

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.
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Newport Beach, CA 92660
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ATTORNEY TO BE NOTICED

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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
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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	<u>1</u>	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: # <u>1</u> Exhibit Exhibit A, # <u>2</u> 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 theCM/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	<u>4</u>	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: # <u>1</u> Standing Order, # <u>2</u> Consent Form, # <u>3</u> 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: # <u>1</u> Proof of Service)(Rygorsky, Daniel) (Entered: 04/17/2013)

04/18/2013	<u>7</u>	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: # <u>1</u> Brief in Support of Plaintiff's Motion to Remand, # <u>2</u> Declaration of Mark P. Robinson, Jr., in Support of Plaintiff's Motion to Remand, # <u>3</u> Proposed Order)(Robinson, Mark) (Entered: 04/18/2013)
04/18/2013	<u>8</u>	CERTIFICATE of SERVICE by Pfizer International LLC,, Pfizer, Inc. re <u>4</u> Civil New Case Documents for LJO, <u>5</u> Statement, <u>1</u> Notice of Removal,. (Rygorsky, Daniel) (Entered: 04/18/2013)
04/18/2013	<u>9</u>	CERTIFICATE of SERVICE by Pfizer International LLC,, Pfizer, Inc.. (Attachments: # <u>1</u> 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 <u>7</u> 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			
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FILED
SUPERIOR COURT, METROPOLITAN DIVISION
COUNTY OF KERN

ENDORSED

JAN 13 2013
TERRY McNALLY, CLERK
BY _____ DEPUTY

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CASE MANAGEMENT CONFERENCE:
Hearing Date: 8-12-13
Time: 8:30am
Department: 17
See GRC Rule 3.720 Et. Seq.

15 SUPERIOR COURT OF THE STATE OF CALIFORNIA
16 COUNTY OF KERN

FAX FILE

17 A [REDACTED] S [REDACTED], a child under the age of 18
18 years, by ELLEN SCUSA his mother and
19 Guardian Ad Litem,

20 Plaintiff,

21 vs

22 PFIZER, INC., a Delaware Corporation;
23 PFIZER INTERNATIONAL LLC, a New
24 York Limited Liability Corporation;
25 MCKESSON CORPORATION, individually
26 and d/b/a NORTHESTAR RX LLC, a
27 Delaware Corporation; WYETH
28 PHARMACEUTICALS, INC., and DOES 1
through 100, Inclusive,

Defendants.

) CASE NO.
) **S-1500-CV- 278692LHB**
) **COMPLAINT FOR DAMAGES; DEMAND**
) **FOR JURY TRIAL**

- 1. Strict Liability - Failure to Warn
- 2. Negligence
- 3. Breach of Implied Warranty
- 4. Breach of Express Warranty
- 5. Deceit by Concealment -
Civil Code §§ 1709, 1710
- 6. Negligent Misrepresentation
- 7. Fraud and Fraudulent Concealment

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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,

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

3 6. On information and belief, Defendant McKesson Corporation is a Delaware corporation
4 with its principal place of business at One Post Street, San Francisco, California 94104. Defendant
5 McKesson Corporation was and is authorized to do business in the state of California and is engaged in
6 substantial commerce and business activity in Kern County. Jurisdiction over Defendant in California is
7 appropriate under California law.

8 7. On information and belief, at all times relevant hereto, Defendant McKesson was engaged
9 in the business of researching, designing, developing, licensing, compounding, testing, producing,
10 manufacturing, assembling, processing, packaging, inspecting, labeling, supplying, distributing,
11 marketing, promoting, advertising, selling and/or warranting Effexor, which is detailed below. Plaintiff
12 is informed and believes Defendant McKesson distributed the Effexor that was dispensed to Ms. Scusa.

13 8. According to Pfizer's website, at all times herein, Defendant McKesson Corporation was
14 the largest single distributor of Defendant Pfizer, Inc.'s pharmaceutical products, including those
15 products Defendant Pfizer, Inc., sold in the State of California. As stated in Pfizer's Form 10-K for
16 2006, the year Ms. Scusa was pregnant with A [REDACTED], 20% of Defendant Pfizer's total revenues were sales
17 to Defendant McKesson Corporation.

18 9. On information and belief, Defendant Pfizer Inc., a Delaware Corporation, was and still is,
19 a corporation duly existing under and virtue of the laws of the State of Delaware with its principal place
20 of business in New York, New York. At all times hereinafter mentioned, defendant Pfizer Inc. was, and
21 still is, a pharmaceutical company involved in research, development, testing, manufacture, production,
22 promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general
23 public the drug Effexor (known generically as venlafaxine), an antidepressant, throughout the United
24 States and the State of California.

