CIVIL

U.S. District Court Eastern District of California - Live System (Fresno) CIVIL DOCKET FOR CASE #: 1:13-cv-00524-LJO-JLT

A.S. v. Pfizer, Inc. et al

Assigned to: District Judge Lawrence J. O'Neill Referred to: Magistrate Judge Jennifer L. Thurston

Case in other court: Kern County Superior Court, S-1500-

CV-278692-LHB

Cause: 28:1441 Petition for Removal- Product Liability

Date Filed: 04/12/2013 Jury Demand: Plaintiff

Nature of Suit: 365 Personal Inj. Prod.

Liability

Jurisdiction: Diversity

Plaintiff

A.S.

a child under the age of 18 years, by Ellen Scusa, his mother and Guardian Ad Litem

represented by Karen Barth Menzies

Robinson Calcagnie Robinson Shapiro Davis, Inc. 19 Corporate Plaza Drive Newport Beach, CA 92660 949-720-1288 Fax: 949-720-1292

Email: kbmenzies@rcrsd.com

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Mark P. Robinson, Jr.

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19 Corporate Plaza Drive Newport Beach, CA 92660

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LEAD ATTORNEY

ATTORNEY TO BE NOTICED

V.

Defendant

Pfizer, Inc.

a Delaware Corporation

represented by Daniel Martin Rygorsky

Skadden Arps Slate Meagher and Flom

LLP

300 South Grand Avenue

Suite 3400

Los Angeles, CA 90071-3144

213-687-5000

Fax: 213-687-5600

Email: Daniel.Rygorsky@Skadden.com

ATTORNEY TO BE NOTICED

Defendant

Pfizer International LLC, a New York Limited Liability Corporation

represented by **Daniel Martin Rygorsky**(See above for address)

ATTORNEY TO BE NOTICED

Defendant

McKesson Corporation individually and Doing business as Northstar Rx LLC

Defendant

Wyeth Pharmaceuticals Inc.

represented by **Daniel Martin Rygorsky**(See above for address)

ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
04/12/2013	1	NOTICE of REMOVAL from California State Superior Court, County of Kern, case number S-1500-CV-278692-LHB. by Pfizer International LLC,, Pfizer, Inc., Wyeth Pharmaceuticals Inc (Attachments: # 1 Exhibit Exhibit A, # 2 Civil Cover Sheet)(Rygorsky, Daniel) (Entered: 04/12/2013)
04/12/2013	2	CLERK'S NOTICE: Attn:Rygorsky, Daniel ****New Civil Case Filing Fee Required****Advance payment of the filing fee in the amount of \$350.00 is required and should be submitted electronically using the event NewCase Credit Card Payments. Your case will not be filed until the fee is paid (Local Rule 77-121c). If you wish to pay with cash,check or money order, the fee must be received by the clerk's office within 48 hours of lodging your complaint, or your documents willbe deleted from the court's server. If you need assistance, please contact the CM/ECF help desk at 866-884-5444, or refer to the CM/ECF User's Manual on the court's website. (Martin-Gill, S) (Entered: 04/12/2013)
04/12/2013		RECEIPT number #CAE100022120 \$350.00 fbo Pfizer Inc et al by Patrick E. Guilfoyle on 4/12/2013. (Marrujo, C) (Entered: 04/12/2013)
04/12/2013	4	CIVIL NEW CASE DOCUMENTS ISSUED: Initial Scheduling Conference set for 7/26/2013 at 08:30 AM in Bakersfield at 19th Street (JLT) before Magistrate Judge Jennifer L. Thurston. (Attachments: # 1 Standing Order, # 2 Consent Form, # 3 VDRP) (Jessen, A) (Entered: 04/12/2013)
04/12/2013	<u>5</u>	STATEMENT of Corporate Disclosure by Defendants Pfizer International LLC,, Pfizer, Inc., Wyeth Pharmaceuticals Inc (Rygorsky, Daniel) (Entered: 04/12/2013)
04/17/2013	<u>6</u>	ANSWER with Jury Demand by Pfizer International LLC,, Pfizer, Inc (Attachments: # 1 Proof of Service)(Rygorsky, Daniel) (Entered: 04/17/2013)

04/18/2013	7	MOTION to REMAND by A.S Motion Hearing set for 5/22/2013 at 08:30 AM in Courtroom 4 (LJO) before District Judge Lawrence J. O'Neill. (Attachments: # 1 Brief in Support of Plaintiff's Motion to Remand, # 2 Declaration of Mark P. Robinson, Jr., in Support of Plaintiff's Motion to Remand, # 3 Proposed Order)(Robinson, Mark) (Entered: 04/18/2013)	
04/18/2013	8	CERTIFICATE of SERVICE by Pfizer International LLC,, Pfizer, Inc. re 4 Civil New Case Documents for LJO, 5 Statement, 1 Notice of Removal, (Rygorsky, Daniel) (Entered: 04/18/2013)	
04/18/2013	9	CERTIFICATE of SERVICE by Pfizer International LLC,, Pfizer, Inc (Attachments: # 1 Attachment A)(Rygorsky, Daniel) (Entered: 04/18/2013)	
04/19/2013	10	MINUTE ORDER (Text Only), signed by Magistrate Judge Jennifer L. Thurston on 4/19/2013. LOCATION AND TIME CHANGE: The Motion to Remand 7 currently set for 5/22/2013 at 08:30 AM before District Judge Lawrence J. O'Neill is RESET to 5/22/2013 at 09:30 AM at the United States Courthouse, 510 19th Street, Bakersfield, before Magistrate Judge Jennifer L. Thurston. Appearances via CourtCall are authorized. (Hall, S) (Entered: 04/19/2013)	

