IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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NICHOLAS SHELDON, Plaintiff, v. JANSSEN PHARMACEUTICALS, INC., a/k/a ORTHO-MCNEIL JANSSEN PHARMACEUTICALS, INC. Defendant.	**VERIFIED COMPLAINT AND JURY DEMAND** ECF

Plaintiff, Nicholas Sheldon, for his complaint against Defendants, avers:

THE PARTIES

1. That at all times herein mentioned, Plaintiff, NICHOLAS SHELDON (hereinafter, "Plaintiff"), is an adult individual and resident of 119 Green Knolls Drive, Rochester, New York, County of Monroe.

2. The following Defendants will be collectively referred to as "Pharmaceutical Defendants" in this Complaint.

3. Defendant JANSSEN PHARMACEUTICALS INC., a/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTRICALS, INC, a/k/a JANSSEN PHARMACEUTICA, INC. (hereinafter, "Janssen") is a Pennsylvania corporation with its principal place of business located

at 1125 Trenton-Harbourton Rd. Titusville, NJ 08560. Janssen may be served at Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd. Titusville, NJ 08560. Defendant Janssen Pharmaceuticals, Inc. has conducted substantial business and derived substantial revenue from and within the State of New York. Defendant expected or should have expected its business activities to have consequences with the State of New York as it was engaged in conduct and regularly transacted business in the State of New York.

4. Defendant JOHNSON & JOHNSON, INC., (hereinafter, "J&J") is a New Jersey corporation, which has its principal place of business at ONE JOHNSON & JOHNSON PLAZA, NEW BRUNSWICK NJ 08933. JOHNSON & JOHNSON, INC. may be served at their principal place of business, ONE JOHNSON & JOHNSON PLAZA, NEW BRUNSWICK NJ 08933. JOHNSON & JOHNSON, INC. has conducted substantial business and derived substantial revenue from and within the State of New York. Defendant expected or should have expected its business activities to have consequences with the State of New York as it was engaged in conduct and regularly transacted business in the State of New York.

5. Defendant JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT L.L.C. (hereinafter, "J&JPRD") is a New Jersey corporation with its principle place of business at 920 Route 202, Raritan, NJ 08869. Defendant Johnson & Johnson Pharmaceutical Research & Development L.L.C. has conducted substantial business and derived substantial revenue from and within the State of New York. Defendant expected or should have expected its business activities to have consequences with the State of New York as it was engaged in conduct and regularly transacted business in the State of New York.

6. Upon information and Belief, J&JPRD is a wholly owned subsidiary of J&J.

7. Upon information and belief, Defendant EXCERPTA MEDICA INC., (hereinafter, "Excerpta") was and is a wholly owned subsidiary of ELSEVIER INC.

8. Upon information and belief, EXCERPTA MEDICA, INC., is a New York corporation with its principal place of business located at 685 U.S. 202, Bridgewater, NJ 08807. Excerpta Medica Inc., may be served at its principal place of business located at 685 U.S. 202, Bridgewater, NJ 08807. Defendant Excerpta Medica Foundation Inc., has conducted substantial business and derived substantial revenue from and within the State of New York. Defendant expected or should have expected its business activities to have consequences with the State of New York as it was engaged in conduct and regularly transacted business in the State of New York.

9. Upon information and belief, Defendant ELSEVIER INC., (hereinafter, "Elsevier") was, at the relevant time, a New York corporation with its principal place of business at 2 Newton Place, Suite 350, Newton, MA 02458. Elevier Inc., may be served at its principal place of business located at 2 newton Place, Suite 350, Newton, MA 02458. Defendant Elsevier Inc., has conducted substantial business and derived substantial revenue from and within the State of New York. Defendant expected or should have expected its business activities to have consequences with the State of New York as it was engaged in conduct and regularly transacted business in the State of New York.

10. Plaintiff alleges that each of the named Defendants is responsible in some manner for the occurrences alleged herein, and caused the hereinafter described injuries and damages sustained by Plaintiff individually.

11. At all times hereto, each of the Defendants was the agent and/or employee of every other Defendant in doing the acts herein alleged and was at all times herein mentioned, acting with the purpose and scope of their agency or employment.

BASIS FOR JURISDICTION AND VENUE

12. This Court has personal jurisdiction over Defendants pursuant to CPLR §§ 301 and 302 because Defendants are present and doing business within New York. Defendants are and were at all relevant times authorized to conduct business in New York and Defendants conducted such business within the state, including the performance of acts that caused or contributed to the harm giving rise to this action.

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs, and there is complete diversity of citizenship between Plaintiff and Defendants. This Court also has supplemental jurisdiction over the claim for relief that arises under New York statutory and/or common law pursuant to 28 U.S.C. § 1376(a) because it forms part of the same controversy and derives from the same facts.

14. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events giving rise to the claim arose in this District.

NATURE OF THE CASE

15. Plaintiff seeks monetary damages for the severe physical, economic and emotional injuries that he suffered as a result from his ingestion of a pharmaceutical drug manufactured and/or marketed by Defendants. Plaintiff alleges that, *inter alia*, Defendants' drug was defective;

Defendants' breached their express warranty of safety of their drug; Defendants' drug was inherently dangerous and was not of merchantable quality or safe nor fit for use; Defendants failed to warn of the harmful effects that Plaintiff ultimately suffered as a result from his ingestion of their drug; Defendant misrepresented and/or intentionally withheld information regarding the harmful effects of their durg; and that Defendants acted willfully, wantonly, and/or willful disregard for Plaintiff, his physicians and medical providers and other persons similarly situated.

FACTS

16. Plaintiff was prescribed Risperdal® (risperidone), in any of its forms, including the authorized generic risperidone ("Drug"), beginning in or around 1997 through 2012.

17. Defendants, Janssen, J&J, J&JPRD, Excerpta, and Elsevier (herein collectively referred to as "Pharmaceutical Defendants"), designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Drug which was originally intended to treat the symptoms of schizophrenia in adults. However, Risperdal does not cure schizophrenia or any other mental health condition.

18. As a result of being exposed to Pharmaceutical Defendants' Drug, starting in or about, 2010, Plaintiff suffered severe physical, economic and emotional injuries as a result of said Drug, including but not limited to, Plaintiff being diagnosed with gynecomastia (the abnormal breast growth in male) in approximately July 2010. The injuries and damages sustained by Plaintiff were caused by Pharmaceutical Defendants' Drug. At that time, Plaintiff did not know that his severe physical, economic, and emotional injuries were caused by Pharmaceutical Defendants' Drug.

19. Pharmaceutical Defendants concealed their knowledge of the Drug's defects from Plaintiff, the Food and Drug Administration (hereinafter referred to as "FDA"), the public in

general, and/or the medical community, specifically that the Drug had a higher rate of causing gynecomastia than actually disclosed, published, and/or reported.

20. When warning of safety and risks of the Drug, Pharmaceutical Defendants negligently and/or fraudulently represented to the medical and healthcare community, the FDA, to the Plaintiff and the public in general, that the Drug had been tested and were found to be safe and/or effective for its indicated use.

21. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase the Drug for use as schizophrenia medication, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

22. Pharmaceutical Defendants negligently and improperly failed to perform sufficient tests, if any, concerning the Drug's potential to cause gynecomastia during clinical trials.

23. Pharmaceutical Defendants were negligent in failing to adhere to and/or take into consideration warnings from the FDA, who determined that the Pharmaceutical Defendants were misleading the public in general, and the medical community in particular, through the use of advertisements which overstated the efficacy of the Drug and minimized the serious risks of the Drug.

24. As a result of the defective nature of the Drug, those persons who use and/or used and relied on the Drug have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, the development of gynecomastia, hyperprolactinemia, diabetes mellitus, galactorrhea, pituitary tumors, rapid weight gain, microadenomas of the pituitary gland, breast

cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetic ketoacidosis, hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome, as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment and/or medications, and fear of developing any of the above named health consequences.

25. Plaintiff herein has sustained certain of the above health consequences due to Plaintiff's use of the Drug.

26. Pharmaceutical Defendants concealed their knowledge of the defects in their products from the Plaintiff, and his physicians, hospitals, pharmacies, the FDA, and the public in general.

