#### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

TYREKE REESE,		)	
	Plaintiff,	) )	
v.		)	CASE NO.
PFIZER INC.,		)	
	Defendant.	)	

#### **COMPLAINT**

Plaintiff Tyreke Reese brings this action for damages against Defendant Pfizer Inc. and alleges:

#### **PARTIES**

1. Tyreke Reese (Plaintiff) brings this action individually for damages relating to birth defects she suffered as a result of her mother having taken the prescription drug ZOLOFT® during Plaintiff's mother's pregnancy.

2. Plaintiff was born on June 19, 1991, in Boston, Massachusetts.

3. Pfizer Inc. (Pfizer) is a Delaware corporation with its principal place of business in New York, New York. Its address is 235 East 42nd Street, New York, NY 10017-5755. At all relevant times, Pfizer and/or its predecessors in interest were engaged in the business of advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, testing, and selling the prescription drug Sertraline under the trade name

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ZOLOFT® in Massachusetts, Missouri, and throughout the United States. Pfizer may be served with process by registered mail, return receipt requested, upon CT Corporation System, 111 Eighth Avenue, New York, NY 10011.

4. At all relevant times, Defendants acted in conjunction with other affiliated, related, jointly owned and/or controlled entities or subsidiaries, including each other, in the development, marketing, and production of ZOLOFT® (known generically as sertraline). Defendants acted jointly and/or as each other's agents, within the course and scope of the agency, with respect to the conduct alleged in this Complaint, such that any individuality and separateness between Defendants had ceased and these Defendants became the alter-ego of one another.

# JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under the diversity of citizenship statute, 28 U.S.C. § 1332. Defendant Pfizer Inc. is incorporated under the laws of Delaware and has its principal place of business in New York; therefore, it is a citizen of Delaware and New York under 28 U.S.C. § 1332(c)(1). Plaintiff is a citizen of Massachusetts. Plaintiff seeks damages in excess of \$75,000, exclusive of interest and costs.

6. Venue is proper in this Court under 28 U.S.C. § 1391 because at all times relevant to this Complaint, Pfizer has engaged in continual business in this District and, for purposes of venue, is deemed to reside in this District under 28 U.S.C. § 1391(c).

# **GENERAL FACTUAL ALLEGATIONS**

7. Plaintiff was born with various birth defects, including an atrial septal defect and other conditions of ill being, caused by Plaintiff's mother's ingestion of ZOLOFT® as prescribed

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by her treating physicians during her pregnancy. Plaintiff's condition has required surgery and extensive medical treatment and medical monitoring.

8. Pfizer, its predecessors in interest, and its subsidiaries, advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, tested, and sold ZOLOFT®.

9. The prescription drug Sertraline is manufactured, promoted, marketed, distributed, and labeled by Pfizer under the trade name ZOLOFT®, ZOLOFT® Oral Suspension, and ZOLOFT® CR (collectively, ZOLOFT®) and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs." ZOLOFT® was approved for use in the United States by the Food and Drug Administration (FDA) for the treatment of Major Depressive Disorder (MDD) on December 30, 1991; Obsessive-Compulsive Disorder (OCD) on October 25, 1996; for children with OCD on October 10, 1997; Panic Disorder on July 8, 1997; Acute Post Traumatic Stress Disorder (PTSD) on December 7, 1999, and for chronic, long term PTSD on August 6, 2001; Premenstrual Dysphoric Disorder on May 16, 2002; and Social Anxiety Disorder on February 7, 2003. ZOLOFT® is supplied for oral administration as scored tablets in doses of 25, 50, and 100 mg.

10. Plaintiff's injuries were a direct result of her mother's ingestion of ZOLOFT® during her pregnancy in a manner and dosage recommended by Pfizer and prescribed by Plaintiff's mother's doctors.

# Pfizer Knew or Should Have Known that ZOLOFT® Causes Serious Birth Defects

11. Prior to Plaintiff's mother becoming pregnant, Pfizer knew or should have known that children were being born with congenital birth defects, including heart defects and other cardiopulmonary conditions, to women who took ZOLOFT® during pregnancy.

12. Prior to Plaintiff's mother becoming pregnant, Pfizer knew or should have known that ZOLOFT® cross the placenta and, thereby, poses significant risks to the developing fetus.