PACER Service Center Transaction Receipt						
PACER Login:	pe0286	Client Code:	1235			
Description:	Docket Report	Search Criteria:	1:13-cv-00524-LJO- JLT			
Billable Pages:	3	Cost:	0.30			

Case MDL No. 2458 Document 1-17 Filed 04/24/13 Page 4 of 25

Case 2:13-cv-02577-MWF-FFM Document 1 Filed 04/12/13 Page 177 of 201 Page ID #:443

	FILED
	SUPERIOR COURT, METROPOLITAN DIVISIO COUNTY OF KERN
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Tell Patt Toll Toll Toll Toll Toll Toll Toll To	ENDORSE AN 1 3 2013
Mark P. Robinson, Jr., CA Bar No. 054426 Karen Barth Menzies, CA Bar No. 180234	
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Ed Blizzard	CASE MANAGEMENT CONFERENCE:
Scot Nabers	Hearing Date: X-12-13
BLIZZARD & NABERS 440 Louisiana, Suite 1710	Time: <u>\$150,700</u>
Houston, Texas 77002	Department: 17
713-844-3750; Fax 713-844-3755	See CRC Rule 3,720 Et. Beq.
eblizzard@blizzardlaw.com	
snabers@blizzardlaw.com Attorneys for Plaintiff	
A A A A A A A A A A A A A A A A A A A	
SUPERIOR COURT OF T	HE STATE OF CALIFORNIA
	FAX FILE
COUNTY	Y OF KERN
A S , a child under the age of 18)	CASE NO.
years, by ELLEN SCUSA his mother and	s-1500-CV- 278692LHB
Guardian Ad Litem,	COMPLAINT FOR DAMAGES; DEMAND
Plaintiff,)	FOR JURY TRIAL
j j	
vs)	1. Strict Liability - Failure to Warn
PFIZER, INC., a Delaware Corporation;	Negligence Breach of Implied Warranty
PFIZER INTERNATIONAL LLC, a New York Limited Liability Corporation;	4. Breach of Express Warranty
MCKESSON CORPORATION, individually)	5. Deceit by Concealment -
and d/b/a NORTHSTAR RX LLC, a)	Civil Code §§ 1709, 1710 6. Negligent Misrepresentation
Delaware Corporation; WYETH PHARMACEUTICALS, INC., and DOES 1	7. Fraud and Fraudulent Concealment
through 100, Inclusive,	The same of the sa
Defendants.	
Detendants,	
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NATURE OF THE ACTION

1. This is a products liability case arising out of the personal injury of A S , who was born on 2007, at Ridgecrest Regional Hospital in Kern County, California, A S suffers from serious birth defects as a result of his mother, Ellen Scusa, ingesting Effexor, a prescription drug manufactured and marketed by Defendants, during her pregnancy with A

PARTIES

- 2. Ellen Scusa is a competent adult and the mother of A S. She is a resident of the State of California, Kern County. She brings this action on behalf of A a child under the age of 18, and individually to recover economic and non-economic damages for the personal injuries of her daughter.
- 3. At all relevant times alleged herein, one or more of the corporate Defendants was, and now is, a corporation with its principal place of business in the State of California.
- 2. At all relevant times alleged herein, one or more of the individual Defendants was, and now is, a resident of the State of California.
- 3. At all relevant times alleged herein, the Defendants were in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising, distributing, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the pharmaceutical product known as Effexor.
- 4. At all times relevant hereto, Defendants designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold Effexor in interstate commerce throughout the United States including, inter alia, Kern County, California. Furthermore, Defendants conducted substantial business, advertised Effexor, received substantial compensation and profits from sales of the Effexor, made material omissions and misrepresentations, and committed breaches of warranties throughout the United States including, inter alia, Kern County, California.
- 5. At all times relevant hereto, Defendants, and each of them, were engaged in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising,

COMPLAINT FOR DAMAGES

 distributing, selling, and introducing Effexor into interstate commerce, either directly or indirectly through third parties or related entities.

