IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

KARA MAE PLETAN,	§	
Plaintiff,	§	2011L004270
	§	CALENDAR/ROOM A
v.	§	CASE NO. TIME 00:00
	§	Product Liability
ABBOTT LABORATORIES,	§	
Defendant.	§	JURY TRIAL DEMANDED

COMPLAINT

NOW COMES Plaintiff, Kara Mae Pletan, and for her causes of action against Defendant, Abbott Laboratories (hereafter "Abbott"), states and alleges as follows.

Nature of the Case

1. This is a personal injury, products liability case. Plaintiff Kara Mae Pletan was prescribed Abbott's blockbuster drug "Humira®" to treat her Crohn's Disease. She received a loading dose in April 2008, followed by bi-monthly injections until July 2008. Kara was subsequently diagnosed with small fiber peripheral neuropathy with permanent nerve damage and pain. Plaintiff alleges, *inter alia*, that Abbott and its agents failed to provide a legally proper warning regarding the risks of Humira®, including the risk of neuropathy, and that her injections of this drug caused her neuropathy.

Parties

2. Plaintiff Kara Mae Pletan is a resident of Bozeman, Montana.

3. Defendant Abbott Laboratories is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott may be served with process by serving its registered agent, Laura J. Schumacher, 100 Abbott Park Rd., Abbott Park, Illinois 60064.

Jurisdiction and Venue

4. This Court has jurisdiction over the parties and this case. Venue is appropriate because Abbott is engaged in the business of designing, manufacturing, testing, advertising, marketing, promoting, distributing and selling prescription pharmaceuticals, including Humira®, throughout the United States, including Chicago, Cook County, Illinois. Abbott directly, and by virtue of its subsidiary, including Abbott Molecular, Inc., purposely availed itself of the privilege of conducting business activities and transactions within the state of Illinois, and Cook County in particular, by placing its products into the stream of commerce with the expectation that they would, and will be purchased and used by consumers in Illinois and throughout Cook County. Such use and purchase also includes Bozeman, Montana where Plaintiff resides.

Timeliness of Suit

5. Prior to the filing of this suit, Plaintiff and Abbott shared information on an informal basis. Pursuant to a tolling agreement entered into between the Parties, the statute of limitations has been tolled. Therefore, this suit is timely.

Factual Statement
The Many Faces of Abbott's Blockbuster TNF Blocker

6. Humira®, the generic name of which is "ADALIMUMAB," is a "biologic" drug, which means that it is a medicine that has been constituted or reconstituted from natural substances in the body. It was the first such drug in its class that was derived from actual human cells.

7. Humira® was first launched by Abbott in 2003 to treat rheumatoid arthritis [hereinafter "RA"]. However, as seems true of so many pharmaceuticals, after that successful launch, Abbott pursued and obtained approval from the FDA to market the drug for other "indications." Five others to be exact. On its website and in its annual report Abbott touts Humira® as a drug that has been "approved in 83 countries and treats nearly 500,000 patients worldwide" for

"six different autoimmune diseases." Abbott Annual Report at p. 22 (2010). Humira® is a true "blockbuster" for Abbott with 2009 worldwide sales of approximately $5.5 billion and 2010 sales of nearly $6.5 billion. *Id.* Variations in sales of Humira® have a direct and publicly reported effect on the price of Abbott's stock.

8. One of the subsequently approved "indications" for Humira® is for the treatment of Crohn's Disease. Humira® was first authorized for the treatment of Crohn's disease in 2007.

9. Crohn's Disease is a lifelong inflammatory bowel disease (IBD) that causes inflammation of the digestive system. In short, many patients with Crohn's Disease produce too much of the protein TNF and this excess TNF attacks the intestines and other parts of the gastrointestinal tract. Humira® is believed to bind TNF and thereby potentially help to block the process of inflammation in the intestines that is caused by Crohn's Disease.

The Risk/Benefit Assessment

10. Undoubtedly, Humira® does help many people. Perhaps it is even efficacious in the treatment of Crohn's Disease. However, it is an extremely potent drug with a number of different, very dangerous side effects. One of these effects (that is the subject of pending litigation in other forums) is lymphomas and other forms of malignancies. Another dangerous side effect is the risk of permanent neurological damage, like the small fiber peripheral neuropathy experienced by Kara Mae Pletan.

