IN RE REGLAN LITIGATION

PLAINTIFFS,

vs.

BRAND NAME DEFENDANTS:

WYETH LLC, WYETH PHARMACEUTICALS, INC., INDIVIDUALLY AND d/b/a ESI LEDERLE, INC., WYETH, INC., WYETH HOLDINGS CORPORATION, INDIVIDUALLY AND d/b/a LEDERLE, SCHWARZ PHARMA, INC., SCHWARZ PHARMA AG, UCB SA, UCB INC., ALAVEN PHARMACEUTICAL LLC, MEDA PHARMACEUTICALS, INC., MEDA AB, BAXTER HEALTHCARE CORPORATION, WOCKHARDT, USA, MORTON GROVE PHARMACEUTICALS, INC.,

GENERIC DEFENDANTS:

TEVA PHARMACEUTICALS USA, INC., GOLDLINE LABORATORIES, Inc., INDIVIDUALLY AND D/B/A IVAX PHARMACEUTICALS, PLIVA, INC., individually and f/k/a SIDMAK LABORATORIES, INC., PLIVA D.D., BARR PHARMACEUTICALS, LLC F/K/A BARR PHARMACEUTICALS, INC.. BARR LABORATORIES, INC., DURAMED PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., and GENERICS BIDCO I., LLC., Individually and d/b/a QUALITEST PHARMACEUTICALS, THE HARVARD DRUG GROUP LLC, INDIVIDUALLY AND D/B/A MAJOR PHARMACEUTICALS, PHARMACEUTICAL ASSOCIATES, INC., BEACH PRODUCTS INC., UNITED RESEARCH LABORATORIES, INC., MUTUAL PHARMACEUTICAL COMPANY, INC., SILARX PHARMACEUTICALS, INC., SANDOZ, INC., ANIP ACQUISITION COMPANY A/K/A ANIP PHARMACEUTICALS A/K/A ANI PHARMACEUTICALS A/K/A A & I PHARMACEUTICALS, WATSON LABORATORIES, INC., RUGBY LABORATORIES, INC. A/K/A RUGBY PHARMACEUTICALS, INC., ACTAVIS ELIZABETH LLC, INDIVIDUALLY AND D/B/A PUREPAC PHARMACEUTICALS, APP PHARMACEUTICALS, LLC, INDIVIDUALLY AND D/B/A ABRAXIS PHARMACEUTICALS, CORPORATION

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY

Case No. 289

CIVIL ACTION

SECOND AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND

SERVICE COMPANY, BEDFORD LABORATORIES, HOSPIRA INC., IPCA PHARMACEUTICALS INC., MCKESSON CORPORATION, NORTHSTAR RX LLC, RUGBY LABORATORIES, INC., NORBROOK INC. USA, SMITH & NEPHEW INC., VISTAPHARM, INC., ROXANE LABORATORIES, INC., PAR PHARMACEUTICAL INC.m ACURA PHARMACEUTICALS, INC., f/k/a HALSEY DRUG COMPANY, PACO PHARMACEUTICAL SERVICES, INC., VINTAGE PHARMACEUTICALS, LLC, SCHERING CORPORATION, RANBAXY PHARMACEUTICALS, INC., BRISTOL MEYERS SQUIBB CO., INDIVIDUALLY and d/b/a APOTHECON, INC., APOTHECON, INC., INVAMED, INC., KING PHARMACEUTICALS INC., Individually and d/b/a ALPHARMA INC., f/k/a A.L. PHARMA Inc. and ALPHARMA, INC.

DOE DEFENDANTS:

JANE DOE DISTRIBUTORS (1-50), JOHN DOE DRUG COMPANY DEFENDANTS (1-50), JANE DOE DRUG DISTRIBUTOR DEFENDANTS (1-50), JIM DOE DOE HEALTH CARE PROVIDERS (1-50), and JILL DOE (1-50),

DEFENDANTS,

SECOND AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this Second Amended Master Long Form Civil Action Complaint upon personal knowledge, investigative efforts, information, and belief. This Second Amended Master Long Form Civil Action Complaint is intended to operate as an administrative device to set forth most of the potential claims Plaintiffs may assert against Defendants in this litigation. This is being filed and served pursuant to Case Management Order 13, and is intended to be accompanied by a Short Form Complaint. Accordingly, Plaintiffs allege as follows:

I. PARTIES

A. Plaintiffs

1. This Complaint is the Second Amended Master Long Form Complaint filed for all Plaintiffs, the individuals, in each action, who have suffered personal injuries, as more particularly set forth herein and in individual actions, as a physical result of either consuming and/or having injected, prescription drugs known as Reglan (a registered brand name) and/or generic metoclopramide, and as a direct and proximate result of the intentional and/or negligent dissemination of inaccurate, false and misleading information and the negligent and/or otherwise wrongful misconduct of named defendants in connection with the design, development, manufacture, testing, packaging, promotion, advertising, warning, marketing, distribution, labeling, prescribing, and/or sale of those drugs. In addition, and where applicable, this Complaint is also filed for Plaintiffs' spouses, children, parents, decedents, wards and/or heirs and/or decedent(s), all as represented by Plaintiffs' counsel. By operation of the Order of this Court, all allegations pled herein are deemed pled in any Short-Form Complaint hereafter filed.

2. Plaintiffs, by the undersigned counsel, hereby submit this Second Amended Master Long Form Complaint against the above named defendants for compensatory and punitive damages, monetary restitution, and/or equitable relief. Plaintiffs make the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts, regarding Reglan, and generic metoclopramide products therapeutically equivalent to Reglan, and their use, effects, marketing, and distribution.

3. This Second Amended Master Complaint is submitted pursuant to Case Management Order No. 13 of this Reglan Litigation, only to serve the administrative functions of

efficiency and economy of presenting certain common claims and common questions of fact and law for consideration by this Court in the context of this proceeding. This Second Amended Master Complaint does not necessarily include all claims asserted in all of the actions that have been transferred to this Court, nor is it intended to consolidate for any purpose the separate claims of the Plaintiffs herein. The separate claims of individual plaintiffs are set forth in the actions filed by the respective plaintiffs. This Second Amended Master Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor by it does any plaintiff relinquish the right to add or assert or seek leave to add or assert any additional claims or predicates for claims depending upon further information that they may uncover. As more particularly set forth herein, each plaintiff maintains that the pharmaceutical drugs, Reglan®/metoclopramide are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in each of the individual states comprising the United States, and lacked proper warnings of the dangers associated with their use and/or the dangers associated with their use were not adequately communicated.

4. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' negligent and wrongful misconduct in connection with the dissemination of inaccurate, false and misleading information and the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of the pharmaceutical drugs Reglan®/metoclopramide.

B. <u>Defendants</u>

5. Defendant Wyeth LLC is a Delaware corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. Defendant may be served with

process by registered mail, return receipt requested, upon: The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628.

6. Defendant Wyeth Pharmaceuticals, Inc., Individually and d/b/a ESI Lederle, Inc. is a Delaware corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. Defendant may be served with process by registered mail, return receipt requested, upon: The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628.

7. Defendant Wyeth, Inc., is a Delaware corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. Defendant may be served with process by registered mail, return receipt requested, upon: The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628.

8. Defendant Wyeth Holdings Corporation, Individually and d/b/a Lederle, is a Maine corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. Service of process may be effectuated upon the defendant at this location.

9. Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc. (including ESI Lederle), Wyeth Holdings Corporation (including ESI Lederle and Lederle) and Wyeth, Inc. may be referred to collectively herein as WYETH. In addition to manufacturing branded product, defendant WYETH, through their Richmond, Lederle and/or E.S.I. Lederle divisions manufactured generic metoclopramide. All references to generic manufacturers hereinafter, shall also be deemed to include these defendants.

10. Defendant Schwarz Pharma, Inc. (hereinafter “Schwarz”) is a Delaware corporation with a principal place of business in Georgia. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt

requested, upon: Henninger S. Bullock, Esquire, MAYER BROWN LLP, 1675 Broadway, New York, NY 10019.

11. Defendant Schwarz Pharma AG is a foreign corporation with its principal place of business in Germany. Defendant Schwarz Pharma AG is the parent company of Defendant Schwarz Pharma, Inc. and therefore is liable for any and all tort liabilities of Defendant Schwarz Pharma, Inc. In addition, Defendant Schwarz Pharma AG was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan detailed below. Defendant regularly conducts business in New Jersey and may be served with process via The Hague Convention, in addition to other methods of service recognized in this jurisdiction.

12. Defendant UCB, SA is a foreign corporation with its principal place of business in Belgium. Defendant UCB, SA is the parent company of Defendant Schwarz Pharma AG and therefore is liable for any and all tort liabilities of Defendant Schwarz Pharma, Inc. and/or Defendant Schwarz Pharma, AG. In addition, Defendant UCB, SA was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan detailed below. Defendant regularly conducts business in New Jersey and may be served with process via The Hague Convention, in addition to other methods of service recognized in this jurisdiction.

13. Defendant UCB, Inc. is a domestic corporation with its principal place of business in Georgia. Defendant UCB, Inc. is a wholly owned subsidiary/division of UCB,SA and engages in all domestic activities for UCB SA. In addition, Defendant UCB, Inc was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan detailed below and/or is liable for any and all tort liabilities of Defendant Schwarz Pharma, Inc. and/or Defendant Schwarz Pharma, AG. Which occurred in the United States. Defendant UCB, Inc., regularly conducts business in New Jersey.

14. Defendants Schwarz Pharma, Inc., Schwarz Pharma, AG, UCB SA, and UCB, Inc., may be referred to collectively herein as SCHWARZ.

15. Defendant Alaven Pharmaceutical LLC (referred to herein as ALAVEN) is a Delaware corporation with a principal place of business in Marietta, Georgia. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Henninger S. Bullock, Esquire, MAYER BROWN LLP, 1675 Broadway, New York, NY 10019.

16. Defendant MEDA Pharmaceuticals, INC., is a Delaware corporation with a principle place of business in Somerset, New Jersey. Defendant Meda Pharmaceuticals, Inc. is the parent company of Defendant Alaven Pharmaceutical LLC and therefore is liable for any and all tort liabilities of Defendant Alaven Pharmaceutical LLC. In addition, Defendant Meda Pharmaceutical, Inc., was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan detailed below.

17. Defendant MEDA AB is a foreign corporation with its principal place of business in Sweden. Defendant MEDA AB is the parent company of Defendant MEDA Pharmaceuticals, Inc. and therefore is liable for any and all tort liabilities of Defendant MEDA Pharmaceuticals, Inc and/or Defendant Alaven Pharmaceutical, LLC. In addition, Defendant MEDA AB was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan detailed below. Defendant regularly conducts business in New Jersey and may be served with process via The Hague Convention, in addition to other methods of service recognized in this jurisdiction.

18. Defendants Alaven Pharmaceutical LLC, MEDA Pharmaceuticals, Inc. and MEDA AB may be collectively referred to as ALAVEN.

19. Defendant Baxter Healthcare Corporation is a Delaware corporation with its principal place of business in Deerfield, Illinois. Defendant regularly conducts business in New Jersey. Defendant was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan detailed below. More specifically, defendant Baxter Healthcare Corporation was the NDA holder for injectable Reglan. Defendant may be served with process by and through its agent for service: C T Corporation System, 116 Pine St., Suite 320, Harrisburg, PA 17101.

20. Defendant Wockhardt USA is a Delaware corporation with a principal place of business in New Jersey. Defendant regularly conducts business in New Jersey. Defendant acquired Defendant Morton Grove Pharmaceuticals, Inc. in October 2007. Defendant may be served with process by registered mail, return receipt requested, upon: Robert E. O'Malley, Esquire, SEGAL, MCCAMBRIDGE, SINGER & MAHONEY, LTD., 233 S. Wacker Drive, Sears Tower - Suite 5500, Chicago, IL 60606.

21. Defendant Morton Grove Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business in Illinois. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Robert E. O'Malley, Esquire, SEGAL, MCCAMBRIDGE, SINGER & MAHONEY, LTD., 233 S. Wacker Drive, Sears Tower - Suite 5500, Chicago, IL 60606.

22. Defendants Wockhardt USA and Morton Grove Pharmaceuticals, Inc. may be collectively referred to as Morton Grove. Morton Grove is the holder of an ANDA for metoclopramide syrup and was also designated as the Reference Listed Drug holder of Reglan® syrup. Defendant Morton Grove, as the Reference Listed Drug holder, is responsible for bioequivalence and label standards for all abbreviated applications requesting approval for the

generic form of Reglan® syrup, otherwise known as metoclopramide. All references to generic manufacturers hereinafter, shall also be deemed to include these defendants.

23. Defendant Teva Pharmaceuticals USA, Inc., ("hereinafter "TEVA") is a Delaware corporation with a principal place of business in Pennsylvania. Defendant regularly conducts business in New Jersey. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by registered mail, return receipt requested, upon: Ms. Jennifer Fuller-Ricciardi, Teva Pharmaceuticals USA, Inc., 425 Privet Road, P.O. Box 1005, Horsham, PA 19044.

24. Defendant GOLDLINE LABORATORIES, INC., INDIVIDUALLY and D/B/A IVAX PHARMACEUTICALS, INC., is a Delaware Corporation with a principle place of business in Florida. Defendant regularly conducts business in New Jersey.

25. Defendant PLIVA, Inc., individually and f/k/a SIDMAK LABORATORIES, Inc., is a New York corporation with a principal place of business in New Jersey. Defendant is a subsidiary or division of PLIVA d.d., a corporation organized, existing and doing business under and by virtue of the laws of the Republic of Croatia, headquartered in Zagreb, Croatia. PLIVA d.d., is a wholly owned subsidiary of Defendant Barr Pharmaceuticals LLC as a result of Barr's acquisition of Pliva in 2006. Because Barr Pharmaceuticals LLC was later acquired by Teva Pharmaceuticals USA, Inc., Pliva, Inc. is now a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Ms. Jennifer Fuller-Ricciardi, Teva Pharmaceuticals USA, Inc., 425 Privet Road, P.O. Box 1005, Horsham, PA 19044.

26. Defendant PLIVA d.d. is a foreign corporation with its principal place of business in Croatia. Defendant PLIVA d.d. is the parent company of Defendant PLIVA, Inc. individually and f/k/a SIDMAK LABORATORIES, INC., and therefore liable for any and all tort liabilities of Defendant PLIVA, Inc., individually and f/k/a SIDMAK LABORATORIES, INC. In addition, Plaintiffs allege, on information and belief, that Defendant PLIVA d.d. regularly conducts business in New Jersey. Defendant may be served with process via The Hague Convention by serving Croatia's Central Authority at: Ministry of Justice of the Republic of Croatia, Dezmanova 6 I 10, Croatia.

27. Defendant Barr Pharmaceuticals, LLC f/k/a Barr Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in New Jersey. Defendant Barr Pharmaceuticals LLC was acquired by Defendant Teva Pharmaceuticals USA, Inc. on December 23, 2008 and is therefore a wholly owned subsidiary of Defendant Teva Pharmaceuticals USA, Inc. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Ms. Jennifer Fuller-Ricciardi, Teva Pharmaceuticals USA, Inc., 425 Privet Road, P.O. Box 1005, Horsham, PA 19044.

28. Defendant Barr Laboratories, Inc. is a Delaware corporation with its principal place of business in New York. Defendant Barr Laboratories, Inc. was acquired by Defendant Teva Pharmaceuticals USA, Inc. on December 23, 2008 and is therefore a wholly owned subsidiary of Defendant Teva Pharmaceuticals USA, Inc. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Ms. Jennifer Fuller-Ricciardi, Teva Pharmaceuticals USA, Inc., 425 Privet Road, P.O. Box 1005, Horsham, PA 19044.

29. Defendant Duramed Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Ohio. Defendant Barr Pharmaceuticals, LLC f/k/a Barr Pharmaceuticals, Inc. is the parent company for Defendant Duramed Pharmaceuticals, Inc. Defendant Duramed Pharmaceuticals, Inc. regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Ms. Jennifer Fuller-Ricciardi, Teva Pharmaceuticals USA, Inc., 425 Privet Road, P.O. Box 1005, Horsham, PA 19044.

30. Defendants PLIVA, Inc., individually and f/k/a SIDMAK LABORATORIES, INC., PLIVA d.d., Barr Pharmaceuticals, LLC f/k/a Barr Pharmaceuticals, Inc., Barr Laboratories, Inc., and Duramed Pharmaceuticals, Inc., may be referred to collectively herein as PLIVA.

31. Defendant Qualitest Pharmaceuticals, Inc. (hereinafter "Qualitest")is an Alabama corporation with a principal place of business in Alabama. Defendant regularly conducts business in New Jersey. Defendant has not designated an agent in this litigation for the purpose of accepting service of process..

32. Defendant GENERICS BIDCO I., LLC., Individually and d/b/a QUALITEST PHARMACEUTICALS, (hereinafter referred to as "GENERICS BIDCO") is an Alabama Limited Liability Company with a principal place of business in Alabama. Defendant regularly conducts business in New Jersey. Defendant has not designated an agent in this litigation for the purpose of accepting service of process.

33. Defendant Vintage Pharmaceuticals, LLC is an Alabama Limited Liability Company with a principal place of business in Alabama. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt

requested, upon: John Mullen, Esquire, NELSON LEVINE DE LUCA & HORST, LLC, 518 Township Line Road, Suite 300, Blue Bell, PA 19422.

34. Defendant The Harvard Drug Group LLC, Individually and d/b/a Major Pharmaceuticals, is a Michigan corporation with a principal place of business in Michigan. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: C. David Miller, II, Esquire, GARAN LUCOW MILLER, P.C., 1000 Woodbridge Street, Detroit, MI 48207-3192.

35. Defendant Pharmaceutical Associates, Inc. is a South Carolina corporation with a principal place of business in South Carolina. Defendant regularly conducts business in New Jersey. Defendant is a wholly owned subsidiary of Defendant Beach Products, Inc. Defendant may be served with process by registered mail, return receipt requested, upon: Daniel J. McCarthy, Esquire, MINTZER SAROWITZ ZERIS LEDVA & MEYERS L.L.P., 2070 Springdale Rd., Suite 400, Cherry Hill, NJ 08003.

36. Defendant Beach Products, Inc. is a Florida corporation with a principal place of business in Florida. Defendant regularly conducts business in New Jersey. Defendant is the parent company of Defendant Pharmaceutical Associates, Inc. Defendant may be served with process by registered mail, return receipt requested, upon: Daniel J. McCarthy, Esquire, MINTZER SAROWITZ ZERIS LEDVA & MEYERS L.L.P., 2070 Springdale Rd., Suite 400, Cherry Hill, NJ 08003.

37. Defendant United Research Laboratories, Inc. is a Pennsylvania corporation with a principal place of business in Philadelphia, Pennsylvania. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered

mail, return receipt requested, upon: Geoffrey Coan, Esquire, Kathleen Kelly, Esquire, WILSON ELSER, 260 Franklin Street, 14th Floor, Boston, MA 02110.

38. Defendant Mutual Pharmaceutical Company, Inc. is a Pennsylvania corporation with a principal place of business in Philadelphia, Pennsylvania. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Geoffrey Coan, Esquire, Kathleen Kelly, Esquire, WILSON ELSER, 260 Franklin Street, 14th Floor, Boston, MA 02110.

