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Attorneys for Plaintiffs

Mable Adams; Rickey D. Adams; Vivian Allen; Patricia A. Arredondo; Robert J. Ausura; Alma Avila, as Next Friend of Amber N. Avila, a Minor; Michael Azevedo; Della Baker; Oscar A. Barbosa; James S. Barnes; Kenneth L. Belt; Loren B. Bennett; Jerome T. Bielak; Susan A. Blake; Bertha M. Bonner; Charles Broadus; Bion L. Brown; Edward M. Brown; Shelettie Brown; Sylvia J. Brown; Willie A. Brown, on behalf of Robin A. Brown, an Incapacitated Adult; Angela Burley, as Next Friend of Lorenzo Stephen, a Minor; Carrie Burrell; Alana A. Calabrese; Juliana Capela; Steve Capela; Rebecca Carlisle; Danny L. Carroll; Elizabeth Carroll, on behalf of Thomas D. Carroll, an Incapacitated Adult; Karen Cesal, on behalf of Gerald M. Cesal, an Incapacitated Adult; Johnny L. Clark; Wayne Clark; David Clay; Thomas Clayton; Rosie Cohen; George Cole; Senora Collins; Libbell Count; Carol Cox; Loraine M. Cox; Barbara A. Cross; Mary Crum; Rafael S. Davis; Mary L. Diamond; Cynthia C Donaldson; Rebecca Dora; Ronald J. Dracy; David Dufrene; Jeanne A. Duggan; Stafford B. Elahi, Jr.; Debra K. Elliott; Jerry R. Erickson; Anthony Evans; 57	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION MIDDLESEX COUNTY DOCKET NO.: CIVIL ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Stephen J. Farrell; Edith Fearce; Mary Fedoris; :
Megan D. Finch; Sheral D. Flowers; Janice :
Ford; Allen Foster; Robbi L. Freed; Judy K. :
Freed, as Next Friend of Amanda F. Freed, a :
Minor; Karla Fuller; Debra A. Garrison; :
Kathleen Gates, as Personal Representative of :
the Estate of Cameron R. Lyseng, Deceased; :
Claudie Grace; Reginald L. Green; Jacqueline :
Griffith; Lametta M. Guerary; Fayquita :
Haggins; Wayne A. Hall; Lyle R. Hamons; Lisa :
Hardy; Mary Harris; Diane Harvey; Patrick :
Harvey; George Hayes, Jr.; Bryan T. Hayward; :
Bonnie Heard, as Next Friend of Russell B. :
Houston, a Minor; Sondra D. Henley; Marianne :
K. Henricks; Job Henry; Paula Hernandez; :
Catherine Henderson; Laura Herring; Brinda :
Hill-West; Rita Hodges; Penelope Holliday; :
Patrick J. Hurson; Diane Hurst; Brenda D. :
Hutson; Ross L. Illsley, Jr.; Rita Issa; Hollie S. :
Jackson; Katie Jackson; Patricia Jackson; :
Robert L. Jackson, Jr.; Belinda Johnson; James :
Johnson; Latricia Johnson, as Next Friend of :
Dequita S. Johnson, a Minor; Kimberly S. :
Jones; Cheryl Joyner; Hattie Keithly; Ella :
Kelly, as Personal Representative of the Estate :
of Myrtle K. Hughes, Deceased; Mary R. :
Kender; Randall C. King; Joan C. Kyle; Larry :
Ladner; Marie P. Laird; Shon E. Laissen; Ruth :
L. Lambert; Edna Langdon; Anne Lawson; :
Kelly S. Lehto; Ronald Lenoir; Ethel G. Lott; :
Mark A. Lovich; Richard Lunn; Lorine :
Malone; Jerry N. Mangan; Mary A. Martin- :
Dover; James D. Maynard; William J. :
McAleer; Tracy McBride, as Next Friend of :
Devon McBride, a Minor; Joseph M. :
McCracken; Joshua McCreary; Mary :
McDaniel; Randy L. McDaniel; Shirley :
McDonald; Willie McGhaw; Earl McNair; :
Tonya E. Melvin; Alonzo L. Mitchell, Sr.; :
Raymond Moore; Ricky Morris; Patricia L. :
Morrison; Harvey Munn; Christy Myers; :
Elizabeth Oribamise; Diane M. Otero; Cynthia :
R. Owens; Lonnie C. Owens, Sr.; Paula :
Pafford; Brenda Parks; Robert E. Paulin; :
Tammy Pelison, as Next Friend of Dwain :
Pelison, Jr., a Minor; Barbara Pilate; Crystal Y. :
Poole; Michael W. Prebe; Ornemus Reed; :
Harry M. Rich; Melody Richardson; Glenda D. :

