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 REGLAN/METOCLOPRAMIDE :  
 LITIGATION :  
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*This Document Relates to All Cases* :  
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 PHILADELPHIA COUNTY  
 JANUARY TERM, 2010  
 NO. 01997

COURT OF COMMON PLEAS PHILADELPHIA CIVIL DIVISION

PLAINTIFFS,

JANUARY TERM, 2010

*Plaintiff,*

vs.

Case No. 01997

BRAND NAME DEFENDANTS:

**Wyeth LLC**

c/o The Corporation Trust Company  
 820 Bear Tavern Road  
 West Trenton, NJ 08628

**Wyeth Pharmaceuticals Inc., Individually  
 and d/b/a ESI Lederle, Inc.**

The Corporation Trust Company  
 820 Bear Tavern Road  
 West Trenton, NJ 08628

**Wyeth Holdings Corporation, Individually  
 and d/b/a ESI Lederle, Inc.**

5 Giralda Farms  
 Madison, NJ 07940

**Pfizer, Inc.**

Agent for Service of Process:  
 C T Corporation System  
 116 Pine St., Suite 320  
 Harrisburg, PA 17101

**Schwarz Pharma, Inc.**

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

**THIRD AMENDED COMPLAINT FOR  
 DAMAGES**

1. **STRICT PRODUCT LIABILITY – FAILURE TO WARN**
2. **STRICT PRODUCT LIABILITY – DESIGN DEFECT**
3. **NEGLIGENCE**
4. **NEGLIGENCE *PER SE***
5. **FRAUD AND INTENTIONAL MISREPRESENTATION**
6. **CONSTRUCTIVE FRAUD**
7. **BREACH OF EXPRESS and IMPLIED WARRANTIES**
8. **UNFAIR AND DECEPTIVE TRADE PRACTICES**
9. **UNJUST ENRICHMENT**
10. **CONSCIOUS OR NEGLIGENT MISREPRESENTATION INVOLVING PHYSICAL HARM**
11. **CIVIL CONSPIRACY**
12. **LOSS OF CONSORTIUM**
13. **WRONGFUL DEATH**
14. **SURVIVAL ACTION**
15. **GROSS NEGLIGENCE/MALICE**
16. **PUNITIVE DAMAGES**

**DEMAND FOR A JURY TRIAL**

**Schwarz Pharma AG**

Agent for Service of Process (Central  
Authority):  
Die Präsidentin des Oberlandesgerichts  
Düsseldorf  
Cecilienallee 3  
40474 Düsseldorf  
GERMANY

**UCB Pharma GmbH**

Alfred-Nobel Strasse 10  
40789 Monheim  
Germany

**Alaven Pharmaceutical LLC**

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

**Baxter Healthcare Corporation**

Agent for Service of Process:  
C T Corporation System  
116 Pine St., Suite 320  
Harrisburg, PA 17101

**Wockhardt USA<sup>1</sup>**

Robert E. O'Malley, Esquire  
SEGAL, MCCAMBRIDGE, SINGER &  
MAHONEY, LTD.  
233 S. Wacker Drive  
Sears Tower - Suite 5500  
Chicago, IL 60606

**Morton Grove Pharmaceuticals, Inc.<sup>2</sup>**

Robert E. O'Malley, Esquire  
SEGAL, MCCAMBRIDGE, SINGER &  
MAHONEY, LTD.  
233 S. Wacker Drive

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<sup>1</sup> Wockhardt USA acquired Morton Grove Pharmaceuticals, Inc in October 2007.

<sup>2</sup> Although Morton Grove Pharmaceuticals, Inc. is a holder of an ANDA for metoclopramide syrup, it is also assigned as the Reference Listed Drug holder of Reglan® syrup. Pursuant to the 21 C.F.R. 314.3 and 314.94, a Referenced Listed drug means the listed drug identified by the United States Food & Drug Administration as the drug product upon which an applicant relies in seeking approval of its abbreviated application. Defendant Morton Grove Pharmaceuticals, Inc., 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.

Sears Tower - Suite 5500  
Chicago, IL 60606

GENERIC DEFENDANTS:

**Teva Pharmaceuticals USA, Inc.,  
Individually and d/b/a IVAX  
Pharmaceuticals**

Ms. Jennifer Fuller-Ricciardi  
Teva Pharmaceuticals USA, Inc.  
425 Privet Road  
P.O. Box 1005  
Horsham, PA 19044

**Teva Pharmaceutical Industries, Ltd.**

Agent for Service of Process (Central  
Authority):  
The Director of Courts  
Directorate of Courts  
22 Kanfei Nesharin St.  
Jerusalem 95464  
P.O.B. 34142  
Israel

**PLIVA, Inc., Individually and f/k/a Sidmak  
Laboratories, Inc.**

Ms. Jennifer Fuller-Ricciardi  
Teva Pharmaceuticals USA, Inc.  
425 Privet Road  
P.O. Box 1005  
Horsham, PA 19044

**PLIVA d.d.**

Agent for Service of Process (Central  
Authority):  
Ministry of Justice of the Republic of Croatia  
Dezmanova 6 I 10  
Croatia

**Barr Pharmaceuticals LLC f/k/a Barr  
Pharmaceuticals, Inc.**

Ms. Jennifer Fuller-Ricciardi  
Teva Pharmaceuticals USA, Inc.  
425 Privet Road  
P.O. Box 1005  
Horsham, PA 19044

**Barr Laboratories, Inc**

Ms. Jennifer Fuller-Ricciardi  
Teva Pharmaceuticals USA, Inc.  
425 Privet Road  
P.O. Box 1005  
Horsham, PA 19044

**Duramed Pharmaceuticals, Inc.**

Ms. Jennifer Fuller-Ricciardi  
Teva Pharmaceuticals USA, Inc.  
425 Privet Road  
P.O. Box 1005  
Horsham, PA 19044

**Qualitest Pharmaceuticals, Inc.,  
Individually and d/b/a Vintage  
Pharmaceuticals, Inc.**

James M. Campbell Esquire  
Kristen E. Dennison, Esquire  
Campbell, Campbell, Edward & Conroy, P.C.  
690 Lee Rd., Suite 300  
Wayne, PA 19087

**Generics Bidco I, LLC, Individually and  
d/b/a Qualitest Pharmaceuticals**

James M. Campbell Esquire  
Kristen E. Dennison, Esquire  
Campbell, Campbell, Edward & Conroy, P.C.  
690 Lee Rd., Suite 300  
Wayne, PA 19087

**Vintage Pharmaceuticals, LLC**

James M. Campbell Esquire  
Kristen E. Dennison, Esquire  
Campbell, Campbell, Edward & Conroy, P.C.  
690 Lee Rd., Suite 300  
Wayne, PA 19087

**The Harvard Drug Group LLC,  
Individually and d/b/a Major  
Pharmaceuticals, Inc.**

C. David Miller, II, Esquire  
GARAN LUCOW MILLER, P.C.  
1000 Woodbridge Street  
Detroit, MI 48207-3192.

**Pharmaceutical Associates, Inc.**

Daniel J. McCarthy, Esquire  
MINTZER SAROWITZ ZERIS LEDVA &  
MEYERS L.L.P.  
1500 Market Street  
Suite 4100  
Philadelphia, PA 19102

**Beach Products Inc.**

Agent for Service of Process:  
Daniel J. McCarthy, Esquire  
MINTZER SAROWITZ ZERIS LEDVA &  
MEYERS L.L.P.  
1500 Market Street  
Suite 4100  
Philadelphia, PA 19102

**United Research Laboratories, Inc. a/k/a  
URL PHARMPRO, LLC d/b/a URL  
PHARMA**

William J. O’Kane, Jr., Esquire  
ARCHER & GRENIER, P.C.  
One Centennial Square  
Haddonfield, NJ 08033

**Mutual Pharmaceutical Company, Inc.**

William J. O’Kane, Jr., Esquire  
ARCHER & GRENIER, P.C.  
One Centennial Square  
Haddonfield, NJ 08033

**Silarx Pharmaceuticals, Inc.**

19 West Street  
Spring Valley, NY 10977

**Sandoz, Inc.**

506 Carnegie Center, Suite 400  
Princeton, NJ 08540

**ANIP Acquisition Company a/k/a ANIP  
Pharmaceuticals a/k/a ANI  
Pharmaceuticals a/k/a A & I  
Pharmaceuticals**

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

**Watson Laboratories, Inc., Individually,  
and d/b/a Rugby Pharmaceuticals, Inc.  
a/k/a Rugby Laboratories, Inc.**

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

**Rugby Pharmaceuticals, Inc. a/k/a Rugby  
Laboratories, Inc.**

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

**Rugby Laboratories, Inc.**

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

**Actavis Elizabeth LLC, Individually and as  
successor in interest to Purepac  
Pharmaceuticals**

Walter "Pete" Swayze, III, Esquire  
SEGAL, MCCAMBRIDGE, SINGER  
&MAHONEY, LTD.  
30 South 17th Street, Suite 1700  
Philadelphia, PA 19103

**Actavis Group hf**

Agent for Service of Process (Central  
Authority):  
Ministry of Justice and Human Rights  
Dalshraun 1  
220 Hafnarfjordur  
Iceland

**APP Pharmaceuticals, LLC, Individually  
and d/b/a Abraxis Pharmaceuticals**

Corporation Service Company  
2704 Commerce Drive, Ste B  
Harrisburg, PA 17110-9380

**BenVenue Laboratories, Inc., Individually  
and d/b/a Bedford Laboratories**

Tia Trout-Perez  
Kirkland & Ellis, LLP  
655 Fifteenth Street, N.W.  
Washington, DC 20005

**Bedford Laboratories**

Tia Trout-Perez  
Kirkland & Ellis, LLP  
655 Fifteenth Street, N.W.  
Washington, DC 20005

**Hospira Inc.**

Agent for Service of Process:  
C T Corporation System  
116 Pine St., Suite 320  
Harrisburg, PA 17101

**Ipca Pharmaceuticals Inc.**

51 Cragwood Road, Suite No.203  
South Plainfield, NJ, 07080

**McKesson Corporation, Individually and  
d/b/a Northstar Rx LLC**

The Prentice Hall Corporation System  
2704 Commerce Dr.  
Harrisburg, PA 17110

**Northstar Rx LLC**  
4971 Southridge Blvd., Suite 101  
Memphis, TN 38141

**Norbrook Inc. USA**  
9733 Loiret Boulevard  
Lenexa, Kansas 66219

**Smith & Nephew Inc., as successor in  
interest to SoloPak Laboratories**

Agent for Service of Process:  
C T Corporation System  
116 Pine St., Suite 320  
Harrisburg, PA 17101

**VistaPharm, Inc.**  
2224 Cahaba Valley Drive, Suite B3  
Birmingham, AL 35242

**Roxane Laboratories, Inc.**  
Tia Trout-Perez  
Kirkland & Ellis, LLP  
655 Fifteenth Street, N.W.  
Washington, DC 20005

**Boehringer Ingelheim Roxane, Inc.,  
Individually and d/b/a/ Roxane  
Laboratories, Inc.**  
1809 Wilson Rd.  
Columbus, OH 43228-9579

**Par Pharmaceutical Inc.**  
300 Tice Boulevard  
Woodcliff Lake, NJ 07677

**Acura Pharmaceuticals, Inc., f/k/a Halsey  
Drug Company**  
Gregory S. Thomas, Esq.  
LeClairRyan  
One Riverfront Plaza  
1037 Raymond Boulevard, Sixteenth Floor  
Newark, New Jersey 07102

**Paco Pharmaceutical Services, Inc., n/k/a  
West Pharmaceutical Services, Inc.  
101 Gordon Drive  
Lionville, PA 19341**

**Schering Corporation**  
2000 Galloping Hill Rd.  
Kenilworth, NJ 07033-1310

**Ranbaxy Pharmaceuticals, Inc.**  
600 College Road East, Suite 2100  
Princeton, NJ 08540 USA

**Ivax Pharmaceuticals, Inc.**  
4400 Biscayne Boulevard  
Miami, FL 33137-3212

**Goldline Laboratories, Inc., Individually  
and d/b/a  
IVAX Pharmaceuticals, Inc.**  
4400 Biscayne Boulevard  
Miami, FL 33137-3212

**Bristol Myers Squibb Co., Individually and  
d/b/a Apothecon, Inc.**  
345 Park Ave  
New York, NY 10154

**Apothecon, Inc.**  
P.O. Box 4500  
Princeton, NJ 08543

**Invamed Inc.**  
2400 Route 130 North  
Dayton, NJ 08810

**King Pharmaceuticals Inc., Individually  
and d/b/a Alparma Inc., f/k/a A.L.  
Pharma Inc. and a/k/a Alparma-Barre  
National**  
501 Fifth Street  
Bristol, TN 37620

**Richmond Pharmaceuticals, Inc.**  
3510 Mayland Ct.  
Richmond, VA 23233

**John Doe Defendants**

*Defendants.*

**PLAINTIFFS' THIRD AMENDED MASTER LONG FORM COMPLAINT**

1. Plaintiffs, by the undersigned counsel, hereby submit this Third Amended Master Long Form Complaint against the above named Defendants (hereinafter named "Brand Name Defendants" and "Generic Defendants") for equitable relief, monetary restitution, and/or compensatory and punitive damages. Plaintiffs make the following allegations based upon their personal knowledge, and upon information and belief, as well as upon their attorneys' investigative efforts, regarding the drug product Reglan and its generic equivalent, metoclopramide.

