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8 UNITED STATES DISTRICT COURT
9 EASTERN DISTRICT OF CALIFORNIA

10
11
12 Travis Vickers and Stacey Vickers,

13 Plaintiffs,

14 v.

15 Bristol-Myers Squibb Company,
Otsuka Pharmaceutical Co., Ltd., and
16 Otsuka America Pharmaceutical, Inc.,

17 Defendants.

Case No. _____

**COMPLAINT AND DEMAND FOR
JURY TRIAL**

18
19 Plaintiffs, Travis Vickers and Stacey Vickers, by and through Plaintiffs'
20 undersigned counsel, bring this civil action against Defendants above-named for
21 personal injuries suffered by Plaintiff Travis Vickers and for Stacey Vickers' loss of
22 consortium, and allege as follows:

23 **INTRODUCTION**

24 1. This is an action for damages suffered by Plaintiffs as a direct and proximate
25 result of Defendants' wrongful conduct in connection with the development, design,
26 testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling
27 of Defendants' prescription drug Abilify.

1 Vickers had ceased taking Abilify in or around October 2013. Due to Defendants'
2 conduct, as detailed herein, Plaintiff's injuries and their relationship to Abilify were not
3 discovered until 2014.

4 9. By way of example, as a result of Abilify use, Plaintiff Travis Vickers has
5 suffered the following losses: monetary losses in excess of \$75,000, loss of financial
6 stability, and other mental, physical, and economic losses. The injurious impact of
7 Abilify on Plaintiff's brain constitutes a physical injury.

8 10. As a result of Abilify use, Plaintiff Travis Vickers has suffered, and will
9 continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and
10 economic loss as alleged herein.

11 11. Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is incorporated
12 in Delaware, with its principal executive office at 345 Park Avenue, New York, New
13 York. Upon information and belief, Bristol-Myers owns and operates six facilities in the
14 state of New Jersey.

15 12. Defendant Otsuka Pharmaceutical Co., Ltd. ("OPC") is a Japanese company,
16 with its principal office at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535,
17 Japan, and has a registered agent located at 351 West Camden Street, Baltimore,
18 Maryland per records filed with the Maryland Department of Assessments and Taxation
19 Business Services. Abilify is a trademark of Defendant Otsuka Pharmaceutical Co., Ltd.
20 Defendant Otsuka Pharmaceutical Co. Ltd. wholly owns Otsuka America, Inc. ("OAI"),
21 a holding company established in the United States in or around 1989. OAI is the parent
22 of Defendant Otsuka America Pharmaceutical, Inc. ("OAPI"), Otsuka Pharmaceutical
23 Development & Commercialization, Inc. ("OPDC"), and Otsuka Maryland Medicinal
24 Laboratories, Inc. ("OMML").

25 13. Defendant OAPI is incorporated in Delaware, with its principal place of
26 business at 508 Carnegie Center, Princeton, New Jersey. OAPI oversees all
27 pharmaceutical commercial activities in North America. OAPI developed, distributed,
28 and marketed Abilify with OPC.

1 14. At all times relevant to this Complaint, Defendant OPC, OAI, OAPI, OPDC,
2 and OMML (the “Otsuka entities”) have operated in concert as it relates to the
3 development, research, distribution, manufacturing, and/or marketing of Abilify. OPC
4 has control over its subsidiaries daily affairs and operations with respect to Abilify. The
5 Otsuka entities work in concert as a single operation known as the Otsuka Group.

6 15. Defendant Bristol-Myers has operated in concert with the other Defendants
7 and jointly marketed, sold, and promoted Abilify in the United States with the Otsuka
8 Group, through Defendant OAPI and otherwise.

9 16. Defendants are collectively engaged in the development, design, testing,
10 labeling, packaging, promoting, advertising, marketing, distribution, and selling of
11 pharmaceutical products, including Abilify. Otsuka “discovered” Abilify in 1988,
12 obtained approval in the United States in November 2002 and in Japan in January 2006.

13 17. Defendants Bristol-Myers and Otsuka are and have been engaged in the
14 business of researching, testing, developing, manufacturing, packaging, distributing,
15 licensing, labeling, promoting, marketing and selling, either directly or indirectly
16 through third parties or related entities, the pharmaceutical drug Abilify, in all states
17 and throughout the United States.

18 **JURISDICTION**

19 18. This Court has federal subject matter jurisdiction pursuant to 28 U.S.C. § 1332
20 because Plaintiffs and Defendants are citizens of different states and the amount in
21 controversy exceeds \$75,000, exclusive of interest and costs.

22 19. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

23 20. In particular, a foreign defendant may be sued in this judicial district pursuant
24 to 28 U.S.C. § 1391(c)(3).

25 21. The domestic Defendant entities are residents of, and operate in, this judicial
26 district for purposes of venue pursuant to 28 U.S.C. §§ 1391(b)(1), (c)(2), and (d).

27 22. At all times relevant to this action, the Defendants have been engaged either
28 directly or indirectly in the business of marketing, promoting, distributing, and selling

1 prescription drug products, including the Abilify products, within the State of
2 California, with a reasonable expectation that the products would be used or consumed
3 in this state, and thus regularly solicited or transacted business in this state.