39. Defendant Silarx Pharmaceuticals, Inc. is a New York corporation with a principal place of business in New York. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office at: 19 West Street, Spring Valley, NY 10977

40. Defendant Sandoz, Inc. is a Colorado corporation with a principal place of business in New Jersey. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office at: 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

41. Defendant ANIP Acquisition Company a/k/a ANIP Pharmaceuticals a/k/a ANI Pharmaceuticals a/k/a A & I Pharmaceuticals is a Delaware corporation with a principal place of business in Minnesota. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Philip D. Priore, Esquire, Stephen M. McManus, Esquire, MCCORMICK & PRIORE, P.C., 4 Penn Center, Suite 800, 1600 John F. Kennedy Boulevard, Philadelphia, PA 19103.

42. Defendant Watson Laboratories, Inc., is a Nevada corporation with a principal place of business in California. Defendant regularly conducts business in New Jersey.

Defendant may be served with process by registered mail, return receipt requested, upon: Michael Plata, Esq., Joseph Lagrotteria, Esq., LeClair Ryan, One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, New Jersey 07102.

43. Defendant Rugby Laboratories, Inc. a/k/a Rugby Pharmaceuticals, Inc. is a New York corporation with a principal place of business in California. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Gregory S. Thomas, Joseph Lagrotteria, Esq., LeClairRyan, One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, New Jersey 07102.

44. Defendant Actavis Elizabeth LLC, individually, and d/b/a Purepac Pharmaceuticals (hereinafter "Actavis") is a New Jersey corporation with a principal place of business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon: Frederick Fern, Esquire, Harris Beach, PLLC, 100 Wall Street, 23rd Floor, New York, N.Y. 10005.

45. Defendant APP Pharmaceuticals, LLC, Individually and d/b/a Abraxis Pharmaceuticals is a Delaware corporation with a principal place of business in Illinois. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its registered agent for service: Corporation Service Company, 2704 Commerce Drive, Ste B, Harrisburg, PA 17110-9380.

46. Defendant Bedford Laboratories is a New York corporation with a principal place of business in Ohio. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 300 Northfield Road, Bedford, OH 44146.

47. Defendant Hospira, Inc. is a Delaware corporation with a principal place of business in Illinois. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its registered agent for service: C T Corporation System, 116 Pine St., Suite 320, Harrisburg, PA 17101.

48. Defendant Ipca Pharmaceuticals Inc. is a foreign corporation with a principal place of business in New Jersey. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 51 Cragwood Road, Suite No. 203, South Plainfield, NJ, 07080.

49. Defendant McKesson Corporation, is a Delaware corporation with a principal place of business in California. Plaintiffs allege that Defendant Northstar Rx LLC is the wholly owned subsidiary of Defendant McKesson Corporation. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its registered agent for service: The Prentice Hall Corporation System, 2704 COMMERCE DRIVE, HARRISBURG PA, 17110.

50. Defendant Northstar Rx LLC is a corporation with a principal place of business in Tennessee. Defendant regularly conducts business in New Jersey. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process at: 4971 Southridge Blvd., Suite 101, Memphis, TN 38141.

51. Defendant Rugby Laboratories, Inc. is a New York corporation with a principal place of business in California. Defendant regularly conducts business in New Jersey. Defendant may be served with process by registered mail, return receipt requested, upon:

Gregory S. Thomas, Joseph Lagrotteria, Esq., LeClairRyan, One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, New Jersey 07102.

52. Defendant Smith & Nephew, Inc. is a Delaware corporation with a principal place of business in Tennessee. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its registered agent for service: CT Corporation, 116 Pine St., Suite 320, Harrisburg, PA 17101.

53. Defendant VistaPharm, Inc. is an Alabama corporation with a principal place of business in Alabama. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 2224 Cahaba Valley Drive, Suite B3, Birmingham, AL 35242.

54. Defendant Roxane Laboratories, Inc. is a Nevada corporation with a principal place of business in Ohio. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 1809 WILSON RD., COLUMBUS, OH 43228-9579.

55. Defendant Par Pharmaceutical Inc. is a Delaware corporation with a principal place of business in Ohio. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

56. ACURA PHARMACEUTICALS, INC., f/k/a HALSEY DRUG COMPANY, is a New York corporation with a principal place of business in Illinois. Defendant regularly conducts business in New Jersey. Defendant may be served with process by certified mail upon: Gregory S. Thomas, Esq., LeClair Ryan, One Riverfront Plaza, 1037 Raymond Blvd., Sixteenth Floor, Newark, NJ 07102.

57. Defendant Paco Pharmaceutical Services, Inc. is a Delaware corporation with a principal place of business in New Jersey. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 1200 Paco Way, Lakewood, NJ 08701-5938.

58. Defendant Norbrook Inc. USA is a domestic corporation with a principal place of business in Kansas. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 9733 Loiret Boulevard, Lenexa, Kansas 66219.

59. Defendant Schering Corporation is a New Jersey corporation with a principal place of business in New Jersey. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 2000 GALLOPING HILL RD., KENILWORTH, NJ 07033-1310.

60. Defendant Ranbaxy Pharmaceuticals, Inc. is a Florida corporation with a principal place of business in New Jersey. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 600 College Rd. E Ste. 2100, Princeton, NJ 08540.

61. Defendant IVAX Pharmaceuticals, Inc. is a Florida corporation with a principal place of business in Florida. Defendant regularly conducts business in New Jersey. Defendant may be served with process by and through its principal office: 4400 Biscayne Blvd., Miami, FL 33137.

62. Defendant BRISTOL MEYERS SQUIBB CO., INDIVIDUALLY and d/b/a APOTHECON, INC., is a Delaware corporation with a principal place of business in New York. Defendant regularly conducts business in New Jersey.

63. Defendant APOTHECON, INC., is a foreign corporation with a principle place of business in New Jersey.

64. Defendant INVAMED. INC., a non-domestic corporation with a principle place of business in New Jersey.

65. Defendant KING PHARMACEUTICALS INC., Individually and d/b/a ALPHARMA INC., f/k/a A.L. PHARMA Inc. is a foreign corporation with a principle place of business in New Jersey.

66. Defendant ALPHARMA INC., is a foreign corporation with a principle place of business in New Jersey.

67. Defendant John Doe Manufacturer Defendants are defendants which are or have been involved in the manufacture, distribution, marketing, sale, and labeling of Reglan and/or generic metoclopramide products but are not yet known by Plaintiffs. Pursuant to Pa. R. C. P. 2177, Plaintiffs may amend this Complaint at a future date so that it shall be brought against the corporate name.

68. Defendants WYETH, SCHWARZ, Alaven Pharmaceutical LLC, Baxter Healthcare Corporation, Wockhardt USA, Morton Grove Pharmaceuticals, Inc., TEVA, Goldline Laboratories, Inc., PLIVA, Qualitest Pharmaceuticals, Inc. and Generics Bidco I., LLC., Individually and d/b/a Qualitest Pharmaceuticals, Inc, Vintage Pharmaceuticals, LLC, The Harvard Drug Group LLC, Pharmaceutical Associates, Inc., Beach Products, Inc., United Research Laboratories, Inc., Mutual Pharmaceutical Company, Inc., Silarx Pharmaceuticals, Inc., Sandoz, Inc., ANIP Acquisition Company, Watson Laboratories, Inc., Rugby Pharmaceuticals, Inc., ACTAVIS, APP Pharmaceuticals, LLC, Bedford Laboratories, Hospira, Inc., Ipca Pharmaceuticals Inc., McKesson Corporation, Northstar Rx, LLC, Rugby Laboratories, Inc.,

VistaPharm, Inc., Roxane Laboratories, Inc., Par Pharmaceutical Inc., Acura Pharmaceuticals, Inc., Paco Pharmaceutical Services, Inc., Norbrook Inc. USA, Schering Corporation, Ranbaxy Pharmaceuticals, Inc., IVAX Pharmaceuticals, Inc., Bristol Myers Squibb Co. Individually and d/b/a Apothecon, Inc., Apothecon, Inc, Invamed, Inc., King Pharmaceuticals Inc., Alpharma, Inc., and yet to be specifically identified Jill Doe Drug Company Defendants (see below) are hereinafter referred to collectively as the DRUG COMPANY DEFENDANTS.

69. Defendants TEVA, Goldline Laboratories, Inc., PLIVA, Qualitest Pharmaceuticals, Inc. and Generics Bidco I., LLC., Individually and d/b/a Qualitest Pharmaceuticals, Inc, Vintage Pharmaceuticals, LLC, The Harvard Drug Group LLC, Pharmaceutical Associates, Inc., Beach Products, Inc., United Research Laboratories, Inc., Mutual Pharmaceutical Company, Inc., Silarx Pharmaceuticals, Inc., Sandoz, Inc., ANIP Acquisition Company, Watson Laboratories, Inc., Rugby Pharmaceuticals, Inc., ACTAVIS, APP Pharmaceuticals, LLC, Bedford Laboratories, Hospira, Inc., Ipca Pharmaceuticals Inc., McKesson Corporation, Northstar Rx, LLC, Rugby Laboratories, Inc., VistaPharm, Inc., Roxane Laboratories, Inc., Par Pharmaceutical Inc., Acura Pharmaceuticals, Inc,, Paco Pharmaceutical Services, Inc., Norbrook Inc. USA, Schering Corporation, Ranbaxy Pharmaceuticals, Inc., IVAX Pharmaceuticals, Inc., Bristol Myers Squibb Co. Individually and d/b/a Apothecon, Inc., Apothecon, Inc, Invamed, Inc., King Pharmaceuticals Inc., Alpharma, Inc., together with WYETH and Morton Grove (to the extent it distributed generic metoclopramide products) and yet to be specifically identified Jill Doe Drug Company Defendants (see below) are hereinafter referred to collectively as the GENERIC DRUG COMPANY DEFENDANTS.

70. As referred to herein, the conduct of each of the DRUG COMPANY DEFENDANTS is deemed to include and encompass the conduct of any and all parents,

subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns, and any of its officers, directors, employees, agents, representatives, and other persons acting on its behalf.

71. Each of the defendants is or has been, at all times relevant to the claims herein asserted against them, engaged in developing, designing, licensing, manufacturing, distributing, selling, marketing, publicizing, and/or introducing into or delivering in interstate commerce, throughout the United States, and in the state of New Jersey, either directly or indirectly through third-parties, subsidiaries, or related entities, Reglan and/or its counterpart generic metoclopramide products.

72. John Doe Drug Company Defendants (1-50), Jane Doe Drug Distributor Defendants (1-50), Jim Doe Health Care Providers (1-50), and Jill Doe (1-50) are corporations, partnerships, companies, or other entities and individuals involved in the marketing, design, development, manufacture, testing, selling, labeling, packaging, advertising, promoting, supplying, distribution, prescription, or release of Reglan and/or generic metoclopramide products. Their specific identities are not at present known by Plaintiffs.

II. JURISDICTION

73. Plaintiffs incorporate by reference all of the above paragraphs.

74. This court has jurisdiction over each of the DRUG COMPANY DEFENDANTS because each has regularly solicited and/or transacted business in this state.

75. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged in disseminating inaccurate, false and isleading information about products containing metoclopraide to physicians in all states in the United States of America, including the state of New Jersey, with a reasonable expectation that the

misleading information would be used and relied on by physicians throughout the United States, including the state of New Jersey.

76. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of manufacturing prescription drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

77. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of designing prescription drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

78. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of testing drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

79. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling prescription drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

80. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of marketing prescription drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

81. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of promoting prescription drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

82. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of distributing prescription drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

83. Each of the DRUG COMPANY DEFENDANTS, at all times relevant to the claims asserted against it, has been engaged, either directly or indirectly, in the business of selling prescription drug products, including products containing metoclopramide, in the state of New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus has regularly and solicited and/or transacted business in this state.

84. Defendants Wyeth LLC, Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. are residents of New Jersey because their principal places of business are in New Jersey.

85. Defendant Wyeth Holdings Corporation is a resident of the State of New Jersey as its principal place of business is located therein.

86. Defendant Wyeth Holdings Corporation maintains its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

87. Defendant Morton Grove Pharmaceutical, Inc. is a resident of New Jersey because its principal place of business is in New Jersey.

88. Defendant Wockhardt USA is a resident of New Jersey because its principal place of business is in New Jersey.

89. Defendant Duramed Pharmaceuticals Inc., is a resident of New Jersey because their principal place of business and offices are maintained in New Jersey.

90. Defendant Ranbaxy Pharmaceuticals, Inc. is a resident of New Jersey because its principal place of business is in New Jersey.

91. Defendant Schering Corporation is a resident of New Jersey because it is a New Jersey corporation and/or its principal place of business is in New Jersey.

92. Defendant Paco Pharmaceutical Services, Inc. is a resident of New Jersey because its principal place of business is in New Jersey.

93. Defendant Ipca Pharmaceuticals Inc. is a resident of New Jersey because its principal place of business is in New Jersey.

94. Defendant Actavis Elizabeth LLC, individually, and d/b/a Purepac Pharmaceuticals is a resident of New Jersey because it is a New Jersey Limited Liability Company and/or its principal place of business in New Jersey.

95. Defendant Sandoz, Inc. is a resident of New Jersey because its principal place of business is in New Jersey.

96. Defendant Barr Pharmaceuticals, LLC f/k/a Barr Pharmaceuticals, Inc. is a resident of New Jersey because its principal place of business is in New Jersey.

97. Defendant PLIVA, Inc. is a resident of New Jersey because its principal place of business is in New Jersey.

98. Defendant APOTHECON, INC., is a resident of New Jersey because its principle place of business is in New Jersey.

99. Defendant INVAMED, INC., is a resident of New Jersey because its principle place of business is in New Jersey.

100. Defendant ALPHARMA INC., is a resident of New Jersey because its principle place of business is in New Jersey.

101. Defendant MEDA Pharmaceuticals, Inc., is a resident of New Jeresy because its principle place of business is in New Jersey.

102. The claims of the individual plaintiffs adopting this master long form complaint pursuant to Case Management Order 3 exceeds fifteen thousand dollars ($15,000).

III. FACTUAL ALLEGATIONS

REGLAN AND METOCLOPRAMIDE PRODUCTS

103. From about 1980 up to approximately the end of 2001, defendant WYETH (as the A.H. Robins Company and/or American Home Products Corporation and/or by some other name) marketed and manufactured and/or distributed that certain name brand prescription drug product known as Reglan.

104. Between approximately the end of 2001 and up to approximately March 2008, the prescription drug product known as Reglan was marketed and manufactured and/or distributed by defendant SCHWARZ.

105. After March 2008, the prescription drug product known as Reglan has been marketed and manufactured and/or distributed by defendant ALAVEN.

106. The term "Reglan" is the registered brand name for a drug known generically as metoclopramide, or metoclopramide hydrochloride or metoclopramide HCl—terms which also refer to the drug substance that is the sole active ingredient in Reglan.

107. At all times relevant to claims asserted against them, the GENERIC DRUG COMPANY DEFENDANTS manufactured generic drug products known variously by such names as "generic metoclopramide" and/or "metoclopramide syrup" and/or "metoclopramide tablets" and/or injectable metoclopramide.

108. At all times relevant to claims asserted against them, the GENERIC DRUG COMPANY DEFENDANTS marketed generic drug products known variously by such names as "generic metoclopramide" and/or "metoclopramide syrup" and/or "metoclopramide tablets" and/or injectable metoclopramide.

109. At all times relevant to claims asserted against them, the GENERIC DRUG COMPANY DEFENDANTS distributed generic drug products known variously by such names as "generic metoclopramide," and/or "metoclopramide syrup" and/or "metoclopramide tablets" and/or injectable metoclopramide.

110. These generic metoclopramide products are bioequivalent to Reglan: they contain the same active ingredient (*i.e.*, drug substance) as Reglan, and are equivalent to Reglan products in dosage, strength, and all other therapeutically material respects, including potentially

beneficial effects and potentially harmful side effects, and differ from Reglan only in therapeutically non-relevant respects such as color, shape, inactive ingredients, and source of manufacture.

111. The terms "Reglan" and "metoclopramide"[1] are both frequently and interchangeably employed, in common usage among the medical community, to refer to all or any of the metoclopramide products, including both the name brand products (Reglan) and their generic equivalents.

DISTRIBUTION OF REGLAN AND GENERIC METOCLOPRAMIDE PRODUCTS

112. As required by law for all prescription drug products, each of the DRUG COMPANY DEFENDANTS included the product's "labeling," as approved by the federal Food and Drug Administration (FDA), on labels, also called "package inserts," placed on or in the packages from which the products were to be dispensed from pharmacies, or from which "product samples," if any, were to be dispensed by doctors. The labeling includes information on the product's active and inactive ingredients, clinical pharmacology, "indications" and usage, contraindications, warnings, precautions, and side effects (adverse reactions and overdosage).

113. The package inserts for each of the generic metoclopramide products are materially identical to the package inserts for Reglan, except for descriptions of therapeutically non-relevant differences among the products, such as color, shape, inactive ingredients, and source of manufacture.

---

[1] ***(Hereinafter in this MASTER COMPLAINT, the term "Reglan" is employed to refer to the name brand product; the term "generic metoclopramide" to refer to the generic equivalent drug products; the term "metoclopramide products" to refer to the name brand and generic drug products both; and the term "metoclopramide" to refer to the drug substance, which is the active ingredient in all the metoclopramide products.)***

114. The GENERIC DRUG COMPANY DEFENDANTS were required to adopt, as the package inserts for their own generic metoclopramide products, the verbatim content of the package insert for Reglan modified only to reflect the therapeutically non-relevant differences, such as color, shape, inactive ingredients, and source of manufacture, among the therapeutically equivalent products.

115. The GENERIC DRUG COMPANY DEFENDANTS revised their package inserts from time to time following modifications initiated by the manufacturer of Reglan

116. The "indications" or "indicated" uses for the metoclopramide products, as reflected in the product labeling, included "short term (4 to 12 weeks) therapy for symptomatic gastroesophogeal reflux," "relief of symptoms associated with acute and recurrent diabetic gastroporesis," and "[t]he usual manifestations of delayed gastric emptying (e.g., nausea, vomiting, heartburn, persistent fullness after meals, and anorexia)."

117. The text of the "indications" or "indicated" uses for the metoclopramide products, reflected in the product labeling, further disclosed that exposure to metoclopramide could cause extrapyramidal syptoms, including tardive dyskinesia and tardive distonia, and other afflictions involving the central nervous system, and that the risk of developing tardive dyskinesia was "believed to increase with duration of treatment and total cumulative dose."

118. The DRUG COMPANY DEFENDANTS knew, or by the reasonable and careful employment of known scientific methods could have known, and, in the exercise of reasonable care toward patients who would be expected to ingest metoclopramide products, should have known, *inter alia*, that:

a) Peer-reviewed scientific and medical literature classify metoclopramide as a

neuroleptic drug because it acts as a dopamine antagonist and causes extrapyramidal reactions.

b) Other neuroleptic drugs are sometimes called antipsychotic drugs because of their use in treating schizophrenia.

c) Studies published in peer-reviewed scientific and medical literature declare that metoclopramide has antipsychotic activity equivalent to chlorpromazine.

d) Specific neuroleptic drugs or dopamine antagonists, in the absence of contrary data specific to the drug, are expected to lead to tardive dyskinesia in a substantial percentage of patients who are exposed to the drug in usual therapeutic doses for periods of six months to a year or more.

e) Clinical trials for Reglan lasted up to three months in duration.

f) Clinical trials over periods longer than three months would reveal the effects of longer term cumulative exposure to metoclopramide.

g) The results of epidemiological studies, published in peer-reviewed scientific and medical literature, have consistently shown, for many years, a high prevalence of tardive dyskinesia and other EPS among metoclopramide product users exposed to the drug for prolonged periods.

h) These published epidemiological studies represent the best scientific evidence available for evaluating the association between metoclopramide exposure and the prevalence of tardive dyskinesia and other extrapyramidal symptoms (EPS)..

i) Heartburn and gastric bloating are typically and often experienced chronically or intermittently over long periods of time.

j) Neuroleptic drugs identified as such are commonly recognized, among internists, family and general practitioners, and gastroenterologists, as leading to a high prevalence of tardive dyskinesia and related EPS when used for prolonged periods of six months to a year or more.

k) Physicians commonly prescribe metoclopramide as treatment or relief for heartburn and bloating, for prolonged periods of six months to a year or more: nearly one-third of all patients who used metoclopramide products during one relevant period received it on doctor's prescriptions for 12 months or longer rather than 12 weeks or less.