25 10. On information and belief, Pfizer International LLC, a New York Corporation, was and
26 still is, a corporation duly existing under and virtue of the laws of the State of New York with its
27 principal place of business in New York, New York. At all time hereinafter mentioned, defendant Pfizer
28 International LLC was, and still is, a pharmaceutical company involved in research, development,

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

4 11. Defendant Wyeth Pharmaceuticals, Inc., a Delaware Corporation, was a corporation duly
5 existing under and by virtue of the laws of the State of Delaware with its principal place of
6 business in Philadelphia, Pennsylvania. Upon information and belief, Wyeth Pharmaceuticals, Inc.
7 was purchased by Pfizer, Inc. in October of 2009. Wyeth Pharmaceuticals, Inc. is now a subsidiary
8 of Pfizer, Inc., and is located in Philadelphia, Pennsylvania.

9 12. Pfizer Inc., Pfizer International LLC and Wyeth Pharmaceuticals, Inc. hereinafter shall be
10 referred to as the "Pfizer Defendants."

11 13. On information and belief, at all times relevant hereto, the Defendants were each engaged
12 in the business of researching, designing, developing, licensing, compounding, testing, producing,
13 manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing,
14 promoting, advertising, distributing, selling, and/or introducing into interstate commerce Effexor, either
15 directly or indirectly through third parties or related entities and/or the Defendants are otherwise
16 responsible as corporate successors for the liabilities of the entities that designed, developed,
17 manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold Effexor. Plaintiff
18 is informed and believes Pfizer Defendants manufactured the Effexor that was dispensed to Ms. Scusa.

19 14. On information and belief, at all relevant times, the Pfizer Defendants were present and
20 doing business in the State of California.

21 15. On information and belief, at all relevant times, the Pfizer Defendants transacted,
22 solicited, and conducted business in the State of California and derived substantial revenue from such
23 business.

24 16. On information and belief, at all relevant times, the Pfizer Defendants expected or should
25 have expected that their acts would have consequences within the United States of America, including
26 the State of California.

27 17. The true names or capacities, whether individual, corporate, or otherwise, of Defendants
28 DOES 1 through 100, inclusive, are unknown to Plaintiff who therefore sues said Defendants by such

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

4 18. At all times herein alleged, "Defendants" include all herein named Defendants as well as
5 Defendants DOES 1 through 100, inclusive.

6 19. At all times herein alleged, each of the Defendants was an agent, servant, partner, aider
7 and abettor, co-conspirator and joint-venturer of each of the remaining Defendants herein and was at all
8 times operating and acting within the purpose and scope of said agency, service, employment,
9 partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the
10 other Defendants, knowing that their conduct constituted a breach of duty owed to Plaintiff.

11 20. There exists, and at all times herein alleged, there existed, a unity of interest in ownership
12 between certain Defendants and other certain Defendants such that any individuality and separateness
13 between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain
14 Defendants and exerted control over those Defendants. Adherence to the fiction of the separate
15 existence of these certain Defendants as an entity distinct from other certain Defendants will permit an
16 abuse of the corporate privilege and would sanction fraud and promote injustice.

17 21. At all times herein alleged, the officers and directors of the Defendants named herein
18 participated in, authorized and directed the production and promotion of Effexor when they knew, or
19 with the exercise of reasonable care should have known, of the hazards and dangerous propensities of
20 Effexor and thereby actively participated in the tortious conduct which resulted in the injuries suffered
21 by Plaintiff.

22 22. DOES 1 through 100, and each of them, acted independently of, or jointly with, other
23 Defendants, and are all in some manner legally responsible for the events and happenings herein referred
24 to, and caused damages proximately and foreseeably to Plaintiff as alleged herein.

25 GENERAL ALLEGATIONS

26 24. The drug "venlafaxine" is manufactured, promoted, distributed, labeled and marketed by
27 Defendants under the trade name Effexor and is a member of the class of drugs known as "serotonin-
28 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

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

5 25. Ellen Scusa, A■■■■ S■■■■'s mother, took Effexor as prescribed by her treating physician
6 while pregnant with A■■■■ in California.

7 26. At the time Effexor was prescribed to Ms. Scusa, Defendants knew through animal
8 studies and post-marketing reports that Effexor was associated with a significant increased risk of
9 cardiac defects in babies whose mothers ingested Effexor during pregnancy. Other studies showed that
10 increased levels of serotonin, the primary human substance affected by Effexor, had profound effects on
11 the pre-natal development of study animals.

12 27. Notwithstanding this knowledge, Defendants aggressively and actively promoted
13 Effexor. The Pfizer Defendants touted Effexor as being a safe alternative for pregnant women. In fact,
14 none of this was true.

