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LINDA SNYDER and CHARLES SNYDER

Husband and Wife

1388 Stoney Creek Circle,

Carmel, Indiana 46032

Plaintiffs,

v.

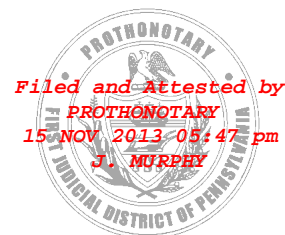
CENTOCOR, INC., d/b/a JANSSEN

BIOTECH, INC.

800 Ridgeview Road

Horsham, Pennsylvania 19044

Defendants.



This is not an arbitration matter.
Assessment of damages hearing is
required.

Attorneys for Plaintiffs

PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION

_____ TERM, 2012

NO. _____

CIVIL ACTION

JURY TRIAL DEMANDED

NOTICE TO DEFEND

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 complaints 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 below to find out where you can get legal help.

Philadelphia Bar Association
Lawyer Referral and Information
One Reading Center
Philadelphia, Pennsylvania
(215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparecencia 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 tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. 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 suficiente de pagar tal servicio, vaya una persona o llame por teléfono a la oficina cuya dirección se encuentra escrita abajo para averiguar donde se puede conseguir asistencia legal.

Asociación De Licenciados
De Filadelfia
Servicio De Referencia E
Información legal
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This is not an arbitration matter.
 Assessment of damages hearing is
 required.

Attorneys for Plaintiffs

LINDA SNYDER and CHARLES SNYDER
Husband and Wife
 1388 Stoney Creek Circle,
 Carmel, Indiana 46032

 Plaintiffs,

 v.

CENTOCOR, INC., d/b/a JANSSEN
BIOTECH, INC.
 800 Ridgeview Road
 Horsham, Pennsylvania 19044

 Defendants.

PHILADELPHIA COUNTY
 COURT OF COMMON PLEAS
 TRIAL DIVISION

 _____ TERM, 2012

 NO. _____

 CIVIL ACTION

 JURY TRIAL DEMANDED

COMPLAINT—CIVIL ACTION
(PRODUCT LIABILITY—2P)

1. Plaintiffs Linda Snyder and Charles Snyder, husband and wife, by and through their undersigned counsel, hereby submit this Complaint against Defendant CENTOCOR, INC., d/b/a JANSSEN BIOTECH, INC. (hereinafter, collectively “Centocor” or “Janssen” or “Defendants”).

2. Plaintiffs allege that, at all relevant times, Defendants' rheumatoid arthritis drug, Remicade®, is and was defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacked proper and adequate warnings as to the dangers associated with its use.

3. Plaintiff Linda Synder took Remicade® to treat her rheumatoid arthritis (RA) from on or about July 11, 2011 to on or about November 17, 2011.

4. On or about November 19, 2011, Plaintiff began suffering from several injuries, including but not limited to shortness of breath and phrenic nerve paralysis.

5. As a result of taking Remicade®, Plaintiff suffered and continues to suffer from several injuries, including but not limited shortness of breath and phrenic nerve paralysis.

PARTIES

6. Plaintiffs Linda and Charles Snyder, at all relevant times, were residents of the State of Indiana, and currently reside at 1388 Stoney Creek Circle, Carmel, Indiana 46032.

7. Defendant CENTOCOR, INC., d/b/a JANSSEN BIOTECH, INC. is a corporation of the Commonwealth of Pennsylvania, with its principal place of business located at 800 Ridgeview Road, Horsham, County of Montgomery, Pennsylvania, 19044.

JURISDICTION AND VENUE

8. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

9. Defendants maintain, and at all relevant times maintained, their principal place of business in Horsham, Pennsylvania.

10. At all relevant times, Defendants, and/or their predecessors in interest and/or their subsidiaries, regularly conducted business, received substantial revenues from conducting business, sold products and performed services, carried on a continuous and systematic part of their businesses, and expected or reasonably should have expected their products, including any and all product labeling, and product advertising to reach consumers, patients, and physicians within the Commonwealth of Pennsylvania.

11. At all relevant times, Defendants, and/or their predecessors in interest and/or their subsidiaries, committed acts and omissions within the Commonwealth of Pennsylvania that gave rise to Plaintiffs' claims and injuries.