119. The package inserts for metoclopramide products, are materially identical to the "monograph" for Reglan published in the Physician's Desk Reference,

120. The package inserts for metoclopramide products, and the "monograph" for Reglan published in the Physician's Desk Reference, omitted information material to the foreseeable and ordinary contemplated uses of the products and, in addition, contained false (inaccurate and/or misleading) statements also material to the foreseeable and ordinary contemplated uses of the products. These statements and omissions include:

a) The statement that the most common EPS occurs in approximately 1 in 500 hundred patients using metoclopramide products. This asserted fact is without scientific evidence of any sort capable of supporting it.

b) The statement that while metoclopramide exposure, like exposure to "the phenothiazines," can cause extrapyramidal reactions, metoclopramide-induced extrapyramidal reactions are "comparatively rare." The assertion that metoclopramide-induced extrapyramidal reactions are "comparatively rare" is without scientific evidence of any sort capable of supporting it.

c) The omission of any reference to epidemiological studies and other evidence suggesting that the prevalence of tardive dyskinesia among patients exposed to metoclopramide for six months or longer is as much as 100 times greater than 1 in 500.

d) The statement that use of metoclopramide products for longer than 12 weeks "had not been evaluated" and therefore "cannot" be recommended. The statement misleadingly implies that the manufacturer no evaluation whatever of longer term use has been undertaken, or that use for longer than 12 weeks would be recommended if only formal evaluations or clinical studies for such periods had been performed.

e) The omission of any statement that therapy with metoclopramide products should not extend beyond three months. This omission implies, in context, that no scientific evidence suggests, or strongly suggests, that longer term use increases substantially the risks of overexposure.

WYETH'S PROMOTION OF REGLAN USE

121. The labeling for Reglan (metoclopramide) in the United States was initially developed by the A. H. Robins Company, Inc., a Virginia corporation ("AHR").

122. In 1972 or 1973 AHR acquired a license to distribute metoclopramide in the United States from Delagrange, a foreign corporation organized pursuant to the laws of France, which held a patent on metoclopramide.

123. In 1974 employees of AHR discussed a strategy of placing studies with U.S. investigators who were sufficiently enthusiastic and extraverted to be willing to stand up in national meetings and present papers concerning metoclopramide for uses that did not receive FDA approval.

124. AHR developed marketing plans for Reglan which promoted it for use in a wide variety of gastrointestinal disorders.

125. AHR filed Chapter 11 Proceedings in August 1985.

126. In December 1989 AHR, a Debtor in Bankruptcy, merged with a wholly-owned subsidiary of American Home Products, Inc. known as AHP Subsidiary (9) Corporation, a Delaware corporation, pursuant to a Plan of Reorganization that was approved by the United States District Court for the Eastern District of Virginia.

127. Contemporaneous with the merger between the A.H. Robins Company, Inc. and AHP Subsidiary (9) Corporation, the wholly owned subsidiary of American Home Products, Inc. changed its name to A.H. Robins Company, Inc., a Delaware corporation.

128. As a result of the merger of the A.H. Robins Company, Inc. with AHP Subsidiary (9) Corporation, American Home Products, Inc. acquired all of the assets of A. H. Robins Company, Inc., including all assets relating to Reglan.

129. As a result of the merger of the A.H. Robins Company, Inc. with AHP Subsidiary (9) Corporation, American Home Products, Inc. acquired all of the liabilities of the A.H. Robins Company, Inc., a Debtor in Bankruptcy, with the exception of liabilities relating to the Dalkon Shield Intrauterine Device.

130. In 1998 American Home Products, Inc.'s wholly owned subsidiary A.H. Robins Company, Inc., formerly known as AHP Subsidiary (9) Corporation, was merged into American Home Products, Inc. and became a division of American Home Products, Inc.

131. In 2002 American Home Products, Inc. changed its name to Wyeth.

132. At all times following the merger of A.H. Robins Company, Inc., a Debtor in Bankruptcy, and AHP Subsidiary (9) Corporation, later called A.H. Robins Company,

Inc., American Home Products, Inc., later known as Wyeth, marketed and distributed Reglan as a product of the A.H. Robins Company, Inc. and utilized the A.H. Robins Company name in all of its product labeling.

133. Defendant WYETH (as the A.H. Robins Company, the American Home Products Corporation, and/or by other names) arranged for publication in the Physician's Desk Reference (PDR), for all years in which it distributed Reglan up to 2002, the Reglan labeling (the verbatim content of the Reglan package insert) as a so-called "monograph" for the product.

134. The PDR is an annual compilation, updated semiannually, composed of such "monographs," typically for name brand prescription drug products.

135. The PDR annual edition and the supplements are distributed free of charge to physicians in the United States and widely relied upon by physicians as a basic reference work for information about prescription drugs.

136. WYETH knew that metoclopramide, as a dopamine antagonist and/or a neuroleptic drug substance, is as likely as other dopamine antagonists and/or other neuroleptic drugs to cause tardive dyskinesia and other EPS.

137. WYETH and its predecessor the A.H. Robins Company, Inc. knew that the conditions for which Reglan would likely be prescribed—i.e. bloating (such as that attending "diabetic gastroparesis") and heartburn (such as that attending "gastroesophageal reflux disease," or "GERD")—are often long-term chronic and/or intermittent conditions.

138. Defendant Wyeth's predecessor, the A.H. Robins

139. Defendant WYETH's predecessor, the A.H. Robins Company, Inc., chose to extend the duration of clinical trials for evaluating the safety and efficacy of the drug Reglan to periods of not more than approximately 12 weeks.

140. Defendant WYETH's predecessor, the A.H. Robins Company purchased a license to market metoclopraide in the United States and numerous other countries from the French pharmaceutical Delagrange, the original manufacturer and the patent owner for metoclopramide.

141. Defendant WYETH's predecessor, the A.H. Robins Company, Inc., conceived a plan to promote off-label use of Reglan, including long-term off-label use, in order to increase profits.

142. Defendant WYETH's predecessor, the A.H. Robins Company, Inc., undertook and sponsored the performance of investigations calculated to suggest, without a methodology adequate to scientifically support such results, that metoclopramide is safe for long-term use; wrote up the results of the investigations purporting to demonstrate that metoclopramide is safe for long-term use; and caused the write-up to be published as if the study were designed, performed, and written up by outside investigators.

143. WYETH, in connection with its promotion of Reglan use, also published and disseminated, among physicians, other information, in the Reglan labeling, through the PDR, and in other materials, to indicate or suggest that EPS side effects, and in particular tardive dyskinesia, are rare or "comparatively rare" side effects of metoclopramide use, whether short-term or long-term,.

144. WYETH systematically suppressed or downplayed contrary evidence about the risks, incidence, and prevalence of the side effects associated with metoclopramide.

145. WYETH knew from its own investigations, including analysis of sales statistics, and from scientific studies published in peer-reviewed medical journals, that many

physicians were unaware of the extent of the risks posed by metoclopramide therapy at high dosages and/or long-term exposure.

146. Wyeth knew , that many physicians were over-prescribing metoclopramide products, and that many patients, developed serious EPS side effects, including tardive dyskinesia, tardive dystonia, and akathisia resulting in suicidal ideation and suicide. Due to this.

147. WYETH declined to make or propose any changes in the Reglan labeling or other promotional materials that would alert physicians and the medical community to the risks of long term metoclopramide exposure, and continued to disseminate information to physicians which indicated or implied that metoclopramide was not unduly unsafe for long term therapy.

148. Through published materials and other promotional efforts toward the introduction and widespread use of a metoclopramide product into the United States market, defendant WYETH planted and cultivated, among physicians and the medical community, the idea that long-term use of metoclopramide was both reasonably safe and effective, and since that time has profited from those efforts. Such promotions included presentations by sales representatives (known as “detail men”) emphasizing the drug’s gastroenterological effects, in particular gastric emptying, at the expense of its injurious neurological effects, viz., extrapyramidal effects, including tardive dyskinesia, tardive dystonia, akathisia and drug induced parkonism; the sponsoring of talks and seminars with company sponsored speakers, who would discuss the supposed benefits and safety of longer term use; and the ghost-authoring, company-sponsored publication, and further dissemination of at least one junk science study calculated to “demonstrate” the safety of long-term metoclopramide use.

149. Defendant WYETH misled physicians and the medical community by informing them, through the PDR and the dissemination of other materials, that exposure to metoclopramide can lead to tardive dyskinesia and other ESP, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than 12 weeks "cannot be recommended," without informing them—at the same time in the same materials, or otherwise—of material facts bearing on the interpretation of those facts, including the fact that that metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to tardive dyskinesia and other ESP with approximately the same high frequency, particularly in longer term use, as other dopamine antagonists and neuroleptic drugs; that epidemiological studies have consistently confirmed this expectation; that the treatment of chronic or intermittent heartburn or bloating with Reglan and/or other metoclopramide products for longer than 12 weeks is unlikely to be reasonably safe; and that earlier-disseminated false information representing long term metoclopramide therapy to be reasonably safe was false and without scientific foundation.

150. WYETH never advised the medical community or patients taking Reglan that its statements regarding the safety of Reglan were inaccurate, even after its own expert witness testified that statements in the label for Reglan were, and still are, inaccurate, false and misleading.

151. In the later part of 2001, SCHWARZ assumed responsibility for the manufacturing, marketing and distribution of Reglan as a result of an Asset Purchase Agreement between American Home Products Corporation ("AHPC"), acting through its Wyeth-Ayerst Laboratories Division and Schwarz Pharma, Inc. ("Schwarz") whereby Schwarz acquired certain assets from AHPC which included the formulation, rights and approval of an application (a "new

drug application" or "NDA") under the provisions of Section 505 (21 USC §355) of the Food, Drug, and Cosmetic Act (FDCA), for Reglan® (metoclopramide) for oral use in humans other than the syrup formulation.

152. Upon purchasing the rights to Reglan® SCHWARZ conducted their own internal evaluation of the accuracy and completeness of the label. Thereafter, SCHWARZ confirmed the existence of the false, misleading and/or inaccurate statements in the label developed by WYETH. Despite this fact, SCHWARZ never corrected, amongst other things, the significant understatement of the rate of risk, never communicated to physicians or others, the facts known to them concerning the inaccuracies in the label and discontinued the publication of any labelling information in the PDR.

153. In 2004 Defendant SCHWARZ initiated a modification to the warning in the label which was never communicated to the healthcare community, never added to the PDR, and therefore, not known by physicians or their patients. SCHWARZ knew that this updated label continued to contain inaccurate, false and misleading statements.

154. Subsequent thereto, Defendant ALAVEN purchased the formulation, rights and approval of an application (a "new drug application" or "NDA") under the provisions of Section 505 (21 USC §355) of the Food, Drug, and Cosmetic Act (FDCA), for Reglan® (metoclopramide) for oral use in humans other than the syrup formulation from SCHWARZ.

155. Upon information and belief, after purchasing the rights to Reglan® ALAVEN confirmed the existence of the false, misleading and/or inaccurate statements in the label developed by WYETH and SCHWARZ. Despite this fact, ALAVEN never corrected, amongst other things, the significant understatement of the rate of risk, the facts known to them

concerning the inaccuracies in the label or the failure to communicate the updated label to the healthcare community.

MARKETING AND DISTRIBUTION OF PRESCRIPTION DRUGS –

NAME BRAND AND GENERIC

156. It is the public policy of the United States and of the several states, including this state, as reflected in the Hatch-Waxman Act, including section 505(j) of the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 355(j), and in so-called drug product selection laws enacted in every state, to encourage the availability and use of cheaper, generic prescription drug products that are therapeutically equivalent to counterpart name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.

157. Defendant WYETH, as a prescription drug manufacturer and/or distributor, knew or should have known that the so-called "drug product selection laws," enacted or adopted in every state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.

158. Defendant WYETH, as a prescription drug manufacturer and/or distributor, knew or should have known that the manufacturers and/or distributors of generic prescription drug products, as required by law, typically and simply copy verbatim, for those package inserts, the therapeutically relevant content of the package insert for the name brand prescription drug product, for which the generic products are therapeutic equivalents; and, further, that the manufacturers of the counterpart generic products typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

159. Defendant WYETH intended and expected that the information about Reglan that it released into the medical community through the PDR, package inserts accompanying drug samples, company sales representatives, company-sponsored speakers at medical conferences and seminars, promotional mailings and advertising, and publications would be credited by doctors and others as reliable information; would be further disseminated through the medical community as reliable information; and would be relied on by practicing doctors as appropriate for use in making prescribing decisions that authorized patients to take either Reglan or bioequivalent generic metoclopramide products, as dispensed by their pharmacies.

160. Defendant WYETH, as a prescription drug manufacturer and/or distributor, knew or should have known that physicians, to obtain basic information about the properties and effects of a drug or drug product that is available in both name brand and generic formulations, commonly and typically consult the information disseminated by the manufacturer/distributor of name brand product, in PDR monographs or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients, whether by brand name or generic name, and that the patients are likely to receive and ingest, per those prescriptions, one or more generic products that are therapeutically equivalent to the name brand product.

161. All else being equal, a physician's reliance on the information concerning the properties and effects of a drug or name brand prescription drug product as contained in the PDR monograph for that drug, and in other materials disseminated by the drug's manufacturer and/or distributor, is foreseeable and reasonable—and equally foreseeable and reasonable as to the properties and effects of therapeutically equivalent generic products.

162. Defendant WYETH, as a prescription drug manufacturer and/or distributor, knew or ought to have realized, specifically, that physicians, in weighing the potential benefits and potential risks of using metoclopramide products, whether name brand or generic or either, and in writing prescriptions that authorized either Reglan or generic metoclopramide to be dispensed and used by their patients, would rely upon information disseminated to them by the manufacturer of the name brand drug product, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic metoclopramide products, and that many patients, in accordance with those prescriptions, would be likely to ingest generic metoclopramide products as lawfully and properly dispensed by their pharmacies.

163. Defendant WYETH, as a prescription drug manufacturer and/or distributor, knew or should have known that patients receiving prescriptions for Reglan or generic metoclopramide written in reliance upon information that it disseminated as the manufacturer/distributor of Reglan, the name brand metoclopramide product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

THE FDA ORDERS A BLACK BOX WARNING

I. 164. Despite having extensive knowledge of the extreme risks associated with

II. the drug as well as the absolute duty to properly and adequately warn foreseeable users, DRUG

III. COMPANY DEFENDANTS never approached the FDA to alter the label for Reglan®,

IV. metoclopramide HCl, and/or metoclopramide so that it properly and adequately warned of the

V. associated risks.

VI. 165. On February 26, 2009, the FDA, ordered a warning that informed physicians and PLAINTIFFS of the dangers of Reglan®, metoclopramide HCl, and metoclopramide.

VII. 166. On February 26, 2009, the FDA mandated a "Black Box "warning,.

VIII. 167. The "Black Box" warning is FDA's strongest warning,

IX. 168. FDA's mandated warning for Reglan®, metoclopramide HCl, and metoclopramide highlights the high risk of tardive dyskinesia with long term, high dose, or pediatric use of metoclopramide, even after the drugs are no longer taken.

X. 169. Specifically, the FDA stated that the risk of EPS disorders can be as high as 20% of the population ingesting Reglan®/metoclopramide.

XI. 170. The FDA also ordered each DEFENDANT to create a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of the drug outweigh the risks based on the new safety information.

ADOPTING THE BRAND LABEL

171. It was the responsibility of the Generic Drug Company Defendants to ensure that their warning label was at all times, the same as those of the Brand Manufacturers.

172. Despite changes in 2004 and 2009 to the warning concerning dangers in the use of Reglan®, metoclopramide HCl, and metoclopramide for periods exceeding 12 weeks, the Generic Drug Company Defendants failed to timely adopt the product labelling provided by the Brand Manufacturers.

173. That the individual Generic Drug Company Defendants did not adopt the label changes within 12 weeks of the announcement of such modification, and in some instances, did not adopt the label changes for in excess of four (4) years.

174. That the Generic Drug Company Defendants further delayed their acceptance of the new labeling provided by the Brand Manufacturers in that even after adopting the label changes, they failed to ship their metoclopramide containing products with the product inserts containing the new information until after they shipped previously packed product which contained the old labeling information.

175. That during the periods of time set forth above, the Generic Drug Company Defendants product labeling was inadequate.

176. That during the periods of time set forth above, the Generic Drug Company Defendants product labeling was inaccurate.

COMMUNICATING THE LABEL

177. After purchasing the rights to Reglan® in the latter part of 2001, Defendant SCHWARZ ceased publication of any details concerning the label information for Reglan®, metoclopramide HCl, and metoclopramide in the Physicians Desk Reference.

178. After purchasing the rights to Reglan® Defendant ALAVEN did not publish any of the details concerning the label information for Reglan®, metoclopramide HCl, and metoclopramide in the Physicians Desk Reference.

179. After acquiring the rights to injectable Reglan® Defendant BAXTER did not publish any of the details concerning the label information for Reglan®, metoclopramide HCl, and metoclopramide in the Physicians Desk Reference.

180. After being designated the RLD Holder for Reglan® syrup, Defendant Morton Grove did not publish any of the details concerning the label information for Reglan®, metoclopramide HCl, and metoclopramide in the Physicians Desk Reference.

181. After purchasing the rights to Reglan® in the latter part of 2001, Defendant SCHWARZ failed to send any Dear Doctor Letter or Dear Healthcare Provider Letter to any medical professionals concerning any of the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide.

182. After purchasing the rights to Reglan® Defendant ALAVEN failed to send any Dear Doctor Letter or Dear Healthcare Provider Letter to any medical professionals concerning any of the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide, until after the "Black Box" warning required by the FDA in 2009.

183. After acquiring the rights to injectable Reglan® Defendant BAXTER failed to send any Dear Doctor Letter or Dear Healthcare Provider Letter to any medical professionals concerning any of the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide.

184. After being designated the RLD Holder for Reglan® syrup, Defendant Morton Grove failed to send any Dear Doctor Letter or Dear Healthcare Provider Letter to any

medical professionals concerning any of the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide.

185. After purchasing the rights to Reglan® in the latter part of 2001, Defendant SCHWARZ failed to undertake any actions which would have communicated the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide to healthcare professionals.

186. After purchasing the rights to Reglan® Defendant ALAVEN failed undertake any actions which would have communicated the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide to healthcare professionals, until after the "Black Box" warning required by the FDA in 2009.

187. After acquiring the rights to injectable Reglan® Defendant BAXTER failed to undertake any actions which would have communicated the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide to healthcare professionals.

188. After being designated the RLD Holder for Reglan® syrup, Defendant Morton Grove failed to undertake any actions which would have communicated the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide to healthcare professionals.