4 23. This Court has personal jurisdiction over Otsuka Pharmaceutical Co., Ltd.
5 based on its contacts with California relating to the subject matter of this action and
6 because Otsuka Pharmaceutical Co., Ltd. has continuous and systematic contacts with
7 this judicial district. On information and belief, Otsuka Pharmaceutical Co., Ltd.
8 regularly places goods into the stream of commerce for distribution in California and
9 throughout the United States. Members of Otsuka Pharmaceutical Co., Ltd.
10 continuously communicate from Japan with members of Otsuka America
11 Pharmaceutical, Inc. Otsuka Pharmaceutical Co., Ltd sells and markets Abilify in the
12 United States and California.

13 24. Defendants are subject to the *in personam* jurisdiction of this Court, and venue
14 is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendants did and do
15 business within and have continuous and systematic contacts with the State of
16 California, and have consented to jurisdiction in the State of California and/or
17 committed a tort in whole or in part in the State of California against Plaintiffs, as more
18 fully set forth herein. On information and belief, Defendants also advertised in this
19 district, made material omissions and representations in this district, and breached
20 warranties in this district.

21 25. Jurisdiction is proper under Cal. Code Civ. Pro. § 410.10 and the Due Process
22 Clause of the Constitution because Defendants have sufficient minimum contacts with
23 the State of California related to Abilify and have purposefully directed conduct toward
24 the State of California.

25 **FACTUAL BACKGROUND**

26 26. Abilify was first introduced to the market in the United States in or around the
27 fall of 2002. Abilify is an atypical anti-psychotic prescription medicine discovered by
28 Defendant Otsuka Pharmaceutical Co., Ltd.

1 27. In or around October or November of 2012, the European Medicines Agency
2 required that Defendants warn patients and the medical community in Europe that
3 Abilify use included the risk of pathological gambling.

4 28. In particular, the European Medicines Agency required the European labeling
5 for Abilify to carry the following language in the Special Warnings and Precautions For
6 Use section of the label:

7 **Pathological gambling**

8 **Post-marketing reports of pathological gambling have been**
9 **reported among patients prescribed ABILIFY, regardless of**
10 **whether these patients had a prior history of gambling. Patients**
11 **with a prior history of pathological gambling may be at increased**
12 **risk and should be monitored carefully.**

13 29. The European labeling for Abilify also carries additional language concerning
14 adverse reactions that have been reported during post-marketing surveillance relating to
15 gambling side effects. Under a section entitled “Undesirable effects,” it provides:

16 **Psychiatric disorders: agitation, nervousness, pathological**
17 **gambling, suicide attempt, suicidal**
18 **ideation, and completed suicide.**

19 30. In or around November 2015, Canadian regulators concluded that there is “a
20 link between the use of aripiprazole and a possible risk of pathological gambling or
21 hypersexuality” and found an increased risk of pathological (uncontrollable) gambling
22 and hypersexuality with the use of Abilify.

23 31. In or about November 2015, the following warning statement for the risk of
24 pathological gambling was added to the Canadian prescribing information for Abilify:

25 **Pathological Gambling**

26 **Post-marketing reports of pathological gambling have been**
27 **reported in patients treated with ABILIFY. In relation to**
28 **pathological gambling, patients with a prior history of gambling**
disorder may be at increased risk and should be monitored
carefully.

32. Despite these warnings and advisories in Europe and Canada—for the same
drug sold to patients in the United States—the labeling for Abilify in the United States
did not adequately warn about the risk of compulsive gambling and contained no

1 mention that pathological gambling has been reported in patients prescribed Abilify. In
2 January 2016, pathological gambling was added only to the Postmarketing Experience
3 section of the label; Defendants did not make any mention of gambling in the patient
4 medication guide, a source of information likely viewed by physicians and patients. On
5 May 3, 2016, the FDA issued a warning that Abilify was associated with “compulsive or
6 uncontrollable urges to gamble, binge eat, shop, and have sex.” The FDA recommended
7 that doctors “make patients and caregivers aware of the risk of these uncontrollable
8 urges,” “closely monitor” patients, and consider reducing or stopping Abilify if
9 compulsivity emerges.

10 33. The labeling for Abilify in the United States contained no mention of the word
11 “gambling” until January 2016.

12 34. Defendants wrongfully and unjustly profited at the expense of patient safety
13 and full disclosure to the medical community by failing to include language about
14 gambling in the United States labeling and by failing to otherwise warn the public and
15 the medical community about Abilify’s association with gambling – despite
16 opportunities and a duty to do so. As a result, Defendants have made significantly more
17 revenue from Abilify sales in the United States compared to Europe.

18 35. Defendant Bristol-Myers touts Abilify as its “2013 largest-selling product”
19 noting sales of \$2.3 billion. Defendant Bristol-Myers recently reported U.S. revenues
20 from Abilify sales of \$417 million over three months ending June 30, 2014, and
21 worldwide revenues of \$555 million over the same time period.