12. For the foregoing reasons, jurisdiction is proper.

13. At all relevant times, Defendants, and/or their predecessors in interest and/or their subsidiaries, regularly conducted business, received substantial revenues from conducting business, sold products and performed services, carried on a continuous and systematic part of their businesses, and expected or reasonably should have expected their products, including any and all product labeling, and product advertising to reach consumers, patients, and physicians within Philadelphia County.

14. At all relevant times, Defendants, and/or their predecessors in interest and/or their subsidiaries, committed acts and omissions within Philadelphia County that gave rise to Plaintiffs' claims and injuries.

15. For the foregoing reasons, venue is proper in Philadelphia County, pursuant to Pa. R. Civ. P. 2179.

DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

16. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

17. Plaintiffs hereby allege and assert any and all applicable state statutory and common law claims, rights, theories, and/or principles of tolling or extension of any and all applicable statute(s) of limitations and statute(s) of repose, including but not necessarily limited to equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

18. Plaintiffs plead that the discovery rule should be applied to toll the running of any applicable statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and/or diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injuries.

19. Despite diligent investigation by Plaintiffs into their injuries and the cause of their injuries, their relationship to Remicade was not discovered, and through reasonable care and/or diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed within the applicable statutory limitations period.

20. Any applicable statute of limitations is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to the fraudulent concealment of Defendants, and/or their predecessors in interest and/or their subsidiaries, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiff's prescribing physicians of the true risks associated with ingesting Remicade. As a result of said fraudulent concealment, Plaintiff her prescribing physicians were unaware, and could not have learned

through reasonable care and/or diligence, that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendants, and/or their predecessors in interest and/or their subsidiaries.

21. Any applicable statute of limitations may be tolled due to the pendency of a class action proceeding against one or more of Defendants, and/or their predecessors in interest and/or their subsidiaries.

22. Any applicable statute of limitations is tolled due to disability.

23. Defendants are estopped from asserting a statute of limitations defense because Defendants, and/or their predecessors in interest and/or their subsidiaries, fraudulently concealed from Plaintiffs the connection between their injuries and Remicade and the connection between their injuries and the acts and omissions of Defendants, and/or their predecessors in interest and/or their subsidiaries.

CAUSES OF ACTION

COUNT I – STRICT LIABILITY (FAILURE TO WARN)

24. Plaintiffs repeat and re-allege each and every paragraph of this Complaint as if fully set forth herein.

25. At all times material hereto the defendants, and each of them, were and are pharmaceutical companies engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise involved in placing into the stream of commerce the prescription pharmaceutical infliximab, sold under the brand name Remicade®(R).

26. At the times and places of aforesaid and at all times material hereto, defendants, and each of them, held themselves out as knowledgeable and possessing the requisite skill

peculiar to the research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale of such product(s).

27. In its role as the federal regulatory agency charged with overseeing pharmaceutical products, the FDA required that Defendant warn patients on risks associated with the use of Remicade®. This document known as a patient information sheet or medication guide is required to be provided to patients and provides patients with warnings, instructions, and guidance on minimizing risks associated with the use of the product.

28. At the times and places aforesaid, and at all times material hereto, Defendants, and each of them, placed into the stream of commerce drug products which failed to contain proper and adequate warnings to physicians and foreseeable users and consumers of their products of the risks posed by the foreseeable uses of their products either singly or in combination, including, but not limited to, the risk of developing numbness, memory loss, and fibromyalgia.

29. The failure to provide proper or adequate warnings about the risks posed by the foreseeable uses of their drug products to foreseeable users or consumers renders the products defective and unreasonably dangerous.

30. Defendants, and each of them, caused or otherwise allowed, enabled or facilitated the placement of dangerous products in a defective condition into the stream of commerce and are strictly liable in tort.

31. As a foreseeable, direct and proximate result of the placement into the stream of commerce by defendants, and each of them, of dangerous products in a defective condition, Plaintiff suffered serious bodily injuries, from which he ultimately died, and Plaintiffs otherwise sustained damages compensable under the laws of this State and/or the laws of the State of

Indiana and/or the United States.

WHEREFORE, Plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages in an amount greater than \$50,000, delay damages pursuant to Pa. R.C.P. No. 238, interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

COUNT II – NEGLIGENCE

32. Plaintiffs repeat and re-allege each and every paragraph of this Complaint as if fully set forth herein.

33. Defendants and each of them, having undertaken the manufacturing, marketing, distribution, and/or promotion of the prescription drug products described herein owed a duty to provide accurate and complete information regarding their products when used foreseeably in foreseeable patients.

