

**IN RE:** : **COURT OF COMMON PLEAS**  
**ANTI-CONVULSANT DRUGS** : **PHILADELPHIA COUNTY**  
**LITIGATION** :  
: **DECEMBER TERM, 2010**  
*This Document Relates to All Cases* : **NO. 1011-04241**



**COURT OF COMMON PLEAS PHILADELPHIA CIVIL DIVISION**

**PLAINTIFFS,**

*Plaintiffs,*

vs.

**TEVA PHARMACEUTICALS USA, INC.,**  
1090 Horsham Road,  
North Wales, Pennsylvania 19454,

and

**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

*Defendants.*

**DECEMBER TERM, 2010**

**Case No. 1011-04241**

**DEMAND FOR A JURY TRIAL**

**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

**ADVISO**

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara

the claims set forth against you. You are warned that if 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 complaint 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, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Lawyer Referral Service  
Philadelphia Bar Association  
1101 Market Street, 11<sup>th</sup> Floor  
Philadelphia, PA 19107  
(215) 238-6338

medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte pueda 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 SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ESTA OFICINA LO PUEDE PROPORCIONAR CON INFORMACION ACERCA DE EMPLEAR A UN ABOGADO. SI USTED NO PUEDE PROPORCIONAR PARA EMPLEAR UN ABOGADO, ESTA OFICINA PUEDE SER CAPAZ DE PROPORCIONARLO CON INFORMACION ACERCA DE LAS AGENCIAS QUE PUEDEN OFRECER LOS SERVICIOS LEGALES A PERSONAS ELEGIBLES EN UN HONORARIO REDUCIDO NINGUN HONORARIO.

Lawyer Referral Service  
Philadelphia Bar Association  
1101 Market Street, 11<sup>th</sup> Floor  
Philadelphia, PA 19107  
(215) 238-6338

**IN RE:** : **COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY**

**ANTI-CONVULSANT DRUGS  
LITIGATION** : :

: **DECEMBER TERM, 2010**

*This Document Relates to All Cases* : **NO. 1011-04241**

**COURT OF COMMON PLEAS PHILADELPHIA CIVIL DIVISION**

**PLAINTIFFS,**

*Plaintiffs,*

vs.

**TEVA PHARMACEUTICALS USA, INC.,**  
1090 Horsham Road,  
North Wales, Pennsylvania 19454

and

**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

*Defendants.*

**DECEMBER TERM, 2010**

**Case No. 1011-04241**

**COMPLAINT FOR DAMAGES**

- 1. STRICT LIABILITY,**
- 2. NEGLIGENCE,**
- 3. NEGLIGENT  
MISREPRESENTATION**
- 4. NEGLIGENCE *PER SE***
- 5. VIOLATION OF  
PENNSYLVANIA'S UNFAIR  
TRADE PRACTICES AND  
CONSUMER PROTECTION LAW**
- 6. LOSS OF CONSORTIUM**
- 7. WRONGFUL DEATH and**
- 8. SURVIVAL ACTION**

**DEMAND FOR A JURY TRIAL**

**PLAINTIFFS' MASTER LONG FORM COMPLAINT**

1. Plaintiffs, by the undersigned counsel, hereby submit this Master Long Form Complaint against the above named Defendants for equitable relief, monetary restitution, and/or compensatory 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 anti-convulsant medications that cause

Stevens - Johnson Syndrome and/or Toxic Epidermal Necrolysis (SJS and TEN, respectively).

2. This Master Long Form Complaint is submitted pursuant to Case Management Order No. 1 of this Anti-Convulsant Drugs 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 Master Long Form Complaint does not necessarily include all claims asserted in all of the actions that have been transferred to this Court, nor is it intended to consolidate for any purposes the separate claims of the Plaintiffs herein. Those matters are set forth in the individual actions filed by each of the respective Plaintiffs. This Master Long Form 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 damages for injuries and/or wrongful deaths suffered as a direct result of ingestion of anti-convulsant medications, Carbamazepine or Lamotrigine. In addition, Secondary Plaintiffs assert derivative claims including, but not limited to, loss of consortium and survivorship. Not all claims asserted in this Master Long Form Complaint will

necessarily be held by, nor asserted by, all Plaintiffs, and not all claims in this Master Long Form Complaint are asserted by each Plaintiff against Defendants.

4. Defendants Teva Pharmaceuticals USA, Inc., is a Delaware corporation with a principal place of business in Pennsylvania. Defendants Teva Pharmaceuticals USA, Inc. regularly conducts business in Philadelphia County, Pennsylvania. Defendants Teva Pharmaceuticals USA, Inc. 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. Defendants Teva Pharmaceuticals USA, Inc. was involved in the manufacture, distribution, marketing, sale, labeling, and design of the Carbamazepine and Lamotrigine detailed below. Pursuant to Case Management Order No.1, Defendants Teva Pharmaceuticals USA, Inc. may be served with process by registered mail, return receipt requested, upon: Teva Pharmaceuticals USA, Inc., Ms. Jennifer Fuller-Ricciardi, Teva Pharmaceuticals USA, Inc. 425 Privet Road, P.O. Box 1005, Horsham, PA 19044.

5. Defendants Teva Pharmaceutical Industries, Ltd. is a foreign corporation with its principal place of business in Israel. Defendants Teva Pharmaceutical Industries, Ltd. is the parent company of Defendants Teva Pharmaceuticals USA, Inc. and therefore liable for any and all tort liabilities of Defendants Teva Pharmaceuticals USA, Inc. In addition, Plaintiffs allege, on information and belief, that Defendants Teva Pharmaceutical Industries, Ltd. was involved in the manufacture, distribution, marketing, sale and labeling of Carbamazepine and Lamotrigine detailed below and regularly conducts business in Philadelphia County, Pennsylvania. Defendants 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.

6. 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 Defendants 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 Defendants 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**

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

8. At all times relevant hereto, Defendants were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, and packaging the pharmaceutical drugs known as Carbamazepine and Lamotrigine in the Commonwealth of Pennsylvania and the County of Philadelphia.

9. At all times relevant hereto, Defendants had offices in Pennsylvania and/or regularly solicited and transacted business in the state of Pennsylvania and the County of Philadelphia. Defendants carried on a continuous and systematic part of their business in Pennsylvania and Philadelphia County. In addition, Defendants reasonably expected that their products, Carbamazepine as well as Lamotrigine, would be used or consumed in Pennsylvania and Philadelphia County.

10. Defendants Teva Pharmaceuticals USA, Inc. is a resident of Pennsylvania because its principal place of business is in Pennsylvania.

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

12. 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).

### **III. Venue**

13. Philadelphia County is the proper forum and venue for these causes of action. Philadelphia County is the epicenter of Anti-convulsant medication SJS/TEN litigation.

14. In addition, Philadelphia County Court of Common Pleas is the only county with the ability to handle, litigate, and resolve the numerous associated cases expected 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.

15. TEVA Pharmaceuticals USA, Inc. (“TEVA”) is a Delaware corporation, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania.

16. At all times relevant herein, Defendants were in the business of designing, testing, manufacturing, labeling and distributing, Carbamazepine and Lamotrigine drug products in the stream of commerce for use by the public, including Plaintiffs.

17. Defendants at all times material hereto have and continue to do business in Pennsylvania.

18. At all times relevant hereto, Defendants were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, labeling, and/or packaging the pharmaceutical drugs known and/or branded as Carbamazepine as well as the pharmaceutical drugs known and/or branded as Lamotrigine in the Commonwealth of Pennsylvania and in interstate commerce.