Ridgway-Coulter; Sheila Riggs, as Next Friend of Kara S. Riggs, a Minor; Sharon A. Roberts; Cora L. Robinson; Sheila Robinson; John Rodgers; Jack K. Rogers; Karl D. Rupp; Jack W. Salamone; Cynthia Saul, as Next Friend of Jade Saul, a Minor; John M. Schum; John Schwamlein; Mildred E. Seymour; Debbie Shaw; Robbie J. Sills; Lara A. Sims; Linda Singleton, as Personal Representative of the Estate of Bobbylee H. McWilliams, Deceased; Gary D. Skala; Carol Smith; Carolyn Smith; Shirley Smith; Daryl W. Smith, II; John R. Sowers; Percival D. Stacy; Terry G. Stalling; Maria L. Stanton; Brenda Stewart; Robert W. Stitt, Jr.; Ruthie Taylor; Rowena G. Teachey; Vanessa Thomas; Carolyn Thompson; Jennifer L. Thompson; Robert L. Tucker, Jr.; Bettie J. Tullos; Natasha Turner; Orlando M. Turner; Kelly Vermette; Robert L. Vogt; Sarah L. Watkins; Everett F. Watson, Jr.; Sylvia Wells; Dorothy White; Shirley L. White; Benjamin O. White, Jr.; Bonnie Williams; Jeanette Williams; Tommy Williams; Kent Willis; Tommy Worcester; Violet R. Wynnemer; Patricia Wysong, on behalf of Donald L. Wysong, an Incapacitated Adult; Verlin G. Yeary; David D. York; Bernard A. Young; and William W. Young,

Plaintiffs,

vs.

JOHNSON & JOHNSON COMPANY; JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a JANSSEN, L.P., a/k/a JANSSEN PHARMACEUTICA, L.P., a/k/a JANSSEN PHARMACEUTICA, INC.; JOHN DOE Nos. 1 through 20; and JANE DOE Nos. 1 through 20,

Defendants.

Plaintiffs, identified more specifically by way of individualized caption pages annexed hereto, for their complaint against the Defendants named herein, say:

THE PARTIES

1. Plaintiffs are individuals who currently reside in various States of the United States, who have suffered personal injuries and incurred other damages as a result of ingesting the atypical antipsychotic drug Risperdal (a trade name for risperidone) that was designed, developed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, distributed and/or sold by Defendants.

2. Defendant Johnson & Johnson is a corporation organized under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

3. Defendant Johnson & Johnson does business in the State of New Jersey and throughout the United States, and at all times relevant hereto designed, developed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, distributed, and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

4. Defendant Janssen Pharmaceutica Products, L.P., a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc. (hereinafter "Janssen") is a subsidiary of Johnson & Johnson, and is a business entity with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

5. Janssen does business in the State of New Jersey and throughout the United States, and at all times relevant hereto designed, developed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, distributed, and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

6. Defendants John Doe Nos. 1 through 20 (fictitious-name-designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto designed, developed, formulated, researched,

manufactured, labeled, packaged, promoted, marketed, distributed and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

7. Defendants Jane Doe Nos. 1 through 20 (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto labeled, packaged, promoted, marketed, distributed and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

8. At all times relevant hereto, each Defendant acted as the agent of every other Defendant, within the course and scope of that agency, regarding the acts and omissions alleged.

