GILLIGAN & PEPPELMAN
BY: Raymond J. Peppelman, Jr., Esquire
Attorney I.D. No.: 17484
606 E. Baltimore Pike
Media, Pa 19063
610-566-7777
610-566-0808 (facsimile)
ray@gandplaw.us

IN RE:	: COURT OF COMMON PLEAS
REGLAN/METOCLOPRAMIDE	: PHILADELPHIA COUNTY
LITIGATION	: JANUARY TERM, 2010
	NO 01997

This Document Relates to all Cases

COURT OF COMMON PLEAS PHILADELPHIA CIVIL DIVISION

CIVIL ACTION

PLAINTIFF'S FIRST AMENDED MASTER LONG FORM COMPLAINT

In Re: Reglan Litigation-CMAMD
10010199700014

IN RE	:	**COURT OF COMMON PLEAS**
	:	**PHILADELPHIA COUNTY**
REGLAN®/METOCLOPRAMIDE LITIGATION	:	
	:	**JANUARY TERM, 2010**
This Document Relates to All Cases	:	**NO. 01997**

COURT OF COMMON PLEAS PHILADELPHIA CIVIL DIVISION

PLAINTIFFS,

Plaintiff,

vs.

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

Pfizer, Inc.
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, SUITE 320
HARRISBURG, PA 17101

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

Schwarz Pharma AG

JANUARY TERM, 2010

Case No. 01997

DEMAND FOR A JURY TRIAL

[1] Wockhardt USA acquired Morton Grove Pharmaceuticals, Inc. in October 2007.

[2] 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 Reference Listed drug means the listed drug identified by 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.

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

UCB GmbH d/b/a Schwarz Pharma AG
Agent for Service of Process (Central Authority):
Service Public Fédéral de la Justice
Service d'entraide internationale en matière civile
Boulevard de Waterloo, 115
1000 BRUXELLES
Belgique

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

Baxter Healthcare Corporation
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, SUITE 320
HARRISBURG, PA 17101

Wockhardt USA[1]
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.[2]
Robert E. O'Malley, Esquire
SEGAL, MCCAMBRIDGE, SINGER &
MAHONEY, LTD.
233 S. Wacker Drive
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.
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.
John Mullen, Esquire
NELSON LEVINE DE LUCA & HORST, LLC
518 Township Line Road, Suite 300
Blue Bell, PA 19422

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.
Geoffrey Coan, Esquire
Kathleen Kelly, Esquire
WILSON ELSER
260 Franklin Street, 14th Floor
Boston, MA 02110

Mutual Pharmaceutical Company, Inc.
Geoffrey Coan, Esquire
Kathleen Kelly, Esquire
WILSON ELSER
260 Franklin Street, 14th Floor
Boston, MA 02110

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.
Michael Plata, 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.
Michael Plata, Esq.
Joseph Lagrotteria, Esq.
LeClairRyan
One Riverfront Plaza
1037 Raymond Boulevard, Sixteenth Floor
Newark, New Jersey 07102

Actavis Elizabeth LLC, Individually and d/b/a 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
Skuggasundi
150 Reykjavik
Iceland

APP Pharmaceuticals, LLC, Individually and d/b/a Abraxis Pharmaceuticals
Corporation Service Company
2704 Commerce Drive, Ste B
Harrisburg, PA 17110-9380

Amneal Pharmaceuticals, LLC
85 Adams Ave.
Hauppauge, NY 11788

Bedford Laboratories
300 Northfield Road
Bedford, OH 44146 U.S.A.

Hospira Inc.
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, 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

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

Norbrook Inc. USA
9733 Loiret Boulevard
Lenexa, Kansas 66219

Smith & Nephew Inc.
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, SUITE 320
HARRISBURG, PA 17101

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

Roxane Laboratories, Inc.
1809 Wilson Rd.
Columbus, OH 43228-9579

USL Pharma, Inc.
6701 Evenstad Dr. N.
Maple Grove, MN 55369-6026

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

Halsey Drug, LLC, Individually and d/b/a Halsey Drug Co., Inc.
345 Deerfield Road
Boone NC 28607

SuperPharm, Inc.
16 Royce Rd. #10
Allston, MA 02134-4116

Paco Pharmaceutical Services, Inc.
1200 Paco Way
Lakewood, NJ 08701-5938

Vintage Pharmaceuticals LLC
John Mullen, Esquire
NELSON LEVINE DE LUCA & HORST, LLC
518 Township Line Road, Suite 300
Blue Bell, PA 19422

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

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

Wax Pharmaceuticals, Inc.
4400 Biscayne Boulevard
Miami, FL 33137

John Doe Defendants

NOTICE TO PLEAD

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that is you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaints or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

Philadelphia Bar Association
Lawyer Referral and Information
One Reading Center
Philadelphia, Pennsylvania
(215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las páginas siguientes, usetd tiene veinte (20) dias de plaza al partif de la fecha de la demanda y la notificación. Hace falta asentar una comparesencia escrita o en persona or con un abogado y entregar a la corte en forma escrite sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin pervio aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELÈFONO A LA OFICINA CUYA DIRECCIÓN SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

Asociación De Licenciados De Filadelfia
Servicio De Deferencia E Información legal
One Reading Center
Filadelfia, Pennsylvania 19107
(215) 238-1701

IN RE : **COURT OF COMMON PLEAS**

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

COURT OF COMMON PLEAS PHILADELPHIA CIVIL DIVISION

PLAINTIFFS,

Plaintiff,

vs.

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

Pfizer, Inc.
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, SUITE 320
HARRISBURG, PA 17101

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

JANUARY TERM, 2010

Case No. 01997

FIRST 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 IMPLIED WARRANTIES**
8. **UNFAIR AND DECEPTIVE TRADE PRACTICES**
9. **UNJUST ENRICHMENT**
10. **NEGLIGENT MISREPRESENTATION**
11. **CIVIL CONSPIRACY**
12. **LOSS OF CONSORTIUM**
13. **WRONGFUL DEATH**
14. **SURVIVAL ACTION**

---

[3] Wockhardt USA acquired Morton Grove Pharmaceuticals, Inc. in October 2007.

[4] 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 Reference Listed drug means the listed drug identified by 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.

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

UCB GmbH d/b/a Schwarz Pharma AG
Agent for Service of Process (Central Authority):
Service Public Fédéral de la Justice
Service d'entraide internationale en matière civile
Boulevard de Waterloo, 115
1000 BRUXELLES
Belgique

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

Baxter Healthcare Corporation
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, SUITE 320
HARRISBURG, PA 17101

Wockhardt USA[3]
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.[4]
Robert E. O'Malley, Esquire
SEGAL, MCCAMBRIDGE, SINGER & MAHONEY, LTD.
233 S. Wacker Drive
Sears Tower - Suite 5500

15. GROSS NEGLIGENCE/MALICE
16. PUNITIVE DAMAGES

DEMAND FOR A JURY TRIAL

Chicago, IL 60606

GENERIC DEFENDANTS:

Teva Pharmaceuticals USA, Inc.
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.
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.
John Mullen, Esquire
NELSON LEVINE DE LUCA & HORST, LLC
518 Township Line Road, Suite 300
Blue Bell, PA 19422

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.
Geoffrey Coan, Esquire
Kathleen Kelly, Esquire

WILSON ELSER
260 Franklin Street, 14th Floor
Boston, MA 02110

Mutual Pharmaceutical Company, Inc.
Geoffrey Coan, Esquire
Kathleen Kelly, Esquire
WILSON ELSER
260 Franklin Street, 14th Floor
Boston, MA 02110

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.
Michael Plata, 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.
Michael Plata, Esq.
Joseph Lagrotteria, Esq.
LeClairRyan
One Riverfront Plaza
1037 Raymond Boulevard, Sixteenth Floor
Newark, New Jersey 07102

Actavis Elizabeth LLC, Individually and d/b/a 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
Skuggasundi
150 Reykjavik
Iceland

APP Pharmaceuticals, LLC, Individually and d/b/a Abraxis Pharmaceuticals
Corporation Service Company
2704 Commerce Drive, Ste B
Harrisburg, PA 17110-9380
Amneal Pharmaceuticals, LLC
85 Adams Ave.
Hauppauge, NY 11788
Bedford Laboratories
300 Northfield Road
Bedford, OH 44146 U.S.A.