2. This Third Amended Master Long Form Complaint is submitted pursuant to Case Management Order No. 1 of this Reglan/Metoclopramide Litigation Mass Tort Program, to serve only 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 Third Amended Master Long Form 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 purposes the separate claims of the Plaintiffs herein. Those matters are set forth in the individual actions filed by each of the respective Plaintiffs. This Third Amended Master Long Form Complaint does not constitute a waiver or dismissal of any actions

or claims asserted in those individual actions, nor do any Plaintiffs 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.

**I. The Parties**

3. Plaintiffs are individuals, or the duly authorized representatives of individuals and/or the estates of deceased individuals who, at all times relevant to the allegations in the complaint, resided in the United States of America. Primary Plaintiffs bring these civil actions for equitable relief, monetary restitution, and/or compensatory and punitive damages for injuries and/or wrongful deaths suffered as a direct result of their ingestion of Reglan and/or metoclopramide. In addition, Secondary Plaintiffs assert derivative claims including, but not limited to, loss of consortium and survivorship. Not all claims asserted in this Third Amended Master Long Form Complaint will necessarily be held by, nor asserted by, all Plaintiffs, and not all claims in this Third Amended Master Long Form Complaint are asserted by each Plaintiff against every Defendant.

4. Defendant Wyeth, LLC is a Delaware corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing manufacture, distribution, marketing, promotion, sale, labeling, and design of Reglan detailed below. Pursuant to Case Management Order No. 1, 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.

5. 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 regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of Reglan detailed below. Pursuant to Case Management Order No. 1, 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 Holdings Corporation, Individually and d/b/a ESI Lederle, Inc is a Maine corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant may be served with process at 5 Giralda Farms, Madison, New Jersey 07940.

7. Defendant Pfizer, Inc. is a Delaware corporation with a principal place of business in New York City, New York. Defendant regularly conducts business in Philadelphia County, Pennsylvania. In October 2009, Defendant acquired Defendants Wyeth, LLC and Wyeth Pharmaceuticals, Inc. and therefore acquired Defendants' tort liabilities. 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.

8. Defendant Schwarz Pharma, Inc. is a Delaware corporation with a principal place of business in Georgia. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of Reglan detailed below. Pursuant to Case Management Order No. 1, 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.

9. 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 liable for any and all tort liabilities of Defendant Schwarz Pharma, Inc. In addition, Defendant Schwarz Pharma AG was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of Reglan detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant may be served with process via The Hague Convention by serving Germany's Central Authority at: Die Präsidentin des Oberlandesgerichts Düsseldorf, Cecilienallee 3, 40474 Düsseldorf, Germany.

10. Defendant UCB Pharma GmbH is a foreign corporation with its principal place of business in Germany. Defendant UCB GmbH is the parent company of Defendant Schwarz Pharma AG and therefore liable for any and all tort liabilities of Defendant Schwarz Pharma AG. In addition, Defendant Schwarz GmbH was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant may be served with process at Alfred-Nobel Strasse 10, 40789 Monheim, Germany.

11. Defendant Alaven Pharmaceutical LLC is a Delaware corporation with a principal place of business in Marietta, Georgia. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of Reglan detailed below. Pursuant to Case Management Order No. 1, 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.

12. Defendant Baxter Healthcare Corporation is a Delaware corporation with its principal place of business in Deerfield, Illinois. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of Reglan detailed below. Defendant may be served with process by and through its agent for service: CT Corporation System, 116 Pine St., Suite 320, Harrisburg, PA 17101.

13. Defendant Wockhardt USA is a Delaware corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. 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.

14. Defendant Morton Grove Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business in Illinois. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, 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.

15. Defendants Wyeth, LLC, Wyeth Pharmaceuticals, Inc., Wyeth Holdings Corporation, Individually and d/b/a ESI Lederle, Pfizer, Inc., Schwarz Pharma, Inc., Schwarz

Pharma AG, UCB Pharma GmbH, Alaven Pharmaceutical LLC, Baxter Healthcare Corporation, Wockhardt USA, and Morton Grove Pharmaceuticals, Inc manufacture and/or sell, or in the past have manufactured and sold, a certain prescription drug product known as Reglan. These defendants may be referred to collectively, from time to time, as NAME BRAND DEFENDANTS.

16. Defendant Teva Pharmaceuticals USA, Inc., Individually and d/b/a IVAX Pharmaceuticals, is a Delaware corporation with a principal place of business in Pennsylvania. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant is a subsidiary or division of Teva Pharmaceutical Industries, Ltd., a corporation organized, existing and doing business under and by virtue of the laws of Israel, headquartered in Petach Tikvah, Israel. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, 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.

17. Defendant Teva Pharmaceutical Industries, Ltd. is a foreign corporation with its principal place of business in Israel. Defendant Teva Pharmaceutical Industries, Ltd. is the parent company of Defendant Teva Pharmaceuticals USA, Inc. and therefore liable for any and all tort liabilities of Defendant Teva Pharmaceuticals USA, Inc. In addition, Defendant Teva Pharmaceutical Industries, Ltd. was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant may be served

with process via The Hague Convention by serving Israel's Central Authority at: The Director of Courts, Directorate of Courts, 22 Kanfei Nesharin St., Jerusalem 95464, P.O.B. 34142, Israel

18. Defendant PLIVA, Inc., Individually and f/k/a Sidmak Laboratories, Inc., (hereinafter referred to as Pliva, 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, Inc. as a result of Barr's acquisition of Pliva in 2006. Because Barr Pharmaceuticals, Inc. 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 Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide. Pursuant to Case Management Order No. 1, 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.

19. 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. and therefore liable for any and all tort liabilities of Defendant PLIVA, Inc. In addition, Defendant PLIVA d.d. was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. 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.

20. 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, 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 Barr Pharmaceuticals, Inc. was involved in the research, testing, manufacture, distribution, marketing, promotion sale, labeling, and design of metoclopramide detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Pursuant to Case Management Order No. 1, 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.

21. 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 Barr Laboratories, Inc was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Pursuant to Case Management Order No. 1, 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.

22. Defendant Duramed Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Ohio. Defendant Barr Pharmaceuticals, Inc. is the parent company for Defendant Duramed Pharmaceuticals, Inc. and was acquired by Defendant Teva

Pharmaceuticals USA, Inc. on December 23, 2008. Defendant Duramed Pharmaceuticals, Inc. was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. 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.

23. Defendant Qualitest Pharmaceuticals, Inc., Individually and d/b/a Vintage Pharmaceuticals, Inc., is an Alabama corporation with a principal place of business in Alabama. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, Defendant may be served with process by registered mail, return receipt requested, upon: James M. Campbell, Esquire, Campbell, Campbell, Edwards & Conroy, P.C., One Constitution Plaza, Boston, Massachusetts 02129 and Kristen E. Dennison, Esquire, Campbell, Campbell, Edwards & Conroy, P.C., 690 Lee Road, Suite 300, Wayne, PA 19087.

24. Defendant Generics Bidco I., LLC, Individually and d/b/a Qualitest Pharmaceuticals is a Delaware corporation with a principal place of business in Alabama. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling and design of metoclopramide detailed below. Pursuant to Case Management Order No.1, Defendant may be served with process by registered mail, return receipt requested, upon: James M. Campbell, Esquire, Campbell, Campbell, Edwards & Conroy, P.C., One Constitution Plaza,

Boston, Massachusetts 02129 and Kristen E. Dennison, Esquire, Campbell, Campbell, Edwards & Conroy, P.C., 690 Lee Road, Suite 300, Wayne, PA 19087.

25. Defendant Vintage Pharmaceuticals, Inc. is an Alabama corporation with a principal place of business in Alabama. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by registered mail, return receipt requested, upon: James M. Campbell, Esquire, Campbell, Campbell, Edwards & Conroy, P.C., One Constitution Plaza, Boston, Massachusetts 02129 and Kristen E. Dennison, Esquire, Campbell, Campbell, Edwards & Conroy, P.C., 690 Lee Road, Suite 300, Wayne, PA 19087.

26. Defendant The Harvard Drug Group LLC d/b/a Major Pharmaceuticals, Inc., Individually is a Michigan corporation with a principal place of business in Michigan. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, 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.

27. Defendant Pharmaceutical Associates, Inc. is a South Carolina corporation with a principal place of business in South Carolina. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant is a wholly owned subsidiary of Defendant Beach Products, Inc. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to

Case Management Order No. 1, 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., 1500 Market Street, Suite 4100, Philadelphia, PA 19102.

28. Defendant Beach Products, Inc. is a Florida corporation with a principal place of business in Florida. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, 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., 1500 Market Street, Suite 4100, Philadelphia, PA 19102.

29. Defendant United Research Laboratories, Inc. a/k/a URL PHARMPRO, LLC and d/b/a URL PHARMA is a Pennsylvania corporation with a principal place of business in Philadelphia, Pennsylvania. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, Defendant may be served with process by registered mail, return receipt requested, upon: William J. O’Kane, Jr., Esquire, Archer & Grenier, P.C., One Centennial Square, Haddonfield, NJ 08033.

30. Defendant Mutual Pharmaceutical Company, Inc. is a Pennsylvania corporation with a principal place of business in Philadelphia, Pennsylvania. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, Defendant may be served with

process by registered mail, return receipt requested, upon: William J. O’Kane, Jr., Esquire, Archer & Grenier, P.C., One Centennial Square, Haddonfield, NJ 08033.

31. Defendant Silarx Pharmaceuticals, Inc. is a New York corporation with a principal place of business in New York. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office at: 19 West Street, Spring Valley, NY 10977

32. Defendant Sandoz, Inc. is a Colorado corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office at: 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

33. 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 Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, 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.

34. Defendant Watson Laboratories, Inc., Individually, and d/b/a Rugby Pharmaceuticals, Inc. a/k/a Rugby Laboratories, Inc. is a Nevada corporation with a principal place of business in California. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, Defendant may be served with process by registered mail, return receipt requested, upon: Gregory S. Thomas Esq. and Joseph Lagroterria, LeClairRyan, One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, New Jersey 07102.

35. Defendant Rugby Pharmaceuticals, Inc. a/k/a Rugby Laboratories, Inc. is a New York corporation with a principal place of business in California. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, Defendant may be served with process by registered mail, return receipt requested, upon: Gregory S. Thomas Esq. and Joseph Lagroterria, LeClairRyan, One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, New Jersey 07102.

36. Defendant Rugby Laboratories, Inc. is a New York corporation with a principal place of business in California. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. 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.

37. Defendant Actavis Elizabeth LLC, Individually, and as successor in interest to Purepac Pharmaceuticals is a New Jersey corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Pursuant to Case Management Order No. 1, Defendant may be served with process by registered mail, return receipt requested, upon: Walter “Pete” Swayze, III, Esquire, SEGAL, MCCAMBRIDGE, SINGER & MAHONEY, LTD., 30 South 17th Street, Suite 1700, Philadelphia, PA 19103.

38. Defendant Actavis Group hf is a foreign corporation with its principal place of business in Iceland. Defendant Actavis Group is the parent company of Defendant Actavis Elizabeth LLC, Individually, and as successor in interest to Purepac Pharmaceuticals and therefore liable for any and all tort liabilities of Defendant Actavis Elizabeth LLC, Individually, and as a successor in interest to Purepac Pharmaceuticals. In addition, Defendant Actavis Group hf was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant may be served with process via The Hague Convention by serving Iceland’s Central Authority at: Ministry of Justice and Human Rights, Dalshraun 1, 220 Hafnarfjörður, Iceland.

39. 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 Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. 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.

40. Defendant BenVenue Laboratories, Inc., Individually is a Delaware corporation with a principal place of business in Ohio. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 300 Northfield Road, Bedford, OH 44146.

41. Defendant Hospira, Inc. is a Delaware corporation with a principal place of business in Illinois. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. 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.

42. Defendant Ipca Pharmaceuticals Inc. is a foreign corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 51 Cragwood Road, Suite No. 203, South Plainfield, NJ, 07080.

43. Defendant McKesson Corporation, Individually and d/b/a Northstar Rx LLC 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 Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. 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.

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

45. Defendant Norbrook Inc. USA is a domestic corporation with a principal place of business in Kansas. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 9733 Loiret Boulevard, Lenexa, Kansas 66219.

46. Defendant Smith & Nephew, Inc., believed to be a successor in interest to SoloPak Laboratories is a Delaware corporation with a principal place of business in Tennessee. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its registered agent for service: CT Corporation, 1209 North Orange Street, Wilmington, DE 19801.

47. Defendant VistaPharm, Inc. is an Alabama corporation with a principal place of business in Alabama. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 2224 Cahaba Valley Drive, Suite B3, Birmingham, AL 35242.

48. Defendant Roxane Laboratories, Inc., n/k/a Boehringer Ingelheim Roxane, Inc is a Delaware corporation with a principal place of business in Ohio. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 1809 WILSON RD., COLUMBUS, OH 43228-9579.

49. Defendant Par Pharmaceutical Inc. is a Delaware corporation with a principal place of business in Ohio. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

50. Defendant 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 Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by registered mail, return receipt

requested, upon George S. Thomas Esquire, LECLAIRRYAN One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, NJ 07102.