11. Because of the dangerous side effects, it is extremely important that *both* physicians and patients be fully informed – not only about the potential benefits of the drug, but also about the risks of side effects. Neither Kara Mae Pletan nor her physicians were warned in any meaningful or legally adequate manner about the risk of small fiber peripheral neuropathy or other forms of neurological damage. Indeed, to the contrary, in the case of Humira®, Abbott has downplayed the

risk of side effects, including the very real risk of permanent neuropathy. Moreover, on information and belief it is alleged that Abbott has made material misrepresentations of fact with regard to its promotion of Humira® for Crohn's Disease and for other maladies.

12. Abbott was certainly on notice of the potential risk of this serious disabling side effect, even before Humira® was launched to treat Crohn's Disease. Indeed, doctors from Angers University in France, in April 2006, issued a report suggesting that Humira® could in fact cause peripheral neuropathy. On information and belief it is alleged that Abbott was actually aware of this article prior to the 2007 launch for Crohn's. But if it was not, it certainly should have been. And, given the permanent, disabling nature of this side effect, it should certainly have prompted a prominent warning to both physicians and patients.

Unwarned = Unlearned

13. Illinois law presumes that legally adequate warnings that are effectively communicated by product manufacturers to the ultimate consumers of those products will be heeded.[1] Therefore, under Illinois law there is a presumption in the law that both Kara Mae Pletan's physicians, and Kara Mae Pletan would have heeded an adequate warning about the risk of small fiber peripheral neuropathy, *if* Abbott had provided one to them. But the converse is equally true, *i.e.,* where, as here, there are no legally adequate warnings, the presumption becomes, in essence, a presumption of causation.

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[1] *Erickson v. Baxter Healthcare, Inc.*, 151 F.Supp.2d 952, 970 (N.D.Ill. 2001), citing *Mahr v. G.D. Searle*, 72 Ill. App.3d 540, 28 Ill. Dec. 624, 390 N.E.2d 1214, 1233 (1979)("The law presumes that warnings, if given, will be heeded and followed and that medical practitioners will act competently.").

14. In the absence of warnings, it is impossible for physicians to be truly informed, objective "learned intermediaries."[2] Therefore, in the specific factual circumstances of this case, as the Illinois Court of Appeals held years ago, "what the doctor might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case."[3]

"Diagnosis"

15. Kara Mae Pletan was first diagnosed with Crohn's Disease in February 2008 by a gastroenterologist at the Bozeman Deaconess Hospital. He tried to treat the condition with several other medications. When these failed, she was referred to the Division of Gastroenterology at the Mayo Clinic. She saw Dr. Edward Loftus at the Mayo Clinic in Rochester, Minnesota, and he prescribed Humira®.

16. Kara Mae Pletan received her first loading dose on April 11, 2008, followed by two more injections, two weeks apart. On May 13, 2008 she began experiencing tingling in her toes. She skipped the May 23 injection as she was scheduled for surgery for Crohn's. Following surgery, on her doctor's orders, she resumed the Humira® injections, and the tingling in her fingertips and toes quickly progressed to stabbing pains and hypersensitivity in her fingertips, toes and the balls of her feet. As her symptoms worsened, Dr. Loftus advised that she discontinue the Humira® injections on July 3, 2008 and referred her to a neurologist at the Mayo Clinic, Dr. Michael Silber, for further treatment.

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[2] There are a number of additional reasons why the "learned intermediary" doctrine, usually asserted as an affirmative defense by most pharmaceutical companies, does not apply in this case. If Abbott chooses to raise that defense, we will provide the Court with ample authority to reject this defense.

[3] *Mahr, supra* at 1232, citing *Hamilton v. Hardy*, 37 Colo. App. 375, 549 P.2d at 1109.

17. On July 31, 2008, Dr. Silber diagnosed Kara Mae Pletan with small fiber neuropathy that was most likely the result of treatment with Humira®. Dr. Loftus concurred with the diagnosis, referring to her condition as "severe," and also told Kara Mae Pletan that it was most likely due to Humira®. He also told her that, unfortunately, there was probably permanent nerve damage in her fingertips and feet.