Hospira Inc.
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, 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

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

Norbrook Inc. USA
9733 Loiret Boulevard
Lenexa, Kansas 66219

Smith & Nephew Inc.
Agent for Service of Process:
CT CORPORATION
116 PINE STREET, SUITE 320
HARRISBURG, PA 17101

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

Roxane Laboratories, Inc.
1809 Wilson Rd.
Columbus, OH 43228-9579

USL Pharma, Inc.
6701 Evenstad Dr. N.
Maple Grove, MN 55369-6026

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

Halsey Drug, LLC, Individually and d/b/a Halsey Drug Co., Inc.
345 Deerfield Road
Boone NC 28607

SuperPharm, Inc.
16 Royce Rd. #10
Allston, MA 02134-4116

Paco Pharmaceutical Services, Inc.
1200 Paco Way
Lakewood, NJ 08701-5938

Vintage Pharmaceuticals LLC
John Mullen, Esquire
NELSON LEVINE DE LUCA & HORST, LLC
518 Township Line Road, Suite 300
Blue Bell, PA 19422

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

John Doe Defendants

Defendants.

PLAINTIFFS' FIRST AMENDED MASTER LONG FORM COMPLAINT

1. Plaintiffs, by the undersigned counsel, hereby submit this 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 First Amended Master 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 First Amended Master Complaint does not necessarily include all claims asserted in all of the actions that have been transferred to this Court, nor is it intended to consolidate for any 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 First Amended Master Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor by it 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 First Amended Master Long Form Complaint will necessarily be held by, nor asserted by, all Plaintiffs, and not all claims in this First 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 manufacture,

distribution, marketing, 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 manufacture, distribution, marketing, 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 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.

7. 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 manufacture, distribution, marketing, sale, and labeling 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.

8. 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, Plaintiffs allege, on information and belief, that Defendant Schwarz Pharma AG was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan® detailed below and 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.

9. Defendant UCB GmbH is a foreign corporation with its principal place of business in Belgium. Defendant UCB GmbH owns 99% of Defendant Schwarz Pharma AG and therefore is liable for any and all tort liabilities of Defendants Schwarz Pharma, Inc. and Schwarz Pharma AG. In addition, Plaintiffs allege, on information and belief, that Defendant UCB GmbH was involved in the manufacture, distribution, marketing, sale, and labeling of Reglan® detailed below and regularly conducts business in Philadelphia County, Pennsylvania. Defendant may be served with process via The Hague Convention by serving Belgium's Central Authority at: Service d'entraide internationale en matière civile, Boulevard de Waterloo, 115, 1000 BRUXELLES, Belgique.

10. 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 manufacture, distribution, marketing, sale, and labeling of Reglan®. 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.

11. 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 manufacture, distribution, marketing, sale, and labeling of Reglan® detailed below. 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.

12. 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 acquired Defendant Morton Grove Pharmaceuticals, Inc. in October 2007. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by registered mail, return receipt requested, upon: Robert E. O'Malley, Esquire, SEGAL, MCCAMBRIDGE, SINGER & MAHONEY, LTD., 233 S. Wacker Drive, Sears Tower - Suite 5500, Chicago, IL 60606.

13. 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 manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. In addition, Defendant was assigned by the United States Food and Drug Administration as the Reference Listed Drug holder of Reglan® syrup. 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.

14. Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc., Pfizer, Inc., Schwarz Pharma, Inc., Schwarz Pharma AG, UCB GmbH, Alaven Pharmaceutical LLC, Baxter Healthcare Corporation, Wockhardt USA, and Morton Grove Pharmaceuticals, Inc. are hereinafter named BRAND NAME DEFENDANTS.

15. 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 manufacture, distribution, marketing, 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.

16. 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, Plaintiffs allege, on information and belief, that Defendant Teva Pharmaceutical Industries, Ltd. was involved in the manufacture, distribution, marketing, sale, and labeling of metoclopramide® detailed below. And 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

17. Defendant 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 LLC as a result of Barr's acquisition of Pliva in 2006. Because Barr Pharmaceuticals LLCwas 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 manufacture, distribution, marketing, 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.

18. 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, Plaintiffs allege, on information and belief, that Defendant PLIVA d.d. was involved in the manufacture, distribution, marketing, sale, and labeling of metoclopramide® detailed below and 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.

19. Defendant Barr Pharmaceuticals, LLC f/k/a Barr Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in New Jersey. Defendant Barr Pharmaceuticals LLC was acquired by Defendant Teva Pharmaceuticals USA, Inc. on December 23, 2008 and is therefore a wholly owned subsidiary of Defendant Teva Pharmaceuticals USA, Inc. Defendant Barr Pharmaceuticals LLC was involved in the manufacture, distribution, marketing, sale, and labeling 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.

20. 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 manufacture, distribution, marketing, sale, and labeling 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 Duramed Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Ohio. Defendant Barr Pharmaceuticals, LLC f/k/a Barr Pharmaceuticals, Inc. is the parent company for Defendant Duramed Pharmaceuticals, Inc. Defendant Duramed Pharmaceuticals, Inc. was involved in the manufacture, distribution,

marketing, sale, and labeling 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 Qualitest 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 manufacture, distribution, marketing, 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: John Mullen, Esquire, NELSON LEVINE DE LUCA & HORST, LLC, 518 Township Line Road, Suite 300, Blue Bell, PA 19422.

23. Defendant Vintage Pharmaceuticals, LLC 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 manufacture, distribution, marketing, 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: John Mullen, Esquire, NELSON LEVINE DE LUCA & HORST, LLC, 518 Township Line Road, Suite 300, Blue Bell, PA 19422.

24. Defendant The Harvard Drug Group LLC, Individually and d/b/a Major Pharmaceuticals, Inc., 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 manufacture, distribution, marketing, 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.

25. 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 manufacture, distribution, marketing, 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.

26. 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 manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant is the parent company of Defendant Pharmaceutical Associates, Inc. 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.

27. Defendant United Research Laboratories, 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 manufacture, distribution, marketing, 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: Geoffrey Coan, Esquire, Kathleen Kelly, Esquire, WILSON ELSER, 260 Franklin Street, 14th Floor, Boston, MA 02110.

28. 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 manufacture, distribution, marketing, 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: Geoffrey Coan, Esquire, Kathleen Kelly, Esquire, WILSON ELSER, 260 Franklin Street, 14th Floor, Boston, MA 02110.

29. 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 manufacture, distribution, marketing, 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

30. 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 manufacture, distribution, marketing, 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.

31. 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 manufacture, distribution, marketing, 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.

32. 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 manufacture, distribution, marketing, 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: Michael Plata, Esq., Joseph Lagrotteria, Esq., LeClairRyan, One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, New Jersey 07102.

33. 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 manufacture, distribution, marketing, 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: Michael Plata, Esq., Joseph Lagrotteria, Esq., LeClairRyan, One Riverfront Plaza, 1037 Raymond Boulevard, Sixteenth Floor, Newark, New Jersey 07102.

34. Defendant Actavis Elizabeth LLC, Individually, and d/b/a 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

manufacture, distribution, marketing, 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.