51. Defendant Paco Pharmaceutical Services, Inc., n/k/a West Pharmaceutical Services, Inc. is a Delaware corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 101 Gordon Drive, Lionville, PA 19341.

52. Defendant Schering Corporation is a New Jersey corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 2000 GALLOPING HILL RD., KENILWORTH, NJ 07033-1310.

53. Defendant Ranbaxy Pharmaceuticals, Inc. is a Florida corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 600 College Rd. E Ste. 2100, Princeton, NJ 08540.

54. Defendant IVAX Pharmaceuticals, Inc. is a Florida corporation with a principal place of business in Florida. Defendant regularly conducts business in Philadelphia Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale,

labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 4400 Biscayne Blvd., Miami, FL 33137.

55. Defendant Goldline Laboratories, Inc., Individually and d/b/a IVAX Pharmaceuticals, Inc., is a Florida Corporation with a principal place of business in Florida. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its registered agent: Corporate Creations Network Inc., 11380 Prosperity Farms Road #221E, Palm Beach Gardens, FL 33410 or through its principal office: 4400 Biscayne Blvd., Attn: Legal Affairs, Miami, FL 33137.

56. Bristol Myers 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 Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its registered agent Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, DE 19801 or through its principal office: 345 Park Ave., New York, NY 10154-0004

57. Defendant Apothecon Inc. is a domestic corporation, incorporated in the State of Delaware with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its registered agent

Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, DE 19801 or its principal office: P.O. Box 4500, Princeton, NJ 08543.

58. Invamed Inc. is a New Jersey Corporation with a principal place of business in New Jersey. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 2400 Route 130 North, Dayton, NJ 08810.

59. King Pharmaceuticals Inc., Individually and d/b/a Alparma Inc., f/k/a A.L. Pharma Inc. and a/k/a Alparma-Barre National is a Tennessee Corporation with a principal place of business in Tennessee. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through registered agent: William L. Phillips, III, 501 Fifth Street, Bristol, TN 37620.

60. Richmond Pharmaceuticals Inc. is a Virginia Corporation with a principal place of business in Virginia. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the research, testing, manufacture, distribution, marketing, promotion, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 3510 Maryland Court, Richmond, VA 23233-1421

61. Defendant John Doe Defendants are defendants involved in the research, testing, manufacture, distribution, marketing, promotion, sale, and labeling of Reglan and/or

metoclopramide not yet known by Plaintiffs. Pursuant to Pa. R. C. P. 2177, Plaintiffs reserve the right to amend this Complaint at a future date so that it shall be brought against the corporate name.

62. Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., PLIVA, Inc., PLIVA d.d., Barr Pharmaceuticals LLC, f/k/a Barr Pharmaceuticals, Inc., Barr Laboratories, Inc., Duramed Pharmaceuticals, Inc., Qualitest Pharmaceuticals, Inc., Generics Bidco I, LLC, Individually and d/b/a Qualitest Pharmaceuticals, Vintage Pharmaceuticals, LLC, The Harvard Drug Group LLC, Individually and d/b/a Major Pharmaceuticals, Inc., Pharmaceutical Associates, Inc., Beach Products, Inc., United Research Laboratories, Inc. d/b/a URL PHARMPRO, LLC, 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 Pharmaceuticals, Inc., a/k/a Rugby Laboratories, Inc., Rugby Laboratories, Inc., Actavis Elizabeth LLC, Individually and as successor-in-interest to Purepac Pharmaceuticals, Actavis Group hf, APP Pharmaceuticals, LLC, Individually and d/b/a Abraxis Pharmaceuticals, BenVenue Laboratories, Inc., Individually and d/b/a Bedford Laboratories , LLC, Bedford Laboratories, Hospira, Inc., Ipca Pharmaceuticals Inc., McKesson Corporation Individually and d/b/a Northstar Rx., LLC, , Northstar Rx, LLC, Norbrook Inc., USA, Smith & Nephew., as successor in-interest to SoloPak Laboratories, VistaPharm, Inc., Roxane Laboratories, Inc., Boehringer Ingelheim Roxane, Inc., Individually and d/b/a Roxane Laboratories, Inc., Par Pharmaceutical Inc., Acura Pharmaceuticals, Inc. f/k/a Halsey Drug Company, Paco Pharmaceutical Services, Inc. n/k/a West Pharmaceutical Services, Inc., Schering Corporation, Ranbaxy Pharmaceuticals, Inc. , Ivax Pharmaceuticals, Inc., Goldline Laboratories, Inc.,

Individually and d/b/a IVAX Pharmaceuticals, Inc. , Bristol Myers Squibb Co., Individually and d/b/a Apothecon, Inc., Apothecon, Inc., Invamed Inc., King Pharmaceuticals Inc., Individually and d/b/a Alparma Inc., f/k/a A.L. Pharma Inc. and a/k/a Alparma-Barre National, and Richmond Pharmaceuticals, Inc. manufacture and/or sell, or in the past have manufactured and sold, certain prescription drug products—known variously as metoclopramide, generic metoclopramide, or metoclopramide HCl,—designed and calculated to be generic versions, or copies in all medically material respects, of the prescription drug known as Reglan. These defendants may be referred to collectively, from time to time, as the GENERIC DEFENDANTS.

63. All of the defendants identified herein may be referred to collectively, from time to time, as the DRUG COMPANY DEFENDANTS.

64. Pursuant to Case Management Order No. 1 in this litigation, service of process of any abbreviated complaints (“Short Form Complaints”) upon Defendants shall be effective when sent by registered U.S. mail, return receipt requested, to the agents of service listed. Should an agent of service not be provided, Plaintiffs must serve Defendant through service of process pursuant to the Pennsylvania Rules of Civil Procedure and/or The Hague Convention. In addition, a copy of each notice transmitted to the Defendant in the foregoing manner shall be provided to Lead and Liaison Counsel for Defendants. Service will be effective ten (10) days after mailing.

## **II. Jurisdiction**

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

66. At all times relevant hereto, the DRUG COMPANY DEFENDANTS were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting,

packaging and/or advertising the pharmaceutical drugs known as Reglan, metoclopramide HCl and/or metoclopramide in the State of Pennsylvania and the County of Philadelphia.

67. At all times relevant hereto, the DRUG COMPANY DEFENDANTS had offices in Pennsylvania and/or regularly solicited and transacted business<sup>3</sup> in the State of Pennsylvania and the County of Philadelphia. The DRUG COMPANY DEFENDANTS carried on a continuous and systematic part of their business in Pennsylvania and Philadelphia County. In addition, the DRUG COMPANY DEFENDANTS reasonably expected that their respective products, Reglan or metoclopramide, would be used or consumed in Pennsylvania and Philadelphia County.

68. Defendant Teva Pharmaceuticals USA, Inc., and therefore now Defendant Barr Pharmaceuticals, Inc, Barr Laboratories, Inc., Duramed Pharmaceuticals Inc., and PLIVA USA, Inc., is a resident of Pennsylvania because its principal place of business is in Pennsylvania.

69. Defendant United Research Laboratories, Inc., a/k/a URL PHARMPRO, LLC d/b/a URL Pharma is a resident of Pennsylvania because its principal place of business is in Philadelphia, Pennsylvania.

70. Defendant Mutual Pharmaceutical Company, Inc. is a resident of Pennsylvania because its principal place of business is in Philadelphia, Pennsylvania.

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<sup>3</sup> Pursuant to 42 Pa. Const. Stat. § 5322, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS have transacted business in Pennsylvania and Philadelphia County by directly, or indirectly through an agent, doing a series of similar acts for the purpose of thereby realizing pecuniary benefit, doing a single act for the purpose of thereby realizing pecuniary benefit, shipping merchandise directly or indirectly into Pennsylvania and Philadelphia County, engaging in business, owning, using or possessing real property, contracting to supply services or things, causing harm or tortuous injury by an act or omission outside Pennsylvania and Philadelphia County, accepting election or appointment or exercise of powers as a director or officer of a corporation, making application to any government unit for any certificate, license, permit, registration or similar instrument or authorization or exercising any such instrument or authorization, committing any violation within the jurisdiction of Pennsylvania of any statute, home rule charter, local ordinance or resolution, or rule or regulation promulgated thereunder by any government unit or of any order of court or other government unit.

71. Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc. are residents of Pennsylvania because their principal places of business are in Pennsylvania.

72. This is an action for damages, which exceeds fifty thousand dollars (\$50,000).

73. Plaintiffs have timely filed this lawsuit within two years of discovering their cause of action as defined and required by Pennsylvania 42 Pa. Cons. Stat. § 5524(2).

## II. Venue

74. Plaintiffs incorporate by reference all of the above paragraphs

75. Philadelphia County is the proper forum and venue for these causes of action. Philadelphia County is the epicenter of Reglan/Metoclopramide litigation. The defendants with the largest roles in this litigation, Teva Pharmaceuticals USA, Inc., and therefore now Defendants Barr Pharmaceuticals, Inc, Barr Laboratories, Inc., Duramed Pharmaceuticals Inc., and PLIVA USA, Inc., Wyeth LLC, and Wyeth Pharmaceuticals, Inc., are located just outside of Philadelphia. In addition, Defendant Mutual Pharmaceuticals Company, Inc. is located within Philadelphia County. The other defendants, defendants' counsel, corporate witnesses, and documents are located in or around Philadelphia County. In fact, Defendants agreed that Philadelphia County is a proper forum when they stated that a Philadelphia courtroom would be “not only convenient for all parties, but is a natural center of gravity of the pending litigation”<sup>4</sup> and “the most convenient of all forums as the overwhelming majority of defendants have their principal place of business in Pennsylvania.”<sup>5</sup>

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<sup>4</sup> Defendant Teva Pharmaceuticals USA, Inc.’s Memorandum in Response to Plaintiffs’ Motion for Transfer of Actions to the District of Nevada Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings, ¶ 1.

<sup>5</sup> Wyeth’s Response to Plaintiffs’ Motion for Transfer of Actions to the District of Nevada Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings, Sec. IV, ¶ B.

76. In addition, Philadelphia County Court of Common Pleas is the only county with the ability to handle, litigate, and resolve the thousands of filed cases. The Philadelphia Mass Tort Program is one of the premier coordinated dockets in the nation as evidenced by its resources to handle numerous pharmaceutical litigation dockets in an organized and efficient fashion. No other county in Pennsylvania is better suited to handle such claims.

77. Finally, pursuant to Pa. R. C. P. 1006(c), in actions alleging joint and several liability against two or more defendants, venue is proper if it is proper as to any of the defendants. In this case, Plaintiffs allege joint and several liability on more than two defendants. Philadelphia County is the proper venue for a number of these defendants. Therefore, venue is proper on all defendants.

#### **IV. Allegations of Fact**

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

##### **A. Reglan/Metoclopramide Background**

79. Reglan is a prescription drug classified as a pro-motility agent and dopamine antagonist. Generic metoclopramide and metoclopramide are designations that refer to bioequivalent generic versions or copies of the drug otherwise known by its brand name Reglan. Metoclopramide is a designation that may refer to any or all versions of the drug, name brand or generic, or to the drug substance that is the sole active ingredient in the drug. The drug products referred to as Reglan and generic metoclopramide are manufactured and sold as tablets (5mg/10mg), as an oral solution, and in an injectable form.

80. Reglan/metoclopramide affects the movement center of a user's brain. The effect typically causes involuntary, repetitive movements.

81. These involuntary movements are known as extrapyramidal symptoms (EPS), that include, but are not limited to, tardive dyskinesia, tardive dystonia, tardive akathisia, Parkinsonism, Neuroleptic Malignant Disorder, and Reglan-induced tremors. Reglan/Metoclopramide has also been associated with central nervous system disorders, depression with suicidal ideation, visual disturbances, and memory loss.

82. Tardive dyskinesia, tardive akathisia, and tardive dystonia are serious neurological movement disorders that result in the involuntary and uncontrollable movements of the head, neck, face, arms, and/or trunk, as well as, involuntary facial grimacing and tongue movements, including tongue thrusting, tongue chewing, extreme anxiety and restlessness and/or other involuntary movements.

83. There is no cure for any of these EPS disorders caused by Reglan/metoclopramide.

84. Reglan/metoclopramide can also cause an aggravation in preexisting conditions.

85. The link between neuroleptic drugs, such as Reglan/metoclopramide, and involuntary movements has been known from as far back as 1973.<sup>6</sup> Between 1973 and present day, dozens upon dozens of studies have specifically evidenced the direct connection between the long term, pediatric, and/or short term use of Reglan and/or metoclopramide and involuntary movement disorders.

86. The “indications” (recommended uses) listed in the product labeling for Reglan/metoclopramide include adult short-term therapy of symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

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<sup>6</sup> Crane GE (September 1973). "Is tardive dyskinesia a drug effect?". *Am J Psychiatry* **130** (9): 1043–4.

87. The “indications” (recommended uses) listed in the product labeling for Reglan/metoclopramide specified therapy for up to twelve (12) weeks in adults, for gastroesophageal reflux (heartburn), and specified no durational limit in therapy for gastric stasis or gastroparesis (bloating).

88. At no point in time has Metoclopramide been shown to be either efficacious or safe when used for long term treatment.

89. Patients who used Reglan/metoclopramide for longer periods of time were at an unreasonably dangerous increased risk of developing one or more severe and permanent neurological movement disorders, significantly and substantially greater than disclosed or suggested in the product labeling for the drug or in any other materials disseminated by the defendants to either the medical community or the public.