- 6. On information and belief, Defendant McKesson Corporation is a Delaware corporation with its principal place of business at One Post Street, San Francisco, California 94104. Defendant McKesson Corporation was and is authorized to do business in the state of California and is engaged in substantial commerce and business activity in Kern County. Jurisdiction over Defendant in California is appropriate under California law.
- 7. On information and belief, at all times relevant hereto, Defendant McKesson was engaged in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, supplying, distributing, marketing, promoting, advertising, selling and/or warranting Effexor, which is detailed below. Plaintiff is informed and believes Defendant McKesson distributed the Effexor that was dispensed to Ms. Scusa.
- 8. According to Pfizer's website, at all times herein, Defendant McKesson Corporation was the largest single distributor of Defendant Pfizer, Inc.'s pharmaceutical products, including those products Defendant Pfizer, Inc., sold in the State of California. As stated in Pfizer's Form 10-K for 2006, the year Ms. Scusa was pregnant with A 20% of Defendant Pfizer's total revenues were sales to Defendant McKesson Corporation.
- 9. On information and belief, Defendant Pfizer Inc., a Delaware Corporation, was and still is, a corporation duly existing under and virtue of the laws of the State of Delaware with its principal place of business in New York, New York. At all times hereinafter mentioned, defendant Pfizer Inc. was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public the drug Effexor (known generically as venlafaxine), an antidepressant, throughout the United States and the State of California.
- 10. On information and belief, Pfizer International LLC, a New York Corporation, was and still is, a corporation duly existing under and virtue of the laws of the State of New York with its principal place of business in New York, New York. At all time hereinafter mentioned, defendant Pfizer International LLC was, and still is, a pharmaceutical company involved in research, development,

 testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public the drug Effexor throughout the United States and the State of California.

- 11. Defendant Wyeth Pharmaceuticals, Inc., a Delaware Corporation, was a corporation duly existing under and by virtue of the laws of the State of Delaware with its principal palce of business in Philadelphia, Pennsylvania. Upon information and belief, Wyeth Pharmaceuticals, Inc. was purchased by Pfizer, Inc. in October of 2009. Wyeth Pharmaceuticals, Inc. is now a subsidiary of Pfizer, Inc., and is located in Philadelphia, Pennsylvania.
- 12. Pfizer Inc., Pfizer International LLC and Wyeth Pharmaceuticals, Inc. hereinafter shall be referred to as the "Pfizer Defendants."
- 13. On information and belief, at all times relevant hereto, the Defendants were each engaged in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising, distributing, selling, and/or introducing into interstate commerce Effexor, either directly or indirectly through third parties or related entities and/or the Defendants are otherwise responsible as corporate successors for the liabilities of the entities that designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold Effexor. Plaintiff is informed and believes Pfizer Defendants manufactured the Effexor that was dispensed to Ms. Scusa.
- 14. On information and belief, at all relevant times, the Pfizer Defendants were present and doing business in the State of California.
- 15. On information and belief, at all relevant times, the Pfizer Defendants transacted, solicited, and conducted business in the State of California and derived substantial revenue from such business.
- 16. On information and belief, at all relevant times, the Pfizer Defendants expected or should have expected that their acts would have consequences within the United States of America, including the State of California.
- 17. The true names or capacities, whether individual, corporate, or otherwise, of Defendants DOES 1 through 100, inclusive, are unknown to Plaintiff who therefore sues said Defendants by such

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 fictitious names. Plaintiff believes and alleges that each of the Defendants designated herein by fictitious names is in some manner legally responsible for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiff as alleged herein.

- 18. At all times herein alleged, "Defendants" include all herein named Defendants as well as Defendants DOES 1 through 100, inclusive.
- 19. At all times herein alleged, each of the Defendants was an agent, servant, partner, aider and abetter, co-conspirator and joint-venturer of each of the remaining Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty owed to Plaintiff.
- 20. There exists, and at all times herein alleged, there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and promote injustice.
- 21. At all times herein alleged, the officers and directors of the Defendants named herein participated in, authorized and directed the production and promotion of Effexor when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of Effexor and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff.
- 22. DOES 1 through 100, and each of them, acted independently of, or jointly with, other Defendants, and are all in some manner legally responsible for the events and happenings herein referred to, and caused damages proximately and foreseeably to Plaintiff as alleged herein.

GENERAL ALLEGATIONS

24. The drug "venlafaxine" is manufactured, promoted, distributed, labeled and marketed by Defendants under the trade name Effexor and is a member of the class of drugs known as "serotonin-norepinephrine reuptake inhibitors" or "SNRIs." Effexor was first approved for use in the United States by the FDA in 1993 and it is licensed for the treatment of major depressive disorder (MDD), generalized

anxiety disorder (GAD), and certain other anxiety and depression disorders. In 2006, the timeframe
when Ellen Scusa was prescribed Effexor during his pregnancy with A State, Effexor was the sixtle
most commonly prescribed antidepressant on the U.S. retail market, with \$2.25 billion in sales the same
year. Effexor has never been approved by the FDA for use in pregnant women.