35. Defendant Actavis Group hf is a foreign corporation with its principal place of business in Iceland. Defendant Actavis Group hf is the parent company of Defendant Actavis Elizabeth LLC, Individually, and d/b/a Purepac Pharmaceuticals and therefore liable for any and all tort liabilities of Defendant Actavis Elizabeth LLC, Individually, and d/b/a Purepac Pharmaceuticals. In addition, Plaintiffs allege, on information and belief, that Defendant Actavis Group hf was involved in the manufacture, distribution, marketing, sale, and labeling of metoclopramide detailed below and 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, Skuggasundi, 150 Reykjavik, Iceland.

36. 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 manufacture, distribution, marketing, 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.

37. Defendant Amneal Pharmaceuticals, LLC 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 manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 85 Adams Ave., Hauppauge, NY 11788.

38. Defendant Bedford Laboratories is a New York corporation with a principal place of business in Ohio. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the manufacture, distribution, marketing, 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

39. 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 manufacture, distribution, marketing, 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.

40. 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 manufacture, distribution, marketing, 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.

41. 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 manufacture, distribution, marketing, 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.

42. 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 manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process at: 4971 Southridge Blvd., Suite 101, Memphis, TN 38141.

43. 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 manufacture, distribution, marketing, 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 Smith & Nephew, Inc. 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 manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its registered agent for service: CT Corporation, 116 Pine St., Suite 320, Harrisburg, PA 17101.

45. 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 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.

46. Defendant Roxane Laboratories, Inc. is a Nevada corporation with a principal place of business in Ohio. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the 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.

47. Defendant USL Pharma, Inc. is a Minnesota corporation with a principal place of business in Minnesota. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 6701 EVENSTAD DR N, MAPLE GROVE, MN 55369-6026.

48. 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 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.

49. Defendant Halsey Drug, LLC, Individually and d/b/a Halsey Drug Co., Inc. is a North

Carolina corporation with a principal place of business in North Carolina. Defendant regularly conducts business in Philadelphia County, Pennsylvania. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 345 Deerfield Road, Boone, NC 28607.

50. Defendant SuperPharm Corporation 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 manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 155 OVAL DRIVE, CENTRAL ISLIP, NY 11722.

51. Defendant Paco 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 manufacture, distribution, marketing, sale, labeling, and design of metoclopramide detailed below. Defendant may be served with process by and through its principal office: 1200 Paco Way, Lakewood, NJ 08701-5938.

52. 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 manufacture, distribution, marketing, 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.

53. 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 manufacture, distribution, marketing, 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.

54. 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 manufacture, distribution, marketing, 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.

55. Defendant 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 manufacture, distribution, marketing, 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.

56. Defendant John Doe Defendants are defendants involved in the manufacture, distribution, marketing, 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.

57. Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., PLIVA, Inc., PLIVA d.d., Barr Pharmaceuticals LLC, Barr Laboratories, Inc., Duramed Pharmaceuticals, Inc., Qualitest Pharmaceuticals, Inc., Vintage Pharmaceuticals, LLC, Defendant The Harvard Drug Group LLC, Pharmaceutical Associates, Inc., Beach Products, Inc., United Research Laboratories, Inc., Mutual Pharmaceutical Company, Inc., Silarx

Pharmaceuticals, Inc., Sandoz, Inc., ANIP Acquisition Company, Watson Laboratories, Inc., Rugby Pharmaceuticals, Inc., Actavis Elizabeth LLC, Actavis Group hf, APP Pharmaceuticals, LLC, Amneal Pharmaceuticals, LLC, Bedford Laboratories, Hospira, Inc., Ipca Pharmaceuticals Inc., McKesson Corporation, Northstar Rx, LLC, Rugby Laboratories, Inc., VistaPharm, Inc., Roxane Laboratories, Inc., USL Pharma, Inc., Par Pharmaceutical Inc., Halsey Drug, LLC, SuperPharm Corporation, Paco Pharmaceutical Services, Inc., Norbrook Inc. USA, Schering Corporation, Ranbaxy Pharmaceuticals, Inc. IVAX Pharmaceuticals, Inc. are hereinafter named GENERIC DEFENDANTS.

58. 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

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

60. At all times relevant hereto, BRAND NAME DEFENDANTS and GENERIC 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.

61. At all times relevant hereto, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had offices in Pennsylvania and/or regularly solicited and transacted business[5] in the State of Pennsylvania and the County of Philadelphia. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS carried on a continuous and systematic part of their business in Pennsylvania and Philadelphia County. In addition, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS reasonably expected that their product, Reglan® or metoclopramide, would be used or consumed in Pennsylvania and Philadelphia County.

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

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

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

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

66. 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).

---

[5] 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.

III. Venue

67. 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 Defendant Barr Pharmaceuticals LLC, 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 agree 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"[6] and "the most convenient of all forums as the overwhelming majority of defendants have their principal place of business in Pennsylvania."[7]

68. In addition, Philadelphia County Court of Common Pleas is the only county with the ability to handle, litigate, and resolve the hundreds, if not thousands, of associated cases to be filed in the near future. 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.

---

[6] 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.

[7] 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.

69. 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

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

A. Reglan®/Metoclopramide Background

71. Reglan®/metoclopramide is a prescription medication classified as a gastrointestinal stimulant, antiemetic and dopamine antagonist. The drug can come in the form of a tablet (5mg/10mg), an injection, or syrup.

72. Reglan®/metoclopramide affects the brain and thereby affects the voluntary movements of a user. The effect typically causes involuntary, repetitive movements, also known as extrapyramidal symptoms (EPS). The term tardive dyskinesia refers to any abnormal, involuntary movement resulting from exposure to at least one dopamine receptor blocking drug, such as Reglan®/metoclopramide, and persisting even after the drug is discontinued.

73. Various subtypes of tardive dyskinesia exist, including, but not limited to, 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.

74. Tardive dyskinesia is a serious neurological movement disorder 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 and/or other involuntary movements.

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

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

77. The link between neuroleptic drugs, such as Reglan®/metoclopramide, and involuntary movements has been known from as far back as 1973.[8] 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.

78. Reglan®/metoclopramide is indicated for adult short-term therapy of symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

79. Reglan®/metoclopramide is indicated for treatment use of no greater than twelve (12) weeks in adults; however, the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS represented that Reglan®/metoclopramide was safe for adult use to treat nausea and/or esophageal reflux for durations that exceeded twelve (12) weeks.

80. At no point in time has Reglan®/metoclopramide been deemed efficacious when used for long term treatment.

81. As BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew, adult patients who used Reglan®/metoclopramide for a longer period of time were at a significant and unreasonably dangerous increased risk of developing a severe and permanent neurological movement disorder.

B. Reglan®/Metoclopramide Ownership Background

[8] Crane GE (September 1973). "Is tardive dyskinesia a drug effect?". *Am J Psychiatry* **130** (9): 1043–4.

82. A.H. Robins Company, Inc. gained approval for Reglan® injectable through the United States Food & Drug Administration ("FDA") on or about February 7, 1979.

83. A.H. Robins Company, Inc. gained approval for Reglan® tablets through the United States Food & Drug Administration ("FDA") on or about December 30, 1980.

84. A.H. Robins Company, Inc. gained approval for Reglan® syrup through the United States Food & Drug Administration ("FDA") on or about March 25, 1983.

85. In 1989, Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc. acquired A.H. Robins Company, Inc. and thereby became the successor-in-interest responsible for all tort liabilities of A.H. Robins Company, Inc.

86. Defendant Pfizer, Inc. has since acquired Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc. and thereby became the successor-in-interest responsible for all tort liabilities of Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc.

87. On or around December 27, 2001, Defendant Schwarz Pharma, Inc. purchased from Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc., formerly known as American Home Products Corporation, the rights and liabilities associated with Reglan® tablets. Defendant Schwarz Pharma, Inc. became entitled to access to all of the information and knowledge then possessed by Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc., formerly known as American Home Products Corporation, concerning Reglan®, metoclopramide HCl and/or metoclopramide, as more particularly alleged above.