27. Consequently, Plaintiff seeks compensatory damages as a result of the Drug, which caused the Plaintiff to suffer the serious and dangerous side effects including, but not limited to, gynecomastia, rapid weight gain to the point of obesity, as well as other severe personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications.

FACTUAL HISTORY AS TO THE PHARMACEUTICAL DEFENDANTS

28. This is an action for injuries and damages suffered by Plaintiff as a direct and proximate result of the Pharmaceutical Defendants' negligent and wrongful conduct in connection

with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Drug.

29. Pharmaceutical Defendants, directly or through their agents, apparent agents, servants, and/or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and/or sold the Drug as a prescription that was initially designed to help treat adults with schizophrenia.

30. According to the National Institute of Mental Health, Schizophrenia is a "chronic, severe, and disabling disorder… which can terrify people with [schizophrenia] and make them withdrawn or extremely agitated." Schizophrenia has a variety of symptoms but they fall into three categories: positive, negative, and cognitive symptoms. The positive symptoms include hallucinations (hearing, seeing, tasting, and or feeling things that others do not), delusions (false belief that people believe despite being proven those beliefs are wrong), though disorders (unusual or dysfunctional ways of thinking like disorganized thinking), and movement disorders (agitated body movements). Negative symptoms include having a dull and monotonous voice, lacking pleasure in every-day life, lacking the ability to being and sustain planned activities, and speaking very little. Cognitive symptoms include a poor ability to understand information to make decisions, difficulty focusing and having problems with working memory (the ability to use information immediately after learning it).[1]

31. In or about 1989, a new class of drugs began to appear on the market to treat schizophrenia called "Second Generation" or "Atypical" antipsychotics.

32. The Drug, Risperdal, belongs to the class of medications called "Second Generation" or "Atypical" antipsychotics. Other atypical antipsychotics include Clozaril

[1] http://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml

(clozapine), Seroquel (quetiapine), Zyprexa (olanzapine), Geodon (ziprasidone), Abilify (apripiprazole), and Invega (paliperidone, which has the active metabolite 9-hydroxy-risperidone, the same active metabolite in Risperdal/risperidone).

33. The drug, risperidone, has several forms. Risperdal is the brand name for the drug risperidone. Invega is the brand name for the drug paliperidone. The active metabolite in risperidone, 9-hydroxy-risperidone, is also the active metabolite in the drug paliperidone. Risperdal comes in an oral tablet, oral dissolving tablet, and oral liquid form. Risperdal CONSTA is an injectable form of Risperdal. Invega comes in an extended release tablet. Invega SUSTENNA is an injectable form of Invega.

34. Risperdal was originally developed and approved for the use in the treatment of the symptoms associated with schizophrenia in the adult population. Risperdal does not cure schizophrenia or any other mental condition. The pharmacological action of Risperdal is unknown but it is thought to be dependent on the ability to block or moderate the level of dopamine, a hormone and neuro transmitter. It is believed that excessive levels of dopamine can cause hallucinations, abnormal thinking, and/or abnormal movements.

FACTUAL HISTORY AS TO RISPERDAL AND/OR INVEGA

35. Risperdal was approved by the Food and Drug Administration (hereinafter, "FDA") on or about December 29, 1993 for the limited treatment of the symptoms associated with schizophrenia, for adults.

36. On or about June 10, 1996, the liquid oral solution formulation of Risperdal was approved for treating schizophrenia symptoms for adults.

37. On or about April 2, 2003, the FDA approved the Risperdal M-Tab for adults, an oral dissolving tablet.

38. On or about October 29, 2003, the FDA approved Risperdal CONSTA, a long-acting intramuscular injection form of Risperdal.

39. On or about December 4, 2003, the FDA approved additional uses for the Risperdal oral tablet, oral solution, and M-Tab as monotherapy for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in adults, and as a combination therapy for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in adults, with Lithium or Valproate.

40. In or about October 2006, Risperdal was approved for the treatment of irritability associated with autistic disorder in children and adolescents (5-16 year olds), including symptoms of aggression towards others, deliberate self-injury, temper tantrums, and quickly changing moods. However, Risperdal was not approved to treat the whole spectrum of autistic disorders.

41. On or about August 22, 2007, Risperdal was approved for the treatment of schizophrenia in adolescents for the ages 13-17 years, and for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in children and adolescents ages 10-17 years.

42. By July 1999, the Risperdal label still contained no warnings concerning diabetes mellitus or hyperglycemia. Under the "adverse reactions" section, the label mentioned micturition disturbances and weight gain were twice as common in Risperdal patients as placebo patients. Under the "Other Events Observed During Pre-Marketing Clinical Trials" stated there was a positive ($p<0.5$) trend for gaining weight with the percentage of patients having a weight change of at least 7% body weight, being 18% for Risperdal vs 9% for placebos. The only mention of diabetes mellitus on page 19 of a 24-page PI, under "other events" and "metabolic and nutritional

disorders," but no indication of any association with Risperdal or the true severity and/or frequency of diabetes mellitus or hyperglycemia, or the need for blood glucose monitoring.

43. By 2005, the Risperdal label still did not mention gynecomastia, hyperprolactinemia, and/or precocious puberty in the WARNINGS section. The label also stated "[a]s with other drugs that antagonize D2 receptors, risperidone elevates prolactin levels" and that "[a]lthough disturbance such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds, the clinical significance of elevated prolactin levels is unknown for most patients."

44. In 2005, the label also did not contain any mention of gynecomastia, hyperprolactinemia, and/or precocious puberty in the ADVERSE REACTIONS section.

45. In 2005, the label claimed that the various "Endocrine disorders," including gynecomastia and male breast pain, were rare.

46. Even the 2006 label did not contain any mention of gynecomastia, hyperprolactinemia, and/or precocious puberty in the WARNING section.

47. The label did state that "[r]isperidone is associated with higher levels of prolactin elevations than other antipsychotic agents." However, the label did still claim that the various "Endocrine Disorders," including gynecomastia and male breast pain, were still "rare."

48. Finally, in 2007, the WARNINGS section finally contained mention of gynecomastia and hyperprolactinemia. However, in the "USE IN SPECIAL POPULATION" section, under "Pediatric Use," the JANSSEN Defendants made the following misleading statement about the propensity of young boys and girls to develop gynecomastia: "In clinical trials… gynecomastia was reported in 2.3% of RISPERDAL-related patients" in 1,885 children.

FACTUAL HISTORY AS TO SAFETY AND EFFICACY REPRESENTATIONS

49. Section 502(a) and 201(n) of the Federal Food Drug and Cosmetic Act ("the Act") require Janssen to fully and accurately disclose information relating to hyperprolactinemia, gynecomastia, diabetes mellitus, diabetic ketoacidosis, tardive dyskinesia, and the other adverse effects in the Risperdal and/or Invega package insert (PI) and other labeling, and to include adequate warnings concerning these and other risks in promotional materials for Risperdal and/or Invega.

50. The Act also prohibits Janssen from minimizing these risks and promulgating misleading claims that Risperdal and/or Invega is safer than the other antipsychotics on the market.

51. Upon information and belief, Janssen and J&J engaged in promotional activities that were false and/or misleading regarding the safety and efficacy of Risperdal and/or Invega, many of which were designed to illegally expand the use of Risperdal and/or Invega for off-label uses, without sufficient scientific proof of the products' safety and efficacy in treating disorders and/or safety and efficacy in specific demographics, in order to increase sales and profits at the expense of the safety, health, and well-being of the public, including the Plaintiff.

52. On or about October 14, 1994, Janssen had received a response from the Division of Drug Marketing Advertising and Communications ("DDMAC") of the FDA regarding new marketing themes that Janssen proposed for Risperdal. The DDMAC letter indicated the FDA was concerned about Janssen's intent to market Risperdal for indications that were broader and more encompassing than schizophrenia. The FDA was concerned the themes promoting use for "bipolar disease, psychotic depression, schizophrenic personality disorders, etc." was "misleading because it would suggest that Risperdal has been studied in that particular illness when, in fact, it has not."

53. In the same DDMAC letter for October 14, 1994, DDMAC also addressed another theme that Janssen proposed, which was geriatric treatment. The FDA was concerned about the

second proposed marketing theme for the geriatric population because labeling stated "[c]linical studies of Risperdal did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients" and DDMAC had determined there was a "lack of data to adequately address geriatric safety and efficacy."