- 25. Ellen Scusa, A S small's mother, took Effexor as prescribed by her treating physician while pregnant with A in California.
- 26. At the time Effexor was prescribed to Ms. Scusa, Defendants knew through animal studies and post-marketing reports that Effexor was associated with a significant increased risk of cardiac defects in babies whose mothers ingested Effexor during pregnancy. Other studies showed that increased levels of serotonin, the primary human substance affected by Effexor, had profound effects on the pre-natal development of study animals.
- 27. Notwithstanding this knowledge, Defendants aggressively and actively promoted Effexor. The Pfizer Defendants touted Effexor as being a safe alternative for pregnant women. In fact, none of this was true.
- 28. The Pfizer Defendants have never informed doctors of these serious risks, even though third-party research shows the association between Effexor and cardiac defects and several other types of birth defects.
- 29. When Adam was born, he was diagnosed a with life-threatening congenital heart defect called pulmonary artery stenosis.
- 30. On February 22, 2007, A underwent a balloon pulmonary valvuloplasty in an effort to repair his heart defect. A continues to be monitored by his physicians and may require future intervention and/or surgeries.
- 31. The heart defect suffered by A was a direct result of his mother's ingestion of Effexor during her pregnancy. Prior to the time Ms. Scusa ingested Effexor during her pregnancy with A the Pfizer Defendants knew or should have known that Effexor was associated with an increased risk of congenital heart defects and other birth defects in babies of mothers who ingest Effexor during pregnancy.
- 32. During the entire time Effexor has been on the market in the United States, FDA regulations required the Pfizer Defendants to issue stronger warnings whenever there existed reasonable evidence of an association between a serious hazard and Effexor. The regulations specifically state that a causal link need not have been proven to issue the new warnings. Further, the regulations explicitly

allowed the Pfizer Defendants to issue such a warning without prior FDA approval.

- 33. Thus, prior to Ms. Scusa's pregnancy with A the Pfizer Defendants had the knowledge, the means and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between Effexor and birth defects through all means necessary including but not limited to labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements and promotional materials, etc. The Pfizer Defendants breached this duty.
- 34. Ms. Scusa filed this lawsuit within the applicable limitations period of first suspecting that Effexor was the cause of A sinjuries.
- 35. Plaintiff was prevented from discovering this information sooner because the Pfizer Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug is safe to take during pregnancy. The Pfizer Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.
- 36. Plaintiff's injuries were caused by Effexor's defects and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of the Pfizer Defendants. As a result of the Pfizer Defendants' claims and representations regarding the effectiveness and safety of Effexor, Ms. Scusa was prescribed Effexor and used and consumed Effexor in accordance with its directions. Had the Defendants properly disclosed risks associated with the Effexor, Ms. Scusa would not have used it during her pregnancy with A would not have suffered the serious and permanent injuries described herein.
- 37. Prior to Ms. Scusa's use of Effexor, the Pfizer Defendants knew or should have known that the use of Effexor created a significantly increased risk of birth defects occurring when taken during pregnancy, and that during pregnancy, even when used as directed, Effexor was unreasonably dangerous to consumers.
- 38. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Effexor during pregnancy, Defendants failed to warn Ms. Scusa, her health care providers, or the public and the medical community of said serious risks before Ms. Scusa used Effexor.

- 39. Had Ms. Scusa's prescribing physicians and health care providers known the risks and dangers associated with Effexor, they would not have prescribed it or would have advised her to discontinue using Effexor during her pregnancy, and A would not have suffered these serious injuries.
- 40. Had Ms. Scusa known the risks and dangers associated with Effexor, she would not have used it during his pregnancy, and A would not have suffered serious injuries and consequent damages.
- 41. As a direct and proximate result of Effexor's defects and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Plaintiff has suffered significant harm.

 A sustained pecuniary loss resulting from the pain and suffering from his heart malformations, by the general surgeries and procedures he underwent between the time of his birth to present, and additional general damages. He continues to require reasonable and necessary health care, attention and services, and has incurred, medical, incidental, and service expenses pertaining to his injuries, and will continue to incur such expenses in the future.
- 42. Plaintiff incurred medical expenses and other economic harm including loss of earnings, and will continue to incur expenses, loss of earnings and future earning capacity.
- 43. Defendants falsely and fraudulently represented to Plaintiff's mother, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, that Effexor was safe and effective for its indicated use during pregnancy.
- 44. These false representations were made by Defendants with the intent of defrauding and deceiving Ms. Scusa, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, and were made with the intent of inducing them to recommend, dispense and purchase Effexor, all of which evinced a callous, reckless and willful indifference to safety.
- 45. Defendants knew and were aware or should have been aware that Effexor had not been sufficiently tested for use during pregnancy, was defective in its design and testing, and lacked adequate and sufficient warnings.