15 28. The Pfizer Defendants have never informed doctors of these serious risks, even though
16 third-party research shows the association between Effexor and cardiac defects and several other types
17 of birth defects.

18 29. When Adam was born, he was diagnosed with a life-threatening congenital heart defect
19 called pulmonary artery stenosis.

20 30. On February 22, 2007, A■■■■ underwent a balloon pulmonary valvuloplasty in an effort
21 to repair his heart defect. A■■■■ continues to be monitored by his physicians and may require future
22 intervention and/or surgeries.

23 31. The heart defect suffered by A■■■■ was a direct result of his mother's ingestion of
24 Effexor during her pregnancy. Prior to the time Ms. Scusa ingested Effexor during her pregnancy with
25 A■■■■, the Pfizer Defendants knew or should have known that Effexor was associated with an increased
26 risk of congenital heart defects and other birth defects in babies of mothers who ingest Effexor during
27 pregnancy.

28 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

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

2 33. Thus, prior to Ms. Scusa's pregnancy with A■■■■, the Pfizer Defendants had the
3 knowledge, the means and the duty to provide the medical community and the consuming public with a
4 stronger warning regarding the association between Effexor and birth defects through all means
5 necessary including but not limited to labeling, continuing education, symposiums, posters, sales calls to
6 doctors, advertisements and promotional materials, etc. The Pfizer Defendants breached this duty.

7 34. Ms. Scusa filed this lawsuit within the applicable limitations period of first suspecting
8 that Effexor was the cause of A■■■■'s injuries.

9 35. Plaintiff was prevented from discovering this information sooner because the Pfizer
10 Defendants herein misrepresented and continue to misrepresent to the public and to the medical
11 profession that the drug is safe to take during pregnancy. The Pfizer Defendants have fraudulently
12 concealed facts and information that could have led Plaintiff to discover a potential cause of action.

13 36. Plaintiff's injuries were caused by Effexor's defects and the wrongful conduct, acts,
14 omissions, and fraudulent misrepresentations of the Pfizer Defendants. As a result of the Pfizer
15 Defendants' claims and representations regarding the effectiveness and safety of Effexor, Ms. Scusa was
16 prescribed Effexor and used and consumed Effexor in accordance with its directions. Had the
17 Defendants properly disclosed risks associated with the Effexor, Ms. Scusa would not have used it
18 during her pregnancy with A■■■■, and A■■■■ would not have suffered the serious and permanent injuries
19 described herein.

20 37. Prior to Ms. Scusa's use of Effexor, the Pfizer Defendants knew or should have known
21 that the use of Effexor created a significantly increased risk of birth defects occurring when taken during
22 pregnancy, and that during pregnancy, even when used as directed, Effexor was unreasonably dangerous
23 to consumers.

24 38. Despite the fact that Defendants knew or should have known of the serious health risks
25 associated with the use of Effexor during pregnancy, Defendants failed to warn Ms. Scusa, her health
26 care providers, or the public and the medical community of said serious risks before Ms. Scusa used
27 Effexor.

28 ///

1 39. Had Ms. Scusa's prescribing physicians and health care providers known the risks and
2 dangers associated with Effexor, they would not have prescribed it or would have advised her to
3 discontinue using Effexor during her pregnancy, and A■■■■ S■■■■ would not have suffered these serious
4 injuries.

5 40. Had Ms. Scusa known the risks and dangers associated with Effexor, she would not have
6 used it during his pregnancy, and A■■■■ S■■■■ would not have suffered serious injuries and consequent
7 damages.

8 41. As a direct and proximate result of Effexor's defects and the wrongful conduct, acts,
9 omissions, and fraudulent misrepresentations of Defendants, Plaintiff has suffered significant harm.
10 A■■■■ S■■■■ sustained pecuniary loss resulting from the pain and suffering from his heart
11 malformations, by the general surgeries and procedures he underwent between the time of his birth to
12 present, and additional general damages. He continues to require reasonable and necessary health care,
13 attention and services, and has incurred, medical, incidental, and service expenses pertaining to his
14 injuries, and will continue to incur such expenses in the future.

15 42. Plaintiff incurred medical expenses and other economic harm including loss of earnings,
16 and will continue to incur expenses, loss of earnings and future earning capacity.

17 43. Defendants falsely and fraudulently represented to Plaintiff's mother, her prescribing
18 physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities,
19 the FDA, and the public in general, that Effexor was safe and effective for its indicated use during
20 pregnancy.