FACTUAL BACKGROUND

9. Risperdal is an "antipsychotic" medication belonging to a class of drugs referred to as atypical antipsychotics, and was approved for certain uses in the United States in 1994.

10. In 1997, the United States Food & Drug Administration ("FDA") approved Risperdal for use for the treatment of schizophrenia.

11. In 1999, the FDA approved Risperdal for use in the short-term treatment of acute mixed or manic episodes associated with bipolar disorder.

12. Risperdal is one of the Defendants' top-selling drugs and produced approximately $3.5 billion in sales in 2005.

13. Plaintiffs used Risperdal pursuant to Defendants' instructions and advice and in a foreseeable manner, and the drug reached Plaintiffs without substantial change in its condition since manufacture or sale.

14. Since the drug's introduction to the market, the FDA has received numerous reports of hyperglycemia, diabetes mellitus, worsening of existing diabetes, pancreatitis and other severe conditions and diseases among patients, including children, who were prescribed

Risperdal.

15. Shortly after Defendants began selling Risperdal, reports began to surface of Risperdal users who were suffering from hyperglycemia, acute weight gain, diabetes mellitus, pancreatitis, and other severe conditions and diseases. Defendants knew or reasonably should have known of these reports. Furthermore, prior to and during the time that Plaintiffs ingested Risperdal, Defendants were aware of studies and journal articles linking the use of Risperdal with these and other severe and permanent hyperglycemia-related adverse events and diseases.

16. The diabetes risk associated with Risperdal is much higher than with older "typical" antipsychotic drugs that were already available and approved for use.

17. In December 2000, the *British Medical Journal* found no clear evidence atypical antipsychotics like Risperdal were any more effective or better-tolerated than conventional antipsychotic drugs, including Haldol and Thorazine.

18. Defendants' marketing efforts were designed and implemented to create the false impression in physicians' minds that Risperdal was safe and effective for their patients, and that it was more efficacious and carried a lower risk of side effects and adverse reactions than other available treatments.

19. The marketing and promotion efforts of Defendants overstated the benefits of Risperdal while minimizing and downplaying the risks associated with the drug. These promotional efforts were made while withholding important safety information from prescribing physicians, the FDA, and the public.

20. For example, Defendants were aware of numerous reports of diabetes mellitus associated with the use of Risperdal, well beyond the background rate, and well beyond the rate associated with older antipsychotic agents.

21. In April 2002, the Japanese Health and Welfare Ministry issued Emergency Safety

Information regarding the risk of diabetes mellitus, diabetic ketoacidosis, and other diabetic conditions, for patients prescribed atypical antipsychotics, including Risperdal.

22. In September 2003, Defendants received a letter from the FDA informing them that the product packaging for Risperdal failed to convey appropriate risk information related to the drug's association with serious diabetes mellitus and related conditions.

23. Despite having this information, Defendants failed to take action to correct this obvious defect in Risperdal product labeling for several months. During this period, Defendants did not pass on to physicians information regarding the risk of diabetes mellitus, nor did they issue new labeling containing specific warnings.

24. On November 6, 2003, Defendants submitted supplemental New Drug Applications covering the addition of information to the Warnings section of the product labeling for Risperdal. The FDA approved the supplements and requested that the Defendants issue a "Dear Healthcare Provider letter" communicating the important new risk information. Additionally, the FDA asked Defendants to submit a copy of the letter to the FDA and to the MedWatch program.

25. Instead of preparing a letter that accurately communicated risk information, on November 10, 2003, Defendants sent a Dear Healthcare Professional letter that misrepresented those risks. The letter stated, in pertinent part:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.

By sending this letter, Defendants prevented physicians and patients from adequately

understanding the risks associated with Risperdal.

26. In response to Defendants' misleading letter of November 10, 2003, the FDA issued a Warning Letter on April 19, 2004 to Ajit Shetty, M.D., CEO of Janssen, reprimanding the company. The FDA determined that the Dear Healthcare Provider letter omitted material information, minimized risks, and claimed superior safety to other drugs in its class without "adequate substantiation." Additionally, by sending the letter, Defendants failed to comply with FDA requirements regarding post-marketing reporting. As a result, the FDA requested that Defendants immediately cease dissemination of promotional materials for Risperdal containing the same or similar claims, and warned that the FDA was continuing to evaluate all aspects of the promotional campaign for Risperdal.