#### **B. Reglan/Metoclopramide Regulatory Background**

90. In 1979, A.H. Robins Company, Inc. gained approval for Reglan injection through the United States Food & Drug Administration.

91. A.H. Robins Company, Inc. gained approval for Reglan tablets through the United States Food & Drug Administration (“FDA”) on December 30, 1980.

92. In 1989, A.H. Robins Company, Inc. merged with and into a corporation wholly-owned by Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc. (then known as the American Home Products Corporation), whereupon the name of the wholly-owned subsidiary corporation was changed to A.H. Robins Company, Inc., under which name it continued to carry on its business activities, including the manufacture, promotion, and sale of Reglan and other drugs, until August 1998, when it was absorbed into its parent corporation, where it survived only as an unincorporated division, also known as the A.H. Robins Company.

93. Defendant Pfizer, Inc. has since acquired Defendants Wyeth, LLC and Wyeth Pharmaceuticals, Inc. and thereby has become the successor-in-interest responsible for all tort liabilities of Defendants Wyeth, LLC and Wyeth Pharmaceuticals, Inc., including the surviving liabilities incurred in the course of business carried on as the A. H. Robins Company, Inc. or the A. H. Robins Company.

94. On or around December 27, 2001, Defendant Schwarz Pharma, Inc. purchased from Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc. the formula for Reglan tablets and all property rights associated with that product, including federal agency approval of an application (a “new drug application” or “NDA”) for the drug under the provisions of Section 505 (21 USC §355) of the federal Food, Drug, and Cosmetic Act (FDCA), which is codified as 21 USC §301 et seq.

95. Subsequently, Defendant Alaven Pharmaceuticals, LLC purchased this formula and these rights from Defendant Schwarz Pharma, Inc.

96. Reglan has been used and referred to, at all relevant times, as the so-called “reference listed drug” (or “RLD”) in abbreviated NDAs (ANDAs) for generic versions of the drug, submitted under the provisions of subsection (j) of FDCA §505, 21 USC §355, and added to that section by Section 101 of the so-called Hatch-Waxman Amendments (P.L. 98-417, 98 Stat. 1585) enacted on September 24, 1984.

97. One who submits an NDA per the provisions and procedures established under FDCA §505, 21 USC §355, is required to fully, truthfully and accurately disclose to the federal Food and Drug Administration (FDA), with its application, and periodically and at other times thereafter, data and information regarding the drug’s chemistry, pharmacology, and other matters, including its proposed labeling. The FDA, as a condition for approval of the NDA, must

be satisfied that the proposed labeling includes data and information about risks and side effects, test results for the drug, results of animal studies, results of clinical studies, and the drug's bioavailability, and other matters, adequate to enable physicians or other like foreseeable prescribers to use the drug safely.

98. Federal law requires one who owns or holds an FDA-approved NDA to ensure at all times that the drug's labeling is and remains accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to periodically and at other times report to the FDA data related to the safety of the drug and/or to the accuracy of the labeling.

99. Reglan and generic metoclopramide have not been approved by the FDA for long-term use or pediatric use.

100. The BRAND NAME DEFENDANTS failed to fully, truthfully and accurately disclose to the FDA (and failed to disseminate to the medical community or to the public) data and information bearing substantially and substantively on the safe use of Reglan and metoclopramide.

### **C. Misrepresentations and Failure to Communicate Adequate Warnings**

101. Through dissemination of inaccurate and misleading information about Reglan and metoclopramide in materials including the product labeling for Reglan, as distributed by sales representatives (with product samples) and as published in the *Physicians' Desk Reference*, defendant Wyeth knowingly, intentionally, and negligently, directly or indirectly, misled physicians, including Plaintiffs' physicians, and the medical community in general, about the risks of tardive dyskinesia and other EPS in long term use and pediatric use of the drug. After 2002, no product labeling information or other information about the drug was published to physicians or the medical community, in the *Physicians' Desk Reference* or otherwise, by any of

the drug's manufacturers, in its name brand or generic versions. Warning information added to the product labeling in 2004, as initiated by Defendant Schwarz Pharma, was never been published generally, never added to the PDR, never distributed to physicians or the medical community, and was therefore not known generally by physicians or their patients. Schwarz Pharma knew that the label was inaccurate and misleading, yet never warned physicians or patients of the inaccuracies and never attempted to advise the medical community of the 2004 changes to the label.)

102. At all times material hereto, the DRUG COMPANY DEFENDANTS knew or should have known that most physicians were not aware of or did not fully appreciate the seriousness of the risks associated with use of Reglan and/or metoclopramide, and that it was common for physicians to prescribe the drug for inappropriate long-term and pediatric use, as well as short term use for certain adults. Published studies confirmed these various forms of inappropriate use by evaluating prescription data. Therefore, the defendants knew or should have known that the *Physician's Desk Reference* monograph for Reglan and the package inserts for Reglan and generic versions of the drug were deficient, inaccurate, false and misleading in communicating to the medical community in general, to physicians, or to the public, information about the risks associated with the drug.

103. At all relevant times, the DRUG COMPANY DEFENDANTS had access to this information and knew or should have known, through their participation in and/or their ability to review published studies and data from clinical studies that were not released publicly, through their review of domestic and international medical literature concerning metoclopramide, and through discovery in ongoing litigation, that severe side effects would result from the long term, pediatric, and even short term use of Reglan or generic metoclopramide, as they were being

prescribed by physicians, most of whom did not fully understand the risks associated with the drug.

104. The defendants failed to adequately inform physicians and misled physicians about the risks associated with their metoclopramide drug products, despite the fact that they knew that the medical community in general, physicians, pharmacists, Plaintiffs, and others similarly situated relied on them to disclose and communicate to doctors what they knew and what experts in the use and effects of the drug would know from a prudent review of the information that they possessed or were reasonably able to obtain.

105. Because of the misleading and inaccurate information that defendants disseminated to physicians, and because of the failure of the DRUG COMPANY DEFENDANTS generally to adequately and effectively inform physicians, the medical community or the FDA about the true risks associated with the use of Reglan and generic metoclopramide, Plaintiffs' physicians did not know or appreciate fully the risks of side effects associated with the use, particularly with the long term use, of the drug.

#### **D. Knowledge - Actual and Constructive**

106. The DRUG COMPANY DEFENDANTS knew or, through the exercise of reasonable care, should have known that the labeling for Reglan and generic metoclopramide substantially understated the frequency of acute and long term side effects of the drug. They failed to use reasonable care to ascertain or communicate to physicians or to the public information that would constitute adequate and effective warnings to physicians or to the public about the true risks of long term, pediatric, and/or short term use of the drug.

107. Defendants Wyeth (including the A. H. Robins Company, Inc., both before and after December 1989), Schwarz and Alaven possessed actual knowledge, from on or about 1979

and after, through their own studies and unpublished studies by independent investigators, that the frequency of side effects reported in the label for Reglan understated the risks of using the drug. These defendants were also aware that doctors frequently and inappropriately over-prescribed Reglan or metoclopramide for long term, pediatric, and/or short term use that was not safe as prescribed through information obtained for the purpose of marketing and promotion.

108. DRUG COMPANY DEFENDANTS had knowledge, either through their own studies, or through publicly available published literature that their metoclopramide labels understated the frequency at which side effects occurred, and that patients were commonly being prescribed metoclopramide for longer than 12 weeks, for pediatric use and/or in situations where the metoclopramide use was not safe for patients.<sup>7</sup> Defendants had actual knowledge, through their own studies and/or studies by independent investigators, that nearly one-third of all patients who used the drug, whether in its name brand or generic versions, received it on doctor's prescriptions for 12 months or longer, rather than 12 weeks or less.<sup>8</sup> Defendants also had actual knowledge, through research by independent investigators, that the frequency of tardive dyskinesia and other extrapyramidal side effects of Reglan and generic metoclopramide in patients who receive the drug for long term use is approximately 100 times greater than disclosed in the package inserts for Reglan and generic metoclopramide and in the *Physician's Desk Reference* monograph for Reglan brand metoclopramide.<sup>9</sup> Defendants also knew, or through the

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<sup>7</sup> See Jankovic, Joseph. "Metoclopramide-Induced Movement Disorders: A Review of the Literature"; *Archives of Internal Medicine*, 1989.; Stewart, Ronald. "An Analysis of Inappropriate Long-Term Use in the Elderly"; *Annals of Pharmacology*, 1992.; Yassa & Jeste, in 1992,

<sup>8</sup> Kaplan S, Staffa JA, Dal Pan GJ. Duration of therapy with metoclopramide: a prescription claims data study. *Pharmacoepi Drug Saf* 2007; 16: 878-881.

<sup>9</sup> Linda Ganzini, MD; Daniel E. Casey, MD; William F. Hoffman, PhD, MD; Anthony L. McCall, MD, PhD, The Prevalence of Metoclopramide-Induced Tardive Dyskinesia and Acute Extrapyramidal Movement Disorders, *Arch Intern Med*. 1993;153(12):1469-1475; Sewell DD, Kodosi A, Caligiuri M, Jeste DV: Metoclopramide and Tardive Dyskinesia. *Biological Psychiatry* 36:630-632, 1994.

exercise of reasonable care should have known, that many patients who use Reglan or generic metoclopramide products are not able to effectively metabolize metoclopramide and that as a foreseeable consequence of their inability to effectively metabolize it, those patients have a greater risk of developing serious and permanent injuries.

109. The DRUG COMPANY DEFENDANTS were aware that their individual and collective failure to communicate to the medical community and physicians information known to them about the risks of long term and other metoclopramide therapy would be likely to result in serious injury to patients who received the drug in accordance with prescriptions issued by physicians who were unaware of this information. By failing to communicate this information to the medical community or the FDA, the DRUG COMPANY DEFENDANTS acted in willful and wanton disregard of the rights of persons in the Plaintiffs' class, and this conduct caused serious injury to the Plaintiffs.

110. As a manufacturer of prescription drug products, specifically Reglan and/or generic metoclopramide, each of the DRUG COMPANY DEFENDANTS has a duty to adequately communicate warnings to physicians and the medical community (or to patients who could be expected to take the drug) and to exercise due care to conduct safety surveillance for the drug and otherwise ensure that the warnings they are required to disseminate about the drug are accurate and adequate, and that these warnings are effectively communicated to physicians, pharmacists, and patients using the drug.

111. Each of the DRUG COMPANY DEFENDANTS breached its duty to ensure that adequate warnings were provided to the medical community, Plaintiffs' physicians, Plaintiffs, and/or other foreseeable metoclopramide users similarly situated, in that they failed to:

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- a. ensure Reglan, metoclopramide and metoclopramide HCl warnings to the medical community, physicians, and Plaintiffs' physician were accurate and adequate, despite having extensive knowledge of the risks associated with the drug;
- b. ensure that Reglan and metoclopramide warnings were effectively communicated to the medical community, physicians and Plaintiffs, despite having extensive knowledge of the inappropriate long term use of the drug;
- c. conduct post market safety surveillance and report that information to the FDA, the medical community, Plaintiffs' physicians, Plaintiffs and other foreseeable users;
- d. review all adverse drug event(ADE)<sup>10</sup> information, and to report information bearing significantly upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by metoclopramide to the FDA, medical community, Plaintiffs' physician, Plaintiffs and other like foreseeable users;
- e. periodically review all medical literature regarding metoclopramide and report to the FDA, the medical community, or other interested individuals significant data concerning the efficacy or safety of Reglan, metoclopramide and metoclopramide HCl;
- f. independently monitor their sales of Reglan and other metoclopramide products, and the medical literature, which would have alerted them to the fact that metoclopramide was widely over prescribed, owing to the inadequate warnings provided to doctors;
- g. Engage in responsible testing, research, and pharmacovigilance practices regarding their Reglan and metoclopramide products, including a failure to perform studies which would accurately determine the risks attendant to both short and long-term metoclopramide use and a failure to engage in marketing practices designed to minimize the risks associated with metoclopramide.

#### **E. Generic Metoclopramide - Regulatory Background and Failure to Communicate Adequate Warnings**

112. In or about 1985, the patent protection for Reglan expired and the first Abbreviated New Drug Application ("ANDA") was filed for approval of a generic version of the drug.

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<sup>3</sup> See 21 C.F.R. § 317.80(b).

113. Since 1985, GENERIC DEFENDANTS have manufactured, packaged, marketed, sold, distributed, and labeled generic versions of Reglan known as generic metoclopramide.

114. Per the provisions and procedures established under Subsections (a) and (j) of FDCA §505, as amended by the Hatch-Waxman Amendments, an ANDA for a generic version of metoclopramide is and has been required to include proposed labeling for the drug that is the same in all material respects to the labeling approved for the so-called Reference Listed Drug (RLD), which was Reglan.

115. GENERIC DEFENDANTS submitted ANDAs for generic versions of the drug that proposed labeling materially the same as the FDA-approved product labeling for Reglan.