- 46. Defendants knew or should have known that Effexor increased the risk of birth defects when used during pregnancy, was inherently dangerous in a manner that exceeded any purported benefit of the medication, and that the labeling was inaccurate and downplayed warnings.
- 47. Defendants were under a duty to disclose to Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, the defective nature of Effexor.
- 48. Defendants had sole access to material facts concerning the defective nature of Effexor and its propensity to increase the risks of birth defects, and hence, cause damage to consumers, including Plaintiff.
- 49. Defendants made the misrepresentations and actively concealed information concerning the safety and efficacy of Effexor with the intention and specific desire that the medical, pharmaceutical and scientific communities, and consumers, including Ms. Scusa, her prescribing physicians and healthcare providers, would rely on such in selecting Effexor to treat his anxiety.
- 50. Defendants made these misrepresentations and actively concealed information concerning the safety and efficacy of Effexor in their labeling, advertising, product inserts, promotional material or other marketing efforts.
- 51. The misrepresentations and active concealments by Defendants were perpetuated directly and indirectly by Defendants, their sales representative, employees, distributors, agents and detail persons.
- 52. Defendants knew that Ms. Scusa, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Effexor, as set forth herein.
- 53. The misrepresentations and active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Effexor when used during pregnancy.
- 54. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and scientific communities, and users and consumers of the drug, including Ms. Scusa, about the potential

 risks and serious side effects associated with the use of Effexor in a timely manner, yet they failed to provide such warnings.

- 55. As a result of the Defendants' advertising and marketing efforts, concealment and misrepresentations, Effexor is and continues to be pervasively prescribed and used throughout the United States,
- 56. During the time that Effexor has been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Effexor.
- 57. At all times material hereto, the Defendants knew or should have known that most physicians were not aware of, or did not fully appreciate the seriousness of the risks associated with use of Effexor during pregnancy, either as Effexor, or in the generic form of venlafaxine, and Defendants knew or should have known that package inserts for Effexor and generic versions of the drug were deficient, inaccurate, false and misleading in communicating to the medical community in general, to physicians, or to the public, information about the risks associated with the drug when used during pregnancy.
- 58. The Defendants failed to adequately inform physicians and misled physicians about the risks associated with Effexor, despite the fact that they knew that the medical community in general, physicians, pharmacists, Ms. Scusa, and others similarly situated relied on them to disclose and communicate to doctors what they knew and what experts in the use and effects of the drug would know from a prudent review of the information that they possessed or were reasonably able to obtain.
- 59. Because of the misleading and inaccurate information that Defendants disseminated to physicians, and because of the failure of the Defendants generally to adequately and effectively inform physicians, the medical community or the FDA about the true risks associated with the use of Effexor and generic venlafaxine, Ms. Scusa's physicians did not know or appreciate fully the risks associated with the using Effexor during pregnancy.
- 60. Defendants knew, and through the exercise of reasonable care should have known, that the labeling for Effexor and generic venlafaxine substantially understated the risks and overstated the efficacy of the drug. They failed to use reasonable care to ascertain or communicate to physicians or to the public information that would constitute adequate and effective warnings to physicians or to the

 public about the true risks of using the drug during pregnancy.

- 61. Defendants were aware that their individual and collective failure to communicate to the medical community and to physicians, information known to them about the risks of use during pregnancy and that using Effexor would be likely to result in serious injury to patients who received the drug in accordance with prescriptions issued by physicians who were unaware of this information. By failing to communicate this information to the medical community or the FDA, the Defendants acted in willful and wanton disregard of the rights of Plaintiff, and this conduct caused serious injury to A
- 62. As manufacturers and distributors of prescription drug products, specifically Effexor and/or generic venlafaxine, each of the Defendants has a duty to adequately communicate warnings to physicians and the medical community (or to patients who could be expected to take the drug) and to exercise due care to conduct safety surveillance for the drug and otherwise ensure that the warnings they are required to disseminate about the drug are accurate and adequate, and that these warnings are effectively communicated to physicians, pharmacists, and patients using the drug.
- 63. Each of the Defendants breached its duty to ensure that adequate warnings were provided to the medical community, Ms. Scusa's physicians, Ms. Scusa, and/or other foreseeable Effexor and/or venlafaxine users similarly situated, in that they failed to:
 - a. ensure Effexor and/or venlafaxine warnings to the medical community,
 physicians, and Ms. Scusa's physician were accurate and adequate, despite
 having extensive knowledge of the risks associated with using the drug
 during pregnancy;
 - ensure that Effexor and/or venlafaxine warnings were effectively communicated to the medical community, physicians and Ms Scusa, despite having extensive knowledge of the inappropriate use of the drug during pregnancy;
 - c. conduct post market safety surveillance and report that information to the FDA, the medical community, Ms. Scusa's physicians, Ms Scusa and other foreseeable users;