27. Three months after the FDA issued its Warning Letter, Defendants mailed another Dear Health Care Provider letter on July 21, 2004, admitting that the previous letter omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety in comparison to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act.

28. By reason of the acts and omissions of Defendants, Plaintiffs have been severely and permanently injured and will require ongoing medical care and treatment.

29. Defendants knew of the hazards associated with Risperdal, but nevertheless affirmatively and actively concealed information that clearly demonstrated the dangers of the drug and misled the public and prescribing physicians with regard to the material and clear risks associated with the drug.

30. Defendants acted with the intent that physicians would continue to prescribe their atypical antipsychotic drug even though the Defendants knew that prescribing physicians would not be in a position to know the true risks of the drug, and that they would rely upon the

misleading information that Defendants promulgated.

31. Defendants, through their funding and control of certain studies concerning the effects of atypical antipsychotic drugs on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between their drugs and various diseases, all to the detriment of the public health, safety and welfare.

32. Defendants acted in concert with one another to fraudulently conceal from the public, Plaintiffs and prescribing physicians the risk of diabetes mellitus and diabetes-related conditions associated with Risperdal, resulting in significant harm to consumers of Risperdal, including Plaintiffs.

33. Defendants also acted in concert to unlawfully and improperly promote Risperdal for "off-label uses" not approved by the FDA.

34. Defendants improperly provided financial inducements to physicians to promote Risperdal for uses beyond those which the FDA approved and beyond those for which the drugs were medically accepted.

35. Defendants improperly provided financial inducements to State government officials to encourage acceptance of their atypical antipsychotic drugs for uses beyond those which the FDA approved and beyond those for which the drugs were medically accepted.

36. At all times relevant hereto, Defendants purposefully and intentionally engaged in these activities, and continue to do so, knowing full well that when the public, including Plaintiffs herein, used Risperdal in the manner that Defendants intended they would be substantially and unreasonably at risk of suffering disease, injury and sickness.

37. The statements, representations and promotional schemes made and undertaken

by the Defendants were deceptive, false, incomplete, misleading and untrue.

38. Defendants knew, or in the exercise of reasonable care should have known, that their statements, representations and advertisements regarding Risperdal were deceptive, false, incomplete, misleading and untrue at the time of making such statements.

39. Neither Plaintiffs nor the physicians who prescribed the Defendants' atypical antipsychotic drug had knowledge of the falsity or untruth of the Defendants' statements, representations and advertisements when prescriptions for the drug were written.

40. Plaintiffs and their prescribing physicians reasonably relied on the Defendants' statements, representations and advertisements and Defendants knew that Plaintiffs and their prescribing physicians would be relying upon Defendants' statements. Each of the statements, representations and advertisements were material to Plaintiffs' purchase of, or otherwise obtaining, the Defendants' atypical antipsychotic drug, in that Plaintiffs would not have purchased nor taken the drug if Plaintiffs had known that Defendants' statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue.

41. Had Plaintiffs been adequately warned of the potential life-threatening side effects of Defendants' atypical antipsychotic drugs, Plaintiffs would not have purchased or taken the drugs and could have chosen to request other medications or treatments.

42. Defendants negligently, recklessly and wantonly failed to warn Plaintiffs and the general public of the risks associated with taking Defendants' atypical antipsychotic drug, and failed to do so even after various studies, including their own, showed that there were problems concerning the risks of diabetes and diabetes-related injuries associated with the drug.

43. Defendants endeavored to deceive Plaintiffs and the general public by not disclosing the findings of various studies, including their own, which revealed problems concerning the dangers of Defendants' atypical antipsychotic drugs.

44. Defendants failed to provide adequate warnings and instructions that would have put Plaintiffs and the general public on notice of the dangers and adverse effects of Defendants' atypical antipsychotic drugs.