116. As holders of ANDAs for generic versions of the drug, GENERIC DEFENDANTS, are and have been required by federal law to ensure continuously that the labeling for their metoclopramide products contained accurate information regarding the drug's intended uses, including common uses other than those described in the drug's "indications"; to conduct post market safety surveillance; to review all adverse drug event information (ADE), to make timely revisions to the labeling of the labels for their metoclopramide products after revisions were made to the RLD; and to ensure that important information regarding the safety of their drug products was communicated to the medical community and consumers. GENERIC DEFENDANTS were required by federal law to report to the FDA significant information discovered in the course of the fulfillment of its obligations as holders of ANDAs for generic versions of a drug, as outlined above, bearing on the risk and/or frequency of side effects caused by metoclopramide.

117. GENERIC DEFENDANTS were also required to ensure that the existing labels were effectively communicated to physicians and patients. An adequate warning requires both

proper language describing the nature and rate of the risk, the nature of the harm that might be encountered and the ways to avoid that harm. In order to be an adequate warning, the drug prescriber and user must be made aware of those warnings – requiring effective communication of the warnings. Printing a label, yet never distributing the label to the physician and patient, is not sufficient to warn the user of the danger. GENERIC DEFENDANTS had many different ways to ensure that the actual warning language was effectively communicated to physicians and patients – both through proper delivery of the existing RLD label, along with other FDA approved means of communication that did not require language different from the RLD label. GENERIC DEFENDANTS failed to deliver the label, or to otherwise effectively communicate the warnings in the label, to physicians and patients.

118. The GENERIC DEFENDANTS breached their duty to effectively communicate warnings to the medical community generally, Plaintiffs’ physicians, Plaintiffs, and/or other foreseeable users of their metoclopramide products similarly situated, in that they failed to:

- a. ensure that warnings they disseminated or relied on to be disseminated to the medical community, Plaintiff’s physician, or to the Plaintiff and other foreseeable users similarly situated, were actually and effectively communicated to physicians and patients.
- b. Evaluate and understand the uses of their product, to identify that significant numbers of physicians and patients were using the metoclopramide in a fashion contrary to warnings in the label, and being harmed by such use, thus confirming that the warnings were not effectively being communicated to the physicians and patients.
- c. Failure to keep abreast of knowledge regarding the safety of their drug products, and to properly research, test and market their metoclopramide products, review all adverse drug event information (ADE) related to the use of Reglan or generic metoclopramide and report to the FDA, physicians (and/or to the public) significant data regarding efficacy or safety of the drug, including the nature and frequency of side effects and/or the existence of additional warnings..
- d. periodically review all medical literature pertaining to metoclopramide use and effects and report to the FDA, physicians (and/or to the public) significant data concerning neurological side effects.

- e. independently monitor the sales of Reglan and metoclopramide products and the medical literature concerning metoclopramide, which would have alerted them to the fact that the drug was widely over prescribed as a result of inadequate warnings in the package inserts for metoclopramide products and PDR monographs for Reglan.
- f. Engage in responsible testing, research, and pharmacovigilance practices regarding their Reglan and metoclopramide products, including a failure to perform studies which would accurately determine the risks attendant to both short and long-term metoclopramide use and a failure to engage in marketing practices designed to minimize the risks associated with metoclopramide.

## **F. FDA Black Box Warning**

119. Despite having extensive knowledge of the extreme risks associated with the drug as well as the absolute duty to properly and adequately warn foreseeable users, the DRUG COMPANY DEFENDANTS failed to make reasonable efforts to ensure that accurate and adequate information regarding metoclopramide was provided to the medical community, physician's and consumers, or to inform the FDA of the need for changes to its label. Defendants failed entirely to communicate any information in a manner calculated to properly and adequately warn physicians and the medical community of the risks associated with metoclopramide use.

120. The FDA, *sua sponte*, on February 26, 2009, exercising new agency powers granted under §901(a) of the Food and Drug Administrative Amendments of 2007, which added a subsection (o) to FDCA §505, 21 USC §355(o), ordered the addition of a black box warning to the labeling for Reglan/metoclopramide, highlighting the high risk of tardive dyskinesia with long term, high dose, or pediatric use of metoclopramide, even after the drugs are no longer taken. The purpose of this black box warning was to both improve the strength of the warning and to ensure that the warning was effectively communicated to both physicians and patients.

121. The FDA also ordered the DRUG COMPANY DEFENDANT(S) to create a Risk Evaluation and Mitigation Strategy (“REMS”), including the creation of a patient medication guide, to ensure that information regarding the risks associated with metoclopramide were communicated directly to the consumers of the drug.<sup>11</sup>

122. Before 2007, the FDA did not have the authority to order or demand such action from defendants. Prior to the black box warning and the patient medication guide in 2009, repeated studies, literature and adverse event reports confirmed that the warnings in the label for metoclopramide were insufficient to apprise the medical community and patients of the serious risks of the drug, yet the DRUG COMPANY DEFENDANTS did nothing to communicate accurate information to individuals prescribing and consuming metoclopramide, resulting in harm to numerous patients.

### **G. Injuries**

123. Plaintiffs’ long term, pediatric, and/ short term ingestion of Reglan and/or generic metoclopramide products resulted in overexposure to the drug, which caused them to suffer serious, permanent and disabling neurological injuries, including but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems, such as Tardive Dyskinesia, as well as an aggravation of preexisting conditions.

124. Use of Reglan and/or generic metoclopramide products caused Plaintiffs to suffer an aggravation of preexisting conditions as well as serious, permanent and disabling injuries including but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems. Because of the injuries, Plaintiffs have experienced and will continue to experience medical and related expenses, loss of ability to provide household services,

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<sup>11</sup> The FDA made these statements and ordered these actions after the review of certain medical studies and investigations from as early as the 1990s—studies which were available to the defendants since their initial publication.

disfigurement, disability, pain and suffering, psychological injury and other injuries and damages.

125. Plaintiffs' serious and permanent injuries, and aggravation of preexisting conditions, as described above (and to be further described in Short Form Complaints), came about as a foreseeable and proximate result of the failure of DRUG COMPANY DEFENDANTS to monitor the safety of their drug products, to provide accurate and complete information to the FDA, to use reasonable means to correct inaccuracies appearing in their labels, and to communicate to the medical community, physicians, Plaintiffs' physician, Plaintiffs and other foreseeable users of the drug, adequate warnings about risks associated with common and foreseeable uses of their metoclopramide products. Concurrently, Plaintiffs' injuries came about as a foreseeable and proximate result of defendants' inaccurate, misleading, materially incomplete, and otherwise false information concerning the potential effects of exposure to the drug substance metoclopramide and the ingestion of the metoclopramide products manufactured and sold by the DRUG COMPANY DEFENDANTS.

126. As a further proximate result of the foregoing acts and omissions, Plaintiff's require and will require health care and services, and have incurred and will continue to incur medical, rehabilitative, and related expenses along with lost wages and earning capacity. Plaintiffs have suffered and will continue to suffer indirect costs, including diminished quality of life, and direct medical costs for follow-up care, including hospitalizations, and other medical care.

**V. Claims for Relief**

**COUNT I - STRICT LIABILITY**

127. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

128. Each of the DRUG COMPANY DEFENDANTS is liable under the common law and/or Product Liability Acts for personal injuries sustained by individual plaintiffs as a proximate result of its innocent, negligent and/or willful failure to give adequate warnings and/or to effectively communicate adequate warnings to physicians (or to their patients) bearing on the expected, intended, and/or common and foreseeable uses of the specific metoclopramide product or products that it made or sold and which those plaintiffs came to use, as prescribed by their physicians and properly dispensed to them by their pharmacies.

129. As manufacturers of pharmaceutical products, specifically Reglan and/or generic metoclopramide, each of the DRUG COMPANY DEFENDANTS is deemed to have possessed the knowledge of an expert in the uses of Reglan and/or generic metoclopramide and the effects of such uses, including dangerous and potentially dangerous side effects of such use.

130. Neither the plaintiffs nor their physicians were in the possession of the knowledge about metoclopramide effects that DRUG COMPANY DEFENDANTS, as manufacturers of the drug, in its name brand or generic versions, actually possessed or are deemed to possess, concerning the risks of personal injury associated the use of the drug, and none of them were given adequate warnings pertaining to such use.

131. The DRUG COMPANY DEFENDANTS had a continuing duty, as information regarding the risks and dangers associated with the ordinary and foreseeable use of Reglan and/or metoclopramide came to them, to exercise reasonable care to communicate to the health

care industry and consumers, including Plaintiffs, or to their physicians, adequate warnings about those risks and dangers.

132. The DRUG COMPANY DEFENDANTS distributed, marketed, promoted, and/or sold an unreasonably dangerous and defective product, namely the prescription drug known as Reglan and/or generic metoclopramide, without adequate warnings and other clinically relevant information and data to consumers, including Plaintiffs, or to their physicians or other health care providers empowered to prescribe and dispense Reglan and/or metoclopramide. Through both omission and affirmative misstatements, defendants severally and collectively misled and/or failed to communicate to the medical community about the risk and benefit balance of Reglan and/or metoclopramide.

133. Despite the fact that the DRUG COMPANY DEFENDANTS knew or should have known that Reglan and/or metoclopramide caused unreasonable and dangerous side effects, they continued to manufacture, sell, and distribute their metoclopramide products without effectively communicating to consumers, or to their physicians or other health care providers, adequate clinically relevant information and data or that there existed safer and more or equally effective alternative drug products.

134. The DRUG COMPANY DEFENDANTS knew or should have known that a class of consumers, which include the Plaintiffs specifically, would foreseeably and needlessly suffer injury as a result of their several and collective failure to provide adequate warnings, and/or provide any information regarding their drug product at all.

135. The DRUG COMPANY DEFENDANTS failed to communicate timely and adequate warnings to consumers, including Plaintiffs, or to their physicians, in the following ways:

1. Defendants, failed to communicate to doctors, pharmacists or to their patients adequate warnings or adequate clinically relevant information and data that would alert them to the dangerous risks of Reglan and/or metoclopramide including, among other things, EPS and involuntary movements;
2. After they knew or should have known of the significant risks of, among other things, involuntary movements, the DRUG COMPANY DEFENDANTS failed to provide adequate post-marketing warnings and instructions;
3. BRAND NAME DEFENDANTS failed to timely and properly correct misstatements and misrepresentations in the label, failed to update the label and failed to ensure that the true risk of EPS were accurately stated in the label, and failed to properly emphasize and reinforce the warnings about the duration of use of the drug.
4. GENERIC DEFENDANTS failed to effectively and adequately communicate the warnings in the label to physicians and patients, to ensure that both were aware of the risk of EPS and to ensure that both were aware of the limitations regarding the duration of use of the drug.
5. BRAND NAME DEFENDANTS continued to aggressively promote Reglan even after it knew or should have known that the use of Reglan or other metoclopramide products, in particular the long term use of the drug, entailed unreasonable risks of serious and potentially crippling involuntary movement disorders.

136. The DRUG COMPANY DEFENDANTS, as manufacturers and distributors and sellers of metoclopramide products, owed to the plaintiffs, and other patients, a duty to provide to them or to physicians adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to metoclopramide, and/or that there existed safer and more or equally effective alternative drug products.

137. By failing to effectively communicate to Plaintiffs or to their physicians adequate clinically relevant information and data and warnings regarding the adverse health risks

associated with the ordinary, expected, and/or intended use of the metoclopramide product or products it manufactured, distributed, and/or sold, including the information that there existed safer and more or equally effective alternative non-metoclopramide drug products, each of the DRUG COMPANY DEFENDANTS breached its duty to purchasers and consumers of its metoclopramide products.

138. The actions of each of the DRUG COMPANY DEFENDANTS, as described above, were performed willfully, intentionally, and/or with reckless disregard for the life and safety of the Plaintiffs and the public.

139. Actions of each of the BRAND NAME DEFENDANTS, as described above, also violated the state and federal statutes, including the FDCA, pertaining to the labeling of drugs and so rendered the metoclopramide product or products sold by that defendant “misbranded,” as that term is used in those statutes.

140. As a direct and proximate result of the actions and inactions of the DRUG COMPANY DEFENDANTS, as set forth above, Plaintiffs were exposed to Reglan and/or metoclopramide and suffered and continue to suffer the injuries and damages set forth with greater specificity in their individual Complaints.

#### COUNT II - STRICT LIABILITY – DESIGN DEFECT

141. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

142. The DRUG COMPANY DEFENDANTS are liable to Plaintiffs for the injuries and damages sustained by Plaintiffs pursuant to state common law and/or state Product Liability Acts due to the defective design and/or formulation of their several products, namely Reglan and/or generic metoclopramide.

143. At times material to these allegations, the DRUG COMPANY DEFENDANTS manufactured, distributed, and/or sold one or more metoclopramide products, as alleged in their individual Complaints.

144. The DRUG COMPANY DEFENDANTS, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and as manufacturers of metoclopramide drug products, to the level of knowledge of an expert in the field of metoclopramide uses and effects, including side effects.

145. The Reglan and/or metoclopramide prescribed for, dispensed to, and administered to or used by Plaintiffs was defective in design or formulation in the following respects:

6. When it left the hands of the DRUG COMPANY DEFENDANT that manufactured and/or sold it, the metoclopramide product was unreasonably dangerous to the extent beyond that which would reasonably be contemplated by Plaintiffs or their physicians;
7. Any benefit of this product was outweighed by the serious and undisclosed risks of its use when used, per doctors' prescriptions, as the DRUG COMPANY DEFENDANTS intended;
8. The dosages and/or formulation of the metoclopramide products manufactured and/or sold by the DRUG COMPANY DEFENDANTS were unreasonably dangerous;
9. The manner in which Defendants packaged their metoclopramide products rendered the product unreasonably dangerous;
10. There are no patients for whom the benefits of Reglan and/or generic metoclopramide outweighed the risks; and/or
11. There are no patients for whom Reglan and/or generic metoclopramide is a safer and more efficacious drug than other drug products in the same class.