18. Kara Mae Pletan's treating physicians from the Mayo Clinic were right. Her small fiber peripheral neuropathy *was caused* by Humira®.

19. Small fiber peripheral neuropathy is extremely painful and debilitating. In Kara Mae Pletan's case, although the progression of the nerve damage seems to have stopped once she stopped taking the Humira® injections, the nerve damage in her fingertips and feet appears to be permanent and the consequences for this young woman's life are horrendous.

20. Kara Mae Pletan is able to function (and sleep), but only with the help of extremely high doses of pain medication. Even with the pain medication, the discomfort and pain effects Kara Mae Pletan day and night. This former athlete is no longer able to work out at the gym or enjoy even regular hikes with her dog, Dakota. Anything touching her feet is uncomfortable and painful, and she tries to walk as little as possible. This is very difficult for Kara Mae Pletan who was a exercise science major in school and who always enjoyed a vigorously active lifestyle. Her Humira®-induced neuropathy brought life as she knew it to an immediate stop at the young age of 32.

21. Just as frustrating and painful for Kara Mae Pletan were her efforts to continue her job in her family's Slumberland furniture store, of which she was co-owner with her brother Lane. Kara Mae Pletan was in charge of the family's Bozeman, Montana store and enjoyed a "hands on" roll that included unloading furniture, interacting with customers, and walking miles a day in the expansive store, making sure business was running smoothly and customers were happy.

Unfortunately for Kara Mae Pletan, her work days have come to an end. Time on her feet is too painful, and she is no longer able to continue in this capacity. Due to her inability to work, the family made the difficult decision to sell the Bozeman, Montana store. Lane simply could not do it on his own.

22. Kara Mae Pletan is currently able to ride a recumbent bike, but only if she exerts pressure with her heels, not the balls of her feet - somewhat of an awkward method. The damage caused by Humira® has affected every aspect of Kara Mae Pletan's life - social, emotional, physical, and professional. Her doctors are still not able to tell her whether or not the pain will eventually subside.

Still No Adequate Warnings

23. As the United States Supreme Court observed in its recent case of *Wyeth v. Levine*, it is drug companies, not the FDA, that are responsible for the adequacy of their labeling and for timely communicating warnings about dangers in an effective manner. Sadly, Abbott has not taken that message to heart.

24. The label for Humira® has been updated and modified to include warnings of adverse side effects on several occasions, but always at the behest of the FDA instead of at the initiative of Abbott. For example, with regard to the risks of lymphomas and other forms of malignancies, the FDA has now required both a **BLACK BOX WARNING** and Patient Medication Guide to alert both physicians and patients to these potentially dangerous side effects.

25. But the FDA has yet to focus in on the risk of neuropathy and other forms of neurological side effects, and Abbott has chosen to provide little if any information about these risks to either physicians or patients. For example, in the current label for Humira®, Abbott briefly

mentions the risk of "paresthesia" under Other Adverse Reactions. This is hardly a sufficient warning for physicians, much less for patients.

26. In light of Abbott's clear knowledge of this risk, given the 2006 article and other available information, and considering the life-altering, devastating effects for patients like Kara Mae Pletan from small fiber peripheral neuropathy, Abbott's decision to withhold warnings about this risk constitutes the kind of "conscious and reckless indifference" which may give rise to the imposition of punitive or exemplary damages.

27. All theories of liability and recovery pled herein are cumulatively and alternatively pled with no election of remedies being made until such time as the trier of fact has resolved disputed issues of fact and the Court compels such an election, if, in fact, the Court does so.

COUNT I
STRICT PRODUCTS LIABILITY DESIGN DEFECT CLAIM

28. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

29. Defendant Abbott is the manufacturer, designer, distributor, seller, and/or supplier of Humira®.

30. The Humira® manufactured and supplied by Defendant Abbott was defective in design or formulation in that, when it left the hands of Defendant Abbott, it was unreasonably dangerous for the use by a reasonable prudent consumer when using it as intended or in a reasonably foreseeable manner.

31. As a direct and proximate result of Plaintiff's reasonably anticipated use of Humira® as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendant Abbott, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for compensatory damages in excess of $50,000.00, her costs incurred, post-judgment interest, and for such other relief as this Court deems just and proper.