54. On or about August 15, 1996, Janssen had sent in a request for a supplemental new drug application. On or about September 17, 1997, Janssen received a letter from the FDA in response to their supplemental new drug application that was dated August 15, 1996. In this letter, the FDA deemed the information in the request as "inadequate, and the supplemental applications are not approvable under section 505(d) of the Act and 21 CFR 314.125(b)." Specifically, the FDA addressed that the proposal acknowledged that they have "not provided substantial evidence from adequate and well-controlled trials to support any pediatric indications nor developed a rationale to extend the results of studies conducted in adults to children" and stated that Janssen's "rationale for proposing this supplement appears to be simply that, since Risperdal is being used in pediatric patients, this use should be acknowledged in some way in labeling." The FDA had deemed "the safety data submitted were also very limited" and concluded that "there is inadequate support for the changes sought."

55. On or about January 5, 1999, Janssen had received a letter from DDMAC regarding the FDA's concern over Janssen's promotional materials and activities for Risperdal. As a part of DDMAC's monitoring and surveillance program, the FDA found campaign materials that marketed Risperdal for geriatric patients, including but not limited to sales aids, journal ads, brochures, letters, a flash card, a calendar, and a computer program. In the letter, the FDA stated that "DDMAC has concluded that these materials are false, misleading, and/or lacking in fair

balance and in violation of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder."

56. On or about March 9, 1999 the FDA had again contacted Janssen regarding "promotional materials for Risperdal that were deemed to be false, misleading, or lacking fair balance, and in violation of the Federal Food, Drug, and Cosmetic Act." The FDA was concerned about the "campaign directed towards the use of Risperdal specifically for geriatric patients."

57. Upon information and belief, in 2003, a researcher at the FDA identified 131 distinct cases of risperidone related diabetes or hyperglycemia in the FDA spontaneous reporting database. However, only seven cases appeared in three publications. Of the patients reported in the FDA database, 78 of the 131 were newly diagnosed hyperglycemia, 46 of the 131 had an exacerbation of a preexisting disease, and 7 of the 131 could not be classified and Janssen never warned the FDA, physicians, or consumers of the growing number of reported cases of diabetes or hyperglycemia, or even the fact that these incidents were associated with Risperdal.

58. In or about September of 2003, the FDA required that a "WARNING" be added to the label for all atypical antipsychotics, including Risperdal, about the association of hyperglycemia and diabetes with these drugs and that there was a need for medical monitoring in certain patients.

59. On or about November 10, 2003, Janssen had sent out a Dear Healthcare Provider ("DHCP") Letter regarding Risperdal. The DHCP letter was regarding the FDA's request that all manufacturers of atypical antipsychotics to include a warning regarding hyperglycemia and diabetes mellitus and monitoring in their product labeling. DDMAC reviewed the DHCP letter for Risperdal and sent a warning letter to Janssen. In the letter, DDMAC stated it "concluded that the DHCP letter is false or misleading in violations of Sections 502(a) and 201(n) of the Federal Food,

Drug, and Cosmetic Act (Act)(21 U.S.C. 532(a) and 321(n)) because it fails to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling (PI), minimizes the risk of hyperglycemia-related adverse events, which in extreme cases is associated with serious adverse events including ketoacidosis, hyperosmolar coma, and death, fails to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible, and misleadingly claims that Risperdal is safer than other atypical antipsychotics." In DDMAC's conclusion and requested actions section of the letter, it stated "[t]he DHCP letter misleadingly omits material information about Risperdal, minimizes potentially fatal risks associated with the drug, and claims superior safety to other drugs in its class without adequate substantiation, in violation of Sections 502(a) and 201(n) of the Act (21 U.S.C. §§352(a) and 321(n))" and requests an immediate "cease and dissemination of promotional materials for Risperdal that contain claims the same or similar to those described above and provide a plan of action to disseminate accurate and complete information to the audience(s) that received the violative promotional materials."

60. On or about April 28, 2004, Janssen submitted a revised DHCP letter for review as well as an action plan to address the issues raised in the previous warning letter.

61. On or about May 27, 2004, the FDA rejected Janssen' corrective DHCP letter because it failed to "adequately address the issues raised in the DDMAC's April 19, 2004 warning letter."

62. On or about July 21, 2004, Janssen mailed a revised DHCP letter which advised that the FDA's "Warning Letter stated that the DCHP letter omitted important information regarding hyperglycemia and diabetes, including the potential consequences and the recommendation of regular glucose control monitoring that was added to the approved product labeling for Risperdal; minimized the potentially fatal risks of hyperglycemia-related adverse

events such as ketoacidosis, hyperosmolar coma, and death; minimized the importance of blood glucose monitoring; suggested that Risperdal did not increase the risk of diabetes, contraindicating the Warning in the revised product labeling; and made misleading claims suggesting that Risperdal has a lower risk of hyperglycemia and diabetes than other atypical antipsychotics without adequate substantiation which is inconsistent with the Prescribing Information for Risperdal" and that it "omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act."

63. Upon information and belief, the Pharmaceutical Defendants strenuously pushed back against any article critical of Risperdal, utilizing key opinion leaders friendly to Risperdal and Janssen as surrogates to submit correspondence attacking such articles.

64. Upon information and belief, Janssen and/or J&J failed and refused to report information concerning spontaneous adverse events to the FDA, physicians, and consumers in a proper and timely fashion.

65. Some or all of the Pharmaceutical Defendants knew, or with reasonable diligence, should have known, that the risk of new-onset diabetes mellitus or hyperglycemia associated with Risperdal and/or Invega was, and is, significantly higher than with older, cheaper, and equally effective "typical" antipsychotics, such as haloperidol and perphenazine.

66. Due to the flawed formulation of the Drug, the Drug increases the risk of gynecomastia, hyperprolactinemia, diabetes mellitus, galactorrhea, pituitary tumors, rapid weight gain, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetic ketoacidosis, hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis,

tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome and other related injuries in the patients to whom it is prescribed.

67. Pharmaceutical Defendants concealed their knowledge that Risperdal and/or Invega caused the above named injuries from Plaintiff, other consumers, the general public, and the medical community.

68. Indeed, the manufacturers did not put gynecomastia in the WARNINGS section when it was first approved in 1993 and only put it in the WARNINGS section 2007.

69. Indeed, the manufacturers did not adequately address diabetes and hyperglycemia until 2004.

70. Upon information and belief, some or all of the Pharmaceutical Defendants negligently and/or fraudulently reported results regarding gynecomastia occurrences from a selected few studies of the 17 studies that were conducted, with the intent to defraud and/or deceive the public in general, and the medical community in particular, which overstated the efficacy of the Drug and minimized the serious risks of the Drug.

71. Upon information and belief, among the 17 studies, there were a mix of short term, as short as 3 weeks, and long term studies, as long as 2 years.

72. Upon information and belief, there were approximately 965 patients in those studies that took Risperdal for a short period of time, duration ranging from 3 weeks to 36 weeks, whom did not develop gynecomastia that were calculated in with long term studies.

73. Upon information and belief, of the 17 studies, 6 of them were long term, 1 year or longer.

74. Upon information and belief, there were some studies that were included in the statistics that did not screen check the boys' chest/breast area.

75. Upon information and belief, of the 6 long term studies, only 4 of the studies performed physical examinations of the boys' chest/breast area.

76. Upon information and belief, J&J concealed the fact that 30 cases of gynecomastia were discovered out of 736 cases.

77. Upon information and belief, J&J concealed the actual occurrence of gynecomastia is almost double, or possibly higher, the reported rate to the FDA and in the label.

78. Upon information and belief, J&J's database contains records covering 1993 to 2005, which show an occurrence of 348 children with gynecomastia or lactating breasts.

79. Upon information and belief, the J&J only reported 136 children with gynecomastia or lactating breasts to the FDA and concealed the other 212 incidents.

FACTUAL HISTORY AS TO EXCERPTA AND ELSEVIER

80. Upon information and belief, the J&J and Jansen hired entities, like Excerpta and Elsevier (Herein collectively referred to as "Excerpta Defendants"), to consult with, plan, and/or execute the marketing and promotion of Risperdal and/or Invega by various methods, including but not limited to, ghostwriting journal articles, ghostwriting opinion pieces, ghostwriting reports, planning medical education, and/or creating poster presentations.