34. Defendants falsely represented to Plaintiffs, in direct-to-consumer advertising, and/or indirectly through misrepresentation to Plaintiffs' prescribing physicians, that their drug products were safe and effective for foreseeable uses as prescription therapies either singly or in combination, provided to patients like Plaintiff Linda Snyder. The representations by Defendants were in fact false and the drugs were not safe for said purposes and in fact dangerous to the health of Plaintiff Linda Snyder and other similarly situated patients.

35. At the time the aforesaid representations were made, Defendants concealed from Plaintiffs and his prescribing physician's information about the propensity of their drugs when used foreseeably either singly or in combination in foreseeable patients, to cause great harm. Defendants and each of them negligently misrepresented claims regarding the safety and efficacy

and/or the balances of the risks and benefits of said drugs despite the lack of information regarding same.

36. The aforementioned misrepresentations were made by defendants, and each of them, with the intents to induce Plaintiff Linda Snyder to use the drugs either singly or in combination with other drugs, to Plaintiff Linda Snyder's detriment.

37. At the time of defendant's misrepresentations and omissions, Plaintiff Linda Snyder was ignorant of the falsity of these statements and reasonably believed them to be true.

38. Defendants had the duty to review all adverse event information in meeting its safety surveillance obligations under 21 C.F.R. § 314.80(b):

Review of adverse drug experiences. Each applicant having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application, shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. Applicants are not required to resubmit to FDA adverse drug experience reports forwarded to the applicant by FDA; however, applicants must submit all follow up information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.

39. Defendants had a duty to exercise reasonable care in the design, manufacture, sale, and/or distribution of Remicade® into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

40. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Remicade® into interstate commerce in that the Defendants knew, or should

have known, that the product caused such significant bodily harm or death and was not safe for use by consumers.

41. Defendants failed to exercise ordinary care in the labeling of Remicade® and failed to issue to consumers and/or their healthcare provider's adequate warnings of the risk of serious bodily injury or death due to the use of Remicade®.

42. Despite the fact that the Defendants knew, or should have known, that Remicade® posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and/or market Remicade® for use by consumers.

43. Defendants knew, or should have known, that consumers, including Plaintiff Linda Snyder, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

44. Remicade® manufactured and supplied by the Defendants was unreasonably dangerous due to inadequate warning or instruction because Defendants knew or should have known that the product created hidden risks of serious bodily harm and death and they failed to adequately warn Plaintiff Linda Snyder and/or her health care providers of the extent of risk of the type of injury Plaintiff Linda Snyder suffered as a result of using Remicade®.

45. Defendants marketed, promoted and advertised Remicade® to healthcare providers and the public as more effective and safe than other treatments for RA at the time that Defendants had actual or constructive knowledge that Remicade® was less safe than the other treatments for RA.

46. Defendants negligently failed to provide full and proper information as to the safety of Remicade® to the FDA, which regulates the sale of Remicade®.

47. Defendants did not reasonably warn the medical profession of precautions and

known potential complications of Remicade® to enable physicians and other health care providers to reasonably assess the risks versus the benefits of the use of Remicade® as treatment for RA.

48. Defendants failed to warn health care providers and the public that Remicade® was associated with increased risk of complications arising from phrenic nerve paralysis as compared to the other treatments for RA.

49. Defendants failed to provide adequate instructions to doctors and patients on methods to mitigate and manage the risk of the use of Remicade®.

50. Plaintiff Linda Snyder and her prescribing physician were unaware of the increased risks and danger of harm inherent in Remicade®, as above described and would have used and prescribed other methods of treatment if they had been so informed.

51. Defendants have an ongoing duty of pharmacovigilance. As part of this duty, Defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including Remicade®. Defendants continually received reports from its own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking Remicade® and Defendants' other marketed drugs. Furthermore, Defendants continue to conduct clinical trials for its marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to Defendants, whether through Defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when Defendants learn, or should have learned, of new safety information associated with its marketed drugs, Defendants have a duty to

promptly disseminate that data to the public. Defendants also have a continuing duty to monitor epidemiology and pharmacovigilance data regarding its marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

52. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to Plaintiff. Defendants, through clinical trials and other adverse event reports, learned that there was a serious problem associated with Remicade® use and failed to adequately inform doctors, regulatory agencies and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time Remicade® has been on the market in the United States. Furthermore, Defendants had a duty to provide adequate instructions to manage or mitigate the known risks associated with the use of Remicade® and failed to so instruct.