19. At all relevant times, Defendants did manufacture, create, design, assemble, test, label, sterilize, package, distribute, supply, market, sell, and/or otherwise distribute in the Commonwealth of Pennsylvania and in interstate commerce Carbamazepine and Lamotrigine.

20. At all relevant times, Defendants sold, delivered and/or distributed such products for ultimate sale and/or use interstate commerce within the United States and the Commonwealth of Pennsylvania by consumers, including Plaintiffs.

#### **IV. Statement of Facts**

##### **CARBAMAZEPINE FACTS**

21. This case involves the pharmaceutical prescription drug Carbamazepine, which is a member of a class of prescription drug products known as Anticonvulsants and is also sold as a mood stabilizer for bipolar disease.

22. TEVA sold Carbamazepine in the United States in variant forms including, 100 mg chewable tablets; 200 mg chewable tablets and 100 mg, 200 mg and 400 mg extended release tablets.

23. Carbamazepine was discovered by chemist Walter Schindler at J.R. Geigy AG in Basel Switzerland in the early 1950's.<sup>1</sup>

24. TEVA sought initial approval for Carbamazepine under an Investigative Drug Application in 1964.

25. After reviewing the safety and toxicity information on October 1, 1966, November 2, 1966, and January 25, 1967, the FDA refused to approval Carbamazepine because “Carbamazepine would appear to be an agent that possess significant toxicity.”<sup>2</sup>

26. On or about April 10, 1967, the FDA found that the Carbamazepine proposed labeling “does not adequately convey to the physician the fact that Carbamazepine has little to no margin of safety based on the animal studies performed” and that “there is an overall attempt by the sponsor to reduce the significance of the findings of toxicity in the experimental animals and we [the FDA] feel that a clear statement of this agent’s toxicity is called for.”<sup>3</sup>

27. On or about March 11, 1968, Carbamazepine was approved by the FDA for the limited indication of pain associated with trigeminal neuralgia.

28. The following is, and at all times relevant hereto, known by TEVA:

- a. On or about July 23, 1973, a Supplemental New Drug Application to the FDA, seeking approval to use Carbamazepine as a treatment for epilepsy.

---

<sup>1</sup> Schindler W. Hafliger F (1954). “Uber Derivate des Iminodibenzyls.” *Helvetica Chimica Acta* 37 (2): 472—83, doi: 10.1002/hica.19540370211.

<sup>2</sup> See [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/pre96/016608\\_Pharm\\_rvw.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/016608_Pharm_rvw.pdf).

<sup>3</sup> *Id.*

b. Carbamazepine is chemically similar to Dilantin.<sup>4</sup>

29. On or about July 23, 1973, a one year rat study was published and/or provided to the FDA in support of the contention that Carbamazepine was safe and not carcinogenic and should be approved for long term use and for use in children.<sup>5</sup>

30. On or about July 23, 1973, the FDA found that “since Carbamazepine is now proposed for chronic administration for treatment of epilepsy this NDA is deficient in that the one year rat study submitted is not sufficient to determine if Carbamazepine or its epoxide metabolite has carcinogenic potential.”<sup>6</sup>

31. Based on information provided, Carbamazepine was subsequently approved only for patients who do not respond to treatment with diiphenylhydantoin, Phenobarbital and/or primidone and who suffered the following conditions (1) partial seizures with complex symptomatology (psychomotor, temporal lobe); (2) Generalized tonic-clonic seizures; (3) Mixed seizure patterns.

32. Carbamazepine was aggressively marketed for expanded indications, including use of Carbamazepine as a first-line treatment of epilepsy and broad use as an anticonvulsant drug in adult and pediatric populations, and as a mood stabilizer.

33. Yet, in 2005, the International League Against Epilepsy (ILEA) published guidelines regarding the selection of anticonvulsant for patients as Initial Monotherapy for Epileptic Seizures and Syndromes and found there was no randomized controlled

---

<sup>4</sup> See [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/pre96/016608\\_Pharm\\_rvw2.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/016608_Pharm_rvw2.pdf).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

trials to establish the efficacy of Carbamazepine for any other seizure type (i.e. absence, atypical absence, myoclonic, atonic, tonic and tonic-clonic seizures).<sup>7</sup>

34. The ILEA study reviewed fifty randomized controlled trial designs, seven meta-analysis and information provided to the panel by pharmaceutical companies.<sup>8</sup> Further, the ILEA panel requested that pharmaceutical companies supplement data from any publicly known randomized controlled trial if data were missing from the package inserts of the studied drugs and to provide data concerning any unpublished potentially relevant clinical trials.<sup>9</sup>

35. The ILEA panel found there was a paucity of adequate studies to support the use of Carbamazepine as initial monotherapy and examined five meta-analyses to analyze efficacy and effectiveness of Carbamazepine for adults with partial-onset seizures and found “no reliable evidence to distinguish Carbamazepine from Valproate Acid for partial onset seizures and generalized on-set seizures.”<sup>10</sup>

36. The ILEA panel also found that studies were insufficient to support a finding that Carbamazepine was effective for pediatric use.<sup>11</sup>

37. By federal law, the labeling is to include accurate information concerning a drug’s active and inactive ingredients, clinical pharmacology, indications, usage, efficacy, contraindications, warnings, precautions and side effects.

---

<sup>7</sup> Glauser, *et al.*, ILAE Treatment Guidelines: Evidence-based Analysis of Antiepileptic Drug Efficacy and Effectiveness as Initial Monotherapy for Epileptic Seizures and Syndromes, *Epilepsia*, 47(7); pp. 1094-1120, 2006.

<sup>8</sup> *Id.* at 1096.

<sup>9</sup> *Id.* at 1097.

<sup>10</sup> *Id.* at 1094; *See also* Marson, AG, Williamson PR, Clough H. *et al.*, Carbamazepine versus valproate monotherapy for epilepsy: a meta-analysis, *Epilepsia*, 2002; 43-505-13.

<sup>11</sup> *Id.* at 1105-1107.

38. Defendants failed to fully and accurately communicate the efficacy of Carbamazepine drug products and negligently misled the medical community, physicians, Plaintiffs' physicians and Plaintiffs about the risks associated with the drug, including, but not limited to the risk of SJS and TEN associated with the use of the drug.

39. Defendants caused its label to be published in a way that minimized the risk of SJS and TEN. For example, upon information and belief, in 2008, the TEVA label stated:

SERIOUS AND SOMETIMES FATAL DERMATOLOGIC REACTIONS, INCLUDING TOXIC EPIDERMAL NECROLYSIS (TEN) AND STEVENS-JOHNSON SYNDROME (SJS), HAVE BEEN REPORTED DURING TREATMENT WITH CARBAMAZEPINE. THESE REACTIONS ARE ESTIMATED TO OCCUR IN 1 TO 6 PER 10,000 NEW USERS IN COUNTRIES WITH MAINLY CAUCASIAN POPULATIONS

40. The Carbamazepine package inserts minimized the risk of a severe cutaneous reactions and severe side effects described herein, including but not limited to Stevens Johnson Syndrome and TEN, despite available literature that Defendants should have reported evidencing a statistically significant higher risk for such reactions.<sup>12</sup>

41. The drug product package inserts were disseminated to Plaintiffs' physicians and other members of the medical community.

42. Defendants' package inserts, physician desk reference and monographs downplayed the significance of the adverse effects of Carbamazepine drug products and the risk of SJS, TEN and severe cutaneous reactions.<sup>13</sup>

---

<sup>12</sup> See e.g. Roujeau, Jean-Claude, Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis, *New England Journal of Medicine*, Vol. 333, No. 24, 1600-1607 (1995) (reporting a crude relative risk of 11).