189. After Defendant SCHWARZ ceased the publication of product label information in the PDR none of the GENERIC DRUG COMPANY DEFENDANTS sought to communicate the risks associated with the use of their generic metoclopramide to healthcare providers by publishing such information in the PDR.

190. After Defendant SCHWARZ ceased the publication of product label information in the PDR none of the GENERIC DRUG COMPANY DEFENDANTS sought to

communicate the risks associated with the use of their generic metoclopramide to healthcare providers by sending a Dear Doctor Letter or Dear Healthcare Provider Letter to medical professionals which contained the label information submitted by the BRAND MANUFACTURERS to the FDA.

191. After Defendant SCHWARZ ceased the publication of product label information in the PDR the GENERIC DRUG COMPANY DEFENDANTS failed to undertake any actions which would have communicated the details relating to the label information for Reglan®, metoclopramide HCl, and metoclopramide to healthcare providers.

192. The BRAND DEFENDANTS and GENERIC DRUG COMPANY DFENDANTS had a longstanding duty to communicate to healthcare professionals the contents of the product label, including all risks and all the warnings, associated with the use of Reglan®, metoclopramide HCl, and metoclopramide.

193. The failure of the BRAND DEFENDANTS and GENERIC DRUG COMPANY DFENDANTS to communicate any information concerning the risks and warnings contained in the product label relating to the use of Reglan®, metoclopramide HCl, and metoclopramide to healthcare professionals constituted a failure to provide an adequate warning.

194. The failure of the BRAND DEFENDANTS and GENERIC DRUG COMPANY DFENDANTS to communicate any information concerning the risks and warnings contained in the product label relating to the use of Reglan®, metoclopramide HCl, and metoclopramide to healthcare professionals constituted a failure to provide an accurate warning.

195. That the failure of the BRAND DEFENDANTS and GENERIC DRUG COMPANY DFENDANTS was so extreme and so perverse, that the FDA issued “Guidances” to the pharmaceutical industry, including the BRAND DEFENDANTS and GENERIC DRUG

COMPANY DFENDANTS, to inform them of ways, amongst many others, in which they could communicate information to healthcare professionals, concerning the risks and warnings contained in the product label for Reglan®, metoclopramide HCl, and metoclopramide.

METOCLOPRAMIDE THERAPY FOR THE PLAINTIFF AND CONSEQUENT INJURY

196. Each PLAINTIFF's physicians, prescribed "Reglan" and/or "metoclopramide" for him or her, on a more or less continuous and/or intermittent basis, between certain dates, as a means of relieving more or less chronic bloating and/or heartburn.

197. In prescribing the metoclopramide products for the PLAINTIFF as they did, the PLAINTIFF's physicians foreseeably and reasonably relied upon the information published in the PDR or otherwise disseminated by WYETH, as the manufacturer/distributor of the name brand product Reglan, and were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false, and/or otherwise inadequate information thus disseminated.

198. The PLAINTIFF's pharmacists filled the prescriptions with Reglan and/or generic metoclopramide products, namely metoclopramide tablets and/or metoclopramide syrup, as authorized or required by state law, including applicable drug product selection laws.

199. The PLAINTIFF took the metoclopramide products, as prescribed by his or her physicians and dispensed by his or her pharmacies, more or less continuously between certain dates.

200. Some or all of the metoclopramide products supplied to and ingested by the PLAINTIFF had been manufactured and/or distributed by certain DRUG COMPANY

DEFENDANTS, which are listed or otherwise specified in the separate claims asserted in the actions filed by the respective plaintiffs.

201. The PLAINTIFF's use of metoclopramide products, as prescribed by his or her physicians, resulted in his or her overexposure to the drug metoclopramide, which caused him or her to suffer (or to be at a greatly increased risk of) serious, permanent and disabling injuries, including but not limited to injuries of or associated with the central nervous and extrapyramidal motor systems, specifically tardive dyskinesia and/or other diagnosed conditions, as may be specified in the separate claims of individual plaintiffs in the actions filed by the respective plaintiffs.

202. Because of these injuries the PLAINTIFF has experienced and will continue to experience disfigurement, disability, embarrassment, loss of ability to provide household services for himself or herself, physical pain, mental anguish, potential death, permanently diminished enjoyment of life, and fear of developing any of the above named health consequences, and has incurred the costs of medical treatment, monitoring and/or medications.

203. Additionally, the plaintiffs are informed and believe, and allege, that because of these injuries, the PLAINTIFF will in the future be required to obtain further medical care and/or hospital care and medical services.

COUNT I
CONSCIOUS MISREPRESENTATION INVOLVING RISK OF PHYSICAL HARM
(Defendant Wyeth)

204. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

205. Defendant WYETH owed a duty in all of its undertakings, including the dissemination of information concerning Reglan and metoclopramide, to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

206. Defendant WYETH disseminated to physicians and the medical community, through the publication of a PDR monograph and otherwise, information concerning the properties and effects of metoclopramide and Reglan, with the intention and expectation that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

207. WYETH knew that information imparted to the medical community would be relied upon by physicians and imparted to patients.

208. WYETH disseminated the false information, as referenced above, to physicians and the medical community knowing the information to be false or in conscious disregard of whether it was false or not false.

209. WYETH disseminated the false information, as referenced above, to physicians and the medical community with the intention to deceive the physicians (and, indirectly, their patients) and to induce the physicians to prescribe Reglan, and in particular to prescribe Reglan for prolonged periods of time, with the knowledge that the patients were likely to ingest other, materially identical metoclopramide products (namely, generic metoclopramide) in addition to or in place of Reglan.

210. WYETH expected or should have expected that patients taking metoclopramide pursuant to prescriptions written or issued in reliance on the false information it disseminated would be thus placed in unnecessary, avoidable, and unreasonable peril of injury

due to toxic overexposure to the drug. Such injury includes tardive dyskinesia, a sometimes disabling, untreatable, and potentially irreversible movement disorder, and other neurological afflictions also classified as extrapyramidal responses.

211. As a foreseeable and proximate result of this conscious dissemination of false information, as referenced above, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his or her physicians, in foreseeable and expected reliance upon this false information, and believing the information to be true, prescribed for the PLAINTIFF the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time, and he or she ingested, per those prescriptions, Reglan and/or other metoclopramide products, leading to his toxic overexposure to metoclopramide.

212. Liability under this Count I is not predicated on the ingestion, if any, by the PLAINTIFF, of either Reglan as distributed by WYETH or generic metoclopramide products as distributed through ESI Lederle as a division of WYETH.

213. As asserted in this claim, the PLAINTIFF's injuries, which were due physically to his or her ingestion of metoclopramide products, were caused directly and proximately by defendant WYETH's negligently disseminating to doctors consciously false statements about the properties and dangerous propensities of metoclopramide, and not by the product as such, which Wyeth did not manufacture, distribute, or sell. Accordingly, the claim stated here is neither a "product liability action" as would be "relative to actions against product sellers," as defined in N.J.S.A. 2A:58C-8.1 or 2A:58C-1.b(3), nor a "product liability action against a manufacturer or seller for harm allegedly caused by a product" within the meaning of

N.J.S.A. 2A:58C-3.a, nor a "product liability action in which a manufacturer or seller of a product may be held liable," within the meaning of N.J.S.A. 2A:58C-2.

COUNT II
NEGLIGENT MISREPRESENTATION INVOLVING RISK OF PHYSICAL HARM
(Defendant Wyeth)

214. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

215. Defendant WYETH owed a duty in all of its several undertakings, including the dissemination of information concerning Reglan and metoclopramide, to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

216. Defendant WYETH disseminated to physicians, through the publication of a PDR monograph and otherwise, information concerning the properties and effects of metoclopramide and Reglan, with the intention and expectation that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

217. Defendant WYETH failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the properties and effects of Reglan (and of metoclopramide) was accurate and not misleading, and as a result disseminated information to physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as the PLAINTIFF, whether ultimately they purchased and ingested Reglan, generic metoclopramide products, or both.

218. As a proximate and foreseeable result of this dissemination of negligently false information, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the negligently

inaccurate, misleading, and otherwise false information disseminated by WYETH, and reasonably but unjustifiably believing the information to be true, prescribed for the PLAINTIFF the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time and he ingested, per those prescriptions, metoclopramide products, leading to his toxic overexposure to metoclopramide.

219. Liability under this Count II is not predicated on the ingestion, if any, by the PLAINTIFF, of either Reglan as distributed by WYETH or generic metoclopramide products as distributed through ESI Lederle as a division of WYETH.

220. As asserted in this claim, the PLAINTIFF's injuries, which were due physically to his or her ingestion of metoclopramide products, were caused directly and proximately by defendant WYETH's negligently disseminating to doctors consciously false statements about the properties and dangerous propensities of metoclopramide, and not by the product as such, which Wyeth did not manufacture, distribute, or sell. Accordingly, the claim stated here is neither a "product liability action" as would be "relative to actions against product sellers," as defined in N.J.S.A. 2A:58C-8.1 or 2A:58C-1.b(3), nor a "product liability action against a manufacturer or seller for harm allegedly caused by a product" within the meaning of N.J.S.A. 2A:58C-3.a, nor a "product liability action in which a manufacturer or seller of a product may be held liable," within the meaning of N.J.S.A. 2A:58C-2.

COUNT III

CONSCIOUS MISREPRESENTATION INVOLVING RISK OF PHYSICAL HARM (DEFENDANT SCHWARZ)

221. Defendant SCHWARZ, as a prescription drug manufacturer and/or distributor, knew or should have known that the so-called "drug product selection laws," enacted or adopted in every state, authorize or require a prescription for a drug identified by product

brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.

222. Defendant SCHWARZ, as a prescription drug manufacturer and/or distributor, knew or should have known that the manufacturers and/or distributors of generic prescription drug products, as required by law, typically and simply copy verbatim, for those package inserts, the therapeutically relevant content of the package insert for the name brand prescription drug product, for which the generic products are therapeutic equivalents; and, further, that the manufacturers of the counterpart generic products typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

223. Defendant SCHWARZ intended and expected that the information about Reglan that it released into the medical community would be further disseminated through the medical community as reliable information; and would be relied on by practicing doctors as appropriate for use in making prescribing decisions that authorized patients to take either Reglan or bioequivalent generic metoclopramide products, as dispensed by their pharmacies.

224. Defendant SCHWARZ, as a prescription drug manufacturer and/or distributor, knew or should have known that physicians, to obtain basic information about the properties and effects of a drug or drug product that is available in both name brand and generic formulations, commonly and typically consult the information disseminated by the manufacturer/distributor of name brand product and rely upon that information in their decisions concerning the prescribing of those products for their patients, whether by brand name or generic name, and that the patients are likely to receive and ingest, per those prescriptions, one or more generic products that are therapeutically equivalent to the name brand product.

225. All else being equal, a physician's reliance on the information concerning the properties and effects of a drug or name brand prescription drug product as contained in the materials disseminated by the drug's manufacturer and/or distributor, is foreseeable and reasonable—and equally foreseeable and reasonable as to the properties and effects of therapeutically equivalent generic products.

226. Defendant SCHWARZ, as a prescription drug manufacturer and/or distributor, knew or ought to have realized, specifically, that physicians, in weighing the potential benefits and potential risks of using metoclopramide products, whether name brand or generic or either, and in writing prescriptions that authorized either Reglan or generic metoclopramide to be dispensed and used by their patients, would rely upon information disseminated to them by the manufacturer of the name brand drug product, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic metoclopramide products, and that many patients, in accordance with those prescriptions, would be likely to ingest generic metoclopramide products as lawfully and properly dispensed by their pharmacies.

227. Defendant SCHWARZ, as a prescription drug manufacturer and/or distributor, knew or should have known that patients receiving prescriptions for Reglan or generic metoclopramide written in reliance upon information that it disseminated as the manufacturer/distributor of Reglan, the name brand metoclopramide product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

228. Defendant SCHWARZ owed a duty in all of its undertakings, including the dissemination of information concerning Reglan and metoclopramide, to exercise reasonable

care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

229. SCHWARZ knew that information imparted to the medical community would be relied upon by physicians and imparted to patients.

230. SCHWARZ disseminated the false information, as referenced above, to physicians and the medical community knowing the information to be false or in conscious disregard of whether it was false or not false.

231. SCHWARZ disseminated the false information, as referenced above, to physicians and the medical community with the intention to deceive the physicians (and, indirectly, their patients) and to induce the physicians to prescribe Reglan, and in particular to prescribe Reglan for prolonged periods of time, with the knowledge that the patients were likely to ingest other, materially identical metoclopramide products (namely, generic metoclopramide) in addition to or in place of Reglan.

232. SCHWARZ expected or should have expected that patients taking metoclopramide pursuant to prescriptions written or issued in reliance on the false information it disseminated would be thus placed in unnecessary, avoidable, and unreasonable peril of injury due to toxic overexposure to the drug. Such injury includes tardive dyskinesia, a sometimes disabling, untreatable, and potentially irreversible movement disorder, and other neurological afflictions also classified as extrapyramidal responses.

233. As a foreseeable and proximate result of this conscious dissemination of false information, as referenced above, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his or her physicians, in foreseeable and expected reliance upon this false information, and believing the information to

be true, prescribed for the PLAINTIFF the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time, and he or she ingested, per those prescriptions, Reglan and/or other metoclopramide products, leading to his toxic overexposure to metoclopramide.

234. Liability under this Count is not predicated on the ingestion, if any, by the PLAINTIFF, of Reglan as distributed by SCHWARZ.

235. As asserted in this claim, the PLAINTIFF's injuries, which were due physically to his or her ingestion of metoclopramide products, were caused directly and proximately by defendant SCHWARZ's negligently disseminating to doctors consciously false statements about the properties and dangerous propensities of metoclopramide, and not by the product as such, which SCHWARZ did not manufacture, distribute, or sell. Accordingly, the claim stated here is neither a "product liability action" as would be "relative to actions against product sellers," as defined in N.J.S.A. 2A:58C-8.1 or 2A:58C-1.b(3), nor a "product liability action against a manufacturer or seller for harm allegedly caused by a product" within the meaning of N.J.S.A. 2A:58C-3.a, nor a "product liability action in which a manufacturer or seller of a product may be held liable," within the meaning of N.J.S.A. 2A:58C-2.

COUNT IV
NEGLIGENT MISREPRESENTATION INVOLVING RISK OF PHYSICAL HARM
(DEFENDANT SCHWARZ)

236. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

237. Defendant SCHWARZ owed a duty in all of its several undertakings, including the dissemination of information concerning Reglan and metoclopramide, to exercise

reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

238. Defendant SCHWARZ disseminated information to physicians concerning the properties and effects of metoclopramide and Reglan, with the intention and expectation that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

239. Defendant SCHWARZ failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the properties and effects of Reglan (and of metoclopramide) was accurate and not misleading, and as a result disseminated information to physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as the PLAINTIFF, whether ultimately they purchased and ingested Reglan, generic metoclopramide products, or both.

240. As a proximate and foreseeable result of this dissemination of negligently false information, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the negligently inaccurate, misleading, and otherwise false information disseminated by SCHWARZ, and reasonably but unjustifiably believing the information to be true, prescribed for the PLAINTIFF the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time and he ingested, per those prescriptions, metoclopramide products, leading to his toxic overexposure to metoclopramide.

241. Liability under this Count is not predicated on the ingestion, if any, by the PLAINTIFF, of Reglan as distributed by SCHWARZ.

242. As asserted in this claim, the PLAINTIFF's injuries, which were due physically to his or her ingestion of metoclopramide products, were caused directly and proximately by defendant SCHWARZ's negligently disseminating to doctors consiously false statements about the properties and dangerous propensities of metoclopramide, and not by the product as such, which SCHWARZ did not manufacture, distribute, or sell. Accordingly, the claim stated here is neither a "product liability action" as would be "relative to actions against product sellers," as defined in N.J.S.A. 2A:58C-8.1 or 2A:58C-1.b(3), nor a "product liability action against a manufacturer or seller for harm allegedly caused by a product" within the meaning of N.J.S.A. 2A:58C-3.a, nor a "product liability action in which a manufacturer or seller of a product may be held liable," within the meaning of N.J.S.A. 2A:58C-2.

COUNT V
CONSCIOUS MISREPRESENTATION INVOLVING RISK OF PHYSICAL HARM
(DEFENDANT ALAVEN)

243. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

244. Defendant ALAVEN, as a prescription drug manufacturer and/or distributor, knew or should have known that the so-called "drug product selection laws," enacted or adopted in every state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.

245. Defendant ALAVEN, as a prescription drug manufacturer and/or distributor, knew or should have known that the manufacturers and/or distributors of generic prescription drug products, as required by law, typically and simply copy verbatim, for those package inserts, the therapeutically relevant content of the package insert for the name brand

prescription drug product, for which the generic products are therapeutic equivalents; and, further, that the manufacturers of the counterpart generic products typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

246. Defendant ALAVEN intended and expected that the information about Reglan that it released into the medical community would be further disseminated through the medical community as reliable information; and would be relied on by practicing doctors as appropriate for use in making prescribing decisions that authorized patients to take either Reglan or bioequivalent generic metoclopramide products, as dispensed by their pharmacies.

247. Defendant ALAVEN, as a prescription drug manufacturer and/or distributor, knew or should have known that physicians, to obtain basic information about the properties and effects of a drug or drug product that is available in both name brand and generic formulations, commonly and typically consult the information disseminated by the manufacturer/distributor of name brand product and rely upon that information in their decisions concerning the prescribing of those products for their patients, whether by brand name or generic name, and that the patients are likely to receive and ingest, per those prescriptions, one or more generic products that are therapeutically equivalent to the name brand product.

248. All else being equal, a physician's reliance on the information concerning the properties and effects of a drug or name brand prescription drug product as contained in the materials disseminated by the drug's manufacturer and/or distributor, is foreseeable and reasonable—and equally foreseeable and reasonable as to the properties and effects of therapeutically equivalent generic products.

249. Defendant ALAVEN, as a prescription drug manufacturer and/or distributor, knew or ought to have realized, specifically, that physicians, in weighing the

potential benefits and potential risks of using metoclopramide products, whether name brand or generic or either, and in writing prescriptions that authorized either Reglan or generic metoclopramide to be dispensed and used by their patients, would rely upon information disseminated to them by the manufacturer of the name brand drug product, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic metoclopramide products, and that many patients, in accordance with those prescriptions, would be likely to ingest generic metoclopramide products as lawfully and properly dispensed by their pharmacies.

250. Defendant ALAVEN, as a prescription drug manufacturer and/or distributor, knew or should have known that patients receiving prescriptions for Reglan or generic metoclopramide written in reliance upon information that it disseminated as the manufacturer/distributor of Reglan, the name brand metoclopramide product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

251. Defendant ALAVEN owed a duty in all of its undertakings, including the dissemination of information concerning Reglan and metoclopramide, to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

252. ALAVEN knew that information imparted to the medical community would be relied upon by physicians and imparted to patients.

253. ALAVEN disseminated the false information, as referenced above, to physicians and the medical community knowing the information to be false or in conscious disregard of whether it was false or not false.

254. ALAVEN disseminated the false information, as referenced above, to physicians and the medical community with the intention to deceive the physicians (and, indirectly, their patients) and to induce the physicians to prescribe Reglan, and in particular to prescribe Reglan for prolonged periods of time, with the knowledge that the patients were likely to ingest other, materially identical metoclopramide products (namely, generic metoclopramide) in addition to or in place of Reglan.