53. Defendants failed to comply with FDA's post-marketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning Remicade® that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendant, failing to promptly investigate all adverse drug experiences concerning Remicade® that are the subject of these post marketing 15-day Alert reports, failing to submit follow-up reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendants further failed to meet the periodic reporting requirements of 21 C.F.R. § 314(c), 21 C.F.R. § 314.81, and 21 C.F.R. § 312.33.

54. Defendants failed to develop and act upon written procedures for the surveillance, receipt, evaluation, and reporting of post marketing adverse drug experiences to FDA.

55. Defendants failed to adequately instruct doctors on patients on risk mitigation concerning infections associated with the use of Remicade®.

56. Despite the publicly availability of adverse event information from the FDA, Defendants failed to make adequate use of this information including information on the relationship between other TNF inhibitors and infections. Defendants failed to promptly review all adverse drug experience information concerning the risk of infections associated with the use of Remicade®.

57. Defendants' failure to perform adequate pharmacovigilance and failure to comply with the post marketing requirements of FDA regulations is evidence of Defendants' negligence and also constitutes negligence *per se*.

58. Plaintiff Linda Snyder 's injuries and damages alleged herein were and are the direct and proximate result of the negligence of the Defendants in one or more of the following non-exclusive respects:

- a) Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that the Defendants knew, or should have known, increased the risk of complications arising from serious and significant infection and/or carried a risk of serious, life-threatening side effects;
- b) Failure to adequately test the products prior to placing them on the market;
- c) Failure to use care in designing, developing and manufacturing their products so as to avoid posing unnecessary health risks to users of such product;
- d) Failure to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the drug;
- e) Failure to advise that consumption of the drug Remicade® could result in severe and disabling side effects, including but not limited to complications arising from serious and significant infection and death;
- f) Failure to advise the medical and scientific communities of the potential to increase the risk for severe and disabling side effects, including but not

limited to complications arising from serious and significant infection and death;

- g) Failure to provide timely and/or adequate warnings about the increased potential health risks associated with use of the drug Remicade®;
- h) Despite mounting evidence that the label and patient information failed to adequately instruct doctors and patients how to mitigate risks of infections, including asymptomatic infections, associated with the use of Remicade®, Defendants failed to enhance the Remicade® label and patient information.
- i) Failure to provide adequate instructions to doctors and patients to manage and mitigate known risks associated with the use of Remicade®; and
- j) Any and all other acts of negligence with respect to the drug Remicade® which may be shown at trial.

59. Defendants failed to comply with the pharmacovigilance and safety reporting requirements as set forth in 21 C.F.R. § 314(c), 21 C.F.R. § 314.81, and 21 C.F.R. § 312.33. As a proximate cause of such failure, Defendants failed to adequately update the product labeling in accordance with 21 C.F.R. § 201.57 to include not only risks, but to instruct doctors and patients on appropriate risk management.

60. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff Linda Snyder suffered greatly and endured pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

61. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff Charles Snyder has been deprived of his spouse's comfort, society and companionship, during the time of her diminished physical and mental health, all to which Plaintiff Charles Snyder is entitled to recover.

62. Defendants, and each of them, breached their duties to Plaintiffs by providing

false, incomplete and/or misleading information regarding their products used foreseeably, either singly or in combination, in foreseeable patients. Plaintiff Linda Snyder reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when purchasing and/or consuming and/or ingesting Defendants' drug products.

63. As a direct and proximate result of one or more of these wrongful acts or omissions of the defendants, and each of them, Plaintiffs suffered damages compensable under the laws of this State and/or the laws of the State of Indiana and/or United States.

WHEREFORE, Plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages in an amount greater than \$50,000, delay damages pursuant to Pa. R.C.P. No. 238, interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

COUNT III – BREACH OF IMPLIED WARRANTY

64. Plaintiffs repeat and re-allege each and every paragraph of this Complaint as if fully set forth herein.

65. At the times and places aforesaid and at all times material hereto, defendants, and each of them, by placing their products into the stream of commerce impliedly warranted that their products were of merchantable quality and safe, effective and fit for human consumption by foreseeable users.

66. The placement by defendants, and each of them, of dangerous products in a defective condition into the stream of commerce, as hereinbefore set forth, was a breach of the implied warranty of merchantability and fitness for a particular purpose.