<sup>13</sup> See e.g. Bigby, M, et. al., Primary Care, Allergic Cutaneous Reactions to Drugs, Vol. 16, no. 3, pp. 713-727, (1989) Stern R., et al., *Jour of the Amer Acad of Dermatol*, Usefulness of Case Report Literature in Determining Drugs Responsible for Toxic Epidermal Necrolysis, Vol. 21,

43. Defendants knew or should have known that a significant portion of deaths and severe side effects, described herein, resulted from Carbamazepine products have included African American persons and children who were found to have increased risks of Carbamazepine SJS and TEN in the medical literature.<sup>14</sup>

44. Despite accounts of severe cutaneous reactions and severe side effects including but not limited to SJS and TEN reported directly to the Defendants, and reports in the literature, the Defendants failed to advise the Plaintiffs' physicians and the medical community of the true and accurate risks and regularly represented to said individuals that the risk associated with exposure to Carbamazepine drug products was minimal when, in fact, it was significantly greater.

45. The Carbamazepine drug products were defective due to inadequate pre-marketing and post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injury associated with the drug, Defendants failed to provide adequate warnings to Plaintiffs' physicians and the medical community who prescribed said drug, and to their patients, including Plaintiffs, who were the ultimate consumers of the drug. Yet, despite Defendants inadequate post-marketing warnings and instructions to said persons, Defendants continued to aggressively promote the drug thereby making Defendants liable for failure to warn.

---

No. 2, Part 1, pp. 317-22, (1989); Roujeau, JC, et. al., Toxic Epidermal Necrolysis (Lyell Syndrome), Incidence and Etiology, *J Am Acad Derm*: 23:1039-58, (1990).

<sup>14</sup> See e.g. Tennis, P and Stern, R.S. (1997) Risk of serious cutaneous disorders after initiation of use of Carbamazepine, Carbamazepine, or sodium valproate: a record linkage study, *Neurology*, 49(2):542-546; Mockenhaupt, M. et al. (2005) Risk of Stevens-Johnson syndrome and toxic epidermal necrolysis in new users of antiepileptics. *Neurology*. 64(7):1134-1138; Man, C.B.L. et al. (2007) Association between HLA-B\*1502 Allele and Antiepileptic Drug-Induced Cutaneous Reactions in Han Chinese. *Epilepsia*, 48(5):1015-1018; Lonjou, C., et al. (2006) A marker for Stevens-Johnson syndrome: ethnicity matters. *Pharmacogenomics J.*, 6(4):265-268; Hung, S.I. et al. (2006) Genetic susceptibility to Carbamazepine-induced cutaneous adverse drug reactions. *Pharmacogenet. Genomics*, 16(4):297-306. Alfirevic, A. et al. (2006) HLA-B locus in Caucasian patients with Carbamazepine hypersensitivity. *Pharmacogenomics*, 7(6):813-818.

46. Plaintiffs and their physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated by Defendants concerning the safety and efficacy of Carbamazepine drug products.

47. Defendants negligently provided misleading information about the true risks associated with the use of said Carbamazepine drug products to the medical community, Plaintiffs' Physician, and Plaintiffs.

48. Plaintiffs used Carbamazepine drug products without substantial change in condition of said drug products between the time of design and manufacture of the drug products and the time of use.

49. Plaintiffs' serious and permanent injuries came about as a foreseeable and proximate result of the Defendants' dissemination of inaccurate, misleading, materially incomplete, and otherwise inadequate information concerning the effects of exposure and ingestion of the drug to the medical community, physicians, Plaintiffs' physician, and Plaintiffs.

50. 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 due to the injuries suffered caused by the ingestion of Defendants' Carbamazepine drug products.

#### **LAMOTRIGINE FACTS**

51. This case also involves the pharmaceutical drug Lamotrigine.

52. The two dosage forms, Lamictal (tablet) and Lamictal CD (chewable-dispersible tablet), received FDA approval on December 27, 1994 and August 24, 1998,

respectively. In 1998, Lamotrigine was approved for the adjunctive treatment of the generalized seizures of Lennox-Gastaut syndrome in adult and pediatric patients. In 2003, Lamotrigine was approved for the adjunctive treatment of partial seizures in adult and pediatric patients equal to or greater than 2 years of age. Also in 2003, the Lennox-Gastaut indication was modified to specify approval in pediatric patients equal to or greater than 2 years of age. In 2006, Lamotrigine was approved as adjunctive treatment of primary generalized tonic-clonic seizures in adults and pediatric patients. Additionally, Lamotrigine is approved for maintenance treatment of Bipolar I Disorder and conversion to monotherapy to treat partial seizures in adults. Pediatric exclusivity was granted on February 14, 2007.

53. Lamotrigine's principal label, known as the "Package Insert" was published and disseminated by Defendants and accompanied all prescription drug products and/or samples. By federal law, the labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, contraindications, warnings, precautions and side effects.

54. Defendants failed to fully, truthfully and accurately communicate the risks of Lamotrigine, and as a result misled the medical community, physicians, Plaintiffs' physician and Plaintiffs about the risks of severe side effects described herein, including but not limited to Stevens Johnson Syndrome (SJS) and Toxic epidermal necrolysis (TEN) associated with the use of Lamotrigine.

55. Defendants caused its Package Insert to be disseminated to Plaintiffs' Physicians and other members of the medical community. Defendants' Package Insert reports minimized the risk of a severe cutaneous reactions and severe side effects

described herein, including but not limited to Stevens Johnson Syndrome in patients ingesting Lamotrigine, despite available literature that Defendants should have found and reported stating a statistically significant higher risk for such reactions.

56. On or after 1999, Defendants continued to minimize the risk of SJS and TEN and failed to fully, truthfully and accurately communicate the risks associated with Lamotrigine, despite available literature that the incidence of SJS and TEN was higher than the label indicated, and as a result misled the medical community, physicians, Plaintiffs' physician and Plaintiffs about the risks of severe side effects described herein, including but not limited to Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) associated with the use of Lamotrigine. For instance, Defendant's 1999 Lamotrigine Label published in the Physician's Desk Reference, which said label is nearly identical to the label and package insert in existence at the time of Plaintiffs' purchase, use and injury, stated:

SEVERE, POTENTIALLY LIFE-THREATENING RASHES HAVE BEEN REPORTED IN ASSOCIATION WITH THE USE OF LAMOTRIGINE. THESE REPORTS, OCCURRING IN APPROXIMATELY ONE IN EVERY THOUSAND ADULTS, HAVE INCLUDED STEVENS-JOHNSON SYNDROME AND, RARELY, TOXIC EPIDERMAL NECROLYSIS. (Emphasis added).

57. On or about 2000 and thereafter, the Defendants, continued to minimize the risk of SJS and TEN in its Lamotrigine Label and failed to fully, truthfully and accurately communicate the risks associated with Lamotrigine, despite available literature that the incidence of SJS and TEN was higher than the label indicated, and as a result mislead the medical community, physicians, Plaintiffs' physician and Plaintiffs about the risks of severe side effects described herein, including but not limited to

Stevens Johnson Syndrome (SJS) and Toxic epidermal necrolysis (TEN) associated with the use of Lamotrigine. For instance, Defendants' 2000 Lamotrigine Label published in the Physician's Desk Reference, which said label is nearly identical to the label and package insert in existence at the time of Plaintiffs' purchase, use and injury, stated:

SERIOUS RASHES REQUIRING HOSPITALIZATION AND DISCONTINUATION OF TREATMENT HAVE BEEN REPORTED IN ASSOCIATION WITH THE USE OF Lamotrigine. THE INCIDENCE OF THESE RASHES, WHICH HAVE INCLUDED STEVENS-JOHNSON SYNDROME, IS APPROXIMATELY 1% (1/100) IN PEDIATRIC PATIENTS (AGE <16 YEARS) AND 0.3% (3/1000) IN ADULTS. IN WORLDWIDE POSTMARKETING EXPERIENCE, RARE CASES OF TOXIC EPIDERMAL NECROLYSIS AND/OR RASH-RELATED DEATH HAVE BEEN REPORTED, BUT THEIR NUMBERS ARE TOO FEW TO PERMIT A PRECISE ESTIMATE OF THE RATE. (Emphasis added).