255. ALAVEN expected or should have expected that patients taking metoclopramide pursuant to prescriptions written or issued in reliance on the false information it disseminated would be thus placed in unnecessary, avoidable, and unreasonable peril of injury due to toxic overexposure to the drug. Such injury includes tardive dyskinesia, a sometimes disabling, untreatable and potentially irreversible movement disorder, and other neurological afflictions also classified as extrapyramidal responses.

256. As a foreseeable and proximate result of this conscious dissemination of false information, as referenced above, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his or her physicians, in foreseeable and expected reliance upon this false information, and believing the information to be true, prescribed for the PLAINTIFF the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time, and he or she ingested, per those prescriptions, Reglan and/or other metoclopramide products, leading to his toxic overexposure to metoclopramide.

257. Liability under this Count is not predicated on the ingestion, if any, by the PLAINTIFF, of Reglan as distributed by ALAVEN.

258. As asserted in this claim, the PLAINTIFF's injuries, which were due physically to his or her ingestion of metoclopramide products, were caused directly and proximately by defendant ALAVEN's negligently disseminating to doctors consciously false statements about the properties and dangerous propensities of metoclopramide, and not by the product as such, which ALAVEN did not manufacture, distribute, or sell. Accordingly, the claim stated here is neither a "product liability action" as would be "relative to actions against product sellers," as defined in N.J.S.A. 2A:58C-8.1 or 2A:58C-1.b(3), nor a "product liability action against a manufacturer or seller for harm allegedly caused by a product" within the meaning of N.J.S.A. 2A:58C-3.a, nor a "product liability action in which a manufacturer or seller of a product may be held liable," within the meaning of N.J.S.A. 2A:58C-2.

COUNT VI
NEGLIGENT MISREPRESENTATION INVOLVING RISK OF PHYSICAL HARM
(DEFENDANT ALAVEN)

259. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

260. Defendant ALAVEN owed a duty in all of its several undertakings, including the dissemination of information concerning Reglan and metoclopramide, to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

261. Defendant ALAVEN disseminated information to physicians concerning the properties and effects of metoclopramide and Reglan, with the intention and expectation that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

262. Defendant ALAVEN failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the properties and effects of Reglan (and of metoclopramide) was accurate and not misleading, and as a result disseminated information to physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as the PLAINTIFF, whether ultimately they purchased and ingested Reglan, generic metoclopramide products, or both.

263. As a proximate and foreseeable result of this dissemination of negligently false information, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the negligently inaccurate, misleading, and otherwise false information disseminated by ALAVEN, and reasonably but unjustifiably believing the information to be true, prescribed for the PLAINTIFF the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time and he ingested, per those prescriptions, metoclopramide products, leading to his toxic overexposure to metoclopramide.

264. Liability under this Count is not predicated on the ingestion, if any, by the PLAINTIFF, of Reglan as distributed by ALAVEN.

265. As asserted in this claim, the PLAINTIFF's injuries, which were due physically to his or her ingestion of metoclopramide products, were caused directly and proximately by defendant ALAVEN's negligently disseminating to doctors consiously false statements about the properties and dangerous propensities of metoclopramide, and not by the product as such, which ALAVEN did not manufacture, distribute, or sell. Accordingly, the claim stated here is neither a "product liability action" as would be "relative to actions against product sellers," as defined in N.J.S.A. 2A:58C-8.1 or 2A:58C-1.b(3), nor a "product liability action

against a manufacturer or seller for harm allegedly caused by a product" within the meaning of N.J.S.A. 2A:58C-3.a, nor a "product liability action in which a manufacturer or seller of a product may be held liable," within the meaning of N.J.S.A. 2A:58C-2.

COUNT VII
LIABILITY AS NDA HOLDER
(DEFENDANTS WYETH, SCHWARZ, ALAVEN, MORTON GRIVE & BAXTER)

266. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

267. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter as prescription drug manufacturers and/or NDA Holders and/or RLD Holders, knew or should have known that they were required by law to provide a label that is "accurate and adequate."

268. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter as prescription drug manufacturers and/or NDA Holders and/or RLD Holders, knew or should have known that the manufacturers and/or distributors of generic prescription drug products, as required by law, typically and simply copy verbatim, for those package inserts, the therapeutically relevant content of the package insert for the name brand prescription drug product, for which the generic products are therapeutic equivalents.

269. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter as prescription drug manufacturers and/or NDA Holders and/or RLD Holders, knew or should have known that the information about metoclopramide that they were required to place in their labels and was required to be used by Generic Manufacturers, would be released into the medical community as reliable information which was accurate and adequate, and would be relied on by practicing doctors and health care providers as appropriate for use in making prescribing

decisions that authorized patients to take either Reglan or bioequivalent generic metoclopramide products, as dispensed by their pharmacies.

270. A physician's reliance on the information concerning the properties and effects of a drug or name brand prescription drug product as contained in the materials disseminated by the drug's manufacturer and/or distributor, is foreseeable and reasonable—and equally foreseeable and reasonable as to the properties and effects of therapeutically equivalent generic products.

271. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter, as prescription drug manufacturers and/or NDA Holders and/or RLD Holders knew or should have known that patients receiving prescriptions for Reglan or generic metoclopramide written in reliance upon information that it disseminated as the manufacturer/distributor of Reglan, the name brand metoclopramide product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was not accurate and adequate.

272. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter, as prescription drug manufacturers and/or NDA Holders and/or RLD Holders owed a duty in all of its undertakings, including the dissemination of information concerning Reglan and metoclopramide, to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

273. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter, as prescription drug manufacturers and/or NDA Holders and/or RLD Holders knew that information imparted to the medical community would be relied upon by Generic Manufacturers, physicians and other healthcare providers, and imparted to patients.

274. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter, as prescription drug manufacturers and/or NDA Holders and/or RLD Holders disseminated an inaccurate and inadequate warning label.

275. Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter, as prescription drug manufacturers and/or NDA Holders and/or RLD Holders expected or should have expected that patients taking metoclopramide pursuant to prescriptions written or issued in reliance on the inadequate and inaccurate information it disseminated would be thus placed in unnecessary, avoidable, and unreasonable peril of injury due to overexposure to the drug. Such injury includes tardive dyskinesia, a sometimes disabling, untreatable, and potentially irreversible movement disorder, and other neurological afflictions also classified as extrapyramidal responses.

276. As a foreseeable and proximate result of this dissemination of inaccurate and inadequate information, as referenced above, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his or her physicians, in foreseeable and expected reliance upon this false information, and believing the information to be true, prescribed for the PLAINTIFF the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time, and he or she ingested, per those prescriptions, Reglan and/or other metoclopramide products, leading to their overexposure to metoclopramide.

277. Liability under this Count is not predicated on the ingestion, if any, by the PLAINTIFF, of Reglan as distributed by Wyeth, Schwarz, Alaven, Morton Grove and Baxter.

278. As asserted in this claim, the PLAINTIFF's injuries, which were due physically to his or her ingestion of metoclopramide products, were caused directly and proximately by Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter, as prescription

drug manufacturers and/or NDA Holders and/or RLD Holders disseminating to Generic Manufacturers inaccurate and inadequate warnings concerning the properties and dangerous propensities of metoclopramide, and not by the product as such, which Defendants Wyeth, Schwarz, Alaven, Morton Grove and Baxter did not manufacture, distribute, or sell. Accordingly, the claim stated here is neither a "product liability action" as would be "relative to actions against product sellers," as defined in N.J.S.A. 2A:58C-8.1 or 2A:58C-1.b(3), nor a "product liability action against a manufacturer or seller for harm allegedly caused by a product" within the meaning of N.J.S.A. 2A:58C-3.a, nor a "product liability action in which a manufacturer or seller of a product may be held liable," within the meaning of N.J.S.A. 2A:58C-2.

COUNT VIII
DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-2.c)

279. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

280. The DRUG COMPANY DEFENDANTS designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, distributed, or have recently acquired entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the metoclopramide products used by the PLAINTIFF, as described above.

281. The DRUG COMPANY DEFENDANTS expected their respective metoclopramide products to reach, and they did reach, the intended consumers, handlers, and persons coming into contact with these products without substantial or material change in the condition in which they were produced, manufactured, sold, distributed, labeled, and marketed by these defendants.

282. At all times relevant the metoclopramide products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, including the PLAINTIFF.

283. At all times relevant, the metoclopramide products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the DRUG COMPANY DEFENDANTS were defective in design and formulation in that when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

284. At all times relevant the claims asserted, the metoclopramide products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the DRUG COMPANY DEFENDANTS were defective in design and formulation, because when they left the hands of their manufacturers and suppliers they were unreasonably dangerous and also were more dangerous than the ordinary consumer would expect.

285. At all times relevant the metoclopramide products were in a defective condition and were unsafe, and Defendants knew and had reason to know that they were defective and unsafe, especially when used in a form and manner instructed by the DRUG COMPANY DEFENDANTS.

286. At all times relevant the metoclopramide products were defective in that there were safer alternative designs and formulations that were not utilized.

287. At all times relevant the DRUG COMPANY DEFENDANTS, knew or should have known, that their metoclopramide products were in a defective condition, and were and are inherently dangerous and unsafe when used in the manner instructed and provided by the DRUG COMPANY DEFENDANTS.

288. At the time of the PLAINTIFF's use of the metoclopramide products, they were being used for their intended purpose, and in a manner normally intended.

289. With respect to products they manufactured and/or sold, the DRUG COMPANY DEFENDANTS had a duty to create products that were not unreasonably dangerous for their normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

290. The metoclopramide products as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by the DRUG COMPANY DEFENDANTS were manufactured defectively because they left the hands of the defendants in a defective condition and were unreasonably dangerous for the intended use for which they were manufactured and sold.

291. The DRUG COMPANY DEFENDANTS designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective metoclopramide products that created an unreasonable risk to the health of consumers, and are therefore strictly liable for the injuries and damages caused by those products, as sustained by the plaintiffs.

292. Plaintiffs could not, by the reasonable exercise of care, have discovered the defects and perceived their danger before their ingestion of the metoclopramide products.

293. The metoclopramide products as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by the DRUG COMPANY DEFENDANTS were defective due to inadequate warnings and instructions, since these defendants knew or should have known that the products created a risk of serious and dangerous side effects, including but not limited to severe neuromuscular

disorders, tardive dyskinesia, dytonias, death, and other serious and severe personal injuries which are permanent and lasting in nature; and Defendants failed to adequately test for and warn of these risks.

294. The metoclopramide products as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by the DRUG COMPANY DEFENDANTS were defective by design because these defendants were aware at the time the products were marketed that chronic, long-term intake of metoclopramide contained in the products would result in causing an increased risk of permanent extrapyramidal symptoms.

295. The metoclopramide products as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by the DRUG COMPANY DEFENDANTS were defective by design because these defendants were aware at the time the products were marketed that a risk/benefit analysis would clearly have indicated that the product as designed, was not fit for its intended use.

296. The metoclopramide products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by the DRUG COMPANY DEFENDANTS were defective due to inadequate post-marketing surveillance and/or warnings because these defendants knew or should have known the risks of serious side effects, including, but not limited to, tardive dyskinesia, dystonias and death, as well as other serious and permanent health consequences from the products.

297. The DRUG COMPANY DEFENDANTS also failed to provide adequate warning for consumers' use of the product, and Defendants continue to improperly advertise,

market, label, and promote their metoclopramide products to the public and the medical community.

298. These design defects in the metoclopramide products were substantial and contributing factors in causing the plaintiffs' injuries. As a foreseeable and proximate result of these design defects, as described, in the metoclopramide products which he or she ingested, and which had been manufactured, supplied, and/or sold in that defective condition by the GENERIC DRUG COMPANY DEFENDANTS and defendants SCHWARZ and ALAVEN, the PLAINTIFF suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when her physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) the defendants provided to physicians for their respective products, prescribed for the PLAINTIFF the use of metoclopramide products for a prolonged and unwarranted period of time and she ingested, per those prescriptions, metoclopramide products manufactured by these defendants, leading to her toxic overexposure to metoclopramide.

299. Defendants' defective design of the metoclopramide products together with the provision of inadequate warnings accompanying the products were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

COUNT IX
FAILURE TO WARN
(N.J.S.A. 2A:58C-2.b)

300. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

301. The dangerous propensities of metoclopramide products (including Reglan), as referenced above, were known to each of the DRUG COMPANY DEFENDANTS,

or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

302. The metoclopramide products (including Reglan), as distributed by the DRUG COMPANY DEFENDANTS, were defective and unreasonably dangerous prescription drug products, inasmuch as the defendants failed to provide warnings and instructions that were appropriate and adequate to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the products for long term metoclopramide therapy.

303. Defendant WYETH, between 1979 and 2002, communicated to doctors inaccurate, false and misleading information that failed to contain relevant warnings, hazards, contraindications, side effects, and precautions, that would enable doctors to prescribe the drug safely for use by his or her patients for the purposes for which it is intended, including commonly employed long term metoclopramide therapy. In particular: WYETH disseminated information that failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with such use of metoclopramide; continued to aggressively promote the Reglan, even after it knew or should have known of the unreasonable risks of involuntary movement disorders from long term use; and overwhelmed, downplayed, and otherwise suppressed, through aggressive marketing and promotion, the minimal warnings it did disseminate.

304. The GENERIC DRUG COMPANY DEFENDANTS, and defendants SCHWARZ and ALAVEN, aware of the inadequate and misleading information disseminated to doctors by co-defendant WYETH, failed to communicate any warnings or instructions at all

concerning their products to doctors (or their patients). Rather than disseminating product information in a manner reasonably calculated to be seen and read by doctors (or patients), these defendants disseminated such information only on or within containers from which the products were to be dispensed by pharmacies to consumers. The information contained in their products' package inserts, which were not distributed in a manner reasonably calculated to be seen or read by physicians (or their patients), contained no additional material information at all.

305. The GENERIC DRUG COMPANY DEFENDANTS, aware of the deficiencies and inadequacies of information disseminated to doctors, nevertheless relied on co-defendant WYETH and/or later manufacturers of Reglan to communicate or to have communicated appropriate information to doctors about Reglan, and thereby to have communicated to doctors appropriate information about their own materially identical products.

306. Owing to these deficiencies and inadequacies, the metoclopramide products manufactured and distributed by the DRUG COMPANY DEFENDANTS were unreasonably dangerous and defective.

307. As a foreseeable and proximate result of these deficiencies and inadequacies set forth above the metoclopramide products which the PLAINTIFF ingested, and which had been manufactured, supplied, and/or sold in that defective condition by the GENERIC DRUG COMPANY DEFNDANTS and defendants SCHWARZ and ALAVEN, the PLAINTIFF suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when her physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) the defendants provided to physicians for their respective products, prescribed for the PLAINTIFF the use of metoclopramide products for a prolonged and unwarranted period of time and he or she ingested, per those prescriptions,

metoclopramide products manufactured by these defendants, leading to his or her toxic overexposure to metoclopramide.

308. Each of the DRUG COMPANY DEFENDANTS, as the manufacturers of prescription drug products, was responsible for researching, developing, designing, testing, manufacturing, inspecting, labeling, marketing, and promoting, the Reglan and/or generic metoclopramide products they respectively distributed, sold, and otherwise released into the stream of commerce, and therefore had a duty to adequately warn of the risks associated with the use of their respective products.

309. The dangerous propensities of metoclopramide products, including Reglan, as referenced above, were known to the DRUG COMPANY DEFENDANTS, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

310. Each of the DRUG COMPANY DEFENDANTS knew, or should have known, that the limited warnings disseminated regarding the risks of tardive dyskinesia, dystonias, and death associated with the use of metoclopramide were inadequate, but they failed to communicate adequate information on the dangers and safe use of their respective metoclopramide products, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug, in particular failing to communicate to doctors warnings and instructions that were appropriate and adequate to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the products for long term metoclopramide therapy.

311. Defendant WYETH, between 1979 and 2002, communicated to doctors information that failed to contain relevant warnings, hazards, contraindications, side effects, and precautions, that would enable doctors to prescribe the drug safely for use by his or her patients for the purposes for which it is intended, including commonly employed long term metoclopramide therapy. In particular, WYETH disseminated information that was inaccurate, false and misleading and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with such use of metoclopramide; continued to aggressively promote the Reglan, even after it knew or should have known of the unreasonable risks of involuntary movement disorders from long term use; and overwhelmed, downplayed, and otherwise suppressed, through aggressive marketing and promotion, the minimal warnings it did disseminate.

312. The GENERIC DRUG COMPANY DEFENDANTS, and defendants SCHWARZ and ALAVEN, knowing or culpably ignorant of the inadequacy of the information disseminated to doctors by co-defendant WYETH, failed utterly to communicate any warnings or instructions at all concerning their products to doctors ,or their patients. Rather than disseminating product information in a manner reasonably calculated to be seen and read by doctors (or patients), these defendants disseminated such information (namely the information contained in each product's "package inserts") only on or within containers from which the products were to be dispensed by pharmacies to consumers. The information contained in their products' package inserts, which were not distributed in a manner reasonably calculated to be seen or read by physicians, or their patients), contained no additional material information at all.

313. Alternatively or in addition, the GENERIC DRUG COMPANY DEFENDANTS, knowing or culpably ignorant of the deficiencies and inadequacies of

information otherwise disseminated to doctors, nevertheless relied on co-defendant WYETH and/or later manufacturers of Reglan to communicate or to have communicated appropriate information to doctors about Reglan, and thereby to have communicated to doctors appropriate information about their own materially identical products.

314. Owing to these deficiencies and inadequacies, the metoclopramide products manufactured and distributed by the DRUG COMPANY DEFENDANTS were unreasonably dangerous and defective.

315. As a foreseeable, direct, and proximate result of these deficiencies, inadequacies, and defects, as described, in the metoclopramide products which he or she ingested, and which had been manufactured, supplied, and/or sold in that defective condition by the DRUG COMPANY DEFNDANTS, the PLAINTIFF suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when her physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) the defendants provided to physicians for their respective products, prescribed for the PLAINTIFF the use of metoclopramide products for a prolonged and unwarranted period of time and he or she ingested, per those prescriptions, metoclopramide products manufactured by these defendants, leading to his or her toxic overexposure to metoclopramide.

316. The DRUG COMPANY DEFENDANTS that manufactured and/or sold the Reglan and/or generic metoclopramide products that the PLAINTIFF ingested are liable to plaintiffs for injuries caused by the innocent, negligent, and/or willful failure, as described above, to provide adequate warnings and other clinically relevant information and data regarding the appropriate use of their respective products and the risks associated with their use.

COUNT X
BREACH OF EXPRESS WARRANTIES
(N.J.S.A. 12A:2-313; N.J.S.A. 2A:58C-1.b(3))

317. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

318. The DRUG COMPANY DEFENDANTS expressly warranted, the labeling for their metoclopramide products and otherwise, that the products were of merchantable quality and safe, effective, fit, and proper for their intended use.

319. Through the product labeling and through reliance on WYETH marketing and advertising of Reglan, the DRUG COMPANY DEFENDANTS have provided the following warranties with respect to their metoclopramide products:

a) "Like the phenothiazines and related drugs, which are also dopamine antagonists, metoclopramide produces sedation and may produce extrapyramidal reactions, although these are comparatively rare (see WARNINGS)";

b) "Extrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosages of 30-40 mg/day of metoclopramide."

c) That the metoclopramide product is effective and safe for its intended use.

d) That the metoclopramide products provide the same efficacy as other gastrointestinal drugs and antiemetics, but with additional benefits.