45. Defendants designed, manufactured, distributed, sold and/or supplied their atypical antipsychotic drug and otherwise placed the drug into the stream of commerce in a defective and unreasonably dangerous condition, taking into consideration the utility of the drug and the risk to Plaintiffs and the general public.

46. Defendants' atypical antipsychotic drug as designed, manufactured, distributed, sold and/or supplied by the Defendants were defective due to inadequate warnings, instructions and/or labeling.

47. The Defendants' atypical antipsychotic drugs as designed, manufactured, distributed, sold and/or supplied by the Defendants were defective due to inadequate testing before and after the Defendants knew, or in the exercise of reasonable care should have known, of the various studies, including their own, evidencing the risks of diabetes and diabetes-related conditions, disease and injuries associated with the drug.

48. Plaintiffs ingested the Defendants' atypical antipsychotic drugs and as a result suffered emotional and personal injury and economic loss.

COUNT I
PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-2*et seq.*)

49. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

50. Defendants designed, formulated, produced, created, made, packaged, labeled and sold Risperdal and held themselves out to users of the product as the manufacturer(s) of Risperdal.

51. Defendants' Risperdal product was not reasonably fit, suitable or safe for its

intended purpose because it failed to contain adequate warnings and/or instructions.

52. Defendants failed to otherwise provide adequate warnings and instructions to consumers of Risperdal who had purchased or received the product, or to their prescribing physicians.

53. Defendants' Risperdal product was not reasonably fit, suitable or safe for its intended purpose because it was designed in a defective manner.

54. The ordinary user or consumer of Defendants' Risperdal product could not reasonably be expected to have knowledge of the product's inherent risks and dangers.

55. The dangerous and defective character of Risperdal was in fact unknown to the product's ordinary consumer or user, including Plaintiffs, and Plaintiffs' injuries were caused by an unsafe aspect of Risperdal that is an inherent characteristic of the product and that would not be recognized by the ordinary person who uses or consumes the product and for whom the product is intended.

56. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
PUNITIVE DAMAGES, PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-5)

57. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

58. Defendants' manufacture, marketing, promotion, distribution and sale of a defective product and their failure to provide adequate warnings and instructions concerning its hazards was willful, wanton, reckless and without regard for the public's safety and welfare. The defendants misled both the medical community and the public at large, including Plaintiffs herein, by making false representations about the safety of Risperdal. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Risperdal despite available information demonstrating that Risperdal was likely to cause serious and potentially fatal side effects to users.

59. At all times relevant hereto, defendants knew of the defective nature of their Risperdal product, and continued to design, manufacture, market, label, and sell Risperdal so as to maximize sales and profits at the expense of public health and safety, with wanton and willful disregard of the safety of product users, consumers, or others who foreseeably might be harmed by the product, including Plaintiffs who did suffer such harm.

60. Defendants misled regulators, the medical community and the public at large, including Plaintiffs, by making false and misleading representations about the safety of Risperdal. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harm suffered by Plaintiffs.

61. As a direct and proximate result of Defendants' reckless, willful and wanton acts in disregard of the safety of the public generally and of Plaintiffs in particular, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require

medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
NEGLIGENCE

62. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

63. Defendants had a duty to exercise reasonable care when they designed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, and/or sold the drug ingested by Plaintiffs, including a duty to ensure that the drug did not cause users to suffer from undisclosed dangerous side effects when used alone or in foreseeable combination with other drugs.

64. Defendants were negligent when they designed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, and/or sold their atypical antipsychotic drug, in that, among other things, they:

a. Failed to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of their drugs;

b. Failed to conduct adequate pre-clinical and clinical testing and

post-marketing surveillance to determine the safety of their drugs;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of their drugs;

d. Failed to warn Plaintiffs while actively encouraging the sale of their drugs, either directly or indirectly (through Plaintiffs' prescribing physicians), orally or in writing, about:

1. The need for diagnostic tests to be performed on the patient prior to ingesting the Defendants' atypical antipsychotic drugs to discover and ensure against potentially fatal side effects; and/or