58. Defendants promoted Lamotrigine to physicians for use in patients, such as Plaintiffs, through medical journal advertisements, use of mass mailings, and direct communications from Defendants sales force, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures as these materials downplayed the significance of the adverse effects of Lamotrigine and the risk of Stevens-Johnson Syndrome and severe cutaneous reactions.

59. Defendants knew there was substantial and mounting evidence of the enormous risk of serious systemic reactions such as hypersensitivity syndrome, SJS and TEN associated with this drug. Yet, despite the scientific and epidemiological evidence that would compel Defendants to issue warnings to physicians and patients, Defendants consciously decided to ignore this pertinent information when it came time to protect the

health of patients in the United States from the severe cutaneous adverse events associated with this drug.

60. Despite accounts of severe cutaneous reactions and severe side effects as described herein including but not limited to Stevens-Johnson Syndrome and TEN reported directly to the Defendants, and reports in the literature, Defendants failed to report the true and accurate risk of said side effects to the Plaintiffs' physicians and the medical community and regularly represented in its advertising and promotional messages to said individuals that the risks of cutaneous adverse reactions associated with exposure to this drug was minimal when in fact it was significantly greater.

61. The Lamotrigine manufactured and/or supplied by Defendants was defective due to inadequate pre-marketing and post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injury from Lamotrigine, Defendants failed to provide adequate warnings to Plaintiffs' physicians, Plaintiffs, physicians and the medical community who prescribed the drug, and to their patients who were the ultimate consumers of the product. Yet despite their inadequate post-marketing warnings and instructions to said persons Defendants continued to sell the product with deficient labeling thereby making Defendants liable for its negligent failure to warn, negligent misrepresentation and misrepresentation by omission.

62. Further, despite knowledge that patients were more likely to suffer a severe cutaneous reactions and severe side effects as described herein including but not limited to Stevens-Johnson Syndrome and TEN in the initial days or weeks following the initial commencement of therapy, and with knowledge that additional care should be taken in the dosage and monitoring of patients during this initial period during which

hypersensitivity was more likely than not to manifest in rashing, if such symptomology was to present, Defendants failed to provide an adequate label on mono and/or adjunct therapy initial dosing and titration schedules thereby placing patients at increased risk for SJS/TEN.

63. In fact, sometime between late 2007 and 2008, Defendants realized the confusion created by a label with multiple sub-sections referring to initial dosages and usual maintenance dosages by which initial dosages were conflated and changed its labeling to better inform patients and their physicians about proper dosing.

64. Moreover, despite knowledge that female patients were more likely to suffer a severe cutaneous reactions and severe side effects as described herein including but not limited to Stevens-Johnson Syndrome and TEN than male patients, Defendants undertook to include vague and ambiguous references in its label regarding the increased prevalence of adverse events only to neutralize the message in succeeding language in its label thereby failing to provide an adequate label resulting in the placing of patients at increased risk for SJS/TEN, including Plaintiffs.

65. Plaintiffs were prescribed, and were dispensed Lamotrigine, and ingested Defendants' Lamotrigine pursuant to instruction.

66. Under the FDA schema, Defendants is allowed to manufacture, sell, market and distribute Lamotrigine, which was ingested by Plaintiffs herein, but has a duty to undertake reasonable measures to ensure that its label is adequate including changing its label unilaterally to ensure it is adequate.

67. Plaintiffs ingested Lamotrigine, as prescribed and ordered by her physician.

68. Plaintiffs' ingestion of Defendants Lamotrigine caused her injuries.

69. Plaintiffs' physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated by Defendants.

70. Defendants provided misleading information about the true risks associated with the use of Defendants Lamotrigine to the medical community, Plaintiffs' Physician, and Plaintiffs, who were foreseeable users.

71. Plaintiffs used Defendants' pharmaceutical drug Lamotrigine without substantial change in condition of the drug between the time of design and manufacture of the drug and the time Plaintiffs used the drug as directed.

72. Plaintiffs' serious and permanent injuries, as described above, came about as a foreseeable and proximate result of the Defendants dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Defendants'

73. Lamotrigine and the ingestion of Lamotrigine to the medical community, physicians, Plaintiffs' physician, Plaintiffs, who were foreseeable users.

74. Plaintiffs has 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 due to the injuries they suffered caused by the ingestion of Defendants' Lamotrigine.

75. Plaintiffs have filed this lawsuit within any applicable statute of limitations period. Plaintiffs acted with diligence in attempting to discover any injury caused by the ingestion of Lamotrigine, including following the advice of their

physicians. Plaintiffs could not have brought a cause of action against any person or entity, including the named Defendants, until Plaintiffs discovered that any injury detected was a result of the action and/or omissions of the named Defendants.

## **V. WRONGFUL CONDUCT**

### **CARBAMAZEPINE ALLEGATIONS**

76. At all relevant times hereto, Defendants did not investigate the accuracy of the Carbamazepine drug product labeling.

77. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of increased risks of severe side effects described herein including SJS and TEN associated with Carbamazepine therapy to the FDA, healthcare providers and patients, including Plaintiffs, in the U.S.

78. FDA regulations required Defendants to report literature, papers, and, to undertake action to add new warnings to the package insert for Carbamazepine drug products, and to report any foreign regulatory actions that included new warnings or new safety information for the drug.

79. At all relevant times hereto, Defendants did not review the medical literature for Carbamazepine drug products.

80. Defendants are under a duty to ensure that their Carbamazepine drug product labels are accurate.

81. Under the Code of Federal Regulations, Defendants, as ANDA holders, have a duty to ensure its Carbamazepine warnings to the medical community were accurate and adequate; have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk

and/or prevalence of side effects caused by Carbamazepine drug products, the medical community, Plaintiffs' physician, and Plaintiffs.

82. Under federal regulations, if Defendants discovers information in the course of the fulfillment of its duties as outlined above, said Defendants must report that information to the medical community, Plaintiffs' physician, and Plaintiffs of Carbamazepine therapy to ensure that its warnings are continually accurate and adequate.

83. Defendants breached their duty to the medical community, Plaintiffs' physicians, and Plaintiffs because it failed to provide warnings to said persons, which were accurate and adequate.

84. Defendants breached their duty to the medical community, Plaintiffs' physicians, and Plaintiffs because it failed to conduct post market safety surveillance of the drug, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of their Carbamazepine drug products.

85. Defendants breached their duty to the medical community, Plaintiffs' physicians, and Plaintiffs because Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of Defendants' warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Carbamazepine drug products to said persons.

86. Defendants breached their duty to the medical community, Plaintiffs' physicians, and Plaintiffs because it failed to periodically review all medical literature and failed to report any significant data concerning severe side effects as described herein, including but not limited to SJS and TEN, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety

of Carbamazepine drug products.

87. If a drug company learns of side effects, risks or misleading and inaccurate information in the Carbamazepine drug product label, it must request and/or submit labeling revisions for said drug, under the FDA schema.