21 44. These false representations were made by Defendants with the intent of defrauding and
22 deceiving Ms. Scusa, her prescribing physicians and healthcare providers, the medical, scientific,
23 pharmaceutical and healthcare communities, the FDA, and the public in general, and were made with the
24 intent of inducing them to recommend, dispense and purchase Effexor, all of which evinced a callous,
25 reckless and willful indifference to safety.

26 45. Defendants knew and were aware or should have been aware that Effexor had not been
27 sufficiently tested for use during pregnancy, was defective in its design and testing, and lacked adequate
28 and sufficient warnings.

1 46. Defendants knew or should have known that Effexor increased the risk of birth defects
2 when used during pregnancy, was inherently dangerous in a manner that exceeded any purported benefit
3 of the medication, and that the labeling was inaccurate and downplayed warnings.

4 47. Defendants were under a duty to disclose to Ms. Scusa and her prescribing physicians
5 and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA,
6 and the public in general, the defective nature of Effexor.

7 48. Defendants had sole access to material facts concerning the defective nature of Effexor
8 and its propensity to increase the risks of birth defects, and hence, cause damage to consumers,
9 including Plaintiff.

10 49. Defendants made the misrepresentations and actively concealed information concerning
11 the safety and efficacy of Effexor with the intention and specific desire that the medical, pharmaceutical
12 and scientific communities, and consumers, including Ms. Scusa, her prescribing physicians and
13 healthcare providers, would rely on such in selecting Effexor to treat his anxiety.

14 50. Defendants made these misrepresentations and actively concealed information
15 concerning the safety and efficacy of Effexor in their labeling, advertising, product inserts, promotional
16 material or other marketing efforts.

17 51. The misrepresentations and active concealments by Defendants were perpetuated directly
18 and indirectly by Defendants, their sales representative, employees, distributors, agents and detail
19 persons.

20 52. Defendants knew that Ms. Scusa, her prescribing physicians and healthcare providers, the
21 medical, scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, had
22 no way to determine the truth behind Defendants' concealment and omissions, and that these included
23 material omissions of facts surrounding Effexor, as set forth herein.

24 53. The misrepresentations and active concealment by Defendants constitute a continuing
25 tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential
26 risks and serious side effects associated with the use of Effexor when used during pregnancy.

27 54. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and
28 scientific communities, and users and consumers of the drug, including Ms. Scusa, about the potential

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

3 55. As a result of the Defendants' advertising and marketing efforts, concealment and
4 misrepresentations, Effexor is and continues to be pervasively prescribed and used throughout the
5 United States.

6 56. During the time that Effexor has been sold in the United States, hundreds of reports of
7 injury and death have been submitted to the FDA in association with Effexor.

8 57. At all times material hereto, the Defendants knew or should have known that most
9 physicians were not aware of, or did not fully appreciate the seriousness of the risks associated with use
10 of Effexor during pregnancy, either as Effexor, or in the generic form of venlafaxine, and Defendants
11 knew or should have known that package inserts for Effexor and generic versions of the drug were
12 deficient, inaccurate, false and misleading in communicating to the medical community in general, to
13 physicians, or to the public, information about the risks associated with the drug when used during
14 pregnancy.

15 58. The Defendants failed to adequately inform physicians and misled physicians about the
16 risks associated with Effexor, despite the fact that they knew that the medical community in general,
17 physicians, pharmacists, Ms. Scusa, and others similarly situated relied on them to disclose and
18 communicate to doctors what they knew and what experts in the use and effects of the drug would know
19 from a prudent review of the information that they possessed or were reasonably able to obtain.

20 59. Because of the misleading and inaccurate information that Defendants disseminated to
21 physicians, and because of the failure of the Defendants generally to adequately and effectively inform
22 physicians, the medical community or the FDA about the true risks associated with the use of Effexor
23 and generic venlafaxine, Ms. Scusa's physicians did not know or appreciate fully the risks associated
24 with the using Effexor during pregnancy.

25 60. Defendants knew, and through the exercise of reasonable care should have known, that
26 the labeling for Effexor and generic venlafaxine substantially understated the risks and overstated the
27 efficacy of the drug. They failed to use reasonable care to ascertain or communicate to physicians or to
28 the public information that would constitute adequate and effective warnings to physicians or to the

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

2 61. Defendants were aware that their individual and collective failure to communicate to the
3 medical community and to physicians, information known to them about the risks of use during
4 pregnancy and that using Effexor would be likely to result in serious injury to patients who received the
5 drug in accordance with prescriptions issued by physicians who were unaware of this information. By
6 failing to communicate this information to the medical community or the FDA, the Defendants acted in
7 willful and wanton disregard of the rights of Plaintiff, and this conduct caused serious injury to A ■■■
8 S ■■■.