88. Subsequently, Defendant Alaven Pharmaceuticals, LLC purchased from Defendant Schwarz Pharma, Inc. the rights and liabilities associated with Reglan®.

89. Defendants Wyeth LLC and Wyeth Pharmaceuticals, Inc., formerly known as American Home Products Corporation, sold the rights and liabilities associated with Reglan® injectable to Baxter Healthcare Corporation on or about December 21, 2002.

90. Defendants Morton Grove Pharmaceuticals, Inc. and Wockhardt USA are currently the Referenced Listed Drug holders for Reglan® syrup.

91. At the time of possession of the rights and liabilities of Reglan®, each Defendant possessed the reference listed drug to which the generic version, metoclopramide, was compared to in order to show bioequivalence.

C. Misrepresentations

92. Under the FDA schema, A.H. Robins Company, Inc., by and through Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc., and Pfizer, Inc., knew, as a New Drug Application (NDA) applicant, that it must fully, truthfully and accurately disclose to the FDA data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling which includes warnings about risks and side effects, test results for the drug, results of animal studies, results of clinical studies and the drug's bioavailability, because the data and information would be relied upon by the medical community, physicians, Plaintiffs' physicians, Plaintiffs and other like foreseeable prescribers and users of Reglan®, metoclopramide and metoclopramide HCl once the NDA was approved.

93. Under the FDA schema, as the Referenced Listed Drug Company for Reglan®, metoclopramide, and metoclopramide HCl, A.H. Robins Company, Inc., by and through Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc., and Pfizer, Inc., as well as Baxter Healthcare Corp., Wockhardt USA, and Morton Grove Pharmaceuticals, Inc. had a duty to ensure its warnings to the medical community are, and remain, accurate and adequate, to conduct

safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug. These same duties were later owed by Defendants Schwarz Pharma and Alaven Pharmaceutical when they became the owners and holders of the Reference Listed Drug, Reglan®.

94. Reglan®, metoclopramide HCl and/or metoclopramide was not approved by the United States Food and Drug Administration for long-term use or pediatric use.

95. All BRAND NAME DEFENDANTS failed to fully, truthfully and accurately disclose Reglan®, metoclopramide and metoclopramide HCl data to the FDA, and as a result intentionally and fraudulently misled the medical community, physicians, Plaintiffs' physicians and Plaintiffs about the risks associated with long term, pediatric, and/or short term use of metoclopramide.

96. All BRAND NAME DEFENDANTS then knowingly, intentionally and negligently disseminated misleading information to physicians' across the country, through a publication known as the *Physicians' Desk Reference*, labeling information for Reglan®, metoclopramide and metoclopramide HCl which mislead the medical community, physicians and Plaintiffs' physicians about the risks of EPS in long term, pediatric use, and/or short term ingestion of the drug. In 2002, the Reference Listed Drug holders even stopped publishing the label information for Reglan® in the *Physicians' Desk Reference*. In fact, changes made to the label in 2004 by Defendant Schwarz Pharma were never even published and therefore physicians and patients did not even know about the changed warnings.

97. At all times material hereto, BRAND NAME 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®, metoclopramide HCl and/or metoclopramide and that

consequently there was a widespread tendency for physicians to prescribe Reglan®, metoclopramide HCl and/or metoclopramide for inappropriate long-term, pediatric, and/or short term use. Published studies confirmed these various forms of misuse by evaluating prescription data. Therefore, Drug Company Defendants knew or should have known that the package insert and the *Physician's Desk Reference* monograph for Reglan®, metoclopramide HCl and/or metoclopramide did not adequately inform physicians about the risks associated with Reglan®, metoclopramide HCl and/or metoclopramide, particularly for patients whose bodies do not metabolize Reglan® and/or metoclopramide effectively.

98. BRAND NAME DEFENDANTS had access to this information and knew that severe side effects would result from the long term, pediatric, and even short term use of Reglan®, metoclopramide HCl and/or metoclopramide in the manner in which physicians were prescribing Reglan®, metoclopramide HCl and/or metoclopramide and the fact that physicians did not fully understand the risks associated with Reglan®, metoclopramide HCl and/or metoclopramide through the defendants' participation, individually and jointly, in or its ability to review published studies and data from clinical studies that were not publicly available, through its review of domestic and international medical literature concerning Reglan®, metoclopramide HCl and/or metoclopramide and through ongoing litigation.

99. BRAND NAME DEFENDANTS failed to adequately warn physicians about the risks associated with Reglan®, metoclopramide HCl and/or metoclopramide despite the fact that BRAND NAME DEFENDANTS knew that physicians, the medical community, the generic pharmaceutical industry, Plaintiffs, and other similarly situated relied on BRAND NAME DEFENDANTS to disclose what it knew and what it should have known from a prudent review of the information that it possessed or to which it had access.

100. Because of the misleading information that the BRAND NAME DEFENDANTS provided to physicians and the FDA about the true risks associated with the use of Reglan®, metoclopramide HCl and/or metoclopramide and because of the failure of the BRAND NAME DEFENDANTS to adequately inform physicians generally, including Plaintiffs' physicians, about the true risks associated with the use of Reglan®, metoclopramide HCl and/or metoclopramide, at all times relevant to this lawsuit, while Plaintiffs were taking Reglan®, metoclopramide HCl, and/or metoclopramide, Plaintiffs' physicians never informed them of any side effects associated with Reglan®, metoclopramide HCl, metoclopramide.

D. Knowledge

101. BRAND NAME DEFENDANTS knew, or should have known through the exercise of reasonable care, that the package insert for Reglan®, metoclopramide HCl and/or metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan®, metoclopramide HCl and/or metoclopramide. BRAND NAME DEFENDANTS failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of long term, pediatric, and/or short term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

102. BRAND NAME DEFENDANTS had actual knowledge, through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan®, metoclopramide HCl and metoclopramide for long term, pediatric, and/or short term use that was not safe for patients.[9] BRAND NAME DEFENDANTS had actual knowledge, through their

[9] *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, regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan®, metoclopramide HCl and/or metoclopramide received it on doctor's prescriptions for 12 months or longer, rather than 12 weeks or less.[10] BRAND NAME DEFENDANTS also had actual knowledge, through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects of Reglan®, metoclopramide HCl and/or metoclopramide in patients who receive the drug for long term use is approximately 100 times greater than disclosed in BRAND NAME DEFENDANTS' package insert for Reglan® and the *Physician's Desk Reference* monograph for Reglan® brand metoclopramide.[11] BRAND NAME DEFENDANTS also knew, or through the exercise of reasonable care should have known, that many patients who use Reglan®, metoclopramide HCl and/or metoclopramide are not able to effectively metabolize Reglan®, metoclopramide HCl and/or metoclopramide and that as a foreseeable consequence of their inability to effectively metabolize Reglan®, metoclopramide HCl and/or metoclopramide, those patients have a greater risk of developing serious and permanent injuries.

103. BRAND NAME DEFENDANTS failed to disclose this information to the medical community and failed to adequately disclose this information to the generic pharmaceutical industry. BRAND NAME DEFENDANTS were aware that its failure to disclose this information to the medical community and its failure to disclose it to the generic

---

[10] Kaplan S, Staffa JA, Dal Pan GJ. Duration of therapy with metoclopramide: a prescription claims data study. Pharmacoepi Drug Saf 2007; 16: 878-881.

[11] 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, Kodsi A, Caligiuri M, Jeste DV: Metoclopramide and Tardive Dyskinesia. Biological Psychiatry 36:630-632, 1994.

pharmaceutical industry would probably result in serious injury to patients who were prescribed Reglan®, metoclopramide HCl and/or metoclopramide by a physician who was not aware of this information. By failing to disclose this information to the medical community and the generic pharmaceutical industry, BRAND NAME 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.