88. Defendants breached their duty to the medical community, Plaintiffs' physicians, and Plaintiffs because they failed to provide warnings to said persons, which were accurate and adequate.

89. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in Carbamazepine drug product labels and withheld that information and or failed to report that information to the medical community, physicians, Plaintiffs' physicians and Plaintiffs.

90. At all times material hereto, Defendants were aware of the serious side effects described herein which were caused by Carbamazepine drug products and failed to fulfill the obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, Plaintiffs' physicians and Plaintiffs about the safety of Carbamazepine drug products.

91. At all times material hereto, Defendants knew or should have known that physicians and Plaintiffs were unaware of or did not fully appreciate the seriousness of the risks associated with use of Carbamazepine drug products.

92. Defendants knew or should have known that the package inserts and the Physician Desk Reference monographs for Carbamazepine drug products did not adequately inform physicians about the risks of severe side effects described herein, and/or SJS or TEN associated with the drug; yet, said Defendants failed to communicate

said information to the medical community, Plaintiffs' physicians and Plaintiffs, and in doing so, misled the medical community, Plaintiffs' physicians and Plaintiffs about the safety of Carbamazepine.

93. Defendants knew, or should have known through the exercise of reasonable care, that the package insert for the drug substantially understated the prevalence of the risk of severe side effects described herein.

94. Defendants failed to disclose and communicate material safety information regarding the risks of Carbamazepine to the medical community, Plaintiffs' physicians, and Plaintiffs despite that such failure would result in serious injury to patients who were prescribed Carbamazepine drug products by a physician and were not aware of the risk of severe skin reactions, SJS and TEN.

95. Defendants misrepresented to physicians, Plaintiffs' physicians, and to Plaintiffs that Carbamazepine drug therapy was safe and that permanent and severe side effects described herein, SJS and TEN were rare and/or infrequent.

96. Defendants did not disclose or warn physicians about the actual prevalence of side effects of Carbamazepine therapy when the drug is used as marketed or sold, or when used in patients such as of Plaintiffs.

97. At the time Defendants made the above-described representations, Plaintiffs and Plaintiffs' physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

98. Plaintiffs' serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' failure to correct misleading information it disseminated to physicians, which contained misleading information

concerning the efficacy, safety and potential side effects of the drug.

99. As a proximate result of the of Defendants' breach of care, Plaintiffs sustained the injuries and damages as described in this Complaint.

100. Defendants have an absolute duty to disclose the true facts regarding the safety of Carbamazepine drug products to the medical community, to physicians and their patients, which they failed to do.

101. Defendants have a duty to ensure that they had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of the drug were accurate which it failed to do.

102. Plaintiffs would not have suffered Plaintiffs' injuries but for the above misrepresentations or omissions of Defendants.

103. Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiffs' damages.

104. At all times mentioned in this Complaint, the Defendants had a duty to truthfully, accurately and fully disclose information and data to Plaintiffs that the risks of severe side effects described herein, including, SJS and TEN, clearly outweighed the utility of the drug or its therapeutic benefits to patients.

105. The Defendants breached their duty owed to the medical community, Physicians, Plaintiffs' physicians, and Plaintiffs with respect to the drug, Carbamazepine.

106. As a result of Defendants' failure to exercise reasonable care, Defendants' Carbamazepine drug products were prescribed to Plaintiffs for their respective use; were used as prescribed; thereby, causing Plaintiffs to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint.

107. Defendants' failure to exercise reasonable care was a proximate cause of Plaintiffs' harm and injuries that Plaintiffs suffered and will continue to suffer.

108. At all times mentioned in this Complaint, the drug was defective and/or unreasonably dangerous to Plaintiffs at the time it left the control of the Defendants.

109. The drug was "defective" and "unreasonably dangerous" when it was promoted and entered into the stream of commerce and was received by Plaintiffs.

110. Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiffs seek recovery.

111. A reasonably competent physician who prescribed the drug and Plaintiffs, as reasonably competent consumers, would not realize the drug's dangerous condition.

112. The reasonably foreseeable use of Carbamazepine drug products involved substantial dangers not readily recognizable by Plaintiffs' physicians, who acted as ordinary, reasonable and prudent physicians would, when prescribing the drug to ordinary, reasonable and prudent patients like Plaintiffs.

113. Defendants knew that Carbamazepine drug products prescribed by physicians and used by Plaintiffs was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

114. Plaintiffs and Plaintiffs' physicians did not know, nor had reason to know, at the time of the use of the drug, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

115. These defects caused serious injuries to Plaintiffs when the drug was used

in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

116. Carbamazepine drug products were not properly prepared nor accompanied by adequate warnings concerning the drugs dangerous propensities that were either known or reasonably scientifically knowable by Defendants at the time of distribution. As a result, the drug proximately caused Plaintiffs to sustain damages and injuries as alleged in this Complaint.

117. By virtue of Defendants' acts and omissions, Defendants are liable to Plaintiffs because Defendants' acts and omissions have proximately caused Plaintiffs to suffer permanent injuries.

118. Plaintiffs used Carbamazepine drug products, which were provided to them, respectively, in a condition that was substantially the same as the condition in which the drugs were manufactured and sold.

119. Defendants, through negligent misrepresentations and omissions, concealed from Plaintiffs and their physicians the true and significant risks associated with taking Carbamazepine drug products; and thus, the running of any applicable statute of limitations has been tolled by reason of Defendants' negligent concealment.

120. As a result of Defendants' actions, Plaintiffs and their prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiffs had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

121. As a direct and proximate result of the acts and omissions of Defendants,

Plaintiffs were prevented from pursuing normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of ordinary pursuits and enjoyments of life.

122. Plaintiffs are also entitled to any procedural protections deemed necessary and appropriate to protect Plaintiffs' legal interests.

123. Plaintiffs are entitled to recovery of an award for the injuries caused by the Defendants.

124. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, Plaintiffs have:

- (a) Suffered severe and permanent injuries, which they will be forced to endure for the remainder of their lives;
- (b) Suffered physical impairment and disfigurement; and
- (c) Suffered physical pain and suffering;
- (d) Suffered mental pain and suffering; and
- (e) Suffered from loss of enjoyment of life; and
- (f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiffs' injuries; and
- (g) Incurred attorney's fees and expenses of litigation related to this action.

#### **LAMICTAL ALLEGATIONS**

125. Under the FDA schema, Defendants are allowed to market and distribute Lamotrigine formulation of Lamotrigine.

126. At all relevant times hereto, Defendants did not investigate the accuracy of its' Lamotrigine drug label.

127. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of increased risks of severe side effects described herein including SJS and TEN associated with Lamotrigine therapy to the FDA, healthcare providers or patients in the U.S. The regulations required them to report these papers, undertake action to add new warnings to the package insert for Lamotrigine, and to report any foreign regulatory actions that included new warnings or new safety information for the product.

128. At all relevant times hereto, Defendants did not review the medical literature for the Lamotrigine

129. Defendants is under a duty to ensure that its' Lamotrigine label is accurate.

130. Under the Code of Federal Regulations, Defendants has a duty to ensure its Lamotrigine warnings to the medical community were accurate and adequate; had a duty 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 Lamotrigine, the medical community, Plaintiffs' physician, Plaintiffs and other foreseeable users.

131. Under the Code of Federal Regulations, if Defendants discover information in the course of the fulfillment of its duties as outlined above, Defendants must report that information to the medical community, Plaintiffs' physician, Plaintiffs and other foreseeable users of Lamotrigine to ensure that its warnings are continually accurate and adequate.