COUNT II
STRICT PRODUCTS LIABILITY DEFECT CLAIM - DUE TO FAILURE TO WARN

32. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

33. The Humira® manufactured and/or supplied by Defendant Abbott was defective due to inadequate warnings or instructions because Defendant Abbott knew or should have known that the product created significant risks of serious bodily harm to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

34. The Humira® manufactured and/or supplied by Defendant Abbott was defective due to inadequate post-marketing warnings or instructions because, after Defendant Abbott knew or should have known of the risk of serious bodily harm from the use of Humira®, Defendant Abbott failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

35. As a direct and proximate result of Plaintiff's reasonably anticipated use of Humira® as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendant Abbott, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for compensatory damages in excess of $50,000.00, her costs incurred, post-judgment interest, and for such other relief as this Court deems just and proper.

COUNT III
NEGLIGENCE CLAIM

36. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

37. Defendant Abbott had a duty to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Humira® into interstate commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

38. Defendant Abbott failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Humira® into interstate commerce in that Defendant Abbott knew or should have known that the product caused such significant bodily harm and was not safe for use by consumers.

39. Defendant Abbott also failed to exercise ordinary care in the labeling of Humira® and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury due to the use of Humira®.

40. Despite the fact that Defendant Abbott knew or should have known that Humira® posed a serious risk of bodily harm to consumers, Defendant Abbott continued to manufacture and market Humira® for use by consumers.

41. Defendant Abbott knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendant Abbott's failure to exercise ordinary care as described above.

42. As a direct and proximate result of Plaintiff's reasonably anticipated use of Humira® as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce

by Defendant Abbott, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for compensatory damages in excess of $50,000.00, her costs incurred, post-judgment interest, and for such other relief as this Court deems just and proper.

COUNT IV
BREACH OF EXPRESS WARRANTY CLAIM

43. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

44. Defendant Abbott expressly warranted that Humira® was a safe and effective prescription medication for the treatment of Crohn's disease.

45. The Humira® manufactured and/or sold by Defendant Abbott did not conform to these express warranties because it caused serious injury to consumers when taken in recommended dosages.

46. Timely notice was tendered to Defendant Abbott pursuant to the applicable provisions of the Uniform Commercial Code and pursuant to 810 ILCS 5/2-607(3)(a) by the filing of this complaint and the service of the same upon said Defendant.

47. As a direct and proximate result of Defendant Abbott's breach of warranty, Plaintiff has suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages, and losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for compensatory damages in excess of $50,000.00, her costs incurred, post-judgment interest, and for such other relief as this Court deems just and proper.

COUNT V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY CLAIM

48. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

49. At the time Defendant Abbott designed, manufactured, marketed, sold, and/or distributed Humira® for use by Plaintiff, Defendant Abbott knew of the use for which Humira® was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

50. Plaintiff reasonably relied upon the skill and judgment of Defendant Abbott as to whether Humira® was of merchantable quality and safe for its intended use and upon Defendant Abbott's implied warranty as to such matters.

51. Contrary to such implied warranty, Humira® was not of merchantable quality or safe or fit for its intended use, because the product was unreasonably dangerous as described above.

52. Timely notice was tendered to Defendant Abbott pursuant to the applicable provisions of the Uniform Commercial Code and pursuant to 810 ILCS 5/2-607(3)(a) by the filing of this complaint and the service of the same upon said Defendant.

53. As a direct and proximate result of Defendant Abbott's breach of warranty, Plaintiff has suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for compensatory damages in excess of $50,000.00, her costs incurred, post-judgment interest, and for such other relief as this Court deems just and proper.

COUNT VI
NEGLIGENT MISREPRESENTATION CLAIM

54. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

55. Defendant Abbott had actual knowledge based upon studies, published reports and clinical experience that its product Humira® created an unreasonable risk of serious bodily injury to consumers, or should have known such information.

56. Defendant Abbott negligently omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safe in order to avoid losses and sustain profits in sales to consumers.

57. Plaintiff reasonably relied to her detriment upon Defendant Abbott's negligent misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff reasonably relied upon Defendant Abbott's misrepresentations to Plaintiff that Humira® was safe for human consumption and/or use and that Defendant Abbott's labeling, advertisements and/or promotions fully described all known risks of the product.