146. The Reglan and/or generic metoclopramide products dispensed to and administered to or used by Plaintiffs were defective at the time they were distributed by or left the control of the DRUG COMPANY DEFENDANTS that manufactured and/or sold them.

147. The Reglan and/or generic metoclopramide products manufactured and/or sold by the DRUG COMPANY DEFENDANTS were expected to and did reach patients for whom they were prescribed, including Plaintiffs, without substantial change in their condition.

148. The Reglan and/or generic metoclopramide products manufactured and/or sold by the DRUG COMPANY DEFENDANTS were administered to or used by Plaintiffs without substantial change in their condition.

149. Plaintiffs were patients for whom the products manufactured and/or sold by the DRUG COMPANY DEFENDANTS reasonably expected Reglan or metoclopramide to be prescribed, and would be expected to use or otherwise receive administration of their metoclopramide products.

150. Each of the DRUG COMPANY DEFENDANTS was entitled to withdraw its metoclopramide product from the market at any time, but failed to do so in a timely and responsible manner.

151. The defects in the Reglan and/or other metoclopramide products used by or administered to Plaintiffs were a direct and proximate cause of the injuries, damages, and death sustained by Plaintiffs as set forth in their individual Complaints.

### COUNT III – NEGLIGENCE

152. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

153. Pursuant to common law and/or Product Liability Acts, and due to its negligent research, development, testing, study, manufacture, marketing, promotion, distribution and sale of Reglan and/or generic metoclopramide, each of the DRUG COMPANY DEFENDANTS is liable to Plaintiffs who consumed its metoclopramide product or products for injuries caused by those products.

154. At all times relevant to this lawsuit, each of the DRUG COMPANY DEFENDANTS owed a duty to consumers, like Plaintiffs, to assess, minimize, and communicate the risks, dangers, and adverse effects of Reglan and/or metoclopramide and to suspend distribution and sale of its Reglan and/or metoclopramide products when it discovered the drug to be unreasonably dangerous.

155. DRUG COMPANY DEFENDANTS' duties included, but were not limited to, carefully and properly designing, testing, studying, manufacturing, promoting, selling, and/or distributing its Reglan and/or metoclopramide product into the stream of commerce as a reasonably safe prescription drug product.

156. DRUG COMPANY DEFENDANTS were required to use all reasonable means available to correct inaccurate information present in the labeling for metoclopramide, and to ensure that prescribers and consumers of the drug were aware of the risks associated with its use, including long-term and pediatric use.

157. DRUG COMPANY DEFENDANTS' duties further included, but were not limited to, distributing their respective Reglan and/or metoclopramide products with adequate information about warnings and precautions, and to ensure that the warnings were effectively communicated to consumers and/or physicians regarding the appropriate use of the drug product.

158. Each of the DRUG COMPANY DEFENDANTS negligently and carelessly breached the above-described duties to Plaintiffs by committing negligent acts and/or omissions including, but not limited to, the following:

12. They failed to use ordinary care in designing, testing, and manufacturing, a product which, would be reasonably safe to use without appropriate labeling, marketing, and/or the provision of adequate information to consumers or doctors;
13. They failed to use ordinary care in marketing, labeling, and communicating adequate warnings about their respective products to consumers and/or their physicians so as to reveal and communicate the high risk to users of unreasonable, dangerous side-effects, such as involuntary movements, when compared to the use of alternative drugs in the same class or compared to the use of no drugs;
14. They failed to exercise ordinary care to communicate, to consumers or to doctors, adequate information that would alert doctors or consumers to the potential adverse side effects associated with the use of their respective Reglan and/or metoclopramide products and the nature, severity and duration of such adverse effects, either compared to the use of alternative drug in the same class or compared to the use of no drugs;
15. They failed to exercise ordinary care either to conduct or in conducting post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses adequate to determine the safety profile and side effects of their respective Reglan and/or metoclopramide products, either compared to the use of alternative drugs in the same class or compared to the use of non-drug therapy;
16. They failed to exercise ordinary care to communicate to Plaintiffs or to their physicians, either directly or indirectly, orally or in writing, adequate warnings about the true risk of involuntary movements, injury and death as a result of the use of their respective Reglan and/or metoclopramide products, either compared to the use of alternative drugs in the same class or compared to the use of non-drug therapy;

17. They failed to exercise ordinary care to protect users of their respective Reglan and/or metoclopramide products from an unreasonable risk of injury due to the ordinary, expected, or common uses of Reglan and/or generic metoclopramide, in the face of continued or past efforts to promote to physicians the safety and effectiveness of the drug, while downplaying its risks, after they knew or should have known that those efforts overstated the safety and downplayed the risks of the drug compared to the use of alternative drugs in the same class or compared to the use of non-drug therapy;
18. They failed to communicate to Plaintiffs or to their physicians information that long-term use of the Reglan and/or generic metoclopramide involved a higher risk of involuntary movements and/or was unreasonably dangerous than was commonly appreciated in the medical community or as compared to the use of alternative drugs in the same class or to the use of non-drug therapy, after they knew or should have known that to be the case.
19. Owing to a failure to exercise due care, they failed to obtain, at the time of Plaintiffs' ingestion, scientific data that would indicate the true association between the use of Reglan and/or metoclopramide and the risk of involuntary movements, either compared to the use of alternative drugs or compared to the use of non-drug therapy, even though they could legally have distributed the information they had or should have had to the FDA, physicians and their patients,;
20. They failed to communicate to physicians, or to consumers, like Plaintiffs, scientific data which indicated that Reglan and/or metoclopramide was unreasonably dangerous, either compared to the use of alternative drugs in the same class or compared to the use of non-drug therapy, and that there were no patients or only very few patients in whom the benefits of their respective products outweighed the risks;
21. They failed to promptly withdraw their respective Reglan and/or metoclopramide products from the market and were otherwise careless or negligent.

22. They failed to implement proper risk management practices including investigation of off-label use of the drug, the injuries that were caused by the improper use of the drug, and determining the true rate of risk of EPS injuries being caused by the drug; they also failed to properly and adequately communicate the warnings to the physicians and patients, such that a large number of patients were improperly taking the drug for long terms, and were harmed by such use.
23. Several of the GENERIC DEFENDANTS were negligent in failing to include information present in the label for the RLD and in failing to implement changes to their own labels to ensure that the information they provided was current and not outdated; in some cases, GENERIC DEFENDANTS waited years to conform their labels to the RLD label.

159. The DRUG COMPANY DEFENDANTS continued to manufacture and distribute their respective versions of the drug when they knew or should have known that metoclopramide caused unreasonably dangerous side effects, which many users of their metoclopramide products would be unable to remedy by any means, and that there were safer and less expensive alternatives available.

160. DRUG COMPANY DEFENDANTS, as manufacturers of brand-name or generic versions of the drug, are by law deemed to possess the knowledge of an expert in the uses and effects of the drug, and as such should have known that consumers, like Plaintiffs, would suffer injury as a result of ingesting their respective metoclopramide products as prescribed by their physicians and properly dispensed by their pharmacies.

161. As a direct and proximate cause of DRUG COMPANY DEFENDANTS' negligent acts and/or omissions, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints.

COUNT IV - NEGLIGENCE *PER SE*

162. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

163. Under the doctrine of negligence *per se*, the duty of the DRUG COMPANY DEFENDANTS to exercise reasonable care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers associated with the use of their respective metoclopramide products, includes the obligation to conform their products and activities related to those products to safety standards imposed by applicable statutes or regulations.

164. Distribution by the DRUG COMPANY DEFENDANTS of their respective metoclopramide products, specifically their acts and omissions as described above, constitute violations of FDCA §301(a), 21 USC §331(a), which declares unlawful the distribution of a drug that is “misbranded,” as that term is defined by standards established in FDCA §502, 21 USC §352, and in regulations duly promulgated to clarify those standards, and also a violation of parallel state statutes and regulations. Conduct in violation of these statutes and regulations constitutes a breach of duty of reasonable care toward the plaintiffs that would subject the defendants to civil liability for personal injuries proximately caused by the violations.

165. DRUG COMPANY DEFENDANTS failed to perform proper pharmacovigilance to identify adverse events associated with their drug products as required by 21 C.F.R. 314.80, and to report significant new information regarding metoclopramide that might affect the safety, effectiveness or labeling of the drug, as required by 21 C.F.R. 314.81

166. As lawful consumers of Reglan and/or metoclopramide distributed by the several DRUG COMPANY DEFENDANTS, Plaintiffs are within the class of persons the statutes and regulations described above are designed to protect, and Plaintiffs' injuries are the type of harm these statutes and regulations are intended to prevent.

167. In addition to the overall misbranding, several of the GENERIC DEFENDANTS failed to conform their labels to the RLD label, in some cases for years, rendering those labels misbranded per se

168. As a direct and proximate cause of the violations of these statutes and regulations by the DRUG COMPANY DEFENDANTS, which therefore constitute negligent acts and/or omissions, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints.

#### COUNT V – FRAUD, MISREPRESENTATION, AND SUPPRESSION

169. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

170. Defendants are liable to Plaintiffs, under the common law, for injuries proximately resulting from its willful and fraudulent misrepresentations to physicians, regarding the safety, efficacy, and risk/benefit ratio of Reglan and, by implication, of generic metoclopramide products that are bioequivalent and therefore medically identical to Reglan.

171. Through its actions and omissions in advertising and other activities to promote the use of Reglan, defendants intentionally and fraudulently made misrepresentations of material facts to physicians and/or concealed material facts from physicians, and indirectly to and from their patients, concerning the character and safety of the drug.

172. From the early 1980s to 2002, defendant Wyeth (including the A. H. Robins Company, Inc.)—through advertising, promotions, in-office and group presentations of sales

representatives (called detail men), sponsored education and continuing education programs and seminar speakers, the planning, sponsorship, ghost-writing, and arranged publication of non-scientific and misleading medical research, and dissemination of the Reglan labeling with product samples distributed by detail men and by publication in the PDR—fraudulently and falsely overstated the benefits and safety of the drug and concomitantly downplayed the risks in its use, thereby inducing physicians, including Plaintiffs’ physicians, through reasonable but misplaced reliance on those misrepresentations, to prescribe long-term metoclopramide therapy for chronic heartburn and bloating, in lieu of other, safer alternatives, and inducing consumer patients, like Plaintiffs, to purchase and use Reglan and/or generic metoclopramide as prescribed, thus exposing them to an undisclosed substantial risk of involuntary movements, aggravation of preexisting injuries, other injuries, and death.

173. When Schwarz Pharma purchased the NDA in 2001, they initiated an internal evaluation of the accuracy and completeness of the label. From their own internal investigation, Schwarz Pharma confirmed that the true incidence rate of EPS or TD was as much as 100 times greater than what was stated in the label written by Wyeth; nevertheless, Schwarz Pharma never corrected this significant understatement of the rate of risk, and never communicated to physicians that the label was terribly inaccurate. Further, Schwarz Pharma’s internal investigation confirmed that a significant population of physicians had no appreciation for the duration of use warnings – and instead were ignorantly keeping patients on the drug for long term use. Schwarz Pharma took years to correct any warnings about duration of use – and when they did attempt to strengthen the warning, Schwarz Pharma never published the label. In other words, they never even attempted to warn physicians or patients of the new language regarding

duration of use – confirming they were fully aware of the problem and injuries of long term use, and consciously chose to do nothing to correct the prescribing habits of physicians.

174. Defendants misrepresentations, by knowingly false statement and omission, specifically include but are not limited to, the misrepresentations as set forth in the general allegations section of this Complaint and the following:

24. They intentionally concealed or withheld from disclosure that the pre-clinical and clinical testing and post-marketing surveillance were inadequate to determine the safety and side effects of Reglan compared to the use of alternative drugs in the same class or to the use of no drug;
25. They intentionally concealed and/or withheld from disclosure data showing that Reglan and/or generic metoclopramide use, particularly in long term therapy, dramatically increase the risk for involuntary movements and other injuries and death, either compared to the use of alternative drugs in the same class or to the use of no drug;
26. They intentionally concealed and/or withheld from the information they disseminated about Reglan data about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including without limitation, the risk of involuntary movements, other injuries and death, either compared to the use of alternative drugs in the same class or compared to the use of no drug;
27. They concealed and/or withheld, from the information they disseminated about Reglan, past and present facts of which they were aware, as specifically with Wyeth, as early as the 1980s, and as late as 2004 for Schwarz Pharma, including the degree of actual likely association between the use of metoclopramide and dangerous side effects, including involuntary movements;

175. The above-described acts and/or omissions of defendants were performed willfully, intentionally, and with reckless disregard for the safety of the consuming public, including the Plaintiffs.