104. Under the FDA schema, as the Referenced Listed Drug Company for Reglan®, metoclopramide and metoclopramide HCl, BRAND NAME DEFENDANTS have a duty to ensure its warnings to the medical community are accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

105. BRAND NAME DEFENDANTS breached their duty to the medical community, Plaintiffs' physicians, Plaintiffs and other foreseeable users similarly situated, in that they failed to:

a) ensure Reglan®, metoclopramide and metoclopramide HCl warnings to the medical community, generic pharmaceutical industry, physicians, Plaintiffs' physician and Plaintiffs were accurate and adequate despite having extensive knowledge of the risks associated with the drug.

b) conduct post market safety surveillance and report that information to the medical community, Plaintiffs' physicians, Plaintiffs and other like foreseeable users.

c) review all adverse drug event information (ADE),[12] and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan®, metoclopramide or metoclopramide HCl, to the medical community, Plaintiffs' physician, Plaintiffs and other like foreseeable users.

---

[3] *See* 21 C.F.R. § 317.80(b).

d) periodically review all medical literature regarding Reglan®, metoclopramide, and metoclopramide HCl, and failed to report data, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan®, metoclopramide and metoclopramide HCl.

e) independently monitor their sales of Reglan® and the medical literature, which would have alerted them to the fact that Reglan®, metoclopramide HCl and/or metoclopramide was widely over prescribed as a result of inadequate warnings in the package inserts and PDR monographs for Reglan® brand and generic metoclopramide.

E. Generic Defendants

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

107. Since 1985, GENERIC DEFENDANTS have manufactured, sold, distributed, marketed, and labeled metoclopramide.

108. Under the ANDA process, the Code of Federal Regulations *required* GENERIC DEFENDANTS to submit a label for metoclopramide and metoclopramide HCl, initially identical in all material aspects to the Reference Listed Drug, Reglan®, label.

109. Each of the GENERIC DEFENDANTS submitted an Abbreviated New Drug Application (hereinafter "ANDA") to the U.S. Food and Drug Administration, based on representations made BRAND NAME DEFENDANTS (as the Reference Listed Drug Company), requesting permission to manufacture, market, and distribute metoclopramide and/or metoclopramide HCl.

110. Under the Code of Federal Regulations, GENERIC DEFENDANTS, as ANDA holders, had a duty to ensure its Reglan®, metoclopramide, and metoclopramide HCl warnings to the medical community were and remain accurate and adequate, to conduct post market safety

surveillance, to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan®, metoclopramide or metoclopramide HCl, to the medical community, Plaintiffs' physicians, Plaintiffs and other foreseeable users.

111. Under the Code of Federal Regulations, if GENERIC DEFENDANTS, as ANDA holders, discover information in the course of the fulfillment of its duties as outlined above, GENERIC DEFENDANTS must report that information to the medical community, Plaintiffs' physician, Plaintiffs and other foreseeable users of Reglan®, metoclopramide and metoclopramide HCl to ensure that its warnings are continually accurate and adequate.

112. GENERIC DEFENDANTS breached their duty to the medical community, Plaintiffs' physicians, Plaintiffs, and other foreseeable users similarly situated because they failed to:

a) ensure Reglan®, metoclopramide, and/or metoclopramide HCl warnings to the medical community, Plaintiff's physician, Plaintiff, other foreseeable users similarly situated were accurate and adequate despite having extensive knowledge of the risks associated with the drug as stated above.

b) conduct post market safety surveillance of Reglan®, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan®, metoclopramide, and/or metoclopramide HCl.

c) review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan®, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

d) periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding

the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan®, metoclopramide, and/or metoclopramide HCl.

e) independently monitor their sales of metoclopramide and the medical literature, which would have alerted them to the fact that Reglan®, metoclopramide HCl and/or metoclopramide was widely over prescribed as a result of inadequate warnings in the package inserts and PDR monographs for Reglan® brand and generic metoclopramide.

F. FDA Black Box Warning

113. 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, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS never approached the FDA to alter the label for Reglan®, metoclopramide HCl, and/or metoclopramide so that it properly and adequately warned of the associated risks.

114. It was the FDA, *sua sponte*, that ordered a warning that informed physicians and Plaintiffs of the dangers of Reglan®, metoclopramide HCl, and metoclopramide. On February 26, 2009, the FDA ordered a black box warning, the FDA's strongest warning, to be placed on Reglan®, metoclopramide HCl, and 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.

115. Specifically, the FDA stated that the risk of EPS disorders can be as high as 20% of the population ingesting Reglan®/metoclopramide.[13]

116. The FDA also ordered each Defendant to create a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of the drug outweigh the risks based on the

[13] The FDA made such statements after the review of certain medical studies and investigations from as early as the 1990s. These same studies were made available to BRAND NAME DEFENDANTS and GENERIC DEFENDANTS. Despite this knowledge, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS never approached the FDA to change the label to warn of the risks associated with Reglan®/metoclopramide use.

new safety information. Until new legislation in 2007, the FDA had previously been unable to demand such strategies from the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS.

G. Injuries

117. Plaintiffs' long term, pediatric, and/ short term ingestion of Reglan®, metoclopramide and/or metoclopramide HCl resulted in overexposure to the drugs Reglan®, metoclopramide, and/or metoclopramide HCl 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.

118. Use of Reglan®, metoclopramide HCl and/or metoclopramide 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, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages.

119. Plaintiffs' aggravation of preexisting conditions and serious and permanent injuries, as described above, came about as a foreseeable and proximate result of BRAND NAME DEFENDANTS (as the Reference Listed Drug and or New Drug Applicant holder and GENERIC DEFENDANTS (the abbreviated New Drug Applicant holder) dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Reglan®, metoclopramide, and/or

metoclopramide HCl and the ingestion of Reglan®, metoclopramide, and/or metoclopramide HCl drug to the medical community, physicians, Plaintiffs' physician, Plaintiffs and other foreseeable users of the drug.

120. As a result of the foregoing acts and omissions, Plaintiffs, 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 - FAILURE–TO–WARN

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

122. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS are liable to Plaintiffs under state common law and/or state Product Liability Acts for innocent, negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the appropriate use of Reglan® and/or metoclopramide to Plaintiffs and to the health care providers that prescribed Reglan® and/or metoclopramide to them.

123. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of involuntary movements and other injuries and death associated with the use of Reglan® and/or metoclopramide were inadequate.

124. Plaintiffs did not have the same knowledge as BRAND NAME DEFENDANTS and GENERIC DEFENDANTS and no adequate warning or other clinically relevant information and data was communicated to them or to their physicians.

125. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had a continuing duty to provide consumers, including Plaintiffs, and their physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with Reglan® and/or metoclopramide, as it became or could have become available to BRAND NAME DEFENDANTS and GENERIC DEFENDANTS.

126. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Reglan® and/or metoclopramide, to health care providers empowered to prescribe and dispense Reglan® and/or metoclopramide to consumers, including Plaintiffs, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS misled the medical community about the risk and benefit balance of Reglan® and/or metoclopramide, which resulted in injury to Plaintiffs.

127. Despite the fact that BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known that Reglan® and/or metoclopramide caused unreasonable and dangerous side effects, they continued to promote and market Reglan® and/or metoclopramide without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

128. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known that consumers, Plaintiffs specifically, would foreseeably and needlessly suffer injury as a result of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' failures.

129. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to provide timely and adequate warnings to physicians, distributors, and consumers, including Plaintiffs and to their intermediary physicians, in the following ways:

(1) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to include adequate warnings and/or providing adequate clinically relevant information and data that would alert Plaintiffs and their physicians to the dangerous risks of Reglan® and/or metoclopramide including, among other things, involuntary movements;

(2) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to provide adequate post-marketing warnings and instructions after the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known of the significant risks of, among other things, involuntary movements;

(3) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS continued to aggressively promote Reglan® and/or metoclopramide, even after they knew or should have known of the unreasonable risks of involuntary movement disorders from this drug.

130. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had an obligation to provide Plaintiffs and their physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Reglan® and/or metoclopramide, and/or that there existed safer and more or equally effective alternative drug products.

131. By failing to provide Plaintiffs and their physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Reglan® and/or metoclopramide, and/or that there existed safer and more or equally

effective alternative drug products, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS breached their duty of reasonable care and safety.

132. BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiffs and the public.

133. BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' actions described above violated the federal and state Food, Drug and Cosmetic Acts and rendered Reglan® and/or metoclopramide misbranded.

134. As a direct and proximate result of the actions and inactions of the BRAND NAME DEFENDANTS and GENERIC 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

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

136. BRAND NAME 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 Reglan® and/or metoclopramide.

137. At all times material to these allegations, BRAND NAME DEFENDANTS manufactured, distributed, and sold Reglan® and/or metoclopramide, as alleged in their individual Complaints.

138. BRAND NAME DEFENDANTS, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field.

139. The Reglan® and/or metoclopramide administered to Plaintiffs was defective in design or formulation in the following respects:

(1) When it left the hands of the BRAND NAME DEFENDANTS, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiffs or their physicians;

(2) Any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as the BRAND NAME DEFENDANTS intended;

(3) The dosages and/or formulation of Reglan® and/or metoclopramide sold by the BRAND NAME DEFENDANTS were unreasonably dangerous;

(4) There are no patients for whom the benefits of Reglan® and/or metoclopramide outweighed the risks; and/or

(5) There are no patients for whom Reglan® and/or metoclopramide is a safer and more efficacious drug than other drug products in its class.

140. The Reglan® and/or metoclopramide administered to Plaintiffs were defective at the time it was distributed by the BRAND NAME DEFENDANTS or left their control.

141. The Reglan® and/or metoclopramide administered to Plaintiffs were expected to reach the user without substantial change in the condition in which it was sold.

142. The Reglan® and/or metoclopramide administered to Plaintiffs reached them without substantial change in the condition in which it was sold.

143. Plaintiffs were patients whom the BRAND NAME DEFENDANTS reasonably expected would be administered Reglan® and/or metoclopramide.

144. BRAND NAME DEFENDANTS were entitled to withdraw Reglan® and/or metoclopramide from the market at any time, but failed to do so in a timely and responsible manner.

145. The defects in the Reglan® and/or metoclopramide 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

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

147. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS are liable to Plaintiffs pursuant to state common law and/or state Product Liability Acts due to their negligent development, study, manufacture, distribution and sale of Reglan® and/or metoclopramide.

148. At all times relevant to this lawsuit, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS owed a duty to consumers, like Plaintiffs and their health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Reglan® and/or metoclopramide and to suspend distribution and sale of Reglan® and/or metoclopramide when Defendants discovered it to be unreasonably dangerous.

149. BRAND NAME DEFENDANTS' duties included, but were not limited to, carefully and properly designing, testing, studying, manufacturing, promoting, selling, and/or distributing Reglan® and/or metoclopramide into the stream of commerce, and providing adequate information regarding the appropriate use of this drug product.

150. GENERIC DEFENDANTS' duties included, but were not limited to, carefully and properly studying, manufacturing, promoting, selling, and/or distributing Reglan® and/or metoclopramide into the stream of commerce, and providing adequate information regarding the appropriate use of this drug product.

151. BRAND NAME DEFENDANTS and GENERIC 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:

(1) BRAND NAME DEFENDANTS failed to use ordinary care in designing, testing, labeling, marketing, and manufacturing Reglan® 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 drug products in its class or compared to the use of no drug products;

(2) GENERIC DEFENDANTS failed to use ordinary care in marketing, labeling, and manufacturing metoclopramide 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 drug products in its class or compared to the use of no drug products;

(3) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to accompany Reglan® and/or metoclopramide with adequate information that would alert doctors, consumers, and other users to the potential adverse side effects associated with the use of these drugs and the nature, severity and duration of such adverse effects either compared to the use of alternative drug products in its class or compared to the use of no drug products;

(4) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to conduct adequate post-marketing studies, non-clinical and clinical testing and post-marketing surveillance and analyses to determine and communicate the safety profile and side effects of Reglan® and/or metoclopramide either compared to the use of alternative drug products in its class or compared to the use of no drug products;

(5) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to warn Plaintiffs or their physicians prior to actively encouraging the sale of Reglan® and/or metoclopramide, either directly or indirectly, orally or in writing, about the possibility of involuntary movements, injury and death as a result of the use of this drug, either compared to the use of alternative drug products in its class or compared to the use of no drug products;

(6) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS continued to promote the safety and effectiveness of Reglan® and/or metoclopramide, while downplaying its risks, even after Defendants knew or should have known of the risks of Reglan® and/or metoclopramide, either compared to the use of alternative drug products in its class or compared to the use of no drug products;

(7) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known that the use of Reglan® and/or metoclopramide involved a risk of involuntary movements and/or that Reglan® and/or metoclopramide was unreasonably dangerous either compared to the use of alternative drug products in its class or compared to the use of no drug products, and failed to communicate that information to Plaintiffs and their physicians;

(8) At the time of Plaintiffs' ingestion, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had or should have had scientific data which indicated the true association between the use of Reglan® and/or metoclopramide and the risk of involuntary movements, either compared to the use of alternative drug products in its class or compared to the use of no drug products, and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the FDA-approved product labeling;

(9) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to provide consumers, like Plaintiffs and their health care providers, with scientific data which indicated that Reglan® and/or metoclopramide was unreasonably dangerous either compared to the use of alternative drug products in its class or compared to the use of no drug products, that there were no patients in whom the benefits of Reglan® and/or metoclopramide outweighed the risks, and failed to promptly withdraw Reglan® and/or metoclopramide from the market;

(10) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were otherwise careless or negligent.

152. Although BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known that Reglan® and/or metoclopramide caused unreasonably dangerous side effects, which many users would be unable to remedy by any means, Defendants continued to market this drug when there were safer and less expensive alternatives available.

153. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known that consumers, like Plaintiffs, would suffer injury as a result of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' failure to exercise ordinary care, as described above. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, as manufacturers of drug products, are held to the level of knowledge of an expert in the field.

154. As a direct and proximate cause of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' negligent acts and/or omissions, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints.

COUNT IV - NEGLIGENCE *PER SE*

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

156. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the drug products it sells.

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

158. Plaintiffs, as patients and purchasers exposed to Reglan® and/or metoclopramide, 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.

159. As a direct and proximate cause of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' negligent acts and/or omissions, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints.

COUNT V – FRAUD, MISREPRESNTATION, AND SUPPRESSION

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

161. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS are liable to Plaintiffs under the state common law and/or state Product Liability Acts for innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk/benefit ratio of Reglan® and/or metoclopramide to Plaintiffs and to the health care providers that prescribed, recommended, ordered, and administered Reglan® and/or metoclopramide to them.

162. Through their actions and omissions in advertising, promoting, and otherwise, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS fraudulently, intentionally and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from physicians and consumers like Plaintiffs, concerning the character and safety of Reglan® and/or metoclopramide.

163. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were required to provide consumers, like Plaintiffs and their health care providers, with scientific data which indicated an association between the use of Reglan® and/or metoclopramide and the risk of involuntary movements, aggravation of preexisting injuries, other injuries, and death. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were able and required to compare Reglan® and/or metoclopramide to alternative drug products in its class or to the use of no drug products, and were able to distribute such data to Plaintiffs and their physicians even if that information was not included in the Package Insert. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were required to provide consumers, like Plaintiffs and their health care providers, with bona fide scientific data which indicated that Reglan® and/or metoclopramide was unreasonably dangerous, that there were no patients in whom the benefits of Reglan® and/or metoclopramide outweighed the risks, and could have withdrawn Reglan® and/or metoclopramide from the market at any time.