2. The need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal side effects;

e. Failed to warn that the risks associated with the ingestion of their drugs exceeded the risks of other alternative forms of medication;

f. Failed to effectively warn about the increased danger and potentially fatal relationship in combining the use of their drugs either together or with various other drugs for use in treatment of Plaintiffs' condition(s);

g. Negligently marketed their drug despite the fact that the risks of the drug were so high and the benefits of the drug were so low that no reasonable pharmaceutical company, exercising due care, would have done so;

h. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of

their drugs from prescribing physicians and the consuming public; had prescribing physicians and the consuming public known of such facts, Defendants' atypical antipsychotic drugs would never have been prescribed to, or used by, Plaintiffs;

i. Remained silent despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of ingestion of their drugs and did so because the prospect of huge profits outweighed their concern for health and safety issues, all to the significant detriment of Plaintiffs;

j. Failed to perform their post-manufacturing and continuing duty to warn which arose when they knew, or in the exercise of reasonable care should have known, that their drugs were being prescribed in a dangerous manner;

k. Unlawfully and improperly marketed and promoted their atypical antipsychotic drugs for "off label" uses beyond those uses approved by the FDA or supported by medical science;

l. Unlawfully and improperly provided financial incentives to physicians and others to prescribe the drugs and approve its use;

m. Were otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard with respect to the rights of Plaintiffs;

n. Continued to market the drugs to consumers, including Plaintiffs and their prescribing physicians, when there were safer alternative methods of treating Plaintiffs' condition(s), despite the fact that Defendants knew or should have known that the drugs caused unreasonable, dangerous side

effects; and

o. Knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

65. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiffs demands judgment against the Defendants for damages for pain and suffering, loss of enjoyment of life, past and future medical expenses, past and future lost wages, and punitive damages, together with interest from the date of injury and costs.

COUNT IV
STRICT LIABILITY

66. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

67. Defendants are manufacturers and/or suppliers and/or marketers of Risperdal and are strictly liable to plaintiff for designing, creating, manufacturing, distributing, selling and placing into the stream of commerce the drug Risperdal.

68. Risperdal manufactured and/or supplied and/or marketed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other forms of antipsychotic treatment available.

69. Risperdal manufactured and/or supplied and/or marketed by defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

70. Risperdal manufactured and/or supplied and/or marketed by defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created, among other things, a risk of diabetes mellitus and diabetes-related conditions when used in the manner intended and/or reasonably foreseeable by Defendants, and failed to adequately warn of said risks.

71. Risperdal manufactured and/or supplied and/or marketed by Defendants was defective due to inadequate pre-marketing testing.

72. Risperdal manufactured and/or supplied and/or marketed by Defendants was defective due to Defendants' failure to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the risks of adverse effects including diabetes mellitus and diabetes-related conditions from Risperdal, and continued to promote the product.

73. Risperdal manufactured and/or supplied and/or marketed by defendants was unreasonably dangerous and defective because it was not accompanied by proper warnings to prescribing physicians and the medical community regarding all possible adverse side effects associated with the use of Risperdal and the comparative severity, incidence, scope and duration of such adverse effects.

74. Such warnings and information that Defendants did provide to the medical community did not accurately reflect the symptoms, scope, severity, or frequency of the potential side effects.

75. Defendants failed to provide warnings that would have dissuaded physicians from

prescribing Risperdal and consumers from purchasing and consuming Risperdal, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Risperdal.

76. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
BREACH OF EXPRESS WARRANTY

77. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

78. Defendants in their manufacturing, design, distribution, marketing and promotion of Risperdal expressly warranted same to be safe and effective for Plaintiffs and members of the public generally.

79. At the time of making of these express warranties, Defendants had knowledge of the purpose for which the product was to be used and warranted same to be in all respects safe, effective, fit and proper for such purpose and use.

80. Defendants further expressly warranted that their Risperdal product was safer and

more effective than other antipsychotic drugs.

81. Risperdal does not conform to these express warranties and representations because Risperdal is not safe or effective, nor is it safer or more effective than other anti-psychotic drugs available, and it may produce serious side effects, including among other things diabetes mellitus and other diabetes-related conditions.