- d. review all adverse drug event (ADE) information for Effexor and/or venlafaxine, and to report information bearing significantly upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Effexor and/or venlafaxine products to the FDA, medical community, Ms. Scusa's physicians, Ms. Scusa and other like foreseeable users;
- e. periodically review all medical literature regarding Effexor and/or venlafaxine products and report to the FDA, the medical community, or other interested individuals significant data concerning the efficacy or safety of Effexor and/or venlafaxine products;
- f. independently monitor sales of Effexor and/or venlafaxine products, and the medical literature, which would have alerted them to the fact that Effexor was widely over prescribed, and was being prescribed to pregnancy women and women in their child-bearing years owing to the inadequate warnings provided to doctors;
- g. engage in responsible testing, research, and pharmacovigilance practices regarding their Effexor and/or venlafaxine products, including a failure to perform studies and/or monitor, which would accurately determine the risks attendant to using Effexor during pregnancy, and failed to engage in marketing practices designed to minimize the risks associated with Effexor and/or venlafaxine.
- 64. The acts, conduct, and omissions of Defendants, and each of them, as alleged throughout this Complaint were fraudulent, willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Effexor and/or venlafaxine products, and for the primary purpose of increasing Defendants' profits from the sale and distribution of the drug. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against each Defendant in an amount appropriate to punish and make an example of each Defendant.

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- 65. Prior to the manufacturing, sale and distribution of Effexor and/or venlafaxine products, Defendants, and each of them, knew that the drugs were in a defective condition as previously described herein and knew that those who were prescribed the drugs would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants and each of them through their officers, directors, managers, and agents, had knowledge that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such, consumers of the drug were unreasonably subjected to risk of injury or death.
- 66. Despite such knowledge, Defendants, and each of them, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in the drugs and failed to warn the public, including to the Plaintiff, his mother's prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, of the extreme risk of injury occasioned by said defects inherent in the drugs. Defendants and their individual agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of the drugs knowing that the public, including Plaintiff, would be exposed to serious danger in order to advance Defendants' own pecuniary interest and monetary profits.
- 67. Defendants' conduct was despicable, and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for safety, entitling Plaintiff to exemplary damages under Civil Code § 3294.
- 68. Plaintiff maintains and reserves his rights to plead additional facts, theories of liability, causes of action in the complaint, and/or to present evidence pertaining to the acts and omissions of Defendants as may be subsequently identified through discovery and investigation in this matter. Plaintiff reserves the right to present such evidence at the time of trial based upon such subsequently discovered acts, omissions or damages that are heretofore unknown or unidentified prior to the date of service of this complaint and maintain and reserve their rights to thereafter move the court to conform pleadings to proof in this matter.

FIRST CAUSE OF ACTION

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STRICT LIABILITY IN TORT – FAILURE TO WARN

- 69. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.
- 70. Effexor was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that, and not by way of limitation, the Effexor warnings, instructions and directions failed to warn of the dangerous risks posed by Effexor, including increased dangerous propensities as compared to other similar and comparable alternatives, which risks were known or reasonably scientifically knowable to Defendants. The Defendants, and each of them, knew or should have known of the defective condition, characteristics and risks associated with Effexor, as previously set forth herein.
- 71. At all times herein alleged, Effexor was defective and Defendants, and each of them, knew that the Effexor was to be used by consumers without inspection for defects therein. Moreover, Ms. Scusa, her prescribing physicians and health care providers, neither knew, nor had reason to know at the time of his use of Effexor of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which Defendants failed to include appropriate warnings.
- 72. At all times herein mentioned, Effexor was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.
- 73. As a result of Effexor's defective condition, namely the lack of sufficient warnings, Plaintiff suffered the injuries and damages as alleged herein.

SECOND CAUSE OF ACTION

NEGLIGENCE

- 74. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.
- 75. At all times relevant hereto, Defendants, and each of them, had a duty to properly manufacture, design, formulate, distribute, compound, produce, process, assemble, test, inspect, research, market, label, package, prepare for use, issue warnings with respect to, promote, advertise, sell

COMPLAINT FOR DAMAGES

 and monitor the use of Effexor, and to adequately test and warn of the risks and dangers of Effexor both before and after sale, and to recall the products upon discovering that the warnings and information issued in connection with Effexor were inadequate, and that prescribing physicians and consumers did not fully understand the risks associated with Effexor.

- 76. At all times relevant hereto, Defendants, and each of them, breached their duties in that they negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, tested, inspected, researched, marketed, labeled, packaged, prepared for use, issued warnings with respect to, promoted, advertised, sold and monitored the use of Effexor; failed to adequately test and warn of the risks and dangers of Effexor both before and after their sale; and failed to recall Effexor after becoming aware that it was defective and causing injuries after becoming aware that the warnings and information issued in connection with Effexor were inadequate, and that prescribing physicians and consumers did not fully understand the risks associated with using Effexor during pregnancy.
- 77. As a result of the breach of the Defendants' duties with respect to Effexor, Plaintiff suffered the injuries and damages as alleged herein.