164. Those public misrepresentations and omissions include, but are not limited to, those set forth in the general allegations section of this Complaint. Those misrepresentations and omissions further include, but are not limited to, the following:

(1) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to disclose that their pre-clinical and clinical testing and post-marketing surveillance were inadequate to determine the safety and side effects of Reglan® and/or metoclopramide, compared to alternative drug products in its class or compared to the use of no drug products;

(2) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to timely disclose, and/or intentionally concealed, data showing that Reglan® and/or metoclopramide use dramatically increased the risk for involuntary movements and other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products;

(3) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to include adequate warnings with Reglan® and/or metoclopramide 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 drug products in its class or compared to the use of no drug products;

(4) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS concealed and continue to conceal past and present facts – including that, as early as the 1980's, Defendants were aware of and concealed their knowledge of an association between the use of Reglan® and/or metoclopramide and dangerous side effects, including involuntary movements – from the consuming public, including Plaintiffs;

165. BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' above-described acts and/or omissions were performed willfully, intentionally, and with reckless disregard for Plaintiffs and the public.

166. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew or should have known that these representations were false and that Plaintiffs and their physicians would rely on them. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were obligated to disclose the foregoing risks, but failed to adequately and timely do so even after they were in possession of information concerning those risks. BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' representations that Reglan® and/or metoclopramide was safe for its intended use, either compared to the use of alternative drug products in its class or compared to the use of no drug products, were false. Reglan® and/or metoclopramide was, in fact, unreasonably dangerous to the health of Plaintiffs, and there were alternative products in the same class of drug products available that were less expensive, equally or more effective, and posed less risks.

167. In the alternative, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS failed to exercise reasonable care in ascertaining the accuracy of the information they provided regarding the safe use of Reglan® and/or metoclopramide and communicating that information to Plaintiffs and their physicians.

168. At the time of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' fraudulent misrepresentations and active concealment, Plaintiffs and their physicians were not aware of the falsity of the foregoing representations, nor were they aware that material facts concerning Reglan® and/or metoclopramide had been concealed or omitted. In reliance upon BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' misrepresentations, Plaintiffs physicians were induced and did prescribe Reglan® and/or metoclopramide to Plaintiffs.

169. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS are obligated to provide consumers like Plaintiffs and their health care providers with scientific information and data regarding the association between exposure to Reglan® and/or metoclopramide and the a risk of involuntary movements, aggravation of preexisting conditions, other injuries, and death and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the Package Insert. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were obligated to provide consumers, like Plaintiffs and their health care providers, with scientific information and data which indicated that Reglan® and/or metoclopramide was unreasonably dangerous, that there were no patients in whom the benefits of Reglan® and/or metoclopramide outweighed the risks.

170. If Plaintiffs and their physicians had known the true facts concerning the risks of the use of Reglan® and/or metoclopramide, in particular the risk of involuntary movements, aggravation of preexisting conditions, other injuries and death, they would not have used Reglan® and/or metoclopramide and would have used one of the alternatives in that class of drug products.

171. The reliance of Plaintiffs and their physicians upon BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Reglan® and/or metoclopramide, while Plaintiffs and their physicians were not in a position to know the true facts. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS overstated the benefits and safety of Reglan® and/or metoclopramide 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, BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' corporate officers, directors and/or managing agents knew or should have known of, and ratified the acts of BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, as alleged herein.

172. BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately or recklessly, in order to induce Plaintiffs to be administered Reglan® and/or metoclopramide. Plaintiffs and their physicians did reasonably and justifiably rely upon the material misrepresentations and omissions made by the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS when agreeing to utilize Reglan® and/or metoclopramide.

173. As a direct and proximate result of the reliance of Plaintiffs and their physicians on BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' misrepresentations and concealment concerning the risks and benefits of Reglan® and/or metoclopramide, Plaintiffs suffered injuries and damages, as set forth in their individuals Complaints.

COUNT VI – CONSTRUCTIVE FRAUD

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

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

176. Through their unique knowledge and expertise regarding the defective nature of Reglan® and/or metoclopramide, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS professed to Plaintiffs' physicians that they were in possession of facts demonstrating that Reglan® and/or metoclopramide was safe and effective for its intended use and was not defective.

177. BRAND NAME DEFENDANTS' and GENERIC 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.

178. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their physicians and engaged in constructive fraud in their relationship.

179. Plaintiffs and their physicians reasonably relied on BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' representations.

180. As a direct and proximate result of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' constructive fraud, Plaintiffs have suffered injuries and damages, as set forth in their individual Complaints.

COUNT VII – BREACH OF IMPLIED WARRANTIES

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

182. Reglan® and/or metoclopramide was designed, tested, manufactured, distributed, promoted and sold by the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS; and was expected to, and did, reach Plaintiffs without a substantial change in its condition.

183. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, through advertising and promotional materials and the statements of sales representatives and paid endorsers, impliedly warranted that Reglan® and/or metoclopramide was safe for the use for which it was intended.

184. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS breached said implied warranties in that Reglan® and/or metoclopramide was unsafe in light of the risk of dangerous side effects associated with its use, including, but not limited to, involuntary movements, aggravation of preexisting conditions, other injuries, and death.

185. Plaintiffs and their physicians relied to their detriment on BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' implied warranties.

186. As a direct and proximate result of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' breach of implied warranties, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints.

COUNT VIII - UNFAIR AND DECEPTIVE TRADE PRACTICES

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

188. Under state laws, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the drug products.

189. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS financed, assisted, supported and participated in the promotion and use of Reglan® and/or metoclopramide in order to create consumer demand for the drug.

190. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS deliberately misrepresented the safety of Reglan® and/or metoclopramide and intentionally concealed the risks attendant to use of the drug. Through their misrepresentations, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS intentionally affected the decisions of consumers and their health care providers to purchase, prescribe and use Reglan® and/or metoclopramide, and to exclude the options of not using a drug product or using a substantially cheaper alternative drug from the same class.

191. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, while engaged in the conduct and practices identified above, committed one or more violations of state laws, including, but not limited to, the following:

(1) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS made false and misleading representations and omissions of material facts regarding Reglan® and/or metoclopramide;

(2) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS concealed and otherwise failed to publicize the risks and injuries associated with Reglan® and/or metoclopramide in order to promote sales of the drug and maximize profits; and

(3) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS 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 Reglan® and/or metoclopramide.

192. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS thereby intended to and did affect the price of Reglan® and/or metoclopramide, unfairly and deceptively maintained the price of Reglan® and/or metoclopramide at an inflated level not otherwise obtainable and caused Plaintiffs and the consuming public generally to pay more for the drug than was warranted or than they would otherwise have paid in the absence of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' misrepresentations and concealment.

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

194. 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 BRAND NAME DEFENDANTS and GENERIC DEFENDANTS.

195. As a consequence of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' wrongful conduct, Plaintiffs suffered an ascertainable financial loss: the difference between the price paid for Reglan® and/or metoclopramide as a result of the BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' unfair trade practices and the cost of any of the substantially cheaper, and safer, drug alternatives.

COUNT IX - UNJUST ENRICHMENT

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

197. As the intended and expected result of their conscious wrongdoing, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS have profited and benefited from the purchase and use of Reglan® and/or metoclopramide by Plaintiffs.

198. BRAND NAME DEFENDANTS and GENERIC 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' and GENERIC DEFENDANTS' wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, or that Plaintiffs, as reasonable consumers, expected to receive.

199. By virtue of the conscious wrongdoing alleged above, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS have been unjustly enriched at the expense of Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' unjust enrichment.