9 62. As manufacturers and distributors of prescription drug products, specifically Effexor
10 and/or generic venlafaxine, each of the Defendants has a duty to adequately communicate warnings to
11 physicians and the medical community (or to patients who could be expected to take the drug) and to
12 exercise due care to conduct safety surveillance for the drug and otherwise ensure that the warnings they
13 are required to disseminate about the drug are accurate and adequate, and that these warnings are
14 effectively communicated to physicians, pharmacists, and patients using the drug.

15 63. Each of the Defendants breached its duty to ensure that adequate warnings were provided
16 to the medical community, Ms. Scusa's physicians, Ms. Scusa, and/or other foreseeable Effexor and/or
17 venlafaxine users similarly situated, in that they failed to:

- 18 a. ensure Effexor and/or venlafaxine warnings to the medical community,
19 physicians, and Ms. Scusa's physician were accurate and adequate, despite
20 having extensive knowledge of the risks associated with using the drug
21 during pregnancy;
- 22 b. ensure that Effexor and/or venlafaxine warnings were effectively
23 communicated to the medical community, physicians and Ms Scusa,
24 despite having extensive knowledge of the inappropriate use of the drug
25 during pregnancy;
- 26 c. conduct post market safety surveillance and report that information to the
27 FDA, the medical community, Ms. Scusa's physicians, Ms Scusa and
28 other foreseeable users;

- 1 d. review all adverse drug event (ADE) information for Effexor and/or
2 venlafaxine, and to report information bearing significantly upon the
3 adequacy and/or accuracy of its warnings, efficacy, or safety, including
4 the risks and/or prevalence of side effects caused by Effexor and/or
5 venlafaxine products to the FDA, medical community, Ms. Scusa's
6 physicians, Ms. Scusa and other like foreseeable users;
- 7 e. periodically review all medical literature regarding Effexor and/or
8 venlafaxine products and report to the FDA, the medical community, or
9 other interested individuals significant data concerning the efficacy or
10 safety of Effexor and/or venlafaxine products;
- 11 f. independently monitor sales of Effexor and/or venlafaxine products, and
12 the medical literature, which would have alerted them to the fact that
13 Effexor was widely over prescribed, and was being prescribed to
14 pregnancy women and women in their child-bearing years owing to the
15 inadequate warnings provided to doctors;
- 16 g. engage in responsible testing, research, and pharmacovigilance practices
17 regarding their Effexor and/or venlafaxine products, including a failure to
18 perform studies and/or monitor, which would accurately determine the
19 risks attendant to using Effexor during pregnancy, and failed to engage in
20 marketing practices designed to minimize the risks associated with
21 Effexor and/or venlafaxine.

22 64. The acts, conduct, and omissions of Defendants, and each of them, as alleged throughout
23 this Complaint were fraudulent, willful and malicious and were done with a conscious disregard for the
24 rights of Plaintiff and other users of Effexor and/or venlafaxine products, and for the primary purpose of
25 increasing Defendants' profits from the sale and distribution of the drug. Defendants' outrageous and
26 unconscionable conduct warrants an award of exemplary and punitive damages against each Defendant
27 in an amount appropriate to punish and make an example of each Defendant.

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1 65. Prior to the manufacturing, sale and distribution of Effexor and/or venlafaxine products,
2 Defendants, and each of them, knew that the drugs were in a defective condition as previously described
3 herein and knew that those who were prescribed the drugs would experience and did experience severe
4 physical, mental, and emotional injuries. Further, Defendants and each of them through their officers,
5 directors, managers, and agents, had knowledge that the medication presented a substantial and
6 unreasonable risk of harm to the public, including Plaintiff, and as such, consumers of the drug were
7 unreasonably subjected to risk of injury or death.

8 66. Despite such knowledge, Defendants, and each of them, acting through their officers,
9 directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and
10 deliberately failed to remedy the known defects in the drugs and failed to warn the public, including to
11 the Plaintiff, his mother's prescribing physicians and healthcare providers, the medical, scientific,
12 pharmaceutical and healthcare communities, the FDA, and the public in general, of the extreme risk of
13 injury occasioned by said defects inherent in the drugs. Defendants and their individual agents, officers,
14 and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of the
15 drugs knowing that the public, including Plaintiff, would be exposed to serious danger in order to
16 advance Defendants' own pecuniary interest and monetary profits.

17 67. Defendants' conduct was despicable, and so contemptible that it would be looked down
18 upon and despised by ordinary decent people, and was carried on by Defendants with willful and
19 conscious disregard for safety, entitling Plaintiff to exemplary damages under Civil Code § 3294.