81. Excerpta advertises itself on its website, www.exerptamedica.com, as "a medical communications agency" which provides the pharmaceutical industry with "medical strategy and innovative medical communication programs" and offers services like "strategic consultancy," "publication planning," "medical education," "digital engagement," and "custom publishing."

82. Upon information and belief, Excerpta Defendants provided medical communications to healthcare professionals, patients, and consumers for over 60 years.

83. Upon information and belief, Janssen and/or J&J met with Excerpta Defendants, through directors, servants employees, and/or agents, met with the medical writers, officers, directors, servants, employees, and/or agents of the Excerpta Defendants by video conference, telephone, email, and/or in person to discuss, agree, and make plans to create, publish, distribute, and present posters, abstracts, medical journal articles, oral presentations, and/or written presentations at Janssen-sponsored events, professional meetings, and/or Continuing Medical Education events.

84. Upon information and belief, the Pharmaceutical Defendants created a publication strategy whereby the Excerpta Defendants would generate favorable articles touting Risperdal, including its off-label uses because there are Federal regulations to guard against drug manufacturers' control over such articles and that the articles and publications had to appear to come from physicians who independently investigate Risperdal.

85. Upon information and belief, with limited clinical support, Excerpta Defendants established Risperdal and/or Invega more prominently within the antipsychotic marketplace by:

a. Positioning Risperdal and/or Invega as a prominent medicine in the drug market as a "broad spectrum antipsychotic"

b. Increasing the base clinical support for off-label uses

c. Setting up Risperdal and/or Invega as an attractive therapeutic option to a much larger customer base than before; and

d. Build up a base of physician awareness of the psychiatric conditions Janssen sought to get approval for from the FDA.

86. Upon information and belief, Excerpta Defendants employed medical marketing companies, physicians, and ghostwriters to produce seemingly unbiased, independent, and reliable publications regarding Risperdal in a favorable light.

87. Upon information and belief, the Pharmaceutical Defendants assembled a portfolio of articles to be published in the medical community that promoted the efficacy of Risperdal and the need for Risperdal.

88. Upon information and belief, the portfolio was primarily written by medical writers and/or educators of the Excerpta Defendants, then those portfolio items were brought to academic authors to become the "author" (in name only) of the article in order to hide the true identity of the real authors, the Excerpta Defendants. This practice is known as ghostwriting, and it is calculated to create a positive hype in the medical community that appears to be unbiased and gives the articles a false sense of credibility.

89. Upon information and belief, these articles that were ghostwritten were written to create dissatisfaction in the antipsychotic market and to establish a need and desire for Risperdal over other drugs.

90. Upon information and belief, the named "authors" were denied access to the data from the clinical trials and were also not allowed to have any meaningful input into the articles and the Excerpta Defendants had exclusive responsibility for drafting and revising the articles.

91. Upon information and belief, Excerpta Defendants created publications that focused on providing scientific, clinically pertinent, and timely information on off-label, and unapproved, uses of Risperdal and/or Invega to build awareness of diseases and condition Risperdal and/or Invega could potentially be used for.

92. Upon information and belief, Excerpta Defendants are accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education to physicians.

93. Upon information and belief, Excerpta Defendants offered a CME program titled "Broadening Horizons: Advances in Understanding the Etiology, Effect and Treatment of Anxiety Disorders" which had several panels, including panels that promoted Risperdal for "adjunctive anxiety therapy," which Risperdal is not an FDA approved indication for Risperdal.

94. Upon information and belief, J&J and/or Janssen, or their entities and/or subsidiaries had sponsored several panels at the Broadening Horizons CME.

95. Upon information and belief, Excerpta Defendants also offered a CME titled "Atypical Antipsychotic Drug Augmentation in Resistant Major Depression Disorder." Risperdal has not been approved by the FDA for treatment of major depression disorder. Excerpta Defendants held the copyright for the materials at this CME and again, J&J and/or Janssen, or their entities and/or subsidiaries, sponsored several of these panels.

96. Upon information and belief, Excerpta Defendants helped J&J and Janssen meet their marketing objectives not only with CME's, publications, but also with interactive solutions and outreach to healthcare professionals, patients, and consumers.

97. Upon information and belief, Excerpta Defendants offered an integrated team of more than 120 experienced professionals to plan, support, and facilitate Janssen's marketing objectives at each phase of Risperdal's and/or Invega's life cycle, who had scientific, business, logistical, and online expertise in the industry.

98. Upon information and belief, Dr. Joseph Biederman and/or Massachusetts General Hospital had received millions of dollars from contracts and funding for Janssen-Sponsored work

promoting the treatment of bipolar disorder in children as young as 2 years old and promoting Risperdal in treating a variety of conditions in children and adolescents in or about 2003 to 2005.

99. According to The Chronicle of Higher Education's article "Major Fraud Plea Has University Scientists Regretting Journal Article," by Paul Basken dated November 20, 2013, that after J&J pleaded guilty to the Department of Justice's investigations, various professors had started distancing themselves and their associations with Risperdal. Some authors had started requesting their names be removed as authors from the journal articles, reconsidering their articles, and/or requesting the journals to retract their articles regarding Risperdal.

100. According to the New York Times article, "Drug Maker Told Studies Would Aid It, Papers Say" by Gardiner Harris, published on March 19, 2009, the influential Harvard child psychiatrist, Dr. Joseph Biederman, had been deposed in a multistate litigation in New Jersey. The investigation revealed documents that showed one of Dr. Biederman's "Key Projects for 2004" was to have a trial to compare Risperdal with its competitors in managing pediatric bipolar disorder which "will clarify the competitive advantages of risperidone vs. other neuroleptics" and that J&J intended to use its connection with Dr. to increase sales.

FDA PROHIBITON OF OFF LABEL MARKETING AND PROMOTION

101. "Off-Label" prescribing of drugs occurs when a drug is prescribed by a medical professional for use beyond those contained in the drug's FDA-approved uses. This includes prescribing the drug for conditions not indicated on the label, treating the indicated condition at doses not indicated on the label, treating the indicated condition at frequencies not indicated on the label, ore treating a different patient population (e.g. treating child patients or geriatric patients with a drug that is approved for adult patients).

102. Pursuant to the FDA Modernization Act of 1997, an off-label use of a drug can cease to be off-label only if the manufacturer conducts studies and submits a new drug application demonstrating to the satisfaction of the FDA that the product is a safe and effective treatment in the new proposed use or uses. 21 U.S.C. §360aaa(b) and (c).

103. Under the FDA laws and regulations, a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for off-label purposes, and a manufacturer illegally "misbrands" a product if the product's labeling (which by definition, includes all manufacturer promotional and advertising material) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

104. Congress and the FDA also prohibited manufacturers from employing indirect methods to accomplish the same end. Congress and the FDA promulgated laws and regulations designed to regulate two of the most prevalent indirect promotional strategies: a) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and b) manufacturer support for Continuing Medical Education programs that advocate off-label uses of their drugs.

105. The FDA does permit a manufacturer to disseminate information regarding off-label usage ONLY in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6.

106. The FDA does not permit any other circumstance where a manufacturer disseminates information concerning the off-label uses of a drug to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or federal and state government agencies UNLESS such information is fair and balance and the manufacturer meets the following 5 conditions:

1. Information concerns the drug that has been approved, licensed, and cleared for marketing by the FDA;
2. The information is in the form of an unabridged copy of a peer-reviewed scientific or medical journal article or reprint, or an unabridged reference publication that permits to a clinical investigation involving the drug and that is considered scientifically sound by experts who are qualified to evaluate the product's safety and efficacy;
3. The information does not pose a significant health risk to the public.
4. The information is not false or misleading; and
5. The information is not derived from clinical research conducted by another manufacturer, unless permission is received from that manufacturer. 21 C.F.R. § 201.6(a) and 21 U.S.C. §§360aaa, 360aaa-1.

107. The FDA has published an agency enforcement policy titled "Guidance for Industry: Industry-Supported Scientific and Educational Activities." 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R)(1997). This document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA considers in determining whether a program is free from a company's influence and bias. Any promotion of off-label drug uses at a CME program that fails the independence test violates Congress' off-label marketing restrictions.