320. The DRUG COMPANY DEFENDANTS made affirmations of fact to the PLAINTIFFs and/or their physicians related to metoclopramide products, to the effect that they conform to the descriptions provided in the marketing materials relied on for the products.

321. In deciding to prescribe metoclopramide drugs, and to purchase the products manufactured by the DRUG COMPANY DEFENDANTS, the PLAINTIFF's physicians and the PLAINTIFF, respectively, relied on the skill, judgment, representations, and express warranties of the DRUG COMPANY DEFENDANTS. These warranties and representations were false in that the metoclopramide products properly dispensed to the PLAINTIFFs, as authorized by the prescriptions of his or her physicians, and ingested by the PLAINTIFF, were not safe and were unfit for the uses for which they were intended and did not conform to the express warranties stated above.

322. The metoclopramide products purchased and ingested by the PLAINTIFF failed to provide the same benefits and efficacy as safer alternatives, as the DRUG COMPANY DEFENDANTS had promised.

323. The DRUG COMPANY breached their warranties of the safety, efficacy, and benefits of their respective metoclopramide products over safer alternatives by continuing and failing to repudiate sales and marketing campaigns highlighting the safety of the metoclopramide products, while they knew or should have known of their dangerous and defective characteristics.

324. As a foreseeable and proximate result of these breaches of express warranties on the part of the DRUG COMPANY DEFENDANTS that manufactured and/or sold the metoclopramide products the PLAINTIFF ingested, the PLAINTIFF suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the express warranties, prescribed for the PLAINTIFF the use of metoclopramide products for a prolonged and unwarranted period of time, and he purchased and

ingested, per those prescriptions, metoclopramide products manufactured by these defendants, leading to his toxic overexposure to metoclopramide.

COUNT XVI
WRONGFUL DEATH
(N.J.S.A. 2A: 31-1, et seq.)

325. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

326. As a direct and proximate result of the acts and/or omissions of DRUG PROPERTY DEFENDANTS, as set forth herein, the PLAINTIFF (a/k/a/ the DECEDENT) suffered serious emotional and bodily injuries resulting in his or her death.

327. The DECEDENT's husband or wife, father, mother, children, and or other surviving relative) are entitled to recover the damages the DECEDENT would be entitled to recover, if he or she were living, due to such injuries sustained as a result of the acts and/or omissions of DRUG COMPANY DEFENDANTS, as specifically pled herein pursuant to N.J.S.A. 2A:31-4.

328. Plaintiffs are entitled to recover punitive damages and damages for the pain and suffering caused to DECEDENT from the acts and omissions of DRUG COMPANY DEFENDANTS, as specifically pled herein, including, without limitation, punitive damages pursuant to N.J.S.A. 2A:15-3, DECEDENT's pecuniary injury, together with all hospital, medical and funeral expenses as specifically provided for under New Jersey Wrongful Death Act, N.J.S.A. 31-1, et seq.

COUNT XII
SURVIVAL ACTION
(N.J.S.A. 2A: 15-3)

329. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

330. As a result of the actions and inactions of DRUG COMPANY DEFENDANTS, the PLAINTIFF (a/k/a/ the DECEDENT) was caused to suffer before his or her death.

331. The plaintiffs, on behalf of the DECEDENTs' estates, seek damages compensable under the Survival Act, N.J.S.A. 2A:15-3 (or any successor statute) against DRUG COMPANY DEFENDANTS. Plaintiffs also, in his/her/their own right, seek damages compensable under the Survival Act (or any successor statute) against the DRUG COMPANY DEFENDANTS.

COUNT XIII
PUNITIVE DAMAGES
UNDER THE COMMON LAW AND PRODUCT LIABILITY ACT
(N.J.S.A. 2A:58C-1)

332. The plaintiffs incorporate by reference all allegations of fact made hereinabove, as if set out word for word in this paragraph.

333. Plaintiffs are entitled to punitive damages because failure of the DRUG COMPANY DEFENDANTS communicate warning information, or adequate warning information, and their affirmative dissemination and adoption of dangerous misinformation and disinformation, was reckless and without regard for the public's safety and welfare.

334. The DRUG COMPANY DEFENDANTS misled the public at large, including PLAINTIFFs and their physicians, by making false representations about the safety of metoclopramide; they downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of metoclopramide, despite available

information demonstrating its use carried an increased risk of serious and even fatal side effects to the users.

335. The DRUG COMPANY DEFENDANTS were or should have been in possession of evidence demonstrating that the metoclopramide products caused increased risk of serious side effects., but nevertheless, they continued to distribute and/or market the metoclopramide products by providing or adopting false and misleading information with regard to safety and efficacy.

336. At all times relevant herein, the DRUG COMPANY DEFENDANTS:

a) knew that the metoclopramide products were dangerous;

b) concealed the dangers and health risks from;

c) made misrepresentations to the public, the plaintiffs, their physicians, and the medical community, as to the safety and efficacy of metoclopramide products; and

d) with full knowledge of the health risks associated with metoclopramide products, and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold and/or distributed metoclopramide products for medical use.

337. The DRUG COMPANY DEFENDANTS, by and through an officer director, or managing agent, authorized sales representatives, employees and/or other agents to engage in malicious, fraudulent, and oppressive conduct towards the public, including the PLAINTIFFs, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of the general public and of the PLAINTIFFs.

338. The acts and/or omissions of Defendant as set forth supra, were also such knowing and willful failures to warn of adverse effects inherent in the use of the metoclopramide

products, that they constituted malicious, willful, wanton, and/or reckless conduct within the meaning of the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.2 et seq.

WHEREFORE, plaintiffs claim damages, including punitive damages, and demand judgment, against defendants identified in COUNTS I-VI, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

ASSERTION OF CLAIMS BY PLAINTIFFS WITH INGESTION OUTSIDE OF NEW JERSEY

I.

II. 339. The plaintiffs incorporate by reference all allegations of fact made

III. hereinabove, as if set out word for word in this paragraph.

IV. 340. Certain of the PLAINTIFFs were prescribed, purchased, and/or were injured as a result of ingestion of the metoclopramide products outside of New Jersey. To the extent the Court chooses to apply the law of a state other than New Jersey for such Plaintiffs, Plaintiffs intend to put Defendants on notice of claims which may be asserted by the individual Plaintiffs from the following states and jurisdictions:

COUNT XIV
STRICT LIABILITY

341. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

342. At the time of PLAINTIFFs' injuries, the metoclopramide products were defective and unreasonably dangerous to foreseeable consumers, including PLAINTIFFs.

343. Plaintiffs from Alaska, Arizona, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Maine, Maryland, Minnesota, Missouri, Montana, Nebraska, Nevada,

New Hampshire, New Mexico, New York, and North Dakota, and such other states where the common law, the *Restatement of Torts (Second)* and/or the *Restatement of Torts (Third)* are adopted, bring strict product liability claims under the common law, *Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third))* against Defendants.

344. Plaintiffs from jurisdictions that provide a statutory cause of action for strict liability assert claims against Defendants under the following statutes:

a. Alabama Code § 6-2-38(1) (Ala 1976);

V. b. Ark. Code Ann. § 16-116-102(5);

VI. c. The Colorado Product Liability Act of 1977, Colo. Rev. Stat.

VII. Ann. §§ 13-21-401 to 13-21-406 (2009);

VIII. d. The Connecticut Products Liability Act, Conn. Gen. Stat.

IX. §§ 52-240(a), 52-240(b), 52-572m-52-572q, and 52-577a (2005);

X. e. The Georgia Products Liability Act, O.C.G.A. § 51-1-11,

XI. *et seq.*;

XII. f. The Idaho Products Liability Reform Act ("ILPRA"),

XIII. Idaho Code §§ 6-1401, *et seq.*;

XIV. g. The Indiana Products Liability Act ("IPLA"), Inc. Code Ann.

XV. § 34-20-1-1 *et seq.*;

XVI. h. The Kansas Product Liability Act, Kan. Stat. Ann. § 60-3302,

XVII. *et seq.* (2005);

i. The Kentucky Product Liability Act, Ky. Rev. Stat. Ann. § 411.300 (Michigan 1992) *et seq.*;

XVIII. j. The Louisiana Product Liability Act, La. Rev. Stat. Ann.

XIX. § 9:2800.51 *et seq.*;

XX. **k.** **The Mississippi Product Liability Act, Miss. Code Ann.**

XXI. **§ 11-1-63 (1993) *et seq*.**

XXII.

XXIII. 345. The metoclopramide products ingested by Plaintiffs were in the same or

XXIV. substantially similar condition as they were when they left the possession of Defendants.

XXV. 346. Plaintiffs did not misuse or materially alter the metoclopramide products.

XXVI. 347. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

XXVII.

a. The metoclopramide products, as designed, manufactured, sold and supplied by Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition causing injury to Plaintiffs;

b. The product defects created a situation that was potentially dangerous to Plaintiffs and other consumers;

XXVIII.

c. Defendants failed to properly market, design, manufacture, distribute, supply and sell the metoclopramide products;

d. Defendants failed to warn and place adequate warnings and instructions on the metoclopramide products;

e. Defendants failed to adequately test the metoclopramide products which would have further indicated through a risk/benefit analysis that the product was not fit for its intended use.

f. Defendants failed to provide timely and adequate post-marketing warnings and instructions long after they knew of the risk of injury associated with the use of the metoclopramide products;

g. A feasible alternative design existed that was capable of preventing Plaintiffs' injuries; and,

h. Defendants' metoclopramide products caused injuries and losses that are of the kind that made each product a basis for strict liability.

XXIX. 348. As a result of Defendants' foregoing acts and omissions, Plaintiffs were

XXX. and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences. Defendants' conduct, as described above, was extreme and outrageous.

XXXI. 349. Defendants risked the lives of the consumers of their metoclopramide products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious

decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

XXXII. **WHEREFORE**, Plaintiffs demand judgment against Defendants, and each of them,

XXXIII. individually, jointly, severally and in the alternative, and requests compensatory damages,

XXXIV. together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems

XXXV. just and proper.

COUNT XV
NEGLIGENCE

350. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

351. Defendants had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of the metoclopramide products, including a duty to assure that the metoclopramide products did not cause unreasonable, dangerous side-effects to users.

352. Defendants failed to exercise ordinary care in the manufacture, sale, marketing, quality assurance, quality control, and distribution of the metoclopramide products into the stream of commerce, in that Defendants knew or should have known that the metoclopramide products created a high risk of unreasonable harm.

353. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to PLAINTIFFs. Defendants, through clinical trials and other adverse event reports, learned that there were serious problems with the metoclopramide products' use and failed to inform doctors, regulatory agencies and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time the metoclopramide products have been on the market in the United States.

354. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of the metoclopramide products.

355. Defendants' negligence included, but was not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, assembling, selling, and distributing the metoclopramide products without thoroughly and adequately testing them;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, designing, assembling, and distributing the metoclopramide products while concealing and suppressing test results;

c. Not conducting sufficient studies and tests to determine whether or not the metoclopramide products were safe for their intended use, because Defendants knew or had reason to know that the metoclopramide products were indeed unsafe and unfit for use by reason of the dangers to users;

d. Failing to warn PLAINTIFFs, the medical and healthcare community, including PLAINTIFFs' physicians, the general public, or the FDA, as soon as Defendants knew or should have known of the dangers of the use of the metoclopramide products, such that the use of the metoclopramide products involved a risk of tardive dyskinesia, dystonias and death, and that there were no patients in whom the benefits of the metoclopramide products outweighed the risks, and the nature, severity, and duration of potential adverse effects of the metoclopramide products is greater than the use of alternative products or to the use of no drug metoclopramide products.

e. Concealing, suppressing, failing to warn about, and/or failing to follow up on the adverse results of clinical testing that occurred, which indeed indicated that the metoclopramide products had a high risk of serious and dangerous adverse health effects and consequences;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use the metoclopramide products;

g. Advertising and recommending the use of the metoclopramide products, while suppressing and concealing the known dangers inherent in the use of the metoclopramide products;

h. Representing that the metoclopramide products were safe for their intended use when they were actually unsafe for their intended purpose, and representing that the metoclopramide products had equivalent safety and efficacy to other forms of contraception;

i. Suppressing, concealing, and omitting information concerning FDA warnings, recommendations, and observations from PLAINTIFFs, PLAINTIFFs' physicians, healthcare professionals and the public, while at the same time knowing that the metoclopramide products were unsafe, dangerous, and/or nonconforming with FDA regulations;

j. Suppressing, concealing, omitting, and/or misrepresenting information to LAINTIFFs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the metoclopramide products, as compared to other forms of contraception;

XXXVI. 356. Defendants were negligent in the design, research, development,

XXXVII. manufacture, production, promotion, assembling, packaging, advertising, distribution, testing, marketing, and sale of the metoclopramide products, because Defendants:

a. Failed to use due care in the design, research, manufacture, and development of the metoclopramide products so as to avoid the aforementioned risks to individuals;

b. Advertised, marketed, and promoted the metoclopramide products for uses other than for FDA-approved purposes;

c. Failed to use ordinary care in designing, testing, labeling, marketing, and manufacturing the metoclopramide products so as to reveal and communicate the high risk to users of unreasonable, dangerous side-effects, such as tardive dyskinesia, dystonia and death, when compared to the use of alternative products in its class or compared to the use of no drug metoclopramide products.

d. Failed to provide that their metoclopramide products were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of the metoclopramide products and that use of the metoclopramide products could and would result in severe injuries such as tardive dyskinesia, dystonias and death as a result of the use of the metoclopramide products, either compared to the use of alternative products in its class or compared to the use of no drug metoclopramide products;

e. Failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of the metoclopramide products;

f. Failed to develop and act upon written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA;

g. Failed to perform adequate pharmacovigilance and failure to comply with the postmarketing requirements of FDA regulations; and

h. Were otherwise careless or negligent.

XXXVIII.

XXXIX. 357. Despite the fact that Defendants knew or should have known that the

XL. metoclopramide products caused unreasonable, dangerous side-effects which many users would be unable to remedy by any means, Defendants continued to market the metoclopramide products to consumers, including the medical community and Plaintiffs.

XLI. 358. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

XLII. 359. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. PLAINTIFFs are informed and believe and further allege that PLAINTIFFs will in the future be required to obtain further medical care and/or hospital care and medical services.

XLIII. 360. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their metoclopramide products, including PLAINTIFFs, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an imposition of punitive damages.

XLIV. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XVI
NEGLIGENCE PER SE

361. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

362. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, and warning of the risks and dangers of the metoclopramide products.

363. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, *inter alia,* failing to report each adverse drug experience concerning the metoclopramide products that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendants, failing to promptly investigate all adverse drug experiences concerning the metoclopramide products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendants' failure to meet these requirements is evidence of defendants' negligence and constitutes negligence *per se*.

364. Defendants acts constitute an adulteration, misbranding, or both, as defined by the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* and parallel state Food, Drug and Cosmetic Acts and state common law. Said acts constitute a breach of duty subjecting Defendants to civil liability for the damages arising there from inasmuch as such acts constitute negligence *per se*.

XLV. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them,

XLVI. individually, jointly, severally and in the alternative, and requests restitution and disgorgement of

XLVII. profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as

XLVIII. this Court deems just and proper.

XLIX.

COUNT XVII
NEGLIGENT CLAIMS UNDER THE APPLICABLE LAWS OF CONNECTICUT

365. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

366. Defendants had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of the metoclopramide products, including a duty to assure that the metoclopramide products did not cause unreasonable, dangerous side-effects to users.

367. Defendants failed to exercise ordinary care in the manufacture, sale, marketing, quality assurance, quality control, and distribution of the metoclopramide products in that Defendants knew or should have known that the drugs created a high risk of unreasonable harm.

368. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

L. **WHEREFORE**, Plaintiffs demand judgment against Defendants, and each of them,

LI. individually, jointly, severally and in the alternative, and requests compensatory damages,

LII. together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems

LIII. just and proper.

COUNT XVIII
COMMON LAW FRAUD

369. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

370. Defendants falsely and fraudulently represented to the medical and healthcare community, PLAINTIFFs, the FDA, and the public that the metoclopramide products had been tested and were found to be safe and effective for their intended purposes.

371. The representations made by Defendants were, in fact, false.

372. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the metoclopramide products.

373. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, PLAINTIFFs, and the public, and also inducing the medical community, PLAINTIFFs, and the public, to recommend, prescribe, dispense, and purchase the metoclopramide products, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of PLAINTIFFs.

374. In representations to PLAINTIFFs and/or to PLAINTIFFs' healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. **That the metoclopramide products were not as safe as alternative drug metoclopramide products in its class;**

b. **That use of the metoclopramide products would result in injuries such as tardive dyskinesia, dystonia and death as a result of the use of the metoclopramide products, either compared to the use of alternative products in its class or compared to the use of no drug metoclopramide products;**

c. **That the risk of adverse events with the metoclopramide products was higher than those with alternative products in its class;**

d. **That the risk of adverse events with the metoclopramide products were not adequately tested and were known by Defendants;**

e. **That the limited clinical testing revealed the metoclopramide products had a higher risk of adverse effects, in addition to, and above and beyond those associated with alternative products in its class;**

f. **That Defendants deliberately failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;**

g. **That Defendants were aware of dangers in the metoclopramide products in addition to and above and beyond those associated with alternative products in its class;**

h. **That the metoclopramide products were defective, and that they caused dangerous and adverse side effects, including but not limited to tardive dyskinesia, dystonia and death, as well as other severe and permanent health consequences, at a much more significant rate than alternative products in its class;**

i. **That patients needed to be monitored more regularly than usual while using the metoclopramide products;**

j. **That the metoclopramide products were manufactured negligently;**

k. **That the metoclopramide products were manufactured defectively; and**

l. **That the metoclopramide products were designed negligently, and designed defectively.**

LIV. 375. Defendants were under a duty to disclose to PLAINTIFFs and their

physicians, the defective nature of the metoclopramide products, including, but not limited to, the heightened risks of tardive dyskinesia, dystonia , other injury, and death due to use of the metoclopramide products.

LV.

376. Defendants had sole access to material facts concerning the defective nature of the metoclopramide products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the metoclopramide products.

LVI.

377. Defendants' concealment and omissions of material fact concerning the safety of the metoclopramide products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause PLAINTIFFs' physicians and healthcare providers to purchase, prescribe, and/or dispense the metoclopramide products; and/or to mislead PLAINTIFFs into reliance and cause PLAINTIFFs to use the metoclopramide products.

LVII.

378. At the time these representations were made by Defendants, and at the time PLAINTIFFs used the metoclopramide products, PLAINTIFFs were unaware of the falsehood of these representations, and reasonably believed them to be true.

LVIII.

379. Defendants knew and had reason to know that the metoclopramide products could and would cause severe and grievous personal injury to the users of the metoclopramide products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

LIX.

380. In reliance upon these false representations, PLAINTIFFs were induced to, and did use the metoclopramide products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that PLAINTIFFs and

LX.

their physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the metoclopramide products, as described in detail herein.

LXI. 381. PLAINTIFFs reasonably relied on revealed facts, which negligently, foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the metoclopramide products.

LXII. 382. As a result of Defendants' research and testing or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring PLAINTIFFs, the public, and PLAINTIFFs' healthcare providers and physicians, that the metoclopramide products were safe for their recommended use or safer than alternative products on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, PLAINTIFFs, and the public at large.

LXIII. 383. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, PLAINTIFFs, PLAINTIFFs' healthcare providers, and the FDA.

LXIV. 384. The information distributed to the public, the medical community, the FDA, and PLAINTIFFs by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the metoclopramide products.