20 68. Plaintiff maintains and reserves his rights to plead additional facts, theories of liability,
21 causes of action in the complaint, and/or to present evidence pertaining to the acts and omissions of
22 Defendants as may be subsequently identified through discovery and investigation in this matter.
23 Plaintiff reserves the right to present such evidence at the time of trial based upon such subsequently
24 discovered acts, omissions or damages that are heretofore unknown or unidentified prior to the date of
25 service of this complaint and maintain and reserve their rights to thereafter move the court to conform
26 pleadings to proof in this matter.

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1 **FIRST CAUSE OF ACTION**

2 **STRICT LIABILITY IN TORT – FAILURE TO WARN**

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

5 70. Effexor was defective at the time of its manufacture, development, production, testing,
6 inspection, endorsement, prescription, sale and distribution in that, and not by way of limitation, the
7 Effexor warnings, instructions and directions failed to warn of the dangerous risks posed by Effexor,
8 including increased dangerous propensities as compared to other similar and comparable alternatives,
9 which risks were known or reasonably scientifically knowable to Defendants. The Defendants, and each
10 of them, knew or should have known of the defective condition, characteristics and risks associated with
11 Effexor, as previously set forth herein.

12 71. At all times herein alleged, Effexor was defective and Defendants, and each of them,
13 knew that the Effexor was to be used by consumers without inspection for defects therein. Moreover,
14 Ms. Scusa, her prescribing physicians and health care providers, neither knew, nor had reason to know at
15 the time of his use of Effexor of the existence of the aforementioned defects. Ordinary consumers
16 would not have recognized the potential risks or side effects for which Defendants failed to include
17 appropriate warnings.

18 72. At all times herein mentioned, Effexor was prescribed and used as intended by
19 Defendants and in a manner reasonably foreseeable to Defendants.

20 73. As a result of Effexor's defective condition, namely the lack of sufficient warnings,
21 Plaintiff suffered the injuries and damages as alleged herein.

22 **SECOND CAUSE OF ACTION**

23 **NEGLIGENCE**

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

26 75. At all times relevant hereto, Defendants, and each of them, had a duty to properly
27 manufacture, design, formulate, distribute, compound, produce, process, assemble, test, inspect,
28 research, market, label, package, prepare for use, issue warnings with respect to, promote, advertise, sell

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

5 76. At all times relevant hereto, Defendants, and each of them, breached their duties in that
6 they negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced,
7 processed, assembled, tested, inspected, researched, marketed, labeled, packaged, prepared for use,
8 issued warnings with respect to, promoted, advertised, sold and monitored the use of Effexor; failed to
9 adequately test and warn of the risks and dangers of Effexor both before and after their sale; and failed
10 to recall Effexor after becoming aware that it was defective and causing injuries after becoming aware
11 that the warnings and information issued in connection with Effexor were inadequate, and that
12 prescribing physicians and consumers did not fully understand the risks associated with using Effexor
13 during pregnancy.

14 77. As a result of the breach of the Defendants' duties with respect to Effexor, Plaintiff
15 suffered the injuries and damages as alleged herein.

16 **THIRD CAUSE OF ACTION**

17 **BREACH OF IMPLIED WARRANTY**

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

20 79. Prior to the use of Effexor, Defendants, and each of them, impliedly warranted to Ms.
21 Scusa, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and
22 healthcare communities, the FDA, and the public in general, that Effexor was merchantable quality and
23 safe and fit for the use for which it was intended.

24 80. Ms. Scusa and her physicians and healthcare providers were, and remain, unskilled in the
25 research, design, and manufacture of Effexor and reasonably relied entirely on the skill, judgment, and
26 implied warranty of Defendants in using Effexor.

27 81. The Defendants breached their warranties in that, Effexor was neither safe for its
28 intended use nor of merchantable quality, as warranted by Defendants, in that Effexor had dangerous

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

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

6 **FOURTH CAUSE OF ACTION**

7 **BREACH OF EXPRESS WARRANTY**

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

10 84. At all times herein alleged, Defendants, and each of them, expressly represented and
11 warranted to the Ms. Scusa and her prescribing physicians and healthcare providers, the medical,
12 scientific, pharmaceutical and healthcare communities, the FDA, and the public in general, by and
13 through statements made by Defendants, their authorized agents, and sales representatives, orally and in
14 publications, package inserts, and other written materials intended for physicians, patients, and the
15 general public, that Effexor was safe, effective, fit, and proper for its intended use, and Effexor was
16 purchased in reliance upon said express warranties.