COUNT X – NEGLIGENT MISREPRESENTATION

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

201. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had actual knowledge of facts which demonstrated that representations in the Reglan® package insert, the PDR monograph for Reglan®, and literature that they distributed concerning Reglan®, metoclopramide HCl and/or metoclopramide to physicians were false and misleading. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had an absolute duty to disclose the true facts regarding the safety of Reglan® to physicians and their patients, pharmacists, and the generic pharmaceutical industry, which they negligently failed to do. Furthermore, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had a duty to ensure that they had a reasonable basis for making the representations described above, to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations, all of which they negligently failed to do.

202. Important information regarding the risks of Reglan®, metoclopramide HCl and/or metoclopramide was in the exclusive control of BRAND NAME DEFENDANTS and GENERIC DEFENDANTS and was exclusively known by them. As part of their business and in the furtherance of their own interests, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS disseminated information regarding Reglan®, metoclopramide HCl and/or metoclopramide to physicians and their patients, pharmacists and the generic metoclopramide industry and did so knowing that the safety of Reglan®, metoclopramide HCl and/or metoclopramide users depended on the accuracy of that information. Further, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew and expected that recipients of that information would rely on it, that they would take action based upon it, that individuals would be put in peril by such action and that those individuals would suffer physical harm as a result.

203. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS expressly and/or impliedly represented to Plaintiffs, their physicians, pharmacists, the generic metoclopramide and/or metoclopramide HCl industry and members of the general public that Reglan®, metoclopramide HCl and/or metoclopramide was safe for adult use to treat nausea and/or esophageal reflux indicated in BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' package inserts and in the *Physician's Desk Reference*. The representations by BRAND NAME DEFENDANTS and GENERIC DEFENDANTS and the lack of them were, in fact, false. The true facts were that Reglan®, metoclopramide HCl and/or metoclopramide was not safe for use in the manner in which it was prescribed and was, in fact, dangerous to the health and body of Plaintiffs.

204. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS made the above described representations with no reasonable grounds for believing them to be true. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS did not have accurate or sufficient information concerning these representations and they failed to exercise reasonable care both in ascertaining the accuracy of the information contained in those representations and in communicating the information. Further, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were aware that without such information they could not accurately make the above described representations.

205. The above misrepresentations or omissions were made to Plaintiffs, their physicians, pharmacists, the generic pharmaceutical industry and the general public, all of whom justifiably and foreseeably relied on those representations or omissions. Plaintiffs would not have suffered their injuries but for the above misrepresentations or omissions. BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiffs' damages.

COUNT XI – CIVIL CONSPIRACY

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

207. BRAND NAME DEFENDANTS and GENERIC 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, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS violated the United States Food, Drug, and Cosmetic Drug Act, 21 U.S.C. § 321 *et seq.* and parallel state Food, Drug and Cosmetic Acts and state common law by selling and distributing a drug product that was misbranded and/or adulterated under the federal Food, Drug and Cosmetic Act.

208. In addition, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS acted with a common purpose to negligently, intentionally, and/or fraudulently withhold information regarding the safety of its drug Reglan® and/or metoclopramide for the purpose of earning profits at the expense of Plaintiffs' health.

209. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS overtly acted by hiding safety information regarding Reglan® and/or metoclopramide and failing to disclose such information to Plaintiffs, Plaintiffs' physicians, the FDA, and the medical community in pursuance of monetary benefit.

210. As a consequence of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' wrongful conduct, actual legal damage has occurred to Plaintiffs and the public.

COUNT XII - LOSS OF CONSORTIUM

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

212. 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

213. 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 BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' conduct.

214. 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.

215. 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.

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

217. As a direct and proximate result of BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' wrongful conduct, 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.

218. BRAND NAME DEFENDANTS and GENERIC 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

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

220. Decedent Plaintiffs died as a result of their exposure to Reglan® and/or metoclopramide and the BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' conduct and are survived by various family members, named and unnamed.

221. The representatives of Decedent Plaintiffs' estates bring these claims on behalf of the Decedent Plaintiffs' lawful heirs.

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

223. Decedent Plaintiffs' estate representatives bring these claims on behalf of Decedent Plaintiffs' lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

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

COUNT XIV - SURVIVAL ACTION

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

226. As a direct and proximate result of their exposure to Reglan® and/or metoclopramide and the conduct of BRAND NAME DEFENDANTS and GENERIC DEFENDANTS 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 Decedent Plaintiffs' deaths.

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

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

COUNT XV - GROSS NEGLIGENCE/MALICE

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

230. The wrongs done by BRAND NAME DEFENDANTS and GENERIC 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 BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' conduct:

(1) When viewed objectively from BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or

(2) included a material representation that was false, with BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

231. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

232. Plaintiffs also allege that the acts and omissions of BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will, as noted, seek exemplary damages in an amount that would punish BRAND NAME DEFENDANTS and GENERIC DEFENDANTS for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XVI – PUNITIVE DAMAGES

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

234. Plaintiffs are entitled to punitive damages because BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' actions were reckless and without regard for the public's safety and welfare. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS misled both the medical community and the public at large, including Plaintiffs and their physicians, by making false representations about and concealing pertinent information regarding Reglan® and/or metoclopramide. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Reglan® and/or metoclopramide, including involuntary movements, despite information demonstrating the product was unreasonably dangerous.

235. The conduct of the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS in designing, testing, manufacturing, promoting, advertising, selling, labeling, marketing, and distributing Reglan® and/or metoclopramide, and in failing to warn Plaintiffs and other members of the public of the dangers inherent in the use of Reglan® and/or metoclopramide, which were known to the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

236. At all times material hereto, BRAND NAME DEFENDANTS and GENERIC DEFENDANTS had 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.

237. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the public generally, and Plaintiffs specifically, in the following ways:

(1) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS actually knew of Reglan® and/or metoclopramide's defective nature, as set forth herein, but continued to design, manufacture, market, and sell Reglan® and/or 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;

(2) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS spent millions of dollars a year aggressively marketing 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;

(3) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS 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

(4) BRAND NAME DEFENDANTS and GENERIC DEFENDANTS 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 BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew of that risk from multiple studies.

238. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS knew that Reglan® and/or metoclopramide had unreasonably dangerous risks and caused serious side effects of which Plaintiffs and their physicians would not be aware. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS nevertheless advertised, marketed, distributed, and sold the medicine knowing that there were safer methods and products available.

239. BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' above-described actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

240. One or more of the aforementioned violations of law by the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were committed with reckless disregard for the safety of the public and of Plaintiffs as a product user.

241. One or more of the aforementioned violations of law by BRAND NAME DEFENDANTS and GENERIC DEFENDANTS were committed willfully and deliberately, and caused substantial financial injury to the consuming public and Plaintiffs.

242. As a direct and proximate result of the wanton and reckless actions and inactions of the BRAND NAME DEFENDANTS and GENERIC DEFENDANTS as set forth above, Plaintiffs are entitled to punitive damages.

XVII. EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

243. The running of any statute of limitation has been tolled by reason of the BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' fraudulent conduct. BRAND NAME DEFENDANTS and GENERIC DEFENDANTS, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and

Plaintiffs' prescribing physicians the true associated with taking Reglan® and/or metoclopramide.

244. As a result of the BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' 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 the BRAND NAME DEFENDANTS' and GENERIC DEFENDANTS' acts and omission.

WHEREFORE, Plaintiffs request trial by jury and that the Court grant them the following relief against BRAND NAME DEFENDANTS and GENERIC 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.

GILLIGAN & PEPPELMAN

BY: _____

Raymond J. Peppelman, Jr.
Attorney I.D. 17484
606 E. Baltimore Pike
Media, Pa 19063
610-566-7777
610-566-0808
ray@gandplaw.us