132. Defendants also violated relevant state laws by failing to provide labeling

that gives adequate warning to the medical community, Plaintiffs' physician, Plaintiffs and other foreseeable users where the use of Lamotrigine is dangerous to the health of those foreseeable users that include Plaintiffs.

133. Defendants breached its duty to the medical community, Plaintiffs' Physician, Plaintiffs, and other foreseeable users similarly situated because it failed to Lamotrigine warnings to the medical community, Plaintiffs' physician, Plaintiffs, other foreseeable users similarly situated were accurate and adequate.

134. Defendants breached its duty to the medical community, Plaintiffs' physician, Plaintiffs, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Lamotrigine, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Lamotrigine.

135. Defendants breached its duty to the medical community, Plaintiffs' physician, Plaintiffs, who were foreseeable, because it failed to 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 Lamotrigine, the medical community, Plaintiffs' physician, and Plaintiffs.

136. Defendants breached their duty to the medical community, Plaintiffs' physician, and Plaintiffs, foreseeable users, because Defendants failed to periodically review all medical literature and failed to report any significant data concerning severe side effects as described herein, including but not limited to SJS and TENS, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings,

efficacy, or safety of Lamotrigine.

137. If a drug company learns of side effects, risks or misleading and inaccurate information in the Lamotrigine label, it must request and/or submit labeling revision for the drug, under the FDA schema.

138. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in its Lamotrigine label and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiffs' physicians and Plaintiffs.

139. At all times material hereto, Defendants was aware of the serious side effects caused by Lamotrigine including, but not limited to, severe side effects described herein and failed to fulfill its obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, Plaintiffs' physician, and Plaintiffs about the safety of the use of the drug.

140. At all times material hereto, Defendants knew or should have known that Plaintiffs' physicians were **not** aware of or did not fully appreciate the seriousness of the risks associated with use of Lamotrigine.

141. Defendants knew or should have known that the package insert and the Physician Desk Reference monograph for Lamotrigine did not adequately inform physicians about the risks of severe side effects described herein, and/or SJS or TEN associated with Lamotrigine; yet, said Defendants failed to communicate said information to the medical community, Plaintiffs' physicians, or Plaintiffs, and in doing so, mislead the medical community, physicians, Plaintiffs' physician, and Plaintiffs about the safety of the use of this drug.

142. Defendants knew, or should have known through the exercise of reasonable care, that the package insert for Lamotrigine substantially understated the prevalence of the risk of severe side effects described herein, SJS and TEN associated with Lamotrigine.

143. Defendants falsely represented to physicians, Plaintiffs physicians, and to foreseeable users, including Plaintiffs that Lamotrigine was safe to use and that permanent and severe side effects described herein, SJS and TEN were rare and/or infrequent.

144. Defendants did not disclose or warn physicians about the actual prevalence of known side effects of Lamotrigine when Lamotrigine is used as marketed by Defendants, or when used in patients such as Plaintiffs of Lamotrigine.

145. At the time Defendants made the above-described representations, Plaintiffs and Plaintiffs' physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

146. Plaintiffs' serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Lamotrigine.

147. Defendants had an absolute duty to disclose the true facts regarding the safety of Lamotrigine to the medical community, to physicians and their patients, pharmacists, and the generic Lamotrigine industry, which it negligently and/or intentionally failed to do.

148. Defendants had a duty to ensure that it had a reasonable basis for making the representations regarding the safety, efficacy, risks and benefits of Lamotrigine, were accurate and was under at duty to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations, all of which it negligently and/or intentionally failed to do.

149. Plaintiffs would not have suffered Plaintiffs' injuries but for the above misrepresentations or omissions of Defendants.

150. Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiffs' damages.

151. At all times mentioned in this Complaint, Defendants had a duty to truthfully, accurately and fully disclose information and data which would reflect that the risks of severe skin reactions, SJS and TEN clearly outweighed the utility of the Lamotrigine or its therapeutic benefits to patients.

152. The Defendants was negligent, and breached its duties owed to the medical community, Physicians, Plaintiffs' physician, and Plaintiff.

153. As a result of the negligence of Defendants, Lamotrigine was prescribed to Plaintiffs for their use; and was used as prescribed; thereby, causing Plaintiffs to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint.

154. The negligence of the Defendants was a proximate cause of Plaintiffs' harm and injuries that Plaintiffs has suffered and will continue to suffer.

155. At all times mentioned in this Complaint, Lamotrigine was defective and/or unreasonably dangerous to Plaintiffs and other foreseeable users at the time it left

the control of the Defendants.

156. Lamotrigine was “defective” and “unreasonably dangerous” when the drug was promoted and entered into the stream of commerce and was received by Plaintiffs.

157. Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiffs seek recovery.

158. A reasonably competent physician who prescribed Lamotrigine and reasonably competent Plaintiffs who consumed Lamotrigine would not realize its dangerous condition.

159. The reasonably foreseeable use of Lamotrigine involved substantial dangers not readily recognizable by Plaintiffs’ physician, who acted as an ordinary reasonable and prudent physicians would, when prescribing Lamotrigine to an ordinary, reasonable and prudent patient, like Plaintiffs.

160. Defendants knew that Lamotrigine which was to be prescribed by physicians and used by foreseeable users without inspection for defects in Lamotrigine or in any of its components or ingredients and that Lamotrigine was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

161. Plaintiffs and Plaintiffs’ physicians did not know, nor had reason to know, at the time of the use of Lamotrigine, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

162. These defects caused serious injuries to Plaintiffs when the Lamotrigine

was used in its intended and foreseeable manner, and in the manner recommended by Defendants or in a non-intended manner that was reasonably foreseeable.

163. By virtue of Defendants' acts and omissions, Defendants is liable to Plaintiffs because Defendants' acts and omissions have proximately caused Plaintiffs to suffer permanent injuries.

164. Plaintiffs used Lamotrigine, which was provided to him, respectively, in a condition that was substantially the same as the condition in which it was manufactured and sold.

165. Defendants through their affirmative misrepresentations and omissions actively concealed from Plaintiffs and her physicians the true and significant risks associated with taking Lamotrigine; and thus, the running of any applicable statute of limitations has been tolled by reason of Defendants' concealment.

166. As a result of Defendants' actions, Plaintiffs and their prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiffs had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

167. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiffs was prevented from pursuing her normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of her ordinary pursuits and enjoyments of life.

168. Equity dictates that this Court provide the Plaintiffs a remedy that provides Plaintiffs with sufficient information and medical monitoring appropriate for

Plaintiffs to make informed decisions related to Plaintiffs' physical well-being. Absent such notice Plaintiffs will be irreparably harmed.

169. Plaintiffs are also entitled to any procedural protections deemed necessary and appropriate to protect Plaintiffs' legal interests.

170. Plaintiffs are entitled to recovery an award for the injuries caused by the Defendants.

171. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, Plaintiffs, has:

- (a) Suffered severe and permanent injuries, which she will be forced to endure for the remainder of Plaintiffs life;
- (b) Suffered physical impairment and disfigurement; and
- (c) Suffered physical pain and suffering;
- (d) Suffered mental pain and suffering; and
- (e) Suffered from loss of enjoyment of life; and
- (f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiffs injuries; and
- (g) Incurred attorney's fees and expenses of litigation related to this action

## **COUNT 1**

### **STRICT LIABILITY**

172. Plaintiffs repeat, reiterate, and re-allege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

173. At all relevant times the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling Carbamazepine drug products as well as Lamotrigine drug products.