17 85. In using Effexor, Ms. Scusa and his prescribing physicians and healthcare providers,
18 relied on the skill, judgment, representations, and express warranties of Defendants. Said warranties and
19 representations were false, in that Effexor was not safe and was unfit for the use for which it was
20 intended.

21 86. As a result of the foregoing breach of express warranties by Defendants, and each of
22 them, Plaintiff sustained the injuries and damages as described above.

23 **FIFTH CAUSE OF ACTION**

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

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

27 88. Defendants, and each of them, from the time that Effexor was first tested, studied,
28 researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, willfully

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

5 89. At all times relevant hereto, Defendants, and each of them, conducted a sales and
6 marketing campaign to promote the sale of Effexor and willfully deceived Ms. Scusa, and her
7 prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare
8 communities, the FDA, and the public in general as to the health risks and consequences of the use of
9 Effexor during pregnancy. Defendants, and each of them, were aware of the foregoing, and that Effexor
10 was not safe, fit, and effective for human consumption. Furthermore, Defendants were aware that the
11 use of Effexor was hazardous to take during pregnancy, and that Effexor has a significant propensity to
12 cause serious injuries to users including, but not limited to, the injuries suffered as described herein.

13 90. Defendants intentionally concealed and suppressed the true facts concerning Effexor with
14 the intent to defraud Ms. Scusa and her prescribing physicians and healthcare providers, the medical,
15 scientific, pharmaceutical and healthcare communities, and the public in general, in that Defendants
16 knew that the physicians and healthcare providers would not have prescribed Effexor for use during
17 pregnancy and Ms. Scusa would not have used Effexor if she had known the true facts concerning the
18 dangers of Effexor.

19 91. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of
20 them, Plaintiff suffered the injuries and damages as described above.

21 **SIXTH CAUSE OF ACTION**

22 **NEGLIGENT MISREPRESENTATION**

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

25 93. Defendants, and each of them, from the time that Effexor was first tested, studied,
26 researched, first manufactured, marketed and distributed, and up to the present, made false
27 representations, as previously set forth herein, to Ms. Scusa and her prescribing physicians and
28 healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public

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

3 94. At all times relevant hereto, Defendants, and each of them, conducted a sales and
4 marketing campaign to promote the sale of Effexor to women of child-bearing years and willfully
5 deceive Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific,
6 pharmaceutical and healthcare communities, and the public in general as to the health risks and
7 consequences of the use of Effexor during pregnancy.

8 95. Defendants made the foregoing misrepresentations without any reasonable ground for
9 believing them to be true. These misrepresentations were made directly by Defendants, by sales
10 representatives, detail persons and other authorized agents of said Defendants, and in publications and
11 other written materials directed to Ms. Scusa and her prescribing physicians and healthcare providers,
12 the medical, scientific, pharmaceutical and healthcare communities, and the public in general, with the
13 intention of inducing reliance and the prescription, purchase, and use of Effexor.

14 96. The foregoing representations by Defendants, and each of them, were in fact false, in that
15 Effexor is not, and at all relevant times alleged herein was not, safe, fit, and effective for human
16 consumption during pregnancy, the use of Effexor is hazardous to health of the unborn child, and
17 Effexor has a significant propensity to cause serious injuries to users including, but not limited to, the
18 injuries suffered as described above. The foregoing misrepresentations by Defendants, and each of
19 them, were made with the intention of inducing reliance and inducing the prescription, purchase, and use
20 of Effexor.

21 97. In reliance on the misrepresentations by Defendants, and each of them, Ms. Scusa and her
22 prescribing physicians and healthcare providers were induced to purchase and use Effexor. If they had
23 known of the true facts and the facts concealed by Defendants, they would not have used Effexor and
24 their reliance upon Defendants' misrepresentations was justified because such misrepresentations were
25 made and conducted by individuals and entities that were in a position to know the true facts.

26 98. As a result of the foregoing negligent misrepresentations by Defendants, and each of
27 them, Plaintiff suffered the injuries and damages as described above.

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1 SEVENTH CAUSE OF ACTION

2 **FRAUD and FRAUDULENT CONCEALMENT**

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

5 100. Plaintiff is informed and believes and based thereon alleges that Defendants, while
6 knowing that Effexor poses a significant risk of harm to the fetus when used during pregnancy,
7 orchestrated a sophisticated, comprehensive, multi-pronged marketing scheme to convince Ms. Scusa
8 and the general consuming public, the healthcare community and others that Effexor was safe and
9 effective for use during pregnancy.

10 101. Plaintiff is informed and believes and based thereon alleges that, while knowing that the
11 Effexor is not effective, and that it poses a significant risk of injury to a fetus when used during
12 pregnancy, Defendants implemented a false, fraudulent and misleading nationwide marketing campaign
13 concerning Effexor.