THIRD CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

- 78. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.
- 79. Prior to the use of Effexor, Defendants, and each of them, impliedly warranted to Ms. Scusa, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, that Effexor was merchantable quality and safe and fit for the use for which it was intended.
- 80. Ms. Scusa and her physicians and healthcare providers were, and remain, unskilled in the research, design, and manufacture of Effexor and reasonably relied entirely on the skill, judgment, and implied warranty of Defendants in using Effexor.
- 81. The Defendants breached their warranties in that, Effexor was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Effexor had dangerous

propensities and known or knowable side effects when put to its intended use during pregnancy and would cause severe injuries to the user and his unborn child, which propensities and side effects were known or knowable but were not warned of by the Defendants.

82. As a result of the aforementioned breach of implied warranties by Defendants and each of them, Plaintiff suffered the injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

- 83. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.
- 84. At all times herein alleged, Defendants, and each of them, expressly represented and warranted to the Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, by and through statements made by Defendants, their authorized agents, and sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, patients, and the general public, that Effexor was safe, effective, fit, and proper for it intended use, and Effexor was purchased in reliance upon said express warranties.
- 85. In using Effexor, Ms. Scusa and his prescribing physicians and healthcare providers, relied on the skill, judgment, representations, and express warranties of Defendants. Said warranties and representations were false, in that Effexor was not safe and was unfit for the use for which it was intended.
- 86. As a result of the foregoing breach of express warranties by Defendants, and each of them, Plaintiff sustained the injuries and damages as described above.

FIFTH CAUSE OF ACTION

DECEIT BY CONCEALMENT - CALIFORNIA CIVIL CODE §§ 1709, 1710

- 87. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.
- 88. Defendants, and each of them, from the time that Effexor was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, willfully

deceived the Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, by concealing from them the true facts concerning Effexor use during pregnancy, which the Defendants had a duty to disclose.

- 89. At all times relevant hereto, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of Effexor and willfully deceived Ms. Scusa, and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general as to the health risks and consequences of the use of Effexor during pregnancy. Defendants, and each of them, were aware of the foregoing, and that Effexor was not safe, fit, and effective for human consumption. Furthermore, Defendants were aware that the use of Effexor was hazardous to take during pregnancy, and that Effexor has a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered as described herein.
- 90. Defendants intentionally concealed and suppressed the true facts concerning Effexor with the intent to defraud Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, in that Defendants knew that the physicians and healthcare providers would not have prescribed Effexor for use during pregnancy and Ms. Scusa would not have used Effexor if she had known the true facts concerning the dangers of Effexor.
- 91. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiff suffered the injuries and damages as described above.

SIXTH CAUSE OF ACTION

NECLIGENT MISREPRESENTATION

- 92. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.
- 93. Defendants, and each of them, from the time that Effexor was first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public

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in general, including, but not limited to, the misrepresentation that Effexor was safe, fit, and effective for human consumption during pregnancy.

- 94. At all times relevant hereto, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of Effexor to women of child-bearing years and willfully deceive Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general as to the health risks and consequences of the use of Effexor during pregnancy.
- Defendants made the foregoing misrepresentations without any reasonable ground for believing them to be true. These misrepresentations were made directly by Defendants, by sales representatives, detail persons and other authorized agents of said Defendants, and in publications and other written materials directed to Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, with the intention of inducing reliance and the prescription, purchase, and use of Effexor.
- The foregoing representations by Defendants, and each of them, were in fact false, in that 96. Effexor is not, and at all relevant times alleged herein was not, safe, fit, and effective for human consumption during pregnancy, the use of Effexor is hazardous to health of the unborn child, and Effexor has a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered as described above. The foregoing misrepresentations by Defendants, and each of them, were made with the intention of inducing reliance and inducing the prescription, purchase, and use of Effexor.
- 97. In reliance on the misrepresentations by Defendants, and each of them, Ms. Scusa and her prescribing physicians and healthcare providers were induced to purchase and use Effexor. If they had known of the true facts and the facts concealed by Defendants, they would not have used Effexor and their reliance upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.
- As a result of the foregoing negligent misrepresentations by Defendants, and each of them, Plaintiff suffered the injuries and damages as described above.

SEVENTH CAUSE OF ACTION

FRAUD and FRAUDULENT CONCEALMENT

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99. Plaintiff re-alleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

- 100. Plaintiff is informed and believes and based thereon alleges that Defendants, while knowing that Effexor poses a significant risk of harm to the fetus when used during pregnancy, orchestrated a sophisticated, comprehensive, multi-pronged marketing scheme to convince Ms. Scusa and the general consuming public, the healthcare community and others that Effexor was safe and effective for use during pregnancy.
- 101. Plaintiff is informed and believes and based thereon alleges that, while knowing that the Effexor is not effective, and that it poses a significant risk of injury to a fetus when used during pregnancy, Defendants implemented a false, fraudulent and misleading nationwide marketing campaign concerning Effexor.
- 102. Plaintiff is informed and believes and based thereon alleges that, while knowing that Effexor poses a significant increase in risk to the fetus when used during pregnancy of adverse events including, but not limited to, birth defects, heart defects, serious injuries and death, Defendants implemented a false, fraudulent and misleading nationwide "Direct to Consumer" (DTC) advertising campaign via television commercials on major television networks, internet advertisements on major internet sites and search engines, and print advertisements in major newspapers and magazines with national circulation.
- 103. Plaintiff is informed and believes and based thereon alleges that Defendants' false, fraudulent and misleading DTC advertising and marketing of Effexor specifically state that Effexor is safe and effective for use during pregnancy.
- 104. Plaintiff is informed and believes and based thereon alleges that said false, fraudulent and misleading advertising, marketing messages, publications and all other such public statements were issued by Defendants in order to conceal (and did so conceal) the true risks of Effexor use during pregnancy, to conceal the causal relationship between use of Effexor and the injuries and damages suffered by Plaintiff, to conceal the grounds and /or basis for a legal cause of action by Plaintiff against