174. Defendants, developed, marketed and distributed Carbamazepine drug products as well as Lamotrigine drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of the drug.

175. Carbamazepine drug products as well as Lamotrigine drug products were defective and unreasonably dangerous and were expected to and did reach Plaintiffs without substantial change.

176. At all times mentioned in this Complaint, Carbamazepine drug products as well as Lamotrigine drug products were defective and/or unreasonably dangerous to Plaintiffs and other foreseeable users at the time the drugs left the control of the Defendants.

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

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

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

180. Prior to the manufacturing, sale and distribution of said drug products, Defendants reasonably should have known Carbamazepine drug products as well as

Lamotrigine drug products were in a defective condition as previously described, and reasonably should have known that those who were prescribed and took the same would experience, and did experience, severe physical, mental and emotional injuries.

181. Defendants reasonably should have known from several sources, prior to the date of dispensing of said drug products to Plaintiffs, that Carbamazepine drug products as well as Lamotrigine drug products presented a substantial and unreasonable risk of harm to the public, including Plaintiffs, and as such said consumers of said drug were unreasonably subjected to risk of injury or death from the consumption of said drug products.

182. Carbamazepine drug products as well as Lamotrigine drug products were “defective” and “unreasonably dangerous” when the drugs initially were patented, and subsequently when the drugs were promoted and entered into the stream of commerce and were received by Plaintiffs, in one or more of the following respects:

- (a) At the time the drug left the control of the Defendants the drugs were defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the drug failed to conform to other expressed factual representations upon which Plaintiffs’ physicians justifiably relied, all of which proximately caused the damages for which Plaintiffs seek recovery herein.
- (b) Carbamazepine drug products as well as Lamotrigine drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the drugs left the possession of the Defendants, and that such risks clearly outweighed the utility of Carbamazepine therapy or Lamotrigine therapy or the therapeutic benefits of either drug.
- (c) At the time the drug left the control of the Defendants the drugs possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were reasonably scientifically knowable at the time the drugs left the possession of the Defendants. Specifically, although the Defendants were well aware that the drug products

could potentially cause severe side effects described herein, SJS and TEN, warnings of such adverse health conditions were either not included on the package insert for the drug and/or the warnings were inadequate to inform reasonably prudent physicians and foreseeable users of the risks. The Defendants failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of the drugs.

- (d) The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the drug taking into account the characteristics of the Carbamazepine as well as Lamotrigine, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases the drugs, such as the Plaintiffs.
- (e) The drugs manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants should have known of the risks of injury from Carbamazepine drug products as well as Lamotrigine drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about severe skin reactions, SJS and TEN to foreseeable users.
- (f) The drugs as manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants should have known of the risks of injury from the drugs associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about an increased risk as reported in the medical literature for severe skin reactions, SJS and TEN posed to patients, who were foreseeable users of the drug products.

183. Defendants, in light of reasonably available scientific knowledge, should have known, about the danger that caused the injuries for which Plaintiffs seek recovery.

184. Defendants in light of reasonably available scientific knowledge should have known about the danger associated with use of the drug that caused the damages for which Plaintiffs seek recovery.

185. The reasonably foreseeable use of the drugs involved substantial dangers not

readily recognizable by the ordinary physician who prescribed the drug or the patient, including Plaintiffs, who consumed Carbamazepine drug products as well as Lamotrigine drug products.

186. The Defendants knew that Carbamazepine drug products as well as Lamotrigine drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that the drugs were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were reasonably scientifically knowable at the time of distribution.

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

188. The above defects caused serious injuries to Plaintiffs when the drugs were used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

189. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs developed severe side effects as described herein, including SJS and/or TEN and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

190. For the above reasons, the Defendants are strictly liable without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT 2

### NEGLIGENCE

191. Plaintiffs repeat, reiterate, and re-allege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

192. Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, and sale of their Carbamazepine drug products as well as Lamotrigine drug products to ensure the safety of the drug products and to ensure that the consuming public, including the Plaintiffs and Plaintiffs' physicians and agents, obtained accurate information and instructions for the use of said drugs.

193. As a direct and proximate cause of Defendants' conduct, Plaintiffs have suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including permanent and substantial physical injuries, and expenses attributable to said injuries.

194. Defendants owed a duty toward foreseeable users of Carbamazepine drug products as well as Lamotrigine drug products, including Plaintiffs, to exercise reasonable care to ensure that Carbamazepine drugs as well as Lamotrigine drugs were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate

testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks of a severe cutaneous reactions, SJS and/or TEN, inherent in such use.

195. Defendants failed to exercise reasonable care in testing the drug for side effects in ordinary and foreseeable users, such as Plaintiffs, and failed to disseminate to physicians information concerning the effects of the drugs, which was accurate, not misleading, and otherwise adequate to enable physicians to make informed choices concerning the use of Carbamazepine drug products as well as Lamotrigine drug products.

196. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality, assurance, quality control and/or distribution of the drugs into the stream of interstate commerce in that Defendants knew or should have known that Carbamazepine drug products as well as Lamotrigine drug products created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

197. The dangerous propensities of Carbamazepine drug products as well as Lamotrigine drug products as referenced above were known or scientifically knowable, through appropriate research and testing, to Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe said drugs for Plaintiffs.

198. The information the Defendants disseminated to physicians concerning Carbamazepine drug products as well as Lamotrigine drug products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

199. As a proximate result, Plaintiffs suffered grievous bodily injuries and

consequent economic and other losses when Plaintiffs ingested said drug products, which had been developed, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by Defendants through third parties or related entities.

200. The Defendants was negligent, and breached duties owed to Plaintiffs with respect to Carbamazepine drug products as well as Lamotrigine drug products in one or more of the following respects:

- (a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of the drugs;
- (b) Defendants failed to conduct adequate testing; and
- (c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product; and
- (d) Despite knowledge of hazards, Defendants failed to adequately warn Plaintiffs' physicians or Plaintiffs that the use of Carbamazepine drug products as well as Lamotrigine drug products could result in a severe side effects as described herein, SJS and/or TEN; and
- (e) Despite the fact that the Defendants knew or should have known that their Carbamazepine drug products as well as Lamotrigine drug products caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks associated with said drug as set forth above; Defendants failed to adequately disclose these risks.

201. As a result of Defendants' negligence was prescribed to Plaintiffs, thereby causing Plaintiffs to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this Complaint.

202. Defendants' negligence was a proximate cause of Plaintiffs' harms and injuries that Plaintiffs suffered and will continue to suffer.

203. In the alternative, Defendants' negligent misrepresentations of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing Carbamazepine drug products and/or Lamotrigine drug products. Furthermore, the economic damages and physical harm caused by Defendants' conduct would not have occurred had Defendants exercised the high degree of care imposed upon it and Plaintiffs therefore plead the doctrine of *res ipsa loquitur*.

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

### **COUNT 3**

#### **NEGLIGENT MISREPRESENTATION**

204. Plaintiffs repeat, reiterate, and re-allege each and every allegation contained in this Complaint with the same force and effect as if fully set forth.

205. Defendants owed a duty to disseminate accurate and adequate information concerning said drugs, and to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

206. Defendants disseminated to physicians, through package inserts, and/or the publication of a PDR monograph, and/or otherwise mediums, information concerning the properties and effects of their Carbamazepine drug products as well as Lamotrigine drug products and knew, or should have known that physicians would rely upon that information when making a decision concerning whether to prescribe Carbamazepine therapy as well as Lamotrigine therapy for their patients.

207. Defendants, as drug manufacturers and/or distributors and/or sellers, knew or ought to have realized that so-called "drug product selection laws," enacted in every state, including this state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.