13. Prior to the time that Plaintiff's mother ingested ZOLOFT® during her pregnancy, Pfizer knew or should have known that ZOLOFT® posed an increased risk of congenital birth defects, including heart defects, Persistent Pulmonary Hypertension of the Newborn (PPHN), and other related conditions.

14. Prior to the time that Plaintiff's mother ingested ZOLOFT® during her pregnancy, Pfizer knew or should have known from available information that ZOLOFT® posed an increased risk of multiple congenital birth defects.

15. At or before FDA approval of ZOLOFT®, Pfizer knew that ZOLOFT® caused birth defects when administered to non-human mammalian species.

16. Prior to the time that Plaintiff's mother ingested ZOLOFT® during her pregnancy, Pfizer knew or should have known that SSRI drugs, as a class, increase the risk of congenital birth defects.

# Pfizer Misrepresented, and Continues to Misrepresent, the Safety and Efficacy of ZOLOFT®

17. A central premise of federal drug regulation is that a drug manufacturer bears responsibility for the content of its label at all times.

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18. Pfizer knew from preclinical studies and subsequent published studies that dangerous birth defects were associated with ZOLOFT® use during pregnancy. Pfizer took no action to properly study ZOLOFT® and/or did not properly publish the results of studies that it did conduct, which would have reflected the increased risks. Pfizer failed to adequately warn or remedy the risks and, instead, concealed, suppressed, and failed to disclose the dangers. Despite the studies, Pfizer continues to deny these dangers.

19. Prior to Plaintiff's mother's pregnancy, Pfizer had the knowledge, the means, and the duty to provide the medical community and the consuming public with more accurate warnings regarding the association between ZOLOFT® and congenital birth defects and other related conditions. Pfizer had a further duty, based upon the evidence and "signals" that had accumulated since the 1990s demonstrating a relationship between ZOLOFT® and birth defects and birth defects and/or fetal demise, including animal and human studies, case reports, adverse event reports, registries, and other available sources, to conduct post-marketing studies to evaluate fully the significance of these studies. Pfizer, through its agents, employees, and servants, breached these duties.

20. Despite Pfizer's knowledge of the danger of birth defects, Pfizer failed and continues to fail to warn and disclose to consumers, including Plaintiff's mother, that ZOLOFT® significantly increases the risk of heart malformations and other birth defects.

21. Pfizer had actual knowledge that doctors frequently prescribed ZOLOFT® to women of childbearing potential for approved uses and for un-approved, or off-label, uses.

22. Pfizer knew that its failure to disclose to the medical community and consumers, including Plaintiff's mother, the increased risk of congenital birth defects associated with

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ZOLOFT® use during pregnancy could result in serious injury and/or death to the children or unborn fetuses of women who were prescribed ZOLOFT® by physicians who were unaware of this information. Pfizer's failure to disclose this information was willful, wanton, and with intentional disregard to the health and safety of consumers, including Plaintiff's mother, and caused serious and permanent injuries to Plaintiff.

23. The current ZOLOFT® label remains deficient to adequately and accurately warn doctors and/or their patients of the increased risk of cardiac malformations and other birth defects that are seen in babies whose mothers took ZOLOFT® during pregnancy.

24. Plaintiff's mother was unaware of the dangerousness of ZOLOFT® when taken during pregnancy. Had she and/or her healthcare providers known of the increased risk of birth defects, she would not have taken ZOLOFT® during her pregnancy, and Plaintiff would not have suffered the birth defects described herein.

# <u>COUNT I</u> Strict Products Liability Defective Design

25. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

26. Pfizer designed, formulated, produced, manufactured, sold, marketed, distributed, supplied, and/or placed into the stream of commerce, in the regular course of its business, the pharmaceutical drug ZOLOFT®.

27. At the time ZOLOFT® was manufactured and sold by Pfizer to Plaintiff's mother, it was defective in design or formulation in that the foreseeable risks of the product

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exceeded the benefits associated with its design or formulation or, alternatively, it was more dangerous than an ordinary consumer would expect.

28. Plaintiff's mother used ZOLOFT® during her pregnancy for the purpose of treating anxiety, depression, and/or mood disorder in a manner that was reasonably anticipated and promoted by Pfizer.