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Defendants herein. Said fraud, fraudulent concealment and fraudulent means to achieve said concealment caused Plaintiff to reasonably and detrimentally rely on such fraudulent statements and conduct until within two years of the filing of this action when Plaintiff discovered the Defendants' fraud, fraudulent concealment and other acts and omissions that resulted in successful suppression and denial of the increased risk of birth defects and other injuries caused by the use of Effexor during pregnancy.

- 105. Plaintiff is informed and believes and based thereon alleges that Defendants, and each of them, further falsely and fraudulently represented to Ms. Scusa and her physicians, and members of the general public, that Effexor was safe for use during pregnancy in treatment of depression and anxiety. The representations by Defendants, and each of them, were in fact, false. The true facts were that Effexor was not safe for use by and members of the general public during pregnancy and was, in fact, extremely dangerous to consumers.
- 106. Plaintiff is informed and believes and based thereon alleges that Defendants, and each of them, further misrepresented the safety of Effexor, represented that Effexor were safe and effective and safe for use during pregnancy, and concealed warnings of the known or knowable risks of taking Effexor during pregnancy.
- 107. Plaintiff is informed and believes and based thereon alleges that when the Defendants, and each of them, made the representations as alleged herein, they knew that such representations were false. Defendants, and each of them, made the representations with the intent to defraud and deceive Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, and with the intent to induce them to use the products and act in the manner alleged in this complaint.
- 108. Ms. Scusa and her prescribing physicians and healthcare providers took the actions alleged in this complaint, while ignorant of the falsity of the representations and reasonably believed them to be true. In reliance upon such representations, she was induced to, and did, use Effexor as described in this complaint. If she had known the actual facts, she would not have taken such actions nor would she have used Effexor during his pregnancy with A Her reliance upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by

 individuals and entities that were in a position to know the true facts. As a direct and proximate result of Defendants' fraud and deceit, Plaintiff sustained the injuries and damages described in this complaint.

- 109. By and through the Defendants' false statements, fraudulent conduct and fraudulent concealment of facts as alleged herein, Plaintiff was prevented from discovering the wrongful conduct of Defendants with regard to Effexor and was thereby prevented from discovering these causes of action against Defendants herein. Therefore, Defendants are estopped from asserting any statute of limitations defenses in this matter as such statutes of limitation have been delayed in accrual and/or have been tolled due to Defendants' conduct. So long as Defendants continue to deny the increased risk of birth defects, the adverse events and the causal relationship between Effexor and Plaintiff's injuries, all such statutes of limitation applicable to the causes of action asserted herein are, and will continue to be, tolled.
- 110. As a direct and proximate result of Defendants' fraud and deceit, Plaintiff sustained the injuries and damages described in this complaint.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment against Defendants PFIZER, INC.; PFIZER INTERNATIONAL LLC; MCKESSON CORPORATION; WYETH PHARMACEUTICALS and DOES 1 through 100, inclusive, jointly and severally, and as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff as follows:

- 1. General damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
 - 2. Economic and special damages according to proof at the time of trial;
 - 3. Loss of earnings and impaired earning capacity according to proof at the time of trial;
 - 4. Medical expenses according to proof at the time of trial;
 - For mental and emotional distress, according to proof;
 - 6. Punitive or exemplary damages according to proof at the time of trial;
 - 7. Attorney's fees;
 - 8. For costs of suit incurred herein;
 - 9. For pre-judgment interest as provided by law; and

COMPLAINT FOR DAMAGES

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1	10. For such other and further relief as the Court may deem just and proper,
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3	Dated: February 12, 2013 ROBINSON CALCAGNIE ROBINSON SHAPIRO DAVIS, INC.
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5 6	BLIZZARD & NABERS
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8	By: Mark P. Robinson, Jr.
9	By:
10	Attorneys for Plaintiff
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13	DEMAND FOR JURY TRIAL
14	Plaintiff hereby demands a jury trial on all claims so triable.
15	Dated: February 12, 2013 ROBINSON CALCAGNIE ROBINSON
16	SHAPIRO DAVIS, INC.
17 18	and .
19	BLIZZARD & NABERS
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	COMPLAINT FOR DAMAGES
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