108. Off-label uses of Risperdal continue to increase. According to a 2006 publication in the Archives of Internal Medicine, Risperdal was used off-label 66% of the time in 2006. Today, according to published market research data, as much as 70% of the prescriptions for Risperdal are for off-label use.

109. According to www.drugs.com, in 2007, Risperdal became the 14th best-selling drug in the US. Additionally, the branded version in 2007 earned Janssen $2.5 billion. The $2.5 billion revenue from Risperdal represented more than 6% of J&J's company-wide sales. Off-label use clearly has greatly increased Risperdal sales.

110. Upon information and belief, the Pharmaceutical Defendants used similar tactics to promote Invega for off-label uses.

111. Upon information and belief, the Pharmaceutical Defendants materially violated the laws and regulations governing off-label promotion activities, labeling, and misbranding as well as the applicable standard of care in promoting use of Risperdal and/or Invega for unapproved uses in children, adolescents, adults, and the elderly by improperly disseminating medical and scientific publications concerning the off-label uses of Risperdal and/or Invega and their support for CME programs that advocated off-label uses for Risperdal and/or Invega.

112. Pharmaceutical Defendants did not adequately and/or timely inform the consumers and the prescribing medical community about the risks associated with the Drug's usage, nor did the Pharmaceutical Defendants warn or otherwise adequately advise physicians to institute monitoring procedures for the first signs of gynecomastia, hyperprolactinemia, diabetes mellitus, galactorrhea, pituitary tumors, rapid weight gain, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetic ketoacidosis, hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome and/or other related injuries.

113. The current warnings for the Drug are still simply inadequate. The Pharmaceutical Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiff herein.

114. Pharmaceutical Defendants willfully, wantonly, and with malice, withheld the knowledge of true risk of gynecomastia, hyperprolactinemia, diabetes mellitus, galactorrhea,

pituitary tumors, rapid weight gain, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetic ketoacidosis, hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome and/or other related injuries in users of the Drug to prevent any chances of their product's registration from being delayed or rejected by the FDA.

115. As the manufacturers, marketers, and distributors of the Drug, Pharmaceutical Defendants knew or should have known that the Drug's true risk and association with gynecomastia, hyperprolactinemia, diabetes mellitus, galactorrhea, pituitary tumors, rapid weight gain, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetic ketoacidosis, hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome and/or other related injuries.

116. With the knowledge of the true relationship between use of the Drug and gynecomastia, hyperprolactinemia, diabetes mellitus, galactorrhea, pituitary tumors, rapid weight gain, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetic ketoacidosis, hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, neuroleptic malignant syndrome and/or other related injuries, rather than taking steps to pull the Drug off the market or provide adequate warnings,

Pharmaceutical Defendants promoted, and continue to promote, the Drug as a safe and effective treatment for children, adolescents, and adults with schizophrenia, bipolar 1 disorder, and autism.

117. While Pharmaceutical Defendants have enjoyed great financial success from their blockbuster Drug, they continue to place American citizens a risk.

118. Consumers, including Plaintiff, who have used the Drug for the treatment of their bipolar disorder, schizophrenia, and/or autism, had several alternative safer products available to treat their condition and have not been adequately warned about the significant risks and lack of benefits associated with the Drug's therapy.

119. Pharmaceutical Defendants, through their affirmative misrepresentations and omissions, actively concealed, from Plaintiff and Plaintiff's physicians, the true and significant risks associated with the Drug's use.

120. As a result of the Pharmaceutical Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not have reasonably known, or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Plaintiff's use of the Drug were the direct and proximate result of Pharmaceutical Defendants' conduct.

121. At all times relevant hereto, the Pharmaceutical Defendants have directly marketed and distributed the Drug to the medical community.

122. At all times relevant hereto, the Pharmaceutical Defendants have directly marketed the Drug to the consuming public throughout the United States, including the Plaintiff herein.

123. Pharmaceutical Defendants departed from, and failed to meet requirements, of laws, regulations, and class and product specific requirements, including failing to adequately

undertake post-approval marketing studies on the safety of the Drug as dictated by good pharmaceutical science standards.

124. Pharmaceutical Defendants both over-promoted the Drug and under-warned about its risks, including, but not limited to:

- In print advertising;
- On their website and blogs;
- Advertised to users that use of the Drug was 'safe' whereas it was not and Pharmaceuticals Defendants knew, or should have known, it was not;
- Promoted the Drug to doctors, clinics, and users as safe and/or safer than other antipsychotic medications;
- Supported CME's that promoted Risperdal; and
- Ghostwrote clinical journal articles, pathophysiology articles, literature reviews, and/or case reports.

125. Pharmaceutical Defendants did not perform adequate safety testing on the Drug as required by good pharmaceutical science practice.

126. Pharmaceutical Defendants failed to provide proper and full information as to the safety of the Drug.

127. Pharmaceutical Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied the Drug to the purchaser.

128. Pharmaceutical Defendants have never voluntarily sought to enlarge the warnings to include adequate warnings of gynecomastia or diabetes mellitus.

129. Instead Pharmaceutical Defendants marketed, and continue to market, the Drug as a low risk drug and continue to minimize and/or conceal the Drug's true risks and serious, and potentially deadly, side effects.

130. Manufacturers, such as the Pharmaceutical Defendants herein, are required to have systems in place to collect and analyze any complaints they receive from doctors and hospitals about their products.

131. Pharmaceutical Defendants did not timely inform the FDA, the public, nor treating physicians, of the defects with the Drug, despite their knowledge that injuries had occurred and had been reported to Pharmaceutical Defendants due to the above-described defects.

132. At all times mentioned herein, Pharmaceutical Defendants knew, or in the exercise of reasonable care should have known, that the Drug was such of a nature that it was not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with proper warnings, was not suitable for the purposes it was intended, and was unreasonably likely to injure the Drug's users.

133. Plaintiff's prescribing healthcare providers were unaware of the true degree and incidence of gynecomastia, hyperprolactinemia, diabetes, and other above-described injures associated use with the Drug and would have used and prescribed other methods for schizophrenia, bipolar disorder, and/or autism symptom treatment if they had been so informed.

134. Plaintiff suffered from severe and personal injuries, which are permanent and lasting in nature, including physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications both in the past and in the future.

135. As a direct and proximate result of the aforementioned conduct of Defendants, and each of them as set forth hereinafter, Plaintiff suffered injuries, including but not limited to gynecomastia, which resulted in damages in a sum in excess of the jurisdictional limits of the Court.

136. As a direct and proximate result of the aforementioned conduct of the Defendants, and each of them, Plaintiff was compelled to incur obligations for physicians, surgeons, nurses, hospital care, medicine, diagnostic testing, medical supplies, and other medical treatment, the true

and exact amount thereof being unknown to Plaintiff at this time, and Plaintiff prays leave to amend to this Complaint accordingly when the true and exact cost thereof is ascertained.

137. As a further direct and proximate result of the said conduct of the Defendants, and each of them, Plaintiff suffered a loss of income, wages, profits and commissions, a diminishment of earning potential, and other pecuniary losses, the full nature and extent of which are not known yet to Plaintiff; and leave is requested to amend this Complaint to confirm to proof at the time of trial.

AS FOR A FIRST CAUSE OF ACTION AGAINST ALL DEFENDANTS:
LACK OF INFORMED CONSENT

138. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

139. Defendants herein failed to inform Plaintiff of the risks, hazards and alternatives connected to the medical care prescribed and releasing the Plaintiff from medical facility, so that informed consent could be given.

140. Reasonably prudent persons in the Plaintiff's position would not have consented to the treatment rendered, in connection with the Plaintiff's condition if they had been fully informed of the risks, hazards and alternatives connected with said procedures.

141. The failure to adequately and fully inform the Plaintiff of the risks, hazards and alternatives of the medications prescribed and the treatment rendered in connection with the treatment of the Plaintiff is a proximate cause of the injuries the Plaintiff sustained.

142. As a consequence of the foregoing, there was no informed consent to the treatment rendered.

143. Reasonably prudent persons in the Plaintiff's position would not have consented to the treatment rendered, in connection with the Plaintiff's condition if they had been fully informed of the risks, hazards and alternatives connected with said procedures.

144. Defendants' failure to adequately and fully inform the Plaintiff of the risks, hazards and alternatives of the medications prescribed and the treatment rendered in connection with the treatment of the Plaintiff is a proximate cause of the injuries the Plaintiff sustained.