208. Defendants as a drug manufacturer and/or distributor, and/or seller, knew or ought to have realized that they have a duty to ensure that the information accompanying Carbamazepine drug products as well as Lamotrigine drug products is accurate, complete, not misleading, and otherwise adequate.

209. Defendants knew or should have known that they have a duty to monitor medical literature and post marketing adverse events and to report any data affecting the safety of said drugs to the appropriate agency and/or alert the medical community, Plaintiffs' physicians, and through them, Plaintiffs.

210. Defendants knew or ought to have realized, specifically, that physicians, in weighing the potential benefits and potential risks of using Carbamazepine as well as Lamotrigine and in writing prescriptions for said drugs would rely upon information disseminated by Defendants.

211. Defendants knew or ought to have realized that patients receiving prescriptions for said drugs were written in reliance upon information Defendants disseminated as the manufacturer/distributor of said drugs.

212. Defendants knew or should have known that persons ingesting said drugs would be placed in peril of grievous personal injury if information disseminated and relied upon was negligently misleading.

213. Defendants failed to exercise reasonable care to ensure that the information disseminated concerning the properties and effects of said drugs were accurate and not misleading, and as a result disseminated information that was negligently misleading.

214. As a proximate and foreseeable result of Defendants' negligence, Plaintiffs suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiffs' physicians, in reasonable reliance upon the negligently inaccurate information disseminated by Defendants, and believing the information to be true, prescribed for the Plaintiffs the use of Defendants' Carbamazepine drug products and/or Lamotrigine drug products and Plaintiffs ingested, per those prescriptions, said drugs leading to Plaintiffs' injuries.

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

#### **COUNT 4**

#### **NEGLIGENCE *PER SE***

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

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

217. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* and parallel state Food, Drug and Cosmetic Acts and state common law. Said acts constitute a breach of duty

subjecting Defendants to civil liability for the damages arising therefrom inasmuch as such acts constitute negligence *per se*.

218. Plaintiffs, as patients and purchasers exposed to Carbamazepine and/or Lamotrigine, 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.

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

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## **COUNT 5**

### **VIOLATION OF PENNSYLVANIA'S UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW**

220. Plaintiffs repeat, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

221. By reason of the conduct as alleged herein, Defendants violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law (UTPCPL), 73 P.S. § 201-1, et seq., by engaging in fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

222. Defendants knowingly and intentionally induced Plaintiffs to use the drugs through the use of false and/or misleading advertising, representations and statements.

223. The products failed to perform as represented and advertised, and in fact

were unsafe.

224. The Defendants induced the Plaintiffs and Plaintiffs' physician, through the use of false and/or misleading advertising, representations, and statements, as described above, to use and/or prescribe Carbamazepine and/or Lamotrigine which Defendants manufactured and/or distributed and sold, all in violation of the UTPCPL which proscribes, among other things:

- i. Engaging in unfair trade practices as defined in the statute by making false and misleading oral and written statements that have the capacity, tendency or effect of deceiving or misleading consumers;
- ii. Engaging in unfair trade practices as defined in the statute by making representations that its' Carbamazepine as well as Lamotrigine had an approval, characteristic, ingredient, use or benefit which they did not have, including but not limited to statements concerning the health consequences of the use of drugs;
- iii. Engaging in unfair trade practices as defined in the statute by failing to state material facts, the omission of which deceive or tend to deceive, including but not limited to, facts relating to the health consequences of the use of these drugs; and
- iv. Engaging in unfair trade practices as defined in the statute through deception, fraud, misrepresentation, and knowing concealment, suppression and omission of material facts with the intent that consumers rely upon the same in connection with the use and continued use of the drugs.

225. As a direct and proximate result of Defendants' statutory violations,

Plaintiffs used Carbamazepine and/or Lamotrigine as prescribed, which Plaintiffs would not have used had Defendants not issued false and/or misleading advertising, representations and statements.

226. By reason of such violations and pursuant to the laws and regulations of this state, Plaintiffs are entitled to recover all of the monies paid for the products; to be compensated for the cost of medical care arising out of the use of the products; together with any and all actual damages recoverable under the law including, but not limited to, past medical expenses, past wage loss, past pain, suffering, disability and emotional distress.

227. In addition, Plaintiffs are entitled to recover fees and disbursements, including costs of investigation, reasonable attorneys' fees, and any other equitable relief as determined by this Court.

228. Defendants marketed to physicians in a manner calculated to increase sales of the drug and resultant profits to the drug company at the expense of, and in conscious disregard for, the health and safety of Plaintiffs, and other patients alike, as safer and more effective alternative treatments existed.

229. The conduct of the Defendants undertaken consciously and with notice, evinces a willful, wanton, and conscious disregard for the rights, healthy, and safety of patients, including the Plaintiffs, who would be expected to be induced, by that conduct, to ingest Carbamazepine and/or Lamotrigine leading to grievous, debilitating, and potentially permanent personal injury.

230. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs developed severe side effects as described herein, including SJS and/or TENS and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and

mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs' earnings capacity; has incurred and will continue to incur expenses for medical treatment of Plaintiffs' injuries; has suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## **COUNT 6**

### **LOSS OF CONSORTIUM**

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

232. 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.

233. 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 Defendants' conduct.

234. 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.

235. 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.

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

237. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe 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 proved at trial.

238. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## **COUNT 7**

### **WRONGFUL DEATH**

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

240. Decedent Plaintiffs died as a result of their exposure to Carbamazepine as well as Lamotrigine and the Defendants' conduct and are survived by various family members, named and unnamed.

241. The representatives of Decedent Plaintiffs' estates bring these claims on

behalf of the Decedent Plaintiffs' lawful heirs.

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

243. 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.

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

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## **COUNT 8**

### **SURVIVAL ACTION**

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

246. As a direct and proximate result of their exposure to Carbamazepine as well as Lamotrigine and the conduct of Defendants outlined above, Decedent Plaintiffs suffered bodily injury and resulting in 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.

247. The representatives/administrators of Decedent Plaintiffs' estates bring this

claim on behalf of Decedent Plaintiffs' estate and Decedent Plaintiffs' beneficiaries for damages.

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

WHEREFORE, Plaintiffs request judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## **VI. DAMAGES**

249. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiffs ingested Carbamazepine drug products and/or Lamotrigine drug products, which were causally related to and contributed to Plaintiffs' injuries.

250. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiffs suffered extreme emotional distress, anguish, physical injuries, and mental suffering.

251. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiffs experienced extreme embarrassment, shame, anguish, anxiety, and have sustained a loss of enjoyment of life.

252. Plaintiffs seek the recovery for past and future special damages, which includes medication, doctor, rehabilitation, therapy, and other assisted living and nursing care and Plaintiffs also seek general damages in the amount to be determined for the wrongful conduct of the Defendants.

## **VII. DEMAND FOR JURY TRIAL**

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

**VIII. PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for relief against Defendants as follows:

254. For judgment for damages sufficient to compensate for damages, including but not limited to past, present, and future economic expenditures in connection with the injuries sustained by Plaintiffs as a result of ingesting Defendants' Carbamazepine drug products and/or Lamotrigine drug products;

255. For compensatory damages according to proof;

256. For all applicable statutory remedies provided that assert liability for Defendants' wrongdoings and improper conduct;

257. For prejudgment interest, as permitted by law;

258. For reasonable costs, including attorneys fees as permitted by law;

259. For punitive damages; and

260. For all other just and proper relief.

Respectfully Submitted,

BY: /s/ James D. Barger  
James Douglas Barger  
ID No. 310056