67. As a foreseeable, direct and proximate result of the breaches of the implied

warranty of merchantability by the defendants, and each of them, Plaintiff suffered serious bodily injuries, and otherwise sustained damages compensable under the laws of this State and/or the laws of the State of Indiana and/or the United States.

WHEREFORE, Plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages in an amount greater than \$50,000, delay damages pursuant to Pa. R.C.P. No. 238, interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

COUNT IV – BREACH OF EXPRESS WARRANTY

68. Plaintiffs repeat and re-allege each and every paragraph of the Complaint as if fully set forth herein.

69. At the times and places aforesaid and at all times material hereto, defendants, and each of them, expressly warranted that their products were of merchantable quality and safe, effective and fit for human consumption by foreseeable users.

70. The placement by defendants, and each of them, of dangerous products in a defective condition into the stream of commerce, as hereinbefore set forth, was a breach of the express warranty of fitness for human consumption by foreseeable users.

71. As a foreseeable, direct and proximate result of the breaches of the express warranties of fitness for human consumption by the defendants, and each of them, Plaintiff suffered serious bodily injuries and otherwise sustained damages compensable under the laws of this State and/or the laws of the State of Indiana and/or the United States.

WHEREFORE, Plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages in an amount greater than \$50,000, delay damages pursuant to Pa. R.C.P. No. 238, interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

COUNT V – FRAUD

72. Plaintiffs repeat and re-allege each and every paragraph of this Complaint as if fully set forth herein.

73. Defendants fraudulently, intentionally and/or negligently misrepresented the safety and effectiveness of their drugs used singly or in combination by foreseeable users and fraudulently, intentionally and/or negligently concealed material adverse information regarding their safety and effectiveness.

74. Defendants made these misrepresentations and/or actively concealed adverse information at a time when the defendants knew or should have known that their products had defects, dangers and characteristics unreasonable dangerous and that were other than what the defendants had represented to the prescribing doctors, the FDA and the consuming public, including Plaintiffs.

75. Defendants omitted, suppressed or concealed material facts concerning the dangers and risks associated with the foreseeable uses of their products, either singly or in combination, including but not limited to the risks of developing numbness, memory loss, and fibromyalgia. Furthermore, Defendants purposely ignored, downplayed, avoided and/or otherwise understated the serious nature of the risks associated with the foreseeable uses of their products either singly or in combination in order to increase the sales of their drugs and thus their

profits.

76. Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed or concealed facts of such materiality regarding the safety and efficacy of their drug products from physicians, the FDA and the consuming public, including the Plaintiffs.

77. Defendants engaged in calculated silence despite their knowledge of the growing public acceptance of the misinformation and misrepresentations regarding both the safety and efficacy of the foreseeable uses of their products, either singly or in combination, and did so because the prospect of huge future profits outweighed health and safety issues, all to the significant detriment of the public and the Plaintiffs herein.

78. Defendants purposefully downplayed the side effects or provided misinformation about adverse reactions and potential harms from the use of their products, either singly or in combination, and succeeded in persuading large segment of the medical community, the FDA and consumers, including Plaintiffs, despite the associated significant dangers of these products used either singly or in combination by foreseeable consumers including the Plaintiffs.

79. Defendants misrepresented the safety of their products in the labeling, advertising, promotion and marketing efforts of these products.

80. Plaintiff and/or her physician(s) relied on and were induced by Defendant's misrepresentations, omissions, and/or active concealment in selecting these drugs for treatment of Plaintiff Linda Snyder 's symptoms.

81. As a foreseeable, direct and proximate result of one or more of those wrongful acts or omissions of the defendants, and each of them, as hereinbefore set forth, Plaintiff suffered profound injuries; required medical treatment and hospitalization; and Plaintiffs became liable for medical and hospital expenses and otherwise sustained damages compensable under the laws

of the State and/or the laws of the State of Indiana and/or United States.

WHEREFORE, Plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for compensatory damages in an amount greater than \$50,000, delay damages pursuant to Pa. R.C.P. No. 238, interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

COUNT VI – VIOLATION OF CONSUMER PROTECTION STATUTES

82. Plaintiff repeats and re-alleges each and every paragraph of this Complaint as if fully set forth herein.

83. Defendants engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts with the intent that others rely upon such concealment suppression or omission.