82. As a direct and proximate result of the breach of express warranties by Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
BREACH OF IMPLIED WARRANTY

83. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

84. Defendants marketed, manufactured, promoted, distributed and/or sold Risperdal for use by the public at large and including the Plaintiffs herein. Defendants knew the use for which their product was intended and impliedly warranted said product to be of merchantable quality, safe and fit for use.

85. Plaintiffs reasonably relied on the skill and judgment of Defendants, and as such

their implied warranty, in using Risperdal. Contrary to same, Risperdal was not of merchantable quality or safe or fit for its intended use, because said product is unreasonably dangerous and unfit for the ordinary purpose for which it was intended and used.

86. As a direct and proximate result of the breach of implied warranties by Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
CONSUMER FRAUD ACT (N.J.S.A. 56:8-2 *et seq.*)

87. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

88. Prescription drugs such as Risperdal are "merchandise," as that term is defined by the Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.

89. Defendants are persons within the meaning of the Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

90. Defendants violated the Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., in the following particulars:

(a) Defendants engaged in unconscionable commercial practices, through

deception, fraud and making false promises and misrepresentations including but not limited to:

i. Failing to make complete and appropriate disclosures to the FDA in conjunction with the approval process for Risperdal;

ii. Marketing and promoting this product as safe and effective for the treatment of schizophrenia, psychosis, dementia and other conditions.

(b) Defendants used and employed deception, fraud, false pretense, false promise and misrepresentation in the following particulars:

i. Failing to disclose to the FDA and the public knowledge of the health hazards posed by the use of this product;

ii. Downplaying and understating the health hazards and risks associated with the use of this product;

iii. The methods and manner by which they undertook to create a market environment, which fostered the aggressive dispensation of this product.

(c) In connection with the sale and advertisement of Risperdal, defendants engaged in knowing concealment, suppression and omission of material facts regarding the health hazards created by the use of this product.

91. The aforesaid promotion and release of Risperdal into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connection with the sale or advertisement of such merchandise by defendants, in violation of the Consumer Fraud Act.,

N.J.S.A. 56:8-1 *et seq.*

92. Defendants' actions in connection with manufacture, distribution, and marketing of Risperdal as set forth herein evidence a lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the Consumer Fraud Act., N.J.S.A. 56:8-2 *et seq.*

93. Defendants' unlawful sale and advertising practices were specifically designed to induce the public to seek out, obtain prescriptions, purchase and consume this product.

94. Defendants knew of the growing public acceptance of their misinformation and misrepresentations regarding the safety and efficacy of Risperdal but remained silent because defendants' appetites for significant future profits far outweighed their concern for the health and safety of the consuming public and Plaintiffs herein.

95. Plaintiffs' physicians prescribed and/or otherwise provided Plaintiffs with Risperdal, and Plaintiffs consumed Risperdal, primarily for personal and family reasons.

96. As a result of Defendants' violation of the Consumer Fraud Act by use or employment of the methods, acts, or practices described herein, Plaintiffs have suffered ascertainable losses, in that Plaintiffs paid money to purchase Risperdal, which was the subject of the aforementioned unlawful practices.

97. Pursuant to the New Jersey Consumer Fraud Act, plaintiff is entitled to recover treble the actual damages sustained, reasonable attorneys fees, filing fees and reasonable costs of suit.

98. Defendants are liable to Plaintiffs for all general and equitable relief to which Plaintiffs are entitled by common law and statute, including but not limited to treble damages, reasonable attorneys fees, filing fees and reasonable costs of suit.

99. As a direct and proximate result of the acts of consumer fraud set forth above,

Plaintiffs purchased an unsafe product and incurred monetary expense as well as risk to themselves, and thereby suffered an increased risk of harm as previously set forth herein.

WHEREFORE Plaintiffs demand judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
NEGLIGENT MISREPRESENTATION

100. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

101. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and/or promotion of Risperdal described herein, owed a duty to provide accurate and complete information regarding their product.