145. As a consequence of the foregoing, there was no informed consent to the treatment rendered.

146. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

147. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

148. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

149. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective

of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

150. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR A SECOND CAUSE OF ACTION AGAINST PHARMACUETICAL DEFENDANTS: NEGLIGENCE

151. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

152. Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of the Drug to ensure the safety of the Drug and to ensure that the consuming public, including the Plaintiff and Plaintiff's physicians and agents, obtained accurate information and instructions for the use of the Drug.

153. Defendants owed a duty toward foreseeable users of the Drug's to exercise reasonable care to ensure that the Drug was reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks increased gynecomastia, hyperprolactinemia, and diabetes mellitus as described above.

154. Defendants failed to exercise reasonable care in testing the Drug for side effects in ordinary and foreseeable users; and failed to disseminate to physicians accurate and truthful information concerning the effects of the Drug; thus, physicians were not able to make informed choices concerning the use of the Drug.

155. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of the Drug into the stream of commerce in that Defendants knew or should have known that the Drug created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

156. The dangerous propensities of the Drug as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the Drug for Plaintiff and other patients, similarly situated.

157. The information Defendants disseminated to physicians concerning the Drug was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

158. As a proximate result, Plaintiff suffered serious bodily injury and consequent economic and other losses when Plaintiff ingested the Drug.

159. The Defendants were negligent, and breached their duties of reasonable care to Plaintiff with respect to the Drug in one or more of the following respects:

a. Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of the Drug;

b. Defendants failed to conduct adequate testing; and

c. Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product; and

d. Despite knowledge of hazards, Defendants failed to adequately warn Plaintiff's physicians or Plaintiff that the use of the Drug could result in severe side effects as described above;

e. Despite the fact that the Defendants knew or should have known that their drug products caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks associated with the Drug as set forth above; Defendants willfully and deliberately failed to adequately disclose

these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety and/or welfare;

f. Defendants failed to design, develop, implement, administer, supervise and monitor its clinical trials for the Drug;

g. Defendants, in its promotion of the Drug, were overly aggressive and deceitful, and promoted the Drug in a fraudulent manner, despite evidence known to Defendants that the Drug was dangerous.

160. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff developed severe side effects as described herein, and suffered serious bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

161. The negligence, carelessness, and the willful and wanton misconduct of the Defendants was a proximate cause of Plaintiff's harms.

162. In the alternative, Defendants' acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing the Drug.

163. Furthermore, the economic damages and physical harm caused by Defendants' conduct would not have occurred had Defendants exercised the high degree of care imposed upon it and Plaintiff therefore also pleads the doctrine of *res ipsa loquitur*.

164. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

165. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss,

irrespective of the provisions of CPLR Section 1601, by reason of the fact that they owed Plaintiff and Plaintiff a non-delegable duty of care.

166. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

167. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

168. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR A THIRD CAUSE OF ACTION TO PHARMACEUTICAL DEFENDANTS: STRICT PRODUCTS LIABILITY

169. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

170. At all relevant times, the Pharmaceutical Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling the Drug.

171. The Drug was defective and unreasonably dangerous to consumers.

172. At all times mentioned in this Complaint, the Drug was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the Pharmaceutical Defendants.

173. The Drug are defective in its design or formulation in that when it left the hands of the Pharmaceutical Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.

174. The foreseeable risks associated with the design or formulation of the Drug, include, but are not limited to, the fact that the design or formulation of the Drug is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

175. At all times material to this action, the Drug was expected to reach, and did reach consumers in the state of New York and throughout the United States, including the Plaintiff, without substantial change in the condition in which it was sold.

176. Pharmaceutical Defendants, developed, marketed and distributed the Drug to the general public even after learning of the design and manufacturing defects that threatened the intended use of the Drug.

177. Pharmaceutical Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the Drug created a high risk of bodily injury and serious harm.

178. The dangerous propensities of the Drug's drug products were known or scientifically knowable, through appropriate research and testing, to the Pharmaceutical Defendants at the time said Pharmaceutical Defendants distributed, supplied, or sold the Drug, and not known to ordinary physicians who would be expected to prescribe the Drug for their patients.

179. The Drug, as distributed, were defective and unreasonably dangerous inasmuch as the Drug were not accompanied by warnings and instructions that were appropriate and adequate to render the Drug reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the Drug.

180. In order to advance Pharmaceutical Defendant's own pecuniary interests, Pharmaceutical Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of the Drug with knowledge that consumers would be exposed to serious danger.

181. At all times material to this action, the Drug were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Pharmaceutical Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was placed in the stream of commerce.

182. The Pharmaceutical Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery.

183. The Pharmaceutical Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of the Drug that caused the damages for which Plaintiff seeks recovery.

184. The reasonably foreseeable use of the Drug involved substantial dangers not readily recognizable by the ordinary physician who prescribed the Drug or the patient, including Plaintiff, who consumed the Drug.

185. The Pharmaceutical Defendants knew that the Drug were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that the Drug were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

186. Plaintiff and Plaintiff 's physicians did not know, nor had reason to know, at the time of the use of Pharmaceutical Defendants' drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

187. The above defects caused serious injury to Plaintiff when the Drug were used in its intended and foreseeable manner, and in the manner recommended by the Pharmaceutical Defendants and/or in a non-intended manner that was reasonably foreseeable.

188. In addition, at the time that the Drug left the control of the Pharmaceutical Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the Drug. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Drug's utility.

189. As a direct and proximate result of the wrongful acts of the Pharmaceutical Defendants, Plaintiff suffered severe bodily injury; suffered great pain of body and mind; suffered great embarrassment and humiliation; suffered the loss of enjoyment of life; and have been otherwise damaged to be further shown by the evidence.

190. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

191. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

192. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

193. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

194. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR FOURTH CAUSE OF ACTION AS TO THE PHARMACEUTICAL DEFENDANTS: MANUFACTURING DEFECT

195. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

196. At all times material to this action, Pharmaceutical Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling the Drug.

197. At all times material to this action, the Drug was expected to reach, and did reach consumers in the state of New York and throughout the United States, including Plaintiff, without substantial change in the condition from which it was sold.

198. At all times material to this action, the Drug were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Pharmaceutical Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following particulars posing a serious risk of injury and/or death.

199. When placed in the stream of commerce, the Drug contained manufacturing defects that rendered the product unreasonably dangerous;

200. The Drug's manufacturing defects occurred while the product was in the possession and control of the Pharmaceutical Defendants;

201. The Drug were not made in accordance with the Pharmaceutical Defendants' product specifications or performance standards; and,

202. The Drug's manufacturing defects existed before it left the control of the Pharmaceutical Defendants.

203. As a direct and proximate result of the wrongful acts of the Pharmaceutical Defendants, Plaintiff suffered severe bodily injury; suffered great pain of body and mind; suffered great embarrassment and humiliation; suffered a loss of enjoyment of life; and have been otherwise damaged to be further shown by the evidence.

204. For the above reasons, the Pharmaceutical Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross negligence.

205. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

206. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff and Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

207. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

208. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

209. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR FIFTH CAUSE OF ACTION AS TO PHARMACEUTICAL DEFENDANTS: FAILURE TO WARN

210. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

211. The Drug were defective and unreasonably dangerous when it left the possession of the Pharmaceutical Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff and/or their health care providers, of the dangerous risks and reactions associated with the Drug, including but not limited to its propensity to cause avoidable strokes, heart attacks, abnormal bleeding, and other serious injuries and side effects despite the

Pharmaceutical Defendants' knowledge of the increased risk of these injuries over similar Drug such as aspirin.

212. The Drug were defective due to inadequate post-marketing warnings or instruction because after Pharmaceutical Defendants knew or should have known of the risk and danger of serious bodily harm and/or death from the use of the Drug, Pharmaceutical Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and/or death.

213. Plaintiff was prescribed and used the Drug for its intended purpose.

214. Plaintiff could not have known about the dangers and hazards presented by the Drug.

215. The warnings that were given by the Pharmaceutical Defendants were not accurate, clear, complete and/or were ambiguous.

216. The warnings that were given by the Pharmaceutical Defendants failed to properly warn physicians of the increased risks of gynecomastia, diabetes mellitus, hyperprolactinemia and other serious injuries and side effects, and failed to instruct physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.