LXV. 385. Defendants intentionally made material misrepresentations to the medical community and public, including PLAINTIFFs, regarding the safety of the metoclopramide products, specifically that the metoclopramide products did not have dangerous and/or serious adverse health safety concerns, and that the metoclopramide products were as safe as alternative products in its class.

LXVI. 386. Defendants chose to over-promote the safety, efficacy and benefits of the metoclopramide products.

LXVII. 387. Defendants promoted the metoclopramide products for medical conditions beyond the limits of the FDA approval, therefore, the FDA was forced to order a black box warning, its strongest warning, on February 26, 2009. The warning highlighted the high risk of tardive dyskinesia with long term, high dose, or pediatric use of metoclopramide, even after the drugs are no longer taken.

LXVIII. 388. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and PLAINTIFFs; to gain the confidence of the public, the medical community, and PLAINTIFFs; to falsely assure them of the quality and fitness for use of the metoclopramide products; and induce PLAINTIFFs, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the metoclopramide products.

LXIX. 389. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the metoclopramide products did not present serious health risks.

LXX. 390. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

LXXI. 391. These representations, and others made by Defendants, were made with the intention of deceiving and defrauding PLAINTIFFs, PLAINTIFFs' healthcare professionals and other members of the healthcare community, and were made in order to induce PLAINTIFFs, and their respective healthcare professionals, to rely on misrepresentations, and caused PLAINTIFFs to purchase, rely, use, and request the metoclopramide products and their healthcare professionals to dispense, recommend, or prescribe the metoclopramide products.

LXXII. 392. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the metoclopramide products to the public at large, for the purpose of influencing the sales of metoclopramide products known to be dangerous and defective, and/or not as safe as other alternative products.

LXXIII. 393. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling PLAINTIFFs, as well as their healthcare professionals, into a false sense of security, so that PLAINTIFFs and their healthcare providers would rely on Defendants' representations, and PLAINTIFFs would request and purchase the metoclopramide products, and that their healthcare providers would dispense, prescribe, and recommend the metoclopramide products.

LXXIV. 394. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the metoclopramide products.

LXXV. 395. At the time the representations were made, PLAINTIFFs and their healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the metoclopramide products. PLAINTIFFs did not discover the true facts about the dangers and serious health and/or safety risks, nor did PLAINTIFFs discover the false representations of Defendants, nor would PLAINTIFFs with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

LXXVI. 39. Had PLAINTIFFs known the true facts about the dangers and serious health and/or safety risks of the metoclopramide products, PLAINTIFFs would not have purchased, used, or relied on Defendants' metoclopramide products.

LXXVII. 397. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on PLAINTIFFs.

LXXVIII. 398. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

LXXIX. 399. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and

believe and further allege that PLAINTIFFs will in the future be required to obtain further medical care and/or hospital care and medical services.

LXXX. 400. As a foreseeable, direct and proximate result of Defendants' willful and wanton misconduct and reckless disregard for PLAINTIFFs' well-being, Plaintiffs are entitled to punitive or exemplary damages as well as compensatory damages.

LXXXI. **WHEREFORE**, Plaintiffs demand judgment against Defendants, and each of them,

LXXXII. individually, jointly, severally and in the alternative, and requests compensatory damages,

LXXXIII. together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems

LXXXIV. just and proper.

COUNT XIX
FRAUDULENT CONCEALMENT

401. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

402. Plaintiffs from Alabama, Arizona, California, Colorado, Delaware, Georgia, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Mississippi, Missouri, Nebraska, New York, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin and such other states as recognize such a cause of action bring this fraudulent concealment claim under the common law.

403. Throughout the relevant time period, Defendants knew that the metoclopramide products were defective and unreasonably unsafe for their intended purpose.

404. Defendants fraudulently concealed from and/or failed to disclose to or warn PLAINTIFFs, their physicians and the medical community that the metoclopramide

products were defective, unsafe, unfit for the purposes intended, and that they were not of merchantable quality.

405. Defendants were under a duty to PLAINTIFFs to disclose and warn of the defective nature of the metoclopramide products because:

a. **Defendants were in a superior position to know the true quality, safety and efficacy of the metoclopramide products;**

b. **Defendants knowingly made false claims about the safety and quality of the metoclopramide products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and**

c. **Defendants fraudulently and affirmatively concealed the defective nature of the metoclopramide products from PLAINTIFFs.**

LXXXV.

LXXXVI. 406. The facts concealed and/or not disclosed by Defendants to PLAINTIFFs

LXXXVII. were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the metoclopramide products.

LXXXVIII. 407. Defendants intentionally concealed and/or failed to disclose the true defective nature of the metoclopramide products so that PLAINTIFFs would request and purchase the metoclopramide products, and that their healthcare providers would dispense, prescribe, and recommend the metoclopramide products, and PLAINTIFFs justifiably acted or relied upon, to their detriment, the concealed and/or non-disclosed facts as evidenced by their purchase of the metoclopramide products.

LXXXIX. 408. Defendants, by concealment or other action, intentionally prevented PLAINTIFFs and PLAINTIFFs' physicians from acquiring material information

regarding the lack of safety and effectiveness of the metoclopramide products, and are subject to the same liability to PLAINTIFFs for PLAINTIFFs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the metoclopramide products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that PLAINTIFFs were thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

XC. 409. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

XCI. 410. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that PLAINTIFFs will in the future be required to obtain further medical care and/or hospital care and medical services.

XCII. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XX
CONSTRUCTIVE FRAUD

411. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

412. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the metoclopramide products, which knowledge is not possessed by PLAINTIFFs or their physicians, and Defendants thereby hold a position of superiority over PLAINTIFFs.

413. Despite their unique knowledge regarding the defective nature of the metoclopramide products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to PLAINTIFFs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the recommended and marketed use of the metoclopramide products, as compared to safer alternative products.

414. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the metoclopramide products had a higher risk of adverse effects, in addition to, and exceeding alternative products in its class. Instead, Defendants have misrepresented the safety and efficacy of the metoclopramide products.

415. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and PLAINTIFFs to prescribe, dispense, recommend and/or purchase the metoclopramide products. PLAINTIFFs and the medical community have relied upon Defendants' representations.

416. Defendants took unconscionable advantage of their dominant position of knowledge with regard to PLAINTIFFs and engaged in constructive fraud in their relationship with PLAINTIFFs. PLAINTIFFs reasonably relied on Defendants' representations.

417. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

418. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

419. As a foreseeable, direct and proximate result of Defendants' willful and wanton misconduct and reckless disregard for PLAINTIFFs' well-being, Plaintiffs are entitled to punitive or exemplary damages as well as compensatory damages.

XCIII. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XXI
NEGLIGENT MISREPRESENTATION

420. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

421. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, PLAINTIFFs and the public, that the metoclopramide products had been tested and were not found to be safe and effective for their intended use. The representations made by Defendants, in fact, were false.

422. Defendants failed to exercise ordinary care in the representations concerning the metoclopramide products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the metoclopramide products' high risk of unreasonable, dangerous, adverse side effects.

423. Defendants breached their duty in representing to PLAINTIFFs' physicians, and the medical and healthcare community that the metoclopramide products have no serious side effects different from alternative products in its class.

424. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the metoclopramide products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, but not limited to, severe blood clots, pulmonary emboli, deep vein thromboses, strokes, heart attacks, gallbladder removal, coma, death, and other severe and personal injuries, which are permanent and lasting in nature.

425. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, and fear of developing any of the above named health consequences.

426. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. PLAINTIFFs are informed and believe and further allege that PLAINTIFFs will in the future be required to obtain further medical care and/or hospital care and medical services.

XCIV. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, **XCV.** individually, jointly, severally and in the alternative, and requests compensatory damages, together

XCVI. with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT XXII
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

427. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

428. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the metoclopramide products to PLAINTIFFs, carelessly and negligently concealing the harmful effects of the metoclopramide products from PLAINTIFFs,

and carelessly and negligently misrepresented the quality, safety and efficacy of the metoclopramide products.

429. PLAINTIFFs were directly impacted by Defendants' carelessness and negligence, in that PLAINTIFFs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase the metoclopramide products sold and distributed by Defendants.

430. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

431. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. PLAINTIFFs are informed and believe and further allege that PLAINTIFFs will in the future be required to obtain further medical care and/or hospital care and medical services.

XCVII. **WHEREFORE**, Plaintiffs demand judgment against Defendants, and each of them,

XCVIII. individually, jointly, severally and in the alternative, and requests restitution and disgorgement of

XCIX. profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as

C. this Court deems just and proper.

COUNT XXIII
BREACH OF EXPRESS WARRANTY

432. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

433. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

434. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the metoclopramide products.

435. At all relevant times, Defendants intended that the metoclopramide products be used in the manner that PLAINTIFFs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other alternative products in its class, and that it was adequately tested and fit for its intended use.

436. At all relevant times, Defendants were aware that consumers, including PLAINTIFFs, would use the metoclopramide products; which is to say that PLAINTIFFs were foreseeable users of the metoclopramide products.

437. PLAINTIFFs were at all relevant times in privity with Defendants.

438. The metoclopramide products were expected to reach and did in fact reach consumers, including PLAINTIFFs, without substantial change in the condition in which it was manufactured and sold by Defendants.

439. Defendants breached various express warranties with respect to the metoclopramide products including the following particulars:

a. **Defendants represented to PLAINTIFFs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the metoclopramide products was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the metoclopramide products;**

b. **Defendants represented to PLAINTIFFs and their physicians and healthcare roviders that the metoclopramide products were as safe, and/or safer than other alternative medications and fraudulently concealed information, which demonstrated that the metoclopramide products were not safer than alternatives available on the market; and**

c. **Defendants represented to PLAINTIFFs and their physicians and healthcare providers that the metoclopramide products were as more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the drug.**

CI. 440. In reliance upon Defendants' express warranty, PLAINTIFFs used the

CII. metoclopramide products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

CIII. 441. At the time of making such express warranties, Defendants knew or should have known that the metoclopramide products do not conform to these express representations because the metoclopramide products were not safe and has numerous serious side effects that were substantially more prevalent than alternative products in its class, many of which Defendants did not accurately warn about, and is thus unreasonably unsafe for its intended purpose.

CIV. 442. Members of the medical community, including physicians and other healthcare professionals, as well as PLAINTIFFs and the Public relied upon the

representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the metoclopramide products.

CV. 443. Defendants breached its express warranties to PLAINTIFFs in that the metoclopramide products was not of merchantable quality, safe and fit for its intended use, or adequately tested.

CVI. 444. Defendants breached the express warranty that the metoclopramide products were safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to alternative products in its class, and that it was adequately tested and fit for its intended use in violation of the following:

a. **Ala. Code § 7-2-313;**

b. **Alaska St. § 45.02.313;**

c. **Ariz. Rev. Stat. Ann. § 47-2313;**

d. **Ark. Code Ann. § 4-2-313;**

e. **Calif. Comm. Code § 2313;**

f. **Co. Rev. St. § 4-2-313;**

g. **Conn. Gen. Stat. Ann. § 42a-2-313;**

h. **6 Del. C. § 2-313;**

i. **D.C. Code Ann. § 28:2-313;**

j. **Fla. Stat. Ann. § 672.313;**

k. **O.C.G.A. § 11-2-313;**

l. **Haw. Rev. Stat. § 490:2-313;**

m. **Id. Code § 28-2-313;**

n. **Ill. Comp. Stat. Ann. Ch. 810, 5/2-313;**

o. **Ind. Code Ann. § 26-1-2-313;**

p. **Iowa Code Ann. § 554.2313;**

q. **Kans. Stat. Ann. § 84-2-313;**

r. **Ky. Rev. Stat. § 355.2-313;**

s. **La. Rev. Stat. §§ 2800.54, 2800.58;**

t. **Me. Rev. Stat. Ann. tit. 11, § 2-313;**

u. **Md. Code Ann., Com. Law § 2-313;**

v. **Mass. Gen. Laws Ann. Ch. 106, § 2-313;**

w. **Mich. Comp. Laws Ann. § 440.2313;**

x. **Minn. Stat. Ann. § 336.2-313;**

y. **Miss. Code Ann. § 75-2-313;**

z. **Mo. Rev. Stat. Ann. § 400.2-313;**

aa. **Mont. Code Ann. § 30-2-313;**

bb. **Neb. Rev. Stat. U.C.C. § 2-313, *et seq.*;**

cc. **Nev. Rev. Stat. U.C.C. § 104.2313, *et seq.*;**

dd. **N.H. Rev. Stat. Ann. § 382-A:2-313, *et seq.*;**

ee. **N.M. Stat. Ann. § 55-2-313, *et seq.*;**

ff. **N.Y. U.C.C. Law 2-313, *et seq.*;**

gg. **N.C. Gen. Stat. Ann. § 25-2-313, *et seq.*;'**

bb. **N.D. Cent. Code § 41-02-30, *et seq.*;**

ii. **Ohio Rev. Code Ann. § 1302.26, *et seq.*;**

jj. **Okla. Stat. tit. 12A, § 2-313 *et seq.*;**

kk. **Or. Rev. Stat. § 72.3130, *et seq.*;**

ll. **13 Pa. Stat. Ann. § 2313, *et seq.*;**

mm. **R.I. Gen. Laws § 6A-2-313, *et seq.*;**

nn. **S.C. Code. Ann. § 36-2-313, *et seq.*;**

oo. **S.D. Stat. 57A-2-313, *et seq.*;**

pp. **Tenn. Code Ann. § 47-2-313, *et seq.*;**

qq. **Tex. Bus. & Com. Code Ann. § 2.313, *et seq.*;**

rr. **Ut. Code Ann. § 70A-2-313, *et seq.*;**

ss. **Va. Code Ann. § 8.2-313, *et seq.*;**

tt. **Vt. Stat. Ann. tit. 9A, § 2-313, *et seq.*;**

uu. **Wa. Rev. Code § 62A.2-313, *et seq.*;**

vv. **W. Va. Code § 46-2-313, *et seq.*;**

ww. **Wis. Stat. Ann. § 402.313, *et seq.*;**

xx. **Wyo. Stat. § 34.1-2-313, *et seq.*.**

CVII.

CVIII. 445. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs

CIX. were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

CX. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them,

CXI. individually, jointly, severally, and in the alternative, and requests compensatory damages,

CXII. together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems

CXIII. just and proper.

COUNT XXIV
BREACH OF IMPLIED WARRANTY

446. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

447. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the metoclopramide products.

448. At all relevant times, Defendants intended that the metoclopramide products be used in the manner that PLAINTIFFs or PLAINTIFFs' Decedent in fact used it and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

449. Defendants were aware that consumers, including PLAINTIFFs or Plaintiffs' Decedents, would use the metoclopramide products as marketed by Defendants, which is to say that PLAINTIFFs or Plaintiffs' Decedents were foreseeable users of the metoclopramide products.

450. PLAINTIFFs or Plaintiffs' Decedent were at all relevant times in privity with Defendants.

451. The drug was expected to reach and did in fact reach consumers, including PLAINTIFFs or Plaintiffs' Decedent, without substantial change in the condition in which it was manufactured and sold by Defendants.

452. Defendants breached various implied warranties with respect to the metoclopramide products, including the following particulars:

a. **Defendants, through advertising and promotional materials and the statements of sales representatives and paid endorsers, impliedly warranted that the metoclopramide products were safe for the use for which they were intended.**

b. **Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the metoclopramide products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the metoclopramide products;**

c. **Defendants represented that the metoclopramide products were safe, and/or safer than other alternative medications and fraudulently concealed information, which demonstrated that the metoclopramide products were not safer than alternatives available on the market; and**

d. **Defendants represented that the metoclopramide products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the drug.**

CXIV.

CXV. 452. In reliance upon Defendants' implied warranty, PLAINTIFFs or Plaintiffs'

CXVI. Decedents used the metoclopramide products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

CXVII. 453. Defendants breached their implied warranty to PLAINTIFFs or Plaintiffs' Decedents in that the metoclopramide products were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of the following statutes:

a. **Ala. Code §§ 7-2-314, *et seq.*;**

b. **Alaska. Stat. §§ 45.02.314, *et seq.*;**

c. **Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*;**

d. **Ark. Code Ann. §§ 4-2-314, *et seq.*;**

e. **Cal. Comm. Code §§ 2314, *et seq.*;**

f. **Colo. Rev. Stat. §§ 4-2-314, *et seq.*;**

g. **Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*;**

h. **Del. Code Ann. tit. 6, §§ 2-314, *et seq.*;**

i. **D.C. Code Ann. §§ 28:2-314, *et seq.*;**

j. **Fla. Stat. Ann. §§ 672.314, *et seq.*;**

k. **O.C.G.A. §§ 11-2-314, *et seq.*;**

l. **Haw. Rev. Stat. §§ 490:2-314, *et seq.*;**

m. **Id. Code §§ 28-2-314, *et seq.*;**

n. **Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*;**

o. **Indiana Code Ann. §§ 26-1-2-314, *et seq.*;**

p. **Iowa Code Ann. §§ 554.2314, *et seq.*;**

q. **Kan. Stat. Ann. §§ 84-2-314, *et seq.*;**

r. **Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*;**

s. **La. Civ. Code Ann. art. 2520, *et seq.* and is liable for redhibition under this statute;**

t. **Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*;**

u. **Md. Code Ann., Com. Law §§ 2-314, *et seq.*;**

v. **Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*;**

w. **Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*;**

x. **Minn. Stat. Ann. §§ 336.2-314, *et seq.*;**

y. **Miss. Code Ann. §§ 75-2-314, *et seq.*;**

z. **Mo. Rev. Stat. §§ 400.2-314, *et seq.*;**

aa. **Mont. Code Ann. §§ 30-2-314, *et seq.*;**

bb. **Neb. Rev. Stat. §§ 2-314, *et seq.*;**

cc. **Nev. Rev. Stat. §§ 104.2314, *et seq.*;**

dd. **N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*;**

ee. **N.J. Stat. Ann. §§ 12A:2-314, *et seq.*;**

ff. **N.M. Stat. Ann. § 55-2-314, *et seq.*;**

gg. **N.Y. U.C.C. Law §§ 2-314, *et seq.*;**

hh. **N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*;**

ii. **N.D. Cent. Code §§ 41-02-31, *et seq.*;**

jj. **Ohio Rev. Code Ann. §§ 1302.27, *et seq.*;**

kk. **Okla. Stat. tit. 12A, §§ 2-314 *et seq.*;**

ll. **Or. Rev. Stat. §§ 72.3140, *et seq.*;**

mm. **13 Pa. Stat. Ann. §§ 2314 *et seq.*;**

nn. **R.I. Gen. Laws §§ 6A-2-314, *et seq.*;**

oo. **S.C. Code Ann. §§ 36-2-314, *et seq.*;**

pp. **S.D. Codified Laws §§ 57A-2-314, *et seq.*;**

qq. **Tenn. Code Ann. §§ 47-2-314, *et seq.*;**

rr. **Tex. Bus. & Com. Code Ann. §§ 2.314, *et seq.*;**

ss. **Utah Code Ann. §§ 70A-2-314, *et seq.*;**

tt. **Va. Code Ann. §§ 8.2-314, *et seq.*;**

uu. **Vt. Stat. Ann. §§ 9A-2-314, *et seq.*;**

vv. **Wash. Rev. Code §§ 62A.2-314, *et seq.*;**

ww. **W. Va. Code §§ 46-2-314, *et seq.*;**

xx. **Wis. Stat. Ann. §§ 402.314, *et seq.*;**

a. Wyo. Stat. Ann. §§ 34.1-2-314, *et seq.*.