102. Defendants falsely represented that the aforesaid product was safe and effective for the treatment of conditions suffered by Plaintiffs. These representations by Defendants were in fact false and the product was not safe for said purpose and was in fact dangerous to the health of Plaintiffs. Defendants concealed, omitted, or minimized the side effects of Risperdal or provided misinformation about adverse reactions, risks and potential harms from Risperdal and succeeded in persuading consumers and Plaintiffs to purchase and ingest Risperdal despite its lack of safety and the risk of adverse effects, including diabetes mellitus and diabetes-related conditions.

103. At the time the aforesaid representations were made, Defendants concealed from Plaintiffs and health care providers information about the propensity of their product to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of said product despite the lack of information regarding same.

104. Defendants' misrepresentations in promoting and marketing Risperdal created and reinforced a false impression as to the safety of Risperdal, thereby placing consumers at risk of serious and potentially lethal effects.

105. The aforesaid misrepresentations were made by Defendants with the intent to induce Plaintiffs to use the product, to the detriment of Plaintiffs.

106. At the time of Defendants' misrepresentations and omissions, Plaintiffs were ignorant of the falsity of these statements and reasonably believed them to be true.

107. Defendants breached their duties to Plaintiffs by providing false, incomplete and/or misleading information regarding their product. Plaintiffs reasonably believed defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Risperdal.

108. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
FRAUDULENT MISREPRESENTATION

109. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

110. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Risperdal described herein, owed a duty to provide accurate and complete information regarding its product.

111. Defendants fraudulently misrepresented information regarding their product including, but not limited to, its propensity to cause serious physical harm.

112. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiffs were unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

113. Defendants breached their duties to Plaintiffs by providing false, incomplete and misleading information regarding their product.

114. Defendants acted with deliberate intent to deceive and mislead Plaintiffs.

115. Plaintiffs reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

116. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
LOSS OF CONSORTIUM

117. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further allege as follows:

118. At all times relevant hereto, such Plaintiffs as are married have spouses who are entitled to their comfort, care, affection, companionship, services, society, advice, guidance, counsel and consortium.

119. As a direct and proximate result of one or more of those wrongful acts or omissions of the Defendants described above, Plaintiffs' spouses have been and will be deprived of Plaintiffs' comfort, care, affection, companionship, services, society, advice, guidance, counsel and consortium.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XI
WRONGFUL DEATH
(Applicable to Plaintiffs Gates, Kelly and Singleton)

120. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further allege as follows:

121. As a result of the acts and/or omissions of the defendants as set forth herein, which resulted in the death of Plaintiffs' decedents, decedents' survivors suffered pecuniary and other losses.

122. Plaintiffs, as personal representatives of their respective decedents' estates, are entitled to recover damages on behalf of decedents' survivors for wrongful death, pursuant to N.J.S.A. 2A:31-2.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII
SURVIVAL ACTION
(Applicable to Plaintiffs Gates, Kelly and Singleton)

123. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further allege as follows:

124. As a result of the acts and/or omissions of the defendants as set forth herein, Plaintiffs' decedents were caused to suffer injuries both physical and mental in nature before their deaths.

125. Plaintiffs, as the personal representatives of their respective decedents' estates, are entitled to recover damages on behalf of decedents' estates pursuant to N.J.S.A. 2A:15-3.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

JURY TRIAL DEMANDED

Plaintifsf hereby demand a trial by jury as to all issues so triable.

Dated: July 20, 2006

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CERTIFICATION PURSUANT TO RULE 4:5-1

Plaintiff(s) upon information and belief is not aware of any pending or contemplated action. Further, upon information and belief, Plaintiff(s) is not aware of any other party who should be joined in this action.

Dated: July 20, 2006

WEITZ & LUXENBERG
A New York Professional Corporation
Attorneys for Plaintiffs

Franklin P. Solomon
John McN. Broaddus
Renee Henderson
Jerry Kristal

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A. 56:8-20, Plaintiffs are mailing a copy of this Complaint and Jury Demand to the Office of Attorney General, CN-006, Trenton, New Jersey, within ten (10) days of the date of filing.

Dated: July 20, 2006

WEITZ & LUXENBERG

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