84. Such unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts constitute conduct in violation of the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-1, *et seq.*, and the Pennsylvania Unfair Trade Practices and Consumer Protection Act, 73 P.S. § 201-1, *et seq.*

85. As a direct and proximate result of one or more of these wrongful acts or omissions of the defendants, and each of them, Plaintiff suffered damages recoverable and/or compensable under the aforementioned statutes.

86. Plaintiffs suffered an ascertainable loss of money or property as a result of Defendants' use of employment of unconscionable commercial practices as set forth above, and seek treble damages, attorney's fees and costs of suit.

WHEREFORE, Plaintiff demands judgment against defendants individually, jointly, severally and in the alternative damages in an amount greater than \$50,000, delay damages under Pa. R.C.P. No. 238, as well as punitive damages together plus interest, costs of suit and attorneys' fees and such other relief as the Court deems equitable and just.

COUNT VII – LOSS OF CONSORTIUM

87. Plaintiff repeats and re-alleges each and every paragraph of this Complaint as if fully set forth herein.

88. Plaintiff Charles Snyder was the spouse of Plaintiff Linda Snyder at the times of the above-described wrongful conduct.

89. By reason of the wrongful conduct of Defendants, and as a direct and proximate result thereof, Plaintiff Charles Snyder has been deprived of his spouse's comfort, society and companionship, during the time of her diminished physical and mental health, all to the general damage of Plaintiff Charles Snyder.

WHEREFORE, Plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative damages in an amount greater than \$50,000, delay damages under Pa. R.C.P. No. 238, as well as punitive damages together plus interest, costs of suit and attorneys' fees and such other relief as the Court deems equitable and just.

COUNT VIII – PUNITIVE DAMAGES

90. Plaintiffs repeat and re-allege each and every paragraph of this Complaint as if fully set forth herein.

91. Plaintiffs are entitled to punitive damages because the failure to warn by

defendants, and each of them, was reckless and without regard for the public's safety and welfare.

92. Defendants misled both the medical community and the public at large, including the Plaintiffs herein, by making false representations about the safety of their products when used foreseeable, either singly or in combination, by foreseeable patients. The defendants, and each of them downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the foreseeable use of their products either singly or in combination, despite available information demonstrating these products were likely to cause serious and even fatal side effects to foreseeable users.

93. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects when used foreseeably, either singly or in combination by foreseeable users. Nevertheless, they continued to market the products by providing false and misleading information with regard to safety and efficacy and/or the balance of the risks and benefits.

94. Defendants failed to provide warnings that would have dissuaded medical providers from prescribing their drugs, either singly or in combination, for foreseeable uses in foreseeable patients, thus preventing medical providers and consumers from fairly weighing the true risks against the benefits of prescribing and/or purchasing and consuming these drugs either singly or in combination.

95. The acts and/or omissions of Defendants, as hereinbefore set forth, were also such knowing and willful failures to warn of adverse effects inherent in the foreseeable uses of their drug, either singly or in combination, that they constituted malicious, willful, wanton, and/or reckless conduct.

WHEREFORE, Plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for compensatory damages in an amount greater than \$50,000, delay damages under Pa. R.C.P. No. 238, as well as punitive damages together with interest, costs of suit and attorneys' fees and such other relief the court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this court enter judgment for Plaintiffs and against Defendants for the following general and specific damages:

- (A) Compensatory, punitive, and exemplary damages;
- (B) Physical and mental pain and suffering of Plaintiff;
- (C) Loss of consortium;
- (D) Medical expenses;
- (E) Treble damages under applicable consumer protection statutes;
- (F) Delay damages;
- (G) Per and post-judgment interest at the lawful rate; and/or
- (H) Such other applicable damages as the Court deems appropriate.

JURY DEMAND

The Plaintiffs demand trial by a jury on all of the triable issues of this complaint.

Dated: November 15, 2013

POGUST BRASLOW & MILLROOD

By: /s/ Harris Pogust
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VERIFICATION

I, Harris L. Pogust, hereby state:

1. I am the attorney representing Plaintiffs in this action.
2. I verify that Plaintiff does hereby state that the averments of fact in the foregoing CIVIL ACTION COMPLAINT are true and correct to the best of her knowledge, information, and belief and are made subject to the penalties of 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities.
3. A Plaintiff verification will be filed with this Court in the near future.

/s/ Harris L. Pogust

Harris L. Pogust
Attorney for Plaintiffs

Dated: November 15, 2013