176. BRAND NAME DEFENDANTS made these material misrepresentations and omissions to physicians knowing that they were not true, and knowing and intending that physicians would consider the misinformation disseminated to be reliable and suitable as a basis for prescribing decisions and would rely on the misinformation in prescribing Reglan or metoclopramide. The representations that Reglan was safe for its intended use, either compared to the use of alternative drugs in the same class or compared to the use of no drug, were inaccurate, untrue, and otherwise false. The use of Reglan and/or generic metoclopramide was, in fact, unreasonably dangerous to the health of patients suffering from heartburn and/or bloating, and there were alternative products in the same class of drugs that were available, less expensive, equally or more effective, and posed less risk.

177. In the alternative, BRAND NAME DEFENDANTS made the false material representations and omissions with reckless disregard of whether these representations were true or not.

178. At no relevant time were the Plaintiffs' physicians or the Plaintiffs aware of the falsity of the foregoing misrepresentations concerning Reglan and/or metoclopramide, nor were they aware of the material facts that had been concealed or withheld, or that any material facts had been concealed or withheld. In reasonable reliance upon these misrepresentations and omissions, Plaintiffs' physicians prescribed the use of Reglan and/or metoclopramide as they did for the Plaintiffs.

179. Each of the DRUG COMPANY DEFENDANTS, as manufacturer of metoclopramide drug products, whether as Reglan or a generic version of the drug, is obligated to give physicians and their patients, like Plaintiffs, accurate and material scientific information and data regarding the association between exposure to metoclopramide and the a risk of

involuntary movements, aggravation of preexisting conditions, other injuries, and death, and/or which indicated that the drug was unreasonably dangerous, and/or which indicated that there were very few if any patients for whom the benefits of long term metoclopramide therapy outweighed the risks, regardless of whether that information had been approved by the FDA for inclusion in the product's labeling.

180. If Plaintiffs and their physicians had known the true facts concerning the risks of using the drug, in particular the risk of involuntary movements, aggravation of preexisting conditions, other injuries and death, from long term cumulative exposure to metoclopramide, they would not have used Reglan and/or generic metoclopramide and would have used one of the alternatives in that class of drug products.

181. The reliance of the Plaintiffs' physicians and the Plaintiffs on these misrepresentations and omissions was reasonable because the defendant was in a better position to know the facts concerning Reglan, and by implication concerning bioequivalent generic versions of the drug, than either the Plaintiffs or their physicians. BRAND NAME DEFENDANTS overstated the benefits and safety of Reglan and concomitantly downplayed the risks in its use, thereby inducing Plaintiffs' physicians to use Reglan and/or metoclopramide in lieu of other, safer alternatives. At all times relevant hereto, the corporate officers, directors, and/or managing agents of the defendants knew about and ratified the acts of their companies, the defendants, as alleged herein.

182. The DRUG COMPANY DEFENDANTS passively assented to and indirectly cooperated in the misrepresentations, concealment, suppression and omissions made directly by the BRAND NAME DEFENDANTS, as described herein. The misrepresentations, concealment, suppression, and omissions were made and done by the BRAND NAME DEFENDANTS

directly, and indirectly through assent and cooperation by all the DRUG COMPANY DEFENDANTS, uniformly and deliberately or recklessly, with willfulness, wantonness, in order to induce doctors to prescribe, and their patients to consume, Reglan and/or generic metoclopramide. Plaintiffs and their physicians did reasonably rely upon the material misrepresentations and omissions made directly by defendant BRAND NAME DEFENDANTS, and indirectly through assent and cooperation by the GENERIC DEFENDANTS, when prescribing Reglan and/or metoclopramide.

183. As a direct and proximate result of this direct and indirect misrepresentation, concealment, suppression, and omission concerning the risks and benefits of Reglan and/or metoclopramide, Plaintiffs suffered injuries and damages, as set forth in their individuals Complaints, when their physicians, in reasonable but misplaced reliance on that misinformation, prescribed the drug inappropriately, and Plaintiffs took the drugs inappropriately, leading to their cumulative toxic exposure to metoclopramide.

#### COUNT VI – CONSTRUCTIVE FRAUD

184. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

185. At the time Reglan and/or generic metoclopramide was manufactured, distributed, and sold to Plaintiffs, the BRAND NAME DEFENDANTS were in a unique position of knowledge, which was not possessed by Plaintiffs or their physicians, concerning the safety and effectiveness of the drug, and thereby held a position of superiority over Plaintiffs.

186. Through their unique knowledge and expertise regarding the defective nature of Reglan and generic metoclopramide, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, BRAND NAME

DEFENDANTS professed to Plaintiffs' physicians that they were in possession of facts demonstrating that Reglan (and, by implication, generic metoclopramide) was safe and effective for its intended use and was not defective.

187. BRAND NAME DEFENDANTS' representations to Plaintiffs' physicians were made to induce the purchase of Reglan and/or metoclopramide, and Plaintiffs and their physicians relied upon those statements when purchasing and administering Reglan and/or metoclopramide.

188. Plaintiffs and their physicians reasonably relied on these misrepresentations.

189. BRAND NAME DEFENDANTS, and also the other GENERIC DEFENDANTS, through their knowing assent and passive cooperation in the dissemination of these misrepresentations to doctors, took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their physicians and engaged in constructive fraud in their relationship.

190. As a direct and proximate result of constructive fraud, as perpetrated by BRAND NAME DEFENDANTS, and knowingly assented to and passively cooperated in by the other GENERIC DEFENDANTS, Plaintiffs have suffered injuries and damages, as set forth in their individual Complaints.

#### COUNT VII – BREACH OF EXPRESS AND IMPLIED WARRANTIES

191. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

192. The drug products known as Reglan and/or generic metoclopramide, as designed, tested, manufactured, distributed, promoted, and sold severally by the DRUG COMPANY

DEFENDANTS, were expected to and did reach Plaintiffs without a substantial change in their condition.

193. BRAND NAME DEFENDANTS, through advertising and promotional materials, statements of sales representatives and paid endorsers, and each of the DRUG COMPANY DEFENDANTS, through product labels shipped with the drug from the factory, expressly warranted its metoclopramide product to have the properties represented therein and impliedly warranted that the product was safe for the use for which it was intended, including those uses that were ordinary, common, and foreseeable. These warranties include, but are not limited to warranties such as those identified in the Uniform Commercial Code §§ 2-313, 2-314 and 2-315.

194. The DRUG COMPANY DEFENDANTS breached said express and implied warranties by failing to deliver products that conformed to the properties described in the label and/or advertising and promotional representations made for their respective products and by failing to deliver products that were safe for their intended uses, including long term metoclopramide therapy, in light of the substantially greater risk of dangerous side effects associated with its ordinary and expected uses, including long term therapy, than disclosed and warranted in the product label and/or other advertising and promotional representations.

195. The express and implied warranties, as described, were part of the basis of the bargain for the purchase and consumption by the Plaintiffs of metoclopramide products made and sold by the DRUG COMPANY DEFENDANTS.

196. As a direct and proximate result of these breaches of express and implied warranties, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints, when their physicians prescribed and they consumed Reglan and/or generic metoclopramide products, leading to their toxic cumulative overexposure to metoclopramide.

COUNT VIII - UNFAIR AND DECEPTIVE TRADE PRACTICES

197. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

198. State laws require the DRUG COMPANY DEFENDANTS, as merchants, to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of their prescription drug products.

199. BRAND NAME DEFENDANTS, with the contemporaneous or later passive assent and cooperation of the other DRUG COMPANY DEFENDANTS, financed, assisted, supported and participated in advertising and other, similar efforts to promote the use of Reglan and/or metoclopramide, in order to create demand for the drug and thereby increase sales and profits.

200. The DRUG COMPANY DEFENDANTS, in the manner described, deliberately misrepresented the safety of Reglan and/or metoclopramide and intentionally concealed the risks attendant to use of the drug. Through these misrepresentations, DRUG COMPANY DEFENDANTS intended to influence (and did influence) the decisions of prescribing physicians and the drug-taking of their patients toward the end of increasing and maintaining the prescribing, purchasing, and use of Reglan and generic metoclopramide products, and excluding the options of not using a drug or using substantially cheaper alternative drugs from the same class.

201. BRAND NAME DEFENDANTS, while engaged in the conduct and practices identified above, and the other DRUG COMPANY DEFENDANTS, through their passive assent and cooperation as identified above, committed one or more violations of state law, including, but not limited to, the following:

28. They made false and misleading representations and omissions of material facts regarding Reglan and/or generic metoclopramide;
29. They concealed and otherwise failed to publicize the risk of injury associated with Reglan and/or generic metoclopramide in order to promote sales of the drug and maximize profits; and
30. They engaged in advertising and promotion of Reglan and/or metoclopramide without conducting sufficient pre-clinical, clinical and post-approval testing and adequate post-marketing surveillance and analyses of the drug.

202. The DRUG COMPANY DEFENDANTS thereby intended to and did affect the price of Reglan and generic metoclopramide, unfairly and deceptively maintained the price of Reglan and generic metoclopramide at an inflated level not otherwise obtainable, and caused Plaintiffs and the consuming public generally to pay more for these products than was warranted or than they would otherwise have paid in the absence of the misrepresentations and concealment.

203. The above-described conduct, practices, acts and omissions were immoral, oppressive, unethical and/or unscrupulous, in violation of international treaty and law, and/or offensive to public policy.

204. The above-described conduct, practices, acts and omissions caused consumers permanent and substantial financial loss, which loss could not reasonably have been avoided, and which was not outweighed by any countervailing benefit to the consuming public. Consumers in general, Plaintiffs in particular, incurred unnecessary expenses for a product that was purchased only because of the unfair, unscrupulous, oppressive and/or deceptive acts or practices of the DRUG COMPANY DEFENDANTS.

205. As a consequence of this wrongful conduct, by BRAND NAME DEFENDANTS and the other DRUG COMPANY DEFENDANTS, Plaintiffs suffered an ascertainable financial

loss: the difference between the price paid for Reglan and/or metoclopramide as a result of these unfair trade practices and the cost of any of the substantially cheaper, and safer, drug alternative.

COUNT IX - UNJUST ENRICHMENT

206. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

207. As the intended and expected result of the conscious wrongdoing of defendant Wyeth, and the conscious passive assent and cooperation of the other DRUG COMPANY DEFENDANTS, all defendants have profited and benefited from the purchase and use of Reglan and/or generic metoclopramide by Plaintiffs.

208. BRAND NAME DEFENDANTS and the other DRUG COMPANY DEFENDANTS have voluntarily accepted and retained these profits and benefits derived from Plaintiffs with full knowledge and awareness that, as a result of BRAND NAME DEFENDANTS wrongdoing, as passively and consciously assented to and cooperated in by the other DRUG COMPANY DEFENDANTS, Plaintiffs were not receiving products of the quality, nature or fitness that had been represented by their manufacturers and sellers, or that Plaintiffs, as reasonable consumers, expected to receive.

209. By virtue of the conscious wrongdoing alleged above, the DRUG COMPANY DEFENDANTS have been unjustly enriched at the expense of Plaintiffs, who are entitled to in equity and hereby seek the disgorgement and restitution of the profits, revenues and benefits obtained through the wrongdoing, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the unjust enrichment of defendant Wyeth and the other DRUG COMPANY DEFENDANTS.

COUNT X – CONSCIOUS or NEGLIGENT MISREPRESENTATION INVOLVING  
PHYSICAL HARM

210. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

211. BRAND NAME DEFENDANTS owed a duty in all of its several undertakings, including the communication 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.

212. Defendant Wyeth through the publication of the Reglan monograph in the PDR, from the early 1980s up to 2002, and otherwise, disseminated information to physicians concerning the properties and effects of metoclopramide and of its product Reglan, with the intent and expectation that physicians would rely on that information in their decisions regarding the prescribing of drug therapy for their patients. Defendant Schwarz Pharma, with their unpublished changes to the 2004 label likewise intended reliance by the physicians and patients on inaccurate and misleading information from the previous labels, and thereby through omission mislead physicians and patients.

213. Alternatively or in addition, when Defendant Wyeth, through the publication of the Reglan monograph in the PDR, from the early 1980s up to 2002, and otherwise, disseminated information to physicians concerning the properties and effects of metoclopramide and of its product Reglan, it should have realized, in the exercise of due care to avoid causing personal injury to others, that physicians would reasonably rely on that information in their decisions concerning the prescription of drug therapy for their patients. Defendant Schwarz Pharma knew or should have known that physicians and patients would have no reason to expect a label change, unless they were informed of a change, and thereby misled by omission.

214. BRAND NAME DEFENDANTS knew, or in the exercise of due care to avoid causing personal injuries to others, should have realized, that a physician's prescribing decisions made in reliance on inaccurate, misleading, or otherwise false information about the therapeutic effects or side effects of a prescription drug would be likely to place his or her patients at potentially grave and unreasonable risk of avoidable personal injury from the effects of the drug.

