or reasonably foreseeable purpose.

78. As a direct and proximate result of the defective and unreasonably dangerous condition of MiraLax®, the Plaintiff suffered the injuries as set forth in this Complaint.

WHEREFORE, Plaintiff demands judgment against defendants, jointly and severally, for compensatory and punitive damages, together with interests, costs of suit, attorneys' fees and all other such relief as may be provided by law in an amount in excess of the jurisdictional limits of the Court for arbitration.

COUNT III
STRICT PRODUCT LIABILITY – MANUFACTURING DEFECT
(Against All Defendants)

79. Plaintiff hereby incorporates by reference each and every paragraph of this Complaint as though the same were set forth more fully herein at length.

80. At all times relevant and material hereto, the defendants, and each of them, were responsible for the manufacturing, distribution and sales of the laxative MiraLax® and/or its active ingredient PEG-3550.

81. At all times relevant and material hereto, MiraLax® was sold in such a fashion to render it defective, as a direct consequence of one or more of the following:

a. contamination with free ethylene glycol;

b. failure to utilize proper quality control measures to avoid and/or reduce the risk of contamination with ethylene glycol;

c. failure to recognize that the product was manufactured in such a way that use of the product could result in deposits of ethylene glycol in the kidneys so as to result in oxalate nephropathy.

82. As a direct and proximate result of the defective and unreasonably dangerous condition of MiraLax®, the Plaintiff suffered the injuries as set forth in this Complaint.

WHEREFORE, Plaintiff demands judgment against defendants, jointly and severally, for compensatory and punitive damages, together with interests, costs of suit, attorneys' fees and all

other such relief as may be provided by law in an amount in excess of the jurisdictional limits of the Court for arbitration.

COUNT IV
BREACH OF EXPRESS AND IMPLIED WARRANTIES
(Against All Defendants)

83. Plaintiff hereby incorporates by reference each and every paragraph of this Complaint as though the same were set forth more fully herein at length.

84. At all times relevant and material hereto, defendants, and each of them, expressly and implicitly warranted that MiraLax® was safe, effective and fit for use by consumers and patients with kidney disease, when used under the advice and supervision of their physicians. It was not.

85. Defendants further expressly and implicitly warranted that MiraLax® was of merchantable quality, that it did not produce dangerous side-effects, and that it was adequately tested and fit for its intended purpose. Specifically, defendants, and each of them, represented such information on the labeling information associated with MiraLax®, websites, through advertising and through marketing materials. Towards that end, it was represented that MiraLax®:

a. "had no harsh side effects"

b. could be used safely by patients who had kidney disease when used under the advice and supervision of their physicians;

86. At the time of making these warranties, defendants, and each of them, knew or should have known that, in fact, the representations and warranties were false, misleading and untrue in that MiraLax® could not be safely used by patients with kidney disease, irrespective of whether it was being used under the supervision and advice of physicians. Moreover, defendants

knew and/or should have known that MiraLax® posed an unreasonable risk of oxalate nephropathy in patients who have underlying kidney disease.

87. Accordingly, defendants, and each of them knew or should have known that the representations and warranties were false, and misleading, and that MiraLax® was not safe for its intended use in patients who had kidney disease, that it was not of merchantable quality when used in those patients, and that it produced dangerous side-effects, and that it was not adequately tested or fit for its intended or foreseeable purposes.

88. Members of the public, including the Plaintiff, reasonably relied upon the skill and judgment of each of the defendants, and upon the express and implied warranties in using MiraLax®, and Plaintiff used MiraLax® for its intended purpose.

89. Defendants, and each of them, breached the express and implied warranties in that MiraLax® was not safe, effective and fit for its intended purpose. It was not of merchantable quality, and, in fact, caused serious and potentially lethal side-effects to the Plaintiff when taken as instructed.

90. Due to the defendants wrongful conduct as alleged herein, Plaintiff and Plaintiff's physicians, could not have known about the nature of the risk and side-effect associated with MiraLax® until after the oxalate nephropathy was diagnosed in Plaintiff, at which point it was too late to reverse these harmful side-effects.

91. As a direct and proximate result of the defendants' breach of express and implied warranties, and due to the unreasonably dangerous and defective characteristics of MiraLax®, Plaintiff suffered injuries as set forth throughout this Complaint.

WHEREFORE, Plaintiff demands judgment against defendants, jointly and severally, for compensatory and punitive damages, together with interests, costs of suit, attorneys' fees and all

other such relief as may be provided by law in an amount in excess of the jurisdictional limits of the Court for arbitration.

FELDMAN SHEPHERD WOHLGELERNTER
TANNER WEINSTOCK & DODIG, LLP

/s/ Mark W. Tanner
Mark W. Tanner
Attorneys for Plaintiff

Date: April 23, 2015

VERIFICATION

The undersigned, having read the foregoing Complaint, verifies that the language of the document is that of counsel based upon information furnished to and gathered by counsel and, to the extent the Responses are based upon information provided to counsel by the undersigned, the facts are true and correct to the best of the undersigned's knowledge, information and belief. This verification is made subject to the penalties of 18 Pa.C.S.A. §4904 relating to unsworn falsification to authorities.

SAMUEL WONIEWALA