217. The warnings that were given by the Pharmaceutical Defendants failed to properly warn consumers of the increased risk of gynecomastia, diabetes mellitus, hyperprolactinemia, and other serious injuries and side effects.

218. The Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of the Pharmaceutical Defendants. The Pharmaceutical Defendants had a continuing duty to warn the Plaintiff and his physicians of the dangers associated with the Drug. Had the Plaintiff received adequate warnings regarding the risks of the Drug, Plaintiff would not have used the Drug.

219. As a direct and proximate result of the Drug's defective and inappropriate warnings, the Plaintiff suffered severe physical injuries and damages as described above.

220. As a direct and proximate result of the wrongful acts of the Pharmaceutical Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered great pain of body and mind; suffered great embarrassment and humiliation; suffered permanent impairment to Plaintiff's earnings capacity; incurred expenses for medical treatment of Plaintiff's injuries; and has been otherwise damaged to be further shown by the evidence.

221. For the above reasons, the Pharmaceutical Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross negligence.

222. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

223. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

224. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

225. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective

of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

226. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR SIXTH CAUSE OF ACTION AS TO PHARMACEUTICAL DEFENDANTS: BREACH OF EXPRESS WARRANTY

227. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

228. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of the Drug was expressly warranted to be safe for use by Plaintiff and other members of the general public.

229. At the time of making of the express warranties, Pharmaceutical Defendants, had knowledge of the purpose for which Pharmaceutical Defendant's products were to be used and warranted the same to be in all respect, fit, safe, and effective and proper for such purpose. Pharmaceutical Defendant's Drug was unaccompanied by warnings of its dangerous propensities that were either known or knowable by Pharmaceutical Defendant at the time of distribution.

230. Pharmaceutical Defendants placed the Drug into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including the Plaintiff, of the risks associated with the use of the Drug, or how to monitor for and avoid those known risks.

231. Pharmaceutical Defendants had a duty to exercise reasonable care in the research, development, design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of the Drug, including the duty to:

a. Ensure that the product did not cause the user unreasonably dangerous side effects;
b. Warn of dangerous and potentially fatal side effects; and
c. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiff.

232. When Plaintiff's physician prescribed the Drug and Plaintiff made the decision to use the Drug, both Plaintiff and his physician reasonably relied upon the Pharmaceutical Defendants and its agents to disclose known defects, risks, dangers and side effects of the Drug.

233. Plaintiff's physician, the FDA, and/or Plaintiff had no knowledge of the falsity or incompleteness of the Pharmaceutical Defendants' statements and representations concerning the Drug when Plaintiff's physician prescribed and/or otherwise provided the Drug and he purchased and used the Drug as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold or otherwise released into the stream of commerce by the Pharmaceutical Defendants.

234. Plaintiff justifiably and detrimentally relied on the warranties and representations of Pharmaceutical Defendants in the purchase and use of the Drug.

235. Pharmaceutical Defendants were under a duty to disclose the defective and unsafe nature of the Drug to physicians, the FDA, consumers and users, such as Plaintiff.

236. Pharmaceutical Defendants had sole access to material facts concerning the defects, and Pharmaceutical Defendants knew that physicians, the FDA and users, such as Plaintiff, could not have reasonably discovered such defects.

237. By the conduct alleged, Pharmaceutical Defendants, their agents and employees expressly warranted to Plaintiff's physician that the products were merchantable and fit for the purpose intended.

238. This express warranty was breached because the Drug was actually not safe and effective as Pharmaceutical Defendants had represented, and Plaintiff suffered injuries as a result.

239. Plaintiff reasonably relied upon the skill and judgment of Pharmaceutical Defendants, and upon said express warranty, in using Pharmaceutical Defendant's product. The warranty and representations were untrue in that the Drug were unsafe, and therefore, unsuitable.

240. As soon as the true nature of the products and the fact that the warranty and representations were false was ascertained, Pharmaceutical Defendant was notified of the breach of said warranty.

241. As a direct and proximate result of Pharmaceutical Defendants' misrepresentations, carelessness and negligence, the Plaintiff suffered severe physical injuries.

242. Because of Plaintiff's injuries, he has endured substantial pain and suffering, have incurred significant expenses for medical care and will continue to suffer emotionally and economically in the future.

243. As a result, Plaintiff seeks actual and punitive damages from Pharmaceutical Defendants.

244. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

245. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss,

irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

246. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

247. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

248. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR SEVENTH CAUSE OF ACTION AS TO PHARMACEUTICAL DEFENDANTS: BREACH OF IMPLIED WARRANTIES

249. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

250. The Pharmaceutical Defendants designed, manufactured, marketed, distributed, supplied and sold the Drug to help manage certain symptoms of schizophrenia, bipolar 1 disorder, and autism.

251. At the time that the Pharmaceutical Defendants manufactured, marketed, distributed, supplied and/or sold the Drug, they knew of the use for which it was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

252. Plaintiff's prescribing physician reasonably relied upon the skill, superior knowledge and judgment of the Pharmaceutical Defendants.

253. Plaintiff was prescribed, purchased and used the Drug in a reasonably foreseeable manner to designed to help manage certain symptoms of bipolar disorder, autism, and/or schizophrenia.

254. Due to the Pharmaceutical Defendant's wrongful conduct as alleged, the Plaintiff and Plaintiff's physician could not have known about the nature of the risks and side effects associated with the subject products, the Drug.

255. Contrary to the implied warranty for the Drug, it was not of merchantable quality and was not safe or fit for its intended uses and purposes.

256. As a direct and proximate result of the Pharmaceutical Defendants' breach of implied warranty, the Plaintiff suffered from pancreatic cancer and death.

257. As a result of Plaintiff's injuries, the Plaintiff has endured substantial pain and suffering and has incurred significant expenses for Plaintiff's medical care.

258. As a result, Plaintiff seeks actual and punitive damages from the Pharmaceutical Defendants.

259. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

260. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

261. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

262. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

263. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR EIGHTH CAUSE OF ACTION AS TO THE PHARMACEUTICAL DEFENDANTS: FRAUDULENT MISREPRESENTATION

264. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

265. Pharmaceutical Defendants had actual knowledge of facts, which demonstrated that representations in the package insert, and/or the PDR monograph, and/or literature and/or other mediums that the Pharmaceutical Defendants distributed concerning the Drug were false and misleading. Pharmaceutical Defendants had an absolute duty to disclose the true facts regarding the safety of the Drug to physicians and their patients and the medical community, which they negligently failed to do. Furthermore, Pharmaceutical Defendants had a duty to ensure that they had a reasonable basis for making the representations described above, to exercise reasonable care

in making those representations, to accurately make those representations, and to not make misrepresentations concerning the Drug, all of which Pharmaceutical Defendants failed to do.

266. Important information regarding the risk of the Drug was in the exclusive control of Pharmaceutical Defendants and was exclusively known by Pharmaceutical Defendants. In the furtherance of Pharmaceutical Defendants' own interests, Pharmaceutical Defendants disseminated false information regarding the Drug to physician and plaintiffs and did so knowing that the safety of the Drug depended on the accuracy of that information. Further, Pharmaceutical Defendants knew and expected that recipients of that information would rely on the information that the recipients would take action based upon the information, and that individuals would be put in peril by such actions and that those individuals would suffer physical harm as a result.

267. Pharmaceutical Defendants expressly and/or impliedly represented to Plaintiff and Plaintiff's physicians, the medical community, and members of the general public that the Drug was safe for use. The representations by Pharmaceutical Defendants were, in fact, false. The true facts were that the Drug were not safe for its intended use and were, in fact, dangerous to the health and body of the Plaintiff.

268. Pharmaceutical Defendants made the above-described representations with no reasonable grounds for believing them to be true. Pharmaceutical Defendants did not have accurate or sufficient information concerning these representations and they failed to exercise reasonable care both in ascertaining the accuracy of the information contained in those representations and in communicating the information.

269. The aforementioned misrepresentations or omissions were made to the Plaintiff and Plaintiff's physicians, and the medical community, all of whom justifiably and foreseeably relied on those representations or omissions. Plaintiff would not have suffered injuries but for the above

misrepresentations or omissions of Pharmaceutical Defendants. Thus, Pharmaceutical Defendants and Pharmaceutical Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

270. As a direct and proximate result of the wrongful acts of the Pharmaceutical Defendants, Plaintiff developed severe side effects as described herein, and suffered serious bodily injuy; suffered great pain of body and mind; suffered great embarrassment and humiliation; suffered the loss of enjoyment of life and have been otherwise damaged to be further shown by evidence.

271. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

272. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff and Plaintiff's damages, including but not limited to, Plaintiff and Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

273. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff and Plaintiff's damages, including but not limited to, Plaintiff and Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

274. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective

of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

275. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR NINTH CAUSE OF ACTION AS TO THE PHARMACEUTICAL DEFENDANTS: FRAUDULENT CONCEALMENT

276. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

277. At all times during the course of dealing between Pharmaceutical Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Pharmaceutical Defendants misrepresented the safety of the Drug for its intended use.

278. Pharmaceutical Defendants knew or were reckless in not knowing that its representations were false.

279. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Pharmaceutical Defendants fraudulently concealed and intentionally omitted the following material information:

a. that the Drug were not safe;
b. that the risks of adverse events with the Drug were high;
c. that the risks of adverse events with the Drug were not adequately tested and/or known by Pharmaceutical Defendants;
d. that Pharmaceutical Defendants were aware of dangers in the Drug, in addition to and above and beyond those associated with alternative medications;
e. that the Drug was defective, and that it caused dangerous side effects;
f. that the Drug was manufactured negligently;
g. that the Drug was manufactured defectively;
h. that the Drug was manufactured improperly;
i. that the Drug was designed negligently;

j. that the Drug was designed defectively; and

k. that the Drug was designed improperly.

280. Pharmaceutical Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Drug.

281. Pharmaceutical Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Drug.

282. Pharmaceutical Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the Drug was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of the Drug, and actions thereon, and to cause them to purchase, prescribe and/or dispense the Drug and/or use the product.

283. Pharmaceutical Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Pharmaceutical Defendants' concealment and omissions, and that these included material omissions of facts surrounding the Drug, as set forth herein.

284. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Pharmaceutical Defendants.

285. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer and/or was at a greatly increased risk of serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

286. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

287. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

288. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

289. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

290. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR TENTH CAUSE OF ACTION AS TO THE PHARMACEUTICAL DEFENDANTS: NEGLIGENT MISREPRESENTATION

291. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

292. Pharmaceutical Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, the Drug, had been tested and found to be a safe and effective form of therapy.

293. The representations made by Pharmaceutical Defendants were, in fact, false.

294. Pharmaceutical Defendants failed to exercise ordinary care in the representation of the Drug, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in those Pharmaceutical Defendants negligently misrepresented the Drug's high risk of unreasonable, dangerous side effects.

295. Pharmaceutical Defendants breached their duty in representing the Drug's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

296. As a result of the negligent misrepresentations of the Pharmaceutical Defendants set forth hereinabove, said Pharmaceutical Defendants knew and were aware or should have known that the Drug had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia gynecomastia, hyperprolactinemia, and/or diabetes mellitus as well as other severe and personal injuries which are permanent and lasting in nature.

297. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

298. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss,

irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

299. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

300. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

301. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR ELEVENTH CAUSE OF ACTION AS TO THE PHARMACUETICAL DEFENDANTS: FRAUD AND DECEIT

302. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

303. Pharmaceutical Defendants conducted research and used the Drug as part of their research.

304. As a result of Pharmaceutical Defendants' research and testing, or lack thereof, Pharmaceutical Defendants blatantly and intentionally omitted certain results of testing and research to the public, healthcare professional, and/or the FDA, including the Plaintiff.

305. Pharmaceutical Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

306. The information distributed to the public, the FDA, and the Plaintiff by the Pharmaceutical Defendants, including, but not limited to, reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

307. The information distributed to the public, the FDA, and the Plaintiff by Pharmaceutical Defendants intentionally included representations that Pharmaceutical Defendants' Drug carried the same risks, hazards, and/or dangers as other alternative medications.

308. These representations were all false and misleading.

309. Upon information and belief, Pharmaceutical Defendants intentionally suppressed, ignored, and disregarded test results not favorable to the Pharmaceutical Defendants, and results that demonstrated that the Drug was not safe.

310. Pharmaceutical Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of the Drug, specifically, but not limited to the Drug not having dangerous and serious health and/or safety concerns.

311. Pharmaceutical Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and Plaintiff, regarding the safety of the Drug.

312. That it was the purpose of Pharmaceutical Defendants in making these representations to deceive and defraud the public, the FDA, and/or Plaintiff, to gain the confidence

of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of the Drug and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use the Drug.

313. Pharmaceutical Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that the Drug were fit and safe for use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other alternative medications.

314. That Pharmaceutical Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the Drug did not present serious health and/or safety risks.

315. That Pharmaceutical Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the Drug did not present health and/or safety risks greater than alternative forms of medication.

316. That these representations and others made by Pharmaceutical Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

317. That these representations and others, made by Pharmaceutical Defendants, were made with the intention of deceiving and defrauding Plaintiff, including Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend and/or prescribe the Drug.

318. That Pharmaceutical Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of The Drug to the public at large, the

Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

319. That Pharmaceutical Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of the Drug by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of the Drug.

320. That Pharmaceutical Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as Plaintiff's respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on the Drug and/or that her healthcare providers would dispense, prescribe, and/or recommend the same.

321. Pharmaceutical Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

322. Pharmaceutical Defendants utilized direct to consumer advertising to market, promote, and/or advertise the Drug.

323. That the Plaintiff and/or Plaintiff's respective healthcare professionals did in fact rely on and believe the Pharmaceutical Defendants' representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Pharmaceutical Defendants' Drug.

324. That at the time the representations were made, the Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of the Drug.

325. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Pharmaceutical Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

326. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of the Drug, Plaintiff would not have purchased, used and/or relied on Pharmaceutical Defendants' Drug.

327. That the Pharmaceutical Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on Plaintiff.

328. As a result of the foregoing acts and omissions Plaintiff was caused to suffer gynecomastia.

329. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

330. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

331. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants

are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

332. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

333. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

AS FOR TWELVTH CAUSE OF ACTION AS TO THE PHARMACEUTICAL DEFENDANTS: CONSUMER FRAUD- VIOLATION OF GBL §349 AND §350

334. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

335. The Pharmaceutical Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff herein and Plaintiff's physicians and medical providers, rely upon such concealment, suppression and omission, in connection with sale, advertisement and promotion of the Drug, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe the Drug to patients/consumers such as the Plaintiff herein. By reason of the Pharmaceutical Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff herein, were caused to suffer ascertainable loss of money and property and actual damages.

336. The Pharmaceutical Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

337. The Pharmaceutical Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

338. The Pharmaceutical Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

339. New York has enacted statutes to protect consumers from deceptive, fraudulent and unconscionable trade and business practices. The Pharmaceutical Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Pharmaceutical Defendants knew it was defective and dangerous, and by other acts alleged herein.

340. The Pharmaceutical Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff.

341. As a direct and proximate result of the Pharmaceutical Defendants' violations of GBL §349 and §350, Plaintiff suffered damages, for which Plaintiff are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

342. As a direct and proximate result of Pharmaceutical Defendants' conduct, the Plaintiff used the Drug and the Plaintiff suffered serious physical injury, harm, and damages.

343. Pharmaceutical Defendants' action and omission as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

344. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

345. Pursuant to CPLR Section 1602 (2) (iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

346. Pursuant to CPLR Section 1602(2)(iv), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

347. Pursuant to CPLR Section 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands this court enter judgment in his favor and against the Defendants herein as follows:

A. Awarding on each of Plaintiff's Claims for such compensatory and punitive damages, inter alia for Plaintiff's severe physical, economic and emotional injuries resulting from the Defendants' tortious actions of at least $100 million, or any sum as the jury may impose;

B. Awarding Plaintiff punitive damages in an amount to be determined;

C. Awarding Plaintiff prejudgment and post-judgment interest on any monetary award in this action;

D. Awarding Plaintiff reasonable attorney fees;

E. Granting such other and further relief as the Court seems just and proper, including the interest, costs and disbursements of this action.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby respectfully demands a trial by jury of all issues triable of right by a jury.

Dated: New York, New York
January 10, 2016

MARC J. BERN & PARTNERS LLP

By: _____

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