29. The ZOLOFT® sold to Plaintiff's mother reached her without substantial change or alteration, as expected by Pfizer, and she ingested it without making any changes or alterations.

30. As a direct and proximate result of Plaintiff's mother's use of ZOLOFT® during pregnancy, Plaintiff suffered birth defects.

31. Pfizer's intentional disregard for the safety of users of ZOLOFT® and ZOLOFT®, including Plaintiff's mother and Plaintiff, justifies an award of punitive damages.

# <u>COUNT II</u> Strict Products Liability Failure to Warn

32. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

33. The ZOLOFT® designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Pfizer was defective in that it failed to include adequate warnings regarding all adverse side effects associated with the use of ZOLOFT® during pregnancy. The warnings given by Pfizer did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in

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particular, the risks of injury to unborn children of women who ingest ZOLOFT® during their pregnancy.

34. Pfizer marketed ZOLOFT® by way of Direct to Consumer advertisements in markets including Massachusetts and Missouri.

35. Pfizer failed to provide adequate warnings to physicians and users, including Plaintiff's mother, of the increased risk of congenital birth defects associated with ZOLOFT® use during pregnancy and aggressively promoted the product to doctors, to hospitals, and directly to consumers.

36. As a direct and proximate result of Pfizer's failure to warn of the potentially severe adverse effects of ZOLOFT®, Plaintiff suffered birth defects.

37. Pfizer's intentional disregard for the safety of users of ZOLOFT®®, including Plaintiff's mother and Plaintiff, justifies an award of punitive damages.

#### COUNT III Negligence

38. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

39. Pfizer had a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, testing, and selling ZOLOFT®.

40. Pfizer, through its agents, servants, and/or employees acting within the course and scope of their employment, breached its duty to exercise reasonable care in one or more of the following ways:

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a. failing to conduct sufficient testing which, if properly performed, would have shown that ZOLOFT® use during pregnancy poses an increased risk of injury to unborn children;

b. failing to disclose adverse test results and other information regarding the risk that ZOLOFT® use during pregnancy will interfere with the proper development of an unborn fetus;

c. failing to review all adverse drug event reports;

d. failing to continually test, monitor, and analyze data regarding the safety, efficacy, and prescribing practices for ZOLOFT®;

e. failing to monitor the sales of ZOLOFT® and related medical literature regarding the over-prescription of ZOLOFT® to women of childbearing potential;

f. failing to periodically review medical literature regarding the side effects associated with ZOLOFT® use;

g. failing to adequately warn the medical community and consumers, including Plaintiff's mother and her healthcare providers, of the increased risks associated with ZOLOFT® use during pregnancy;

h. misrepresenting that ZOLOFT® was safe for use during pregnancy when it knew or should have known that it was associated with congenital birth defects;

i. failing to conduct post-marketing safety surveillance and report any information bearing upon the adequacy and/or accuracy of the warnings, efficacy, or safety, including the risks and/or prevalence of adverse effects associated with

ZOLOFT® use during pregnancy, to the medical community and consumers, including Plaintiff's mother and her healthcare providers;

j. failing to provide post-marketing warnings after Pfizer knew or should have known of the significant risks of congenital birth defects associated with ZOLOFT® use during pregnancy;

k. promoting and marketing ZOLOFT® as safe and effective for use during pregnancy when Pfizer knew or should have known that ZOLOFT® was associated with an increased risk of congenital abnormalities; and

1. promoting and marketing ZOLOFT® for non-approved (off-label) uses and/or over-promoting, marketing, advertising, and selling ZOLOFT® without warning of the potential danger to an unborn fetus, which resulted in overprescription of ZOLOFT® to women of childbearing potential.

41. As a consequence of one or more of the foregoing acts or omissions, Pfizer failed to act as a reasonably prudent drug manufacturer.

42. As a direct and proximate result of Pfizer's negligence, Plaintiff suffered birth defects.

43. Pfizer's intentional disregard for the safety of users of ZOLOFT®, including Plaintiff's mother and Plaintiff, justifies an award of punitive damages.

# **<u>COUNT IV</u>** Fraudulent Misrepresentation and Concealment

44. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

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45. Pfizer owed a duty to the medical community and consumers, including Plaintiff's mother and her healthcare providers, to provide accurate and complete information regarding ZOLOFT®.