14 102. Plaintiff is informed and believes and based thereon alleges that, while knowing that
15 Effexor poses a significant increase in risk to the fetus when used during pregnancy of adverse events
16 including, but not limited to, birth defects, heart defects, serious injuries and death, Defendants
17 implemented a false, fraudulent and misleading nationwide "Direct to Consumer" (DTC) advertising
18 campaign via television commercials on major television networks, internet advertisements on major
19 internet sites and search engines, and print advertisements in major newspapers and magazines with
20 national circulation.

21 103. Plaintiff is informed and believes and based thereon alleges that Defendants' false,
22 fraudulent and misleading DTC advertising and marketing of Effexor specifically state that Effexor is
23 safe and effective for use during pregnancy.

24 104. Plaintiff is informed and believes and based thereon alleges that said false, fraudulent and
25 misleading advertising, marketing messages, publications and all other such public statements were
26 issued by Defendants in order to conceal (and did so conceal) the true risks of Effexor use during
27 pregnancy, to conceal the causal relationship between use of Effexor and the injuries and damages
28 suffered by Plaintiff, to conceal the grounds and /or basis for a legal cause of action by Plaintiff against

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

7 105. Plaintiff is informed and believes and based thereon alleges that Defendants, and each of
8 them, further falsely and fraudulently represented to Ms. Scusa and her physicians, and members of the
9 general public, that Effexor was safe for use during pregnancy in treatment of depression and anxiety.
10 The representations by Defendants, and each of them, were in fact, false. The true facts were that
11 Effexor was not safe for use by and members of the general public during pregnancy and was, in fact,
12 extremely dangerous to consumers.

13 106. Plaintiff is informed and believes and based thereon alleges that Defendants, and each of
14 them, further misrepresented the safety of Effexor, represented that Effexor were safe and effective and
15 safe for use during pregnancy, and concealed warnings of the known or knowable risks of taking
16 Effexor during pregnancy.

17 107. Plaintiff is informed and believes and based thereon alleges that when the Defendants,
18 and each of them, made the representations as alleged herein, they knew that such representations were
19 false. Defendants, and each of them, made the representations with the intent to defraud and deceive
20 Ms. Scusa and her prescribing physicians and healthcare providers, the medical, scientific,
21 pharmaceutical and healthcare communities, the FDA, and the public in general, and with the intent to
22 induce them to use the products and act in the manner alleged in this complaint.

23 108. Ms. Scusa and her prescribing physicians and healthcare providers took the actions
24 alleged in this complaint, while ignorant of the falsity of the representations and reasonably believed
25 them to be true. In reliance upon such representations, she was induced to, and did, use Effexor as
26 described in this complaint. If she had known the actual facts, she would not have taken such actions
27 nor would she have used Effexor during his pregnancy with A [REDACTED]. Her reliance upon Defendants'
28 misrepresentations was justified because such misrepresentations were made and conducted by

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

3 109. By and through the Defendants' false statements, fraudulent conduct and fraudulent
4 concealment of facts as alleged herein, Plaintiff was prevented from discovering the wrongful conduct
5 of Defendants with regard to Effexor and was thereby prevented from discovering these causes of action
6 against Defendants herein. Therefore, Defendants are estopped from asserting any statute of limitations
7 defenses in this matter as such statutes of limitation have been delayed in accrual and/or have been
8 tolled due to Defendants' conduct. So long as Defendants continue to deny the increased risk of birth
9 defects, the adverse events and the causal relationship between Effexor and Plaintiff's injuries, all such
10 statutes of limitation applicable to the causes of action asserted herein are, and will continue to be,
11 tolled.

12 110. As a direct and proximate result of Defendants' fraud and deceit, Plaintiff sustained the
13 injuries and damages described in this complaint.

14 **RELIEF REQUESTED**

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

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

1 10. For such other and further relief as the Court may deem just and proper.

2
3 Dated: February 12, 2013

ROBINSON CALCAGNIE ROBINSON
SHAPIRO DAVIS, INC.

4
5 and

6 BLIZZARD & NABERS

7
8 By: Mark P. Robinson, Jr.
9 Mark P. Robinson, Jr.
10 Attorneys for Plaintiff

11
12
13 **DEMAND FOR JURY TRIAL**

14 Plaintiff hereby demands a jury trial on all claims so triable.

15 Dated: February 12, 2013

16 ROBINSON CALCAGNIE ROBINSON
SHAPIRO DAVIS, INC.

17 and

18 BLIZZARD & NABERS

19
20 By: Mark P. Robinson, Jr.
21 Mark P. Robinson, Jr.