215. BRAND NAME DEFENDANTS also knew, or in the exercise of due care to avoid causing personal injuries to others, should have realized, that a physician's prescribing decisions made in reliance on inaccurate, misleading, or otherwise false information about the therapeutic effects or side effects of a prescription drug would, under the circumstances prevailing, place his or her patients at the same risk of suffering the same injuries, whether a pharmacy dispensed, per the prescription, the name brand version or a generic version of the drug, and that the pharmacy was likely to dispense a generic version. Defendant Schwarz Pharma, through omission and failure to notify physicians and patients of the information in their possession about inaccurate rate of risk and significant duration of use, failed to effectively communicate changes in the label. As regards any and all prescription drugs that may lawfully be distributed in this country, and therefore would generally be distributed in this country, those circumstances include:

- a) With respect to any generic prescription drug, for which the FDA has approved an ANDA, the drug is accepted by physicians to be, a bioequivalent generic version of a prescription drug, usually a counterpart name brand drug, for which the FDA has already approved an NDA or ANDA.
- b) A generic version of a drug that is intended to be bioequivalent to a brand name version of the drug generally is accepted by physicians to be, medically and therapeutically identical to the name brand version of the drug and all other bioequivalent generic versions of the drug, and therefore is expected to have, the same therapeutic effects and side effects.

c) There is no reason in general to suspect, and physicians generally do accept as reliable, bioequivalence, and therefore that generic versions of a drug are bioequivalent and therapeutically identical to the name brand version of the drug, and expected to have the same therapeutic effects and side effects.

d) The labeling for the name brand version of a drug is equally applicable to generic versions of the drug, and generally is identical to the labeling of all generic versions of the drug, in all medically and therapeutically material respects, including the drug's expected therapeutic effects and side effects.

e) By uniformly honored custom and practice and in conformity with the requirements of federal regulations, the label for a prescription drug product, whether name brand or generic, as it is distributed to pharmacies for dispensing to patients, per the prescriptions of their physicians, accompanies or is placed on or in the package from which the drug is to be dispensed.

f) A drug company will generally distribute to physicians the labels for a name brand prescription drug product along with samples of the product, when it is being introduced to the market, and disseminate the content of the labels (*i.e.*, the product labeling) to physicians through publication of the drug's monograph in the PDR, and otherwise communicate information regarding the drug through advertising, distribution of promotional materials, sales presentations by company sales representatives, group sales presentations, and sponsored publications and seminar speakers.

BRAND NAME DEFENDANTS disseminated false information, as referenced above, to physicians and the medical community and to their patients) with knowledge that the information was false or in conscious its truth or falsity.

216. BRAND NAME DEFENDANTS disseminated the false information, as referenced above, to physicians, the medical community and their patients with the intention to deceive physicians and their patients and to induce the physicians to prescribe Reglan. In particular, BRAND NAME DEFENDANTS induced physicians to prescribe Reglan for prolonged periods of time, with the knowledge that the patients were likely to use generic metoclopramide in addition to or in place of Reglan.

217. Alternatively or in addition, BRAND NAME DEFENDANTS failed to exercise reasonable care to ensure that the information disseminated to physicians concerning the properties and effects of Reglan and metoclopramide was accurate and not misleading, and instead that only information to physicians that was materially inaccurate, misleading, false, and unreasonably dangerous was available to physicians and the medical community in general. whether patients ultimately purchased and used Reglan, generic metoclopramide products, or both. Defendants Schwarz and Alaven failed to exercise reasonable care to insure that, during the time it held the NDA for Reglan, accurate and not misleading information was disseminated to physicians concerning the properties and effects of Reglan and metoclopramide by failing to publish or disseminate current and accurate information.

218. BRAND NAME DEFENDANTS expected or should have expected that patients taking metoclopramide, pursuant to prescriptions written or issued in reliance on false information., would be placed in unnecessary, avoidable, and unreasonable danger due to toxic overexposure to the drug. Defendants Schwarz and Alaven expected or should have expected that patients taking metoclopramide pursuant to prescriptions written during the time they held the NDA, were also relying on false information or misleading inaccuracies, and thus would be placed in unnecessary, avoidable, and unreasonable peril of injury due to toxic overexposure to the drug.

219. As a proximate and foreseeable result of this dissemination to physicians, by defendants Wyeth, Schwarz and Alaven, of consciously or negligently disseminating false information, the Plaintiffs suffered grievous bodily injury and consequent economic and other loss, as described above, when their physicians, in reasonable reliance upon the negligently inaccurate, misleading and otherwise false information disseminated by these defendants, and

reasonably but unjustifiably believing the information to be true, prescribed for the Plaintiffs the use of Reglan and/or generic metoclopramide for a prolonged and unwarranted period of time and they used, per those prescriptions, metoclopramide products, leading to their toxic overexposure to metoclopramide.

220. Liability under this Count X is not predicated on the ingestion, if any, by the Plaintiffs, of either Reglan as distributed by defendants or generic metoclopramide products as distributed through ESI Lederle as a division of Wyeth, nor by Schwarz or Alaven.

221. As asserted in this claim, the Plaintiffs' injuries, are due physically to their ingestion of name brand or generic metoclopramide products, and were caused directly and proximately by these defendants' either consciously or negligently disseminating to doctors false statements about the properties and dangerous propensities of metoclopramide, and not due to any defect in the products manufactured by these defendants. Accordingly, the claim stated here is not a claim against a manufacturer or seller for harm allegedly caused by its product..

#### COUNT XI – CIVIL CONSPIRACY

222. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

223. The DRUG COMPANY 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, they violated safety standards established by the FDCA, FDA regulations, and parallel state statutes and regulations, by selling and distributing a drug product that was misbranded within the intendment of those laws.

224. In addition, DRUG COMPANY DEFENDANTS acted with a common purpose to intentionally and/or fraudulently withhold information from the medical community and physicians regarding the safety of Reglan and generic metoclopramide for the purpose of earning profits at the expense of Plaintiffs' health.

225. The DRUG COMPANY DEFENDANTS overtly acted, in pursuance of monetary benefit, by failing to disclose such information safety information regarding Reglan and generic metoclopramide and hiding it from the medical community, Plaintiffs' physicians, and Plaintiffs.

226. As a consequence of this wrongful conduct, as engaged in and/or passively assented to by two or more of the DRUG COMPANY DEFENDANTS, actual legal damage has occurred to Plaintiffs and the public.

#### COUNT XII - LOSS OF CONSORTIUM

227. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

228. At all times relevant hereto, the Plaintiffs' spouses (hereinafter referred to as "Spouse Plaintiffs") and/or family members (hereinafter referred to as "Family Member Plaintiffs") suffered injuries and losses as a result of Plaintiffs' injuries.

229. Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of the wrongful conduct of the DRUG COMPANY DEFENDANTS.

230. 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.

231. For all Spouse Plaintiffs, Plaintiffs allege his/her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

232. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

233. As a direct and proximate result of the wrongful conduct of the DRUG COMPANY DEFENDANTS, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe 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.

234. The DRUG COMPANY DEFENDANTS are liable to Spouse Plaintiffs and/or Family Member Plaintiffs jointly and/or severally for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

#### COUNT XIII - WRONGFUL DEATH

235. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

236. Decedent Plaintiffs died as a result of their exposure to metoclopramide and the wrongful conduct of the DRUG COMPANY DEFENDANTS and are survived by various family members, named and unnamed.

237. The representatives of Decedent Plaintiffs' estates or other persons as designated by law bring these claims on behalf of the Decedent Plaintiffs' lawful heirs and statutory beneficiaries.

238. Defendants' wrongful conduct has proximately caused Decedent Plaintiffs' heirs and statutory beneficiaries to suffer the loss of Decedents' companionship, services, society, marital association, love and consortium.

239. Decedent Plaintiffs' representatives bring these claims on behalf of Decedent Plaintiffs' lawful heirs and statutory beneficiaries for these damages and for all pecuniary losses sustained by them.

240. Decedent Plaintiffs' representatives further plead all wrongful death damages allowed by statute in the state or states in which the wrongful death causes of action accrued.

#### COUNT XIV - SURVIVAL ACTION

241. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

242. As a direct and proximate result of their exposure to metoclopramide and the wrongful conduct of DRUG COMPANY DEFENDANTS as 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, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to their deaths.

243. The representatives/administrators of Decedent Plaintiffs' estates bring this claim on behalf of Decedent Plaintiffs' estates and Decedent Plaintiffs' beneficiaries for damages.

244. The representatives/administrators of Decedent Plaintiffs' estates further plead all survival damages allowed by statute in the state or states in which the survival causes of action accrued.

BASIS FOR PUNITIVE DAMAGES REMEDY

245. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

246. The wrongs done by the DRUG COMPANY DEFENDANTS were aggravated by the kind of malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiffs 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 conduct:

- a) When viewed objectively from the standpoint of the DRUG COMPANY DEFENDANTS at the time of the wrongful conduct, that conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and DRUG COMPANY DEFENDANTS were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b) included one or more material representations that were false, with DRUG COMPANY DEFENDANTS knowing that the representation or representations to be false or with reckless disregard as to their truth and as positive assertions, with the intent that the representations be acted on by Plaintiffs' physicians and Plaintiffs. Plaintiffs' physicians and Plaintiffs relied on the representation or representations and suffered injury as a proximate result of this reliance.

247. Plaintiffs therefore will seek, at the appropriate time under governing law, awards of exemplary damages in amounts within the jurisdictional limits of the Court.

248. Plaintiffs also allege that the acts and omissions of the DRUG COMPANY DEFENDANTS, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard also, Plaintiffs will seek awards of exemplary damages in amounts that would punish the DRUG COMPANY DEFENDANTS for their conduct and deter others from engaging in such misconduct in the future.

#### PUNITIVE DAMAGES REMEDY

249. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

250. Punitive damages should be assessed because actions, passive assent, and cooperation of the DRUG COMPANY DEFENDANTS, were reckless and without regard for the public's safety and welfare. The actions, passive assent and cooperation of the DRUG COMPANY DEFENDANTS, misled the medical community and the public at large, including Plaintiffs' physicians and the plaintiffs themselves, by making false representations about and concealing pertinent information regarding Reglan and/or metoclopramide. The affirmative representations and those representations implied by the omission of material information downplayed and understated the risk of serious and permanent side effects, including involuntary movements, associated with the use of Reglan and generic drug products bioequivalent to Reglan—despite direct knowledge that the risks were much greater than DRUG COMPANY DEFENDANTS reported and that the products were unreasonably dangerous to use for most conditions..

251. The conduct of DRUG COMPANY DEFENDANTS, in affirming to doctors the comparative safety of Reglan (and by clear implication, generic bioequivalent versions of the drug) and in withholding, from doctors and their patients, contrary information, which would indicate the true degree of danger inherent in the use of Reglan and/or generic metoclopramide, despite their knowledge of same, constituted fraud, malice, willfulness, and wantonness, both heedless and reckless and without regard to injurious consequences or the safety of others, including Plaintiffs.

252. At all times material hereto, the DRUG COMPANY DEFENDANTS owed a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Reglan and/or metoclopramide.

253. The DRUG COMPANY DEFENDANTS were wanton and reckless, in their misrepresentations and omissions and other actions, toward the public generally, and also breached their duty to the Plaintiffs specifically, in the following ways:

- a) They actually knew of Reglan and/or generic metoclopramide's defective nature, as set forth herein, but continued to design, manufacture, market, and sell Reglan and/or generic metoclopramide so as to maximize sales and profits at the expense of the health and safety of the consuming public, including Plaintiff's Decedent, and in conscious disregard of the foreseeable harm caused by Reglan and/or metoclopramide;
- b) They aggressively marketed Reglan and/or metoclopramide, but devoted far less attention to conducting sufficient pre-clinical testing, clinical testing, comparison testing, and adequate post-marketing surveillance of this drug;
- c) They violated state and/or federal laws by selling and distributing a drug product that was misbranded and/or adulterated under 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; and

- d) They continued to promote the safety of Reglan and/or metoclopramide, while providing no warnings at all about the unreasonable risk to consumers of involuntary movements and/or death associated with it, even after knew of that risk from multiple studies.

254. DRUG COMPANY DEFENDANTS advertised, marketed, distributed, and/or sold Reglan and/or metoclopramide even after they knew that metoclopramide posed unreasonably dangerous risks, caused serious side effects of which Plaintiffs and their physicians would not be aware, and that were safer and more available methods and products available to physicians and consumers.

255. The above-described actions of the DRUG COMPANY DEFENDANTS were performed and given willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

256. One or more of the aforementioned violations of standards established by statute or regulation were committed with reckless disregard for the safety of the public and of Plaintiffs as a product user.

257. One or more of the aforementioned violations of standards established by statute or regulation were committed willfully and deliberately, and caused substantial financial injury to the consuming public and Plaintiffs.

258. As a direct and proximate result of these wanton and reckless actions and inactions, as set forth above, this court should impose punitive damages on the DRUG COMPANY DEFENDANTS.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

259. The running of any statute of limitation has been tolled by reason of the fraudulent conduct of the DRUG COMPANY DEFENDANTS, through affirmative misrepresentations and omissions, actively concealing from Plaintiffs and Plaintiffs' prescribing physicians the true risks associated with taking Reglan and/or generic metoclopramide.

260. As a result of these fraudulent actions; Plaintiffs and Plaintiffs' prescribing physicians were unaware, and could not reasonably have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of wrongful acts and omissions of the DRUG COMPANY DEFENDANTS.

**WHEREFORE**, Plaintiffs request trial by jury and that the Court grant them the following relief against DRUG COMPANY DEFENDANTS, jointly and severally, on all counts of this Complaint, including:

- (A) Money Damages representing fair, just and reasonable compensation for their respective common law and statutory claims;
- (B) Punitive and/or Treble Damages pursuant to state law;
- (C) Disgorgement of profits and restitution of all costs;
- (D) Attorneys' fees pursuant to state law;
- (E) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;
- (F) Costs of suit; and

(G) Such other relief as is deemed just and appropriate.

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