58. As a direct and proximate result of Defendant Abbott's negligent actions, omissions and misrepresentations, Plaintiff has suffered physical injury, harm, damages, economic and non-economic loss, and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for compensatory damages in excess of $50,000.00, her costs incurred, post-judgment interest, and for such other relief as this Court deems just and proper.

COUNT VII
UNJUST ENRICHMENT CLAIM

59. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

60. As the intended and expected result of their conscious wrongdoing, Defendant Abbott has profited and benefitted from the purchase and implementation of Humira® by Plaintiff.

61. Defendant Abbott has voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendant Abbott's fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality, nature, or fitness that had been represented by Defendant Abbott or that Plaintiff, as a reasonable consumer, expected to receive.

62. By virtue of the conscious wrongdoing alleged above, Defendant Abbott has been unjustly enriched at the expense of Plaintiff, who is entitled in equity, and hereby seeks, the disgorgement and restitution of Defendant Abbott's wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendant Abbott's unjust enrichment.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for compensatory damages in excess of $50,000.00, her costs incurred, post-judgment interest, and for such other relief as this Court deems just and proper.

COUNT VIII
VIOLATION OF ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT CLAIM

63. Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein and further alleges as follows:

64. At all times pertinent hereto, Plaintiff was a "consumer" and "person" as those terms are defined in the Illinois Consumer Fraud and Deceptive Business Practices Act (the "Consumer Fraud Act") 815 ILCS 505/1.

65. That at all times pertinent hereto, Defendant Abbott was engaged in providing "advertisements" and "merchandise" in "trade" and "commerce" as those terms are defined in the Consumer Fraud Act, 815 ILCS 505/1.

66. That Defendant Abbott (a) engaged in unfair and deceptive acts and practices by providing unfair, false, deceptive, and unconscionable representations and statements in its advertisements, telemarketing, public relations and other promotional materials, including but not limited to:

> Overstating the efficacy and safety of Humira® by suggesting that Humira® is safe and not associated with, or otherwise causes neuropathy

in order to attract and lure Plaintiff and other consumers to use the prescription drug Humira®; (b) with the intent on Defendant Abbott's part that Plaintiff and other consumers would rely on this deception; and (c) which all occurred in a course of conduct involving trade and commerce.

67. That the above and foregoing unfair and deceptive acts and practices constitute violations of the Consumer Fraud Act, 815 ILCS 505/2.

68. That as a direct and proximate result of the unfair and deceptive acts and practices of Defendant Abbott, Plaintiff was deceived.

69. Defendant Abbott's acts, omissions, misrepresentations, non-disclosures and practices could foreseeably lead to a likelihood of confusion, and did confuse Plaintiff when purchasing Defendant Abbott's defective and misrepresented product.

70. Plaintiff is entitled to damages and other statutory relief provided in the Act including but not limited to, appropriate injunctive and equitable relief.

71. The policies, acts and practices alleged herein were substantial, were not outweighed by any countervailing benefits to Plaintiff and caused damages to Plaintiff that could have been avoided. Such conduct is unethical, unscrupulous and against public policy.

72. The above-described unfair and unconscionable acts and practices conducted by Defendant Abbott continue to this day and will likely result in damages in the future.

73. As a result of the conduct described herein, Defendant Abbott has been unjustly enriched at Plaintiff's expense.

74. Plaintiff seeks an order of this court declaring such deceptive acts and practices to be violative of the Act, requiring Defendant Abbott to immediately cease such unfair methods of competition and enjoining Defendant Abbott from continuing to conduct business via the unfair and unconscionable acts and practices as complained herein. Plaintiff additionally requests an order disgorging Defendant Abbott's ill-gotten gains and awarding Plaintiff full damages, plus attorney's fees and costs.

WHEREFORE, Plaintiff prays that she be awarded her actual economic damages in excess of $50,000; her costs incurred, her attorney's fees and costs; and for injunctive relief in the form of an order declaring Defendant Abbott's conduct to be deceptive and a violation of the Consumer Fraud Act, and to order and direct Defendant Abbott cease and desist from engaging in such unfair and deceptive advertising and enjoining it further violations of the Consumer Fraud Act.

Respectfully submitted,

GARY D. MCCALLISTER & ASSOCIATES, LLC

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