46. Pfizer's advertising program, by affirmative misrepresentations and omissions, falsely and deceptively created the image and impression that ZOLOFT® was safe for human use, had no unacceptable side effects, had fewer side effects than other antidepressants, and would not interfere with daily life.

47. Pfizer purposefully concealed, failed to disclose, misstated, downplayed, and/or understated the risks associated with ZOLOFT®. Pfizer, through promotional literature, deceived potential users and prescribers of ZOLOFT® by relying only on positive information, such as testimonials from allegedly satisfied users, and manipulating statistics to suggest widespread acceptability while concealing, misstating, and/or downplaying the known serious adverse effects. Pfizer suggested that the risks associated with the discontinued use of ZOLOFT® may be greater than any potential risk associated with use during pregnancy and intentionally withheld relevant information from potential ZOLOFT® users and prescribers regarding the safety and efficacy of ZOLOFT® used during pregnancy.

48. Specifically, Pfizer misrepresented and/or omitted a number of material facts in its materials, including but not limited to:

a. the presence, accuracy, and adequacy of testing of ZOLOFT®; and

b. the severity and frequency of adverse congenital birth defects, heart defects, PPHN, and/or other related conditions associated with ZOLOFT® use during pregnancy.

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49. Pfizer misrepresented and/or concealed these material facts with the intent to deceive ZOLOFT® users, including Plaintiff's mother, and prescribers and induce users to ingest ZOLOFT® during pregnancy.

50. Plaintiff's mother ingested ZOLOFT® during her pregnancy in justifiable reliance on the facts as she knew them.

51. As a direct and proximate result of Pfizer's misrepresentation and/or concealment of these material facts, Plaintiff suffered birth defects.

52. Pfizer's intentional disregard for the safety of users of ZOLOFT®, including Plaintiff's mother and Plaintiff, justifies an award of punitive damages.

# PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in her favor and seeks the following relief against Pfizer:

- A. Compensatory damages in excess of \$75,000, exclusive of interest and costs;
- B. Costs of suit;
- C. Prejudgment and post-judgment interest;
- D. Punitive damages; and
- E. Such other relief as this Court deems just and proper under the circumstances.

# JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

DATED: June 19, 2012

Respectfully submitted,

# CAREY DANIS & LOWE

By: /s/ Jeffrey J. Lowe Jeffrey J. Lowe Joseph P. Danis Andrew J. Cross Sarah Shoemake Doles 8235 Forsyth Blvd., Suite 1100 St. Louis, Missouri 63105 Telephone (314) 725-7700 Facsimile (314) 721-0905 Email: jlowe@careydanis.com Email: jdanis@careydanis.com Email: across@careydanis.com

# ATTORNEYS FOR PLAINTIFF

JS 44 (Rev. 09/11)

# **CIVIL COVER SHEET**

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadngs or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States inSeptember 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS Tyreke Reese				DEFENDANTS Pfizer, Inc.		
(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)				County of Residence	(IN U.S. PLAINTIFF CASES C	ASES, USE THE LOCATION OF
(c) Attorneys (Firm Name, ) Jetfrey J. Lowe, Carey, D Louis, MO 63105 (314) 6		syth Blvd., Ste. 1	100, St.	Attorneys <i>(if Known)</i>		
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<ul> <li>&amp; Enforcement of Judgment</li> <li>I51 Medicare Act</li> <li>I52 Recovery of Defaulted Student Loans (Excl. Veterans)</li> </ul>	Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product	Personal Injury Product Liability 368 Asbestos Person Injury Product Liability	ลไ	<u></u>	820 Copyrights     830 Patent     840 Trademark     860 CIATESECTURITY	<ul> <li>460 Depertation</li> <li>470 Racketeer Influenced and Corrupt Organizations</li> <li>480 Consumer Credit</li> <li>490 Cable/Sat TV</li> </ul>
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<ul> <li>196 Franchise</li> <li>RUAMPROBERTMENT</li> <li>210 Land Condemnation</li> </ul>	Injury D 362 Personal Injury - Med. Malpractice Med. Malpractice	<ul> <li>385 Property Damag Product Liability</li> <li>************************************</li></ul>	0 79 0 79 NSW	Leave Act 90 Other Labor Litigation 91 Empl, Ret, Inc. Security Act	U 870 Taxes (U.S. Plaintiff	<ul> <li>895 Freedom of Information Act</li> <li>896 Arbitration</li> <li>899 Administrative Procedure Act/Review or Appeal of</li> </ul>
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VI. CAUSE OF ACTION	$ON \frac{28 \text{ U.S.C. § } 1332}{\text{Brief description of ca}}$	2 (c)( <u>1)</u>		(Do not clte jurisdictional st	atutes unless diversity):	
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS UNDER F.R.C.P.	IS A CLASS ACTIO	N D	DEMAND \$ 00.00	CHECK YES only JURY DEMAND	if demanded in complaint: : 🕼 Yes 🗇 No
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#### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI

Tyreke Ree	se ,	)
	Plaintiff,	)
v. Pfizer, Inc.	C	) Case No.
	5	) )
	Defendant,	)

#### ORIGINAL FILING FORM

# THIS FORM MUST BE COMPLETED AND VERIFIED BY THE FILING PARTY WHEN INITIATING A NEW CASE.

THIS SAME CAUSE, OR A SUBSTANTIALLY EQUIVALENT COMPLAINT, WAS

PREVIOUSLY FILED IN THIS COURT AS CASE NUMBER

AND ASSIGNED TO THE HONORABLE JUDGE

THIS CAUSE IS RELATED, BUT IS NOT SUBSTANTIALLY EQUIVALENT TO ANY

PREVIOUSLY FILED COMPLAINT. THE RELATED CASE NUMBER IS \_\_\_\_\_\_ AND

THAT CASE WAS ASSIGNED TO THE HONORABLE \_\_\_\_\_\_. THIS CASE MAY,

THEREFORE, BE OPENED AS AN ORIGINAL PROCEEDING.

NEITHER THIS SAME CAUSE, NOR A SUBSTANTIALLY EQUIVALENT

COMPLAINT, HAS BEEN PREVIOUSLY FILED IN THIS COURT, AND THEREFORE

MAY BE OPENED AS AN ORIGINAL PROCEEDING.

The undersigned affirms that the information provided above is true and correct.

gnature

Date: 06/19/2012

AO 399 (01/09) Waiver of the Service of Summons

# **UNITED STATES DISTRICT COURT**

for the

Eastern District of Missouri

Tyreke Reese Plaintiff

v.

Pfizer, Inc

Civil Action No.

Defendant

#### WAIVER OF THE SERVICE OF SUMMONS

To: Jeffrey J. Lowe

(Name of the plaintiff's attorney or unrepresented plaintiff)

I have received your request to waive service of a summons in this action along with a copy of the complaint, two copies of this waiver form, and a prepaid means of returning one signed copy of the form to you.

I, or the entity I represent, agree to save the expense of serving a summons and complaint in this case.

I understand that I, or the entity I represent, will keep all defenses or objections to the lawsuit, the court's jurisdiction, and the venue of the action, but that I waive any objections to the absence of a summons or of service.

I also understand that I, or the entity I represent, must file and serve an answer or a motion under Rule 12 within , the date when this request was sent (or 90 days if it was sent outside the 60 days from 06/19/2012 United States). If I fail to do so, a default judgment will be entered against me or the entity I represent.

06/19/2012 Date:

Printed name of party waiving service of summons

Signature of the attorney or unrepresented party

Printed name

Address

E-mail address

Telephone number

Duty to Avoid Unnecessary Expenses of Serving a Summons

Rule 4 of the Federal Rules of Civil Procedure requires certain defendants to cooperate in saving unnecessary expenses of serving a summons and complaint. A defendant who is located in the United States and who fails to return a signed waiver of service requested by a plaintiff located in the United States will be required to pay the expenses of service, unless the defendant shows good cause for the failure.

"Good cause" does not include a belief that the lawsuit is groundless, or that it has been brought in an improper venue, or that the court has no jurisdiction over this matter or over the defendant or the defendant's property.

If the waiver is signed and returned, you can still make these and all other defenses and objections, but you cannot object to the absence of a summons or of service.

If you waive service, then you must, within the time specified on the waiver form, serve an answer or a motion under Rule 12 on the plaintiff and file a copy with the court. By signing and returning the waiver form, you are allowed more time to respond than if a summons had been served.