CXVIII. 454. As a result of Defendants' foregoing acts and omissions, PLAINTIFFs

CXIX. were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, permanently diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

CXX. 455. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that PLAINTIFFs will in the future be required to obtain further medical care and/or hospital care and medical services.

CXXI. WHEREFORE, Plaintiffs demand judgment against Defendants and seekscompensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT XXV
VIOLATION OF CONSUMER PROTECTION LAWS

456. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

457. PLAINTIFFs purchased and used the metoclopramide products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

458. Had Defendants not engaged in the deceptive conduct described herein, PLAINTIFFs would not have purchased and/or paid for the metoclopramide products, and would not have incurred related medical costs and injury.

459. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from PLAINTIFFs for the metoclopramide products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

460. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

CXXII. 461. PLAINTIFFs were injured by the cumulative and indivisible nature of

CXXIII. Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the metoclopramide products. Each aspect of Defendants' conduct combined to artificially create sales of the metoclopramide products.

CXXIV. 462. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the metoclopramide products.

CXXV. 463. Had Defendants not engaged in the deceptive conduct described above, PLAINTIFFs would not have purchased and/or paid for the metoclopramide products, and would not have incurred related medical costs.

CXXVI. 464. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including PLAINTIFFs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

CXXVII. 465. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

CXXVIII. 466. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of:

ee. **Ala. Code §§ 8-19-1 *et seq.*;**

ff. **Alaska Stat. §§ 45.50.471 *et seq.*;**

dd. **Ariz. Rev. Stat. Ann. §§ 44-1522 *et seq.*;**

ee. **Ark. Code Ann. §§ 4-88-101 *et seq.*;**

ff. **Cal. Civ. Code §§ 1770 *et seq.* and Cal. Bus. & Prof. Code §§ 17200 *et seq.*;**

gg. **Colo. Rev. Stat. §§ 6-1-105 *et seq.*;**

hh. **Conn. Gen. Stat. §§ 42-110a *et seq.*;**

ii. **Del. Code Ann. tit. 6, §§ 2511 *et seq.* and §§ 2531 *et seq.*;**

jj. **D.C. Code Ann. §§ 28-3901 *et seq.*;**

kk. **Fla. Stat. Ann. §§ 501.201 *et seq.*;**

ll. **O.C.G.A. §§ 10-1-372 *et seq.*;**

mm. **Haw. Rev. Stat. §§ 480-1 *et seq.*;**

nn. **Id. Code Ann. §§ 48-601 *et seq.*;**

rr. **Ill. Comp. Stat. Ann ch. 815, 505/1 *et seq.*;**

pp. **Ind. Code Ann. §§ 24-5-0.5-1 *et seq.*;**

qq. **Iowa Code Ann. §§ 714.16 *et seq.*;**

rr. **Kan. Stat. Ann. §§ 50-623 *et seq.*;**

ss. **Ky. Rev. Stat. Ann. §§ 367.170 *et seq.*;**

tt. **La. Rev. Stat. Ann. §§ 51:1401 *et seq.*;**

uu. **Me. Rev. Stat. Ann. tit. 5, §§ 205A *et seq.*;**

vv. **Md. Code Ann., Com. Law §§ 13-101 *et seq.*;**

zz. **Mass. Gen. Laws Ann. Ch. 93A *et seq.*;**

aaa. **Mich. Comp. Laws §§ 445.901 *et seq.*;**

yy. **Minn. Stat. §§ 325D.43 *et seq.* and §§ 325F.67 *et seq.*;**

zz. **Miss. Code Ann. §§ 75-24-1 *et seq.*;**

aa. **Mo. Ann. Stat. §§ 407.010 *et seq.*;**

bb. **Mont. Code Ann. §§ 30-14-101 *et seq.*;**

cc. **Neb. Rev. Stat. §§ 59-1601 *et seq.*;**

dd. **Nev. Rev. Stat. §§ 598.0903 *et seq.*;**

ee. **N.H. Rev. Stat. Ann. §§ 358-A:1 *et seq.*;**

ff. **N.M. Stat. Ann. §§ 57-12-1 *et seq.*;**

gg. **N.Y. Gen. Bus. Law §§ 349 *et seq.* and §§ 350-e *et seq.*;**

hh. **N.C. Gen. Stat. §§ 75-1.1 *et seq.*;**

ii. **N.D. Cent. Code §§ 51-12-01 *et seq.* and §§ 51-15-01 *et seq.*;**

jj. **Ohio Rev. Code Ann. §§ 1345.01 *et seq.*;**

kk. **Okla. Stat. tit. 15 §§ 751 *et seq.*;**

ll. **Or. Rev. Stat. §§ 646.605 *et seq.*;**

mm. **73 Pa. Stat. §§ 201-1 *et seq.*;**

nn. **R.I. Gen. Laws. §§ 6-13.1-1 *et seq.*;**

oo. **S.C. Code Ann. §§ 39-5-10 *et seq.*;**

pp. **S.D. Codified Laws §§ 37-24-1 *et seq.*;**

qq. **Tenn. Code Ann. §§ 47-18-101 *et seq.*;**

rr. **Tex. Bus. & Com. Code Ann. §§17.41 *et seq.*;**

ss. **Utah Code Ann. §§ 13-11-1 *et seq.*;**

tt. **Vt. Stat. Ann. tit. 9, §§ 2451 *et seq.*;**

uu. **Va. Code Ann. §§ 59.1-196 *et seq.*;**

vv. **Wash. Rev. Code. §§ 19.86.010 *et seq.*;**

ww. **W. Va. Code §§ 46A-6-101 *et seq.*;**

xx. **Wis. Stat. Ann. §§ 100.20 *et seq.*; and**

yy. **Wyo. Stat. Ann. §§ 40-12-101 *et seq.***

CXXIX. 467. Under the statute listed above to protect consumers against unfair,

CXXX. deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

CXXXI. 468. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the metoclopramide products were fit to be used for the purpose for which they were intended, when in fact the drugs were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

CXXXII. 469. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

CXXXIII. 470. Defendants had actual knowledge of the defective and dangerous condition of the metoclopramide products and failed to take any action to cure such defective and dangerous conditions.

CXXXIV. 471. PLAINTIFFs and the medical community relied upon Defendants' misrepresentations and omissions in determining which products to use and prescribe.

CXXXV. 472. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

CXXXVI. 473. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, PLAINTIFFs have suffered ascertainable losses and damages.

CXXXVII. 474. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, PLAINTIFFs have sustained economic losses and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

CXXXVIII. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XXVI
WRONGFUL DEATH

475. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

476. Plaintiffs as Decedent's surviving relative (wife, husband, father, mother, etc.), the next of kin, statutory heir, or survivor of Decedent bring herein this wrongful death claim.

477. Decedent died as a direct and proximate result of the metoclopramide products and are survived by various family members, named and unnamed.

478. Defendants' wrongful conduct has proximately caused Decedent PLAINTIFFs' heirs to suffer the loss of Decedents' companionship, services, society, marital association, love and consortium.

479. Plaintiffs as Decedent's surviving relative (husband, father, mother, child, etc.) or court appointed representative, are entitled to recover damages as Decedent would have if she were living, as a result of the acts and/or omissions of Defendants as specifically pled herein pursuant to the following statutes:

a. **Ala. Code § 6-5-410;**

b. **Alaska Stat. § 09.55.580;**

c. **Ariz. Rev. Stat. § 12-611,12-612 and 12-613;**

d. **Ark. Code Ann. § 16-62-102;**

e. **Cal. Civ. Code § 377.60 *et seq.*;**

f. **Colo. Rev. Stat. § 13-21-201, -202, -203;**

g. **Conn. Gen. Stat. § 52-555;**

h. **Del. Code Ann. Tit 10 § 3724;**

i. **D.C. Code Ann. § 16-2701;**

j. **Fla. Stat. Ann. § 768.16 -768.26;**

k. **O.C.G.A. § 51-4-1;**

l. **Haw. Rev. Stat. § 663-3;**

m. **Idaho Code Ann. § 5-311;**

n. **Ill. Comp. Stat. ch. 740, 180/2;**

o. **Ind. Code § 34-23-1-1;**

p. **Iowa Code § 611.22;**

q. **Kan. Stat. Ann. § 60-1901;**

r. **Ky. Rev. Stat § 411.130;**

s. **La. Civ. Code Ann. art. 2315.2;**

t. **Me. Rev. Stat. tit. 18A, § 2-804;**

u. **Md. Code Ann. § 3-901,902,904;**

v. **Mass. Gen. Laws Ann. Ch. 229, § 2;**

w. **Mich. Comp. Laws § 600.2922;**

x. **Minn. Stat. § 573.02;**

y. **Miss. Code Ann. § 11-7-13;**

z. **Mo. Rev. Stat. § 537.080, Mo. Rev. Stat. § 537.090;**

aa. **Mont. Code Ann. § 27-1-513;**

bb. **Neb. Rev. Stat. § 30-809 and § 30-810;**

cc. **Nev. Rev. Stat. Ann. § 41.085;**

dd. **N.H. Rev. Stat. Ann. § 556.12;**

ee. **N.M. Stat. Ann. § 41-2-1 and § 41-2-3;**

ff. **N.Y. CLS EPTL § 5-4.1;**

gg. **N.C. Gen. Stat. § 28A-18-2;**

hh. **N.D. Cent. Code, § 32-21-01 and § 32-21-03;**

ii. **Ohio Rev. Code Ann. § 2125.02(D);**

jj. **Okla. Stat. tit. 12, § 1053(A);**

kk. **Or. Rev. Stat. § 30.020;**

ll. **42 Pa. Stat. Ann. § 8301;**

mm. **R.I. Gen. Laws § 10-7-1, 10-7-2 thru 10-7-7;**

nn. **S.C. Code Ann. § 15-51-10,-20, -40;**

oo. **S.D. Codified Laws § 15-4-1;**

pp. **Tenn. Code Ann. § 20-5-107,113;**

qq. **Tex. Civ. Prac. & Rem. Code Ann. §§ 71.001;**

rr. **Utah Code Ann. S 78-11-7;**

ss. **Vt. Stat. Ann. tit. 14, § 1491-1492;**

tt. **Va. Code Ann. § 8.01-50;**

uu. **Wa. Rev. Code § 4.20.010, Wa. Rev. Code § 4.20.020;**

vv. **W. Va. Code § 55-7-5, W. Va. Code § 55-7-6;**

ww. **Wis. Stat. § 895.04;**

xx. **Wyo. Stat. § 1-38-102.**

CXXXIX. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XXVII
SURVIVAL ACTION

480. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

481. Plaintiffs are the next of kin, statutory heir, and survivor of Decedent, and brings herein this survival claim.

482. As a direct and proximate result of Defendants' conduct outlined above, Decedent PLAINTIFFs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, and expenses of hospitalization, medical and nursing care and treatment, monitoring, and loss of earnings as well as loss of ability to earn money and other economic damages prior to Decedent PLAINTIFFS' death.

483. Plaintiffs, on behalf of the Decedents' estates, seeks damages compensable against Defendants under the following statutes (or any successor statute). Plaintiffs, in his/her/their own right, seek damages compensable against Defendants.

a. **Ala. Code § 6-5-462;**

b. **Alaska Stat. 09.55.580;**

c. **Ariz. Rev. Stat. Ann. § 14-3110;**

d. **Cal. Code Civ. Proc. § 377.30;**

e. **Colo. Rev. Stat. § 13-20-101;**

f. **Conn. Gen. Stat. Ann. § 52-599 *et seq.*;**

g. **Del. Code Ann. tit. 10, § 3702;**

h. **D.C. Code Ann. § 12-101;**

i. **Fla. Stat. Ann. § 46;**

j. **O.C.G.A. § 9-2-40;**

k. **Haw. Rev. Stat. § 663-7 and 663-8;**

l. **Idaho Code § 5-327;**

m. **Ill. Comp. Stat. ch. 755, 5/27-6;**

n. **Ind. Code Ann. § 34-9-3-1;**

o. **Iowa Code Ann. § 611.20;**

p. **Kan. Stat. Ann. § 60-1801;**

q. **Ky. Rev. Stat. § 411.133;**

r. **La. Civ. Code Ann. art.. 2315.1;**

s. **Me. Rev. Stat tit. 18A, § 3-817;**

t. **Md. Code Ann., Com. Law § 6-401;**

u. **Mass. Gen. Laws. Ann. Ch. 228, § 1 *et seq.*;**

v. **Mich. Comp. Laws Ann. § 600.2921;**

w. **Minn. Stat. Ann. § 573.01**;

x. **Miss. Code Ann. § 11-7-13**

y. **Mo. Rev. Stat. Ann. § 537.020;**

z. **Mont. Code Ann. § 27-1-501;**

aa. **Neb. Rev. Stat.. § 25-1401;**

bb. **Nev. Rev. Stat. Ann. § 41.100;**

cc. **N.H. Rev. Stat. Ann. § 556:9;**

dd. **N.M. Stat. Ann. § 37-2-;**

ee. **N.Y. Cls. Eptl. § 11-3.2;**

ff. **N.C. Gen. Stat. § 28A-18-1;**

gg. **N.D. Cent. Code, § 28-01-26.1;**

hh. **Ohio Rev. Code Ann § 2305.21;**

ii. **Okla. Stat. tit. 12, § 1051;**

jj. **Or. Rev. Stat. § 115.305;**

kk. **42 Pa. Stat.. § 8302;**

ll. **R.I. Gen. Laws § 9-1-6;**

mm. **S.C. Code Ann. § 15-5-90;**

nn. **S.D. Codified Laws § 15-4-2;**

oo. **Tenn. Code Ann. § 20-5-102, 106 (2010) Tenn. Code Ann. § 20-5-108;**

pp. **Tex. Civ. Prac. & Rem. Code Ann. § 71.021;**

qq. **Utah Code Ann. § 78B-3-107;**

rr. **Vt. Stat. Ann. tit. 14, § 1451-1453;**

ss. **Va. Code Ann. § 8.01-25;**

tt. **Rev. Code Wash. (ARCW) § 4.20.046; Rev. Code Wash. (ARCW) § 4.20.060;**

uu. **W. Va. Code § 55-7-8;**

vv. **Wis. Stat. Ann. § 895.01;**

ww. **Wyo. Stat. Ann. § 1-4-101.**

CXL. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

CLAIMS ASSERTED BY ALL PLAINTIFFS

I. 484. Plaintiffs reallege and incorporate by reference all other paragraphs of this

II.

III. Complaint as if fully set forth herein.

IV.

V. 485. Plaintiffs intend to put Defendants on notice of the following claims arising under the common law.

COUNT XXVIII
GROSS NEGLIGENCE

486. Plaintiffs repeat and reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

487. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and PLAINTIFF for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to PLAINTIFFs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or

welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by PLAINTIFFs.

488. PLAINTIFFs relied on the representation and suffered injury as a proximate result of this reliance.

489. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

490. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to PLAINTIFFs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

VI. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XXIX
UNJUST ENRICHMENT

491. Plaintiffs repeat and reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

492. Defendants are and at all times were the manufacturer, sellers, and/or supplier of the prescription medications, the metoclopramide products.

493. PLAINTIFFs paid for the metoclopramide products for the purpose of contraception.

494. Defendants have accepted payment by PLAINTIFFs for the purchase of the metoclopramide products.

495. PLAINTIFFs have not received the safe and effective product for which they paid.

496. It would be inequitable for Defendants to keep this money if PLAINTIFFs did not in fact receive a safe product.

VII. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

VIII. COUNT XXX
CIVIL CONSPIRACY

IX. 497. Plaintiffs repeat and reallege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

X. 498. Defendants, in a combination of two or more persons, acted with a common purpose to do an illegal act and/or to do a lawful act by unlawful means or for an unlawful purpose. Specifically, Defendants violated the United States Food, Drug, and Cosmetic Drug Act, 21 U.S.C. § 321 *et seq.* and parallel state Food, Drug and Cosmetic Acts and state common law by selling and distributing a drug product that was misbranded and/or adulterated under the federal Food, Drug and Cosmetic Act.

XI. 499. In addition, Defendants acted with a common purpose to negligently, intentionally, and/or fraudulently withhold information regarding the safety of the

metoclopramide products for the purpose of earning profits at the expense of PLAINTIFFs' health.

XII. 500. Defendants overtly acted by hiding safety information regarding the metoclopramide products and failing to disclose such information to PLAINTIFFs, PLAINTIFFs' physicians, the FDA, and the medical community in pursuance of monetary benefit.

XIII. 501. As a consequence of Defendants' wrongful conduct, actual legal damage has occurred to PLAINTIFFs and the public.

XIV. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

XV. COUNT XXXI
XVI. LOSS OF CONSORTIUM

XVII. 502. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

XVIII. 503. At all relevant times hereto, the PLAINTIFFs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of PLAINTIFFs' injuries.

XIX. 504. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid,

treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

XX. 505. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

XXI. 506. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

XXII. 507. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

XXIII. 508. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

XXIV. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XXXII
PUNITIVE DAMAGES

509. Plaintiffs reallege each and every allegation of this Complaint contained herein, with the same force and effect as if fully set forth.

510. At all times relevant hereto, Defendants knew or should have known that the metoclopramide products were inherently more dangerous with respect to the risks of tardive dyskinesia, dystonias, extrapyramidal symptoms and other severe and personal injuries which are permanent and lasting in nature than alternative products in its class.

511. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the metoclopramide products.

512. Defendants misrepresentation included knowingly withholding material information from the medical community and the public, including PLAINTIFFs, concerning the safety of the metoclopramide products.

513. At all times material hereto, Defendants knew and recklessly disregarded the fact that the metoclopramide products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products in its class.

514. At all times material hereto, Defendants knew and recklessly disregarded the fact that the metoclopramide products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products in its class and recklessly failed to advise the FDA of same.

515. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the clotting risks caused by the metoclopramide products.

516. Notwithstanding the foregoing, Defendants continue to aggressively market the metoclopramide products to consumers, without disclosing the true risk of side effects where there were safer alternative products.

517. Defendants knew of the metoclopramide products' defective and unreasonably dangerous nature, but continue to manufacture, produce, assemble, market, distribute, and sell the metoclopramide products so as to maximize sales and profits at the expense of the health and safety of the Public, including PLAINTIFFs, in conscious and/or negligent disregard of the foreseeable harm caused by the metoclopramide products.

518. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including PLAINTIFFs, the potentially life threatening side effects of the metoclopramide products in order to ensure continued and increased sales.

519. Defendants intentionally reckless and/or grossly negligent failure to disclose information deprived PLAINTIFFs of necessary information to enable them to weigh the true risks of using the metoclopramide products against their benefits.

520. As a direct and proximate result of the foregoing acts and omissions, PLAINTIFFs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that PLAINTIFFs will in the future be required to obtain further medical care and/or hospital care and medical services.

XXV. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and

disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

I. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

a. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by PLAINTIFFs, health and medical care costs, together with interest and costs as provided by law;
b. Restitution and disgorgement of profits;
c. Reasonable attorneys' fees;
d. The costs of these proceedings;
e. All ascertainable economic damages;
f. Punitive damages;
g. Survival damages (if applicable);
h. Wrongful death damages (if applicable); and
i. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

Dated: August 1, 2011

_____

Plaintiffs' Liaison Counsel

DEMAND FOR JURY TRIAL

II. Plaintiffs hereby demand trial by jury as to all issues.

III.

Respectfully submitted,

Dated: August 1, 2011

_____

Plaintiffs' Liaison Counsel