22 36. Since its introduction to the United States market, Abilify has generally been
23 used to treat patients with schizophrenia, bipolar disorder, as an adjunct for depression,
24 and autism spectrum disorders.

25 37. In 2001, Defendant Otsuka Pharmaceutical Co., Ltd. submitted a New Drug
26 Application (“NDA”) to the United States Food and Drug Administration (“FDA”) for
27 Abilify (aripiprazole). This initial NDA sought approval to market Abilify in 2, 5, 10, 15,
28 20 and 30 mg tablets as a treatment for schizophrenia. The NDA was approved on

1 November 15, 2002.

2 38. In November 2002, the FDA required Defendants to submit results of Study
3 138047 to address the longer-term efficacy of Abilify in the treatment of adults with
4 schizophrenia.

5 39. On December 3, 2002, Defendant Otsuka America Pharmaceutical, Inc.
6 submitted a Supplemental New Drug Application (NDA 21-436/S-001) on the longer-
7 term efficacy of Abilify in the treatment of schizophrenia. This application was
8 approved on August 28, 2003.

9 40. In June 2003, Otsuka Maryland Research Institute submitted another
10 Supplemental New Drug Application (NDA 21-436/S-002) for Abilify tablets as a
11 treatment for bipolar disorder. This application was approved on September 29, 2004.

12 41. In May 2007, Otsuka Pharmaceutical Development & Commercialization, Inc.
13 submitted another Supplemental New Drug Application (NDA 21-436/S-018) for Abilify
14 tablets as an adjunctive treatment for patients with major depressive disorder. This
15 application was approved on November 16, 2007.

16 42. In contrast, in Europe, Abilify is not indicated to treat depression. The
17 European Medicines Agency declined to approve Abilify as an add-on treatment for
18 depression because of concerns about its efficacy for that indication.

19 43. In or around 1999, Defendants Bristol-Myers and Otsuka entered into an
20 agreement to co-develop and “commercialize” Abilify (hereinafter referred to as
21 “Defendants’ Marketing Agreement”). Under the terms of Defendants’ Marketing
22 Agreement, Defendant Bristol-Myers was to market and promote Abilify in the United
23 States and the European Union, in collaboration with Defendant Otsuka Pharmaceutical
24 Co., Ltd., and under Defendant Otsuka Pharmaceutical Co., Ltd.’s trademark.

25 44. Defendants’ Marketing Agreement also provided that Defendants Bristol-
26 Myers and Otsuka Pharmaceutical Co., Ltd. would collaborate to complete clinical
27 studies for schizophrenia, and that Defendant Bristol-Myers would conduct additional
28 studies for new dosage forms and new indications.

1 45. Defendant Bristol-Meyers began co-promoting Abilify with Defendant Otsuka
2 Pharmaceutical Co., Ltd. in the United States and Puerto Rico in or around November
3 2002. Defendants' Marketing Agreement was extended in or around 2009.

4 46. Defendant Bristol-Myers' relationship with Otsuka had been due to expire in
5 or around April 2015, just after the predicted expiration of Abilify's patent protection in
6 the United States. According to a revised marketing agreement, Defendant Bristol-
7 Myers purported to no longer market and promote Abilify as of January 1, 2013, but
8 would continue to carry out its other responsibilities, including manufacturing for sale
9 to third-party customers. Nevertheless, Defendant Bristol-Myers continued to market
10 and promote Abilify, for example, through its website, through September 2015.

11 47. Defendants had, or should have had, knowledge that Abilify can cause
12 compulsive behaviors like gambling. Despite their significant collective resources, and
13 signals that Abilify is associated with compulsive behaviors such as gambling,
14 Defendants have failed to fully and adequately test or research Abilify and its
15 association with compulsive behaviors to the detriment of Plaintiffs, Abilify users, the
16 public, the medical community, and prescribing doctors.

17 48. Compulsive gambling is a major psychiatric disorder. The American
18 Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* ("DSM")
19 first recognized pathological gambling as a psychiatric disorder in 1980.

20 49. Originally, the disorder was classified as an impulse control disorder. The
21 current version of the DSM, the DSM-V, renamed pathological gambling as "gambling
22 disorder." DSM-V reclassified gambling disorder under the category Substance-Related
23 and Addictive Disorders in order to reflect evidence that gambling behaviors activate or
24 are activated by reward systems similar to those activated by drugs of abuse, and
25 produce some behavioral symptoms comparable to those produced by substance abuse
26 disorders.

27 50. Abilify is a partial and full dopamine agonist. Dopamine is a neurotransmitter
28 that helps control the brain's reward and pleasure centers.

1 51. Dopamine's role in compulsive behavior and pathological gambling is well-
2 known. Dopaminergic reward pathways have frequently been implicated in the
3 etiology of addictive behavior. Scientific literature has identified dopamine as a
4 potential cause of pathological gambling for years.

5 52. Abilify's dopaminergic activity at the mesolimbic circuit, especially at the
6 nucleus accumbens, has been associated with compulsive behavior in Abilify patients.

7 53. Defendants' September 2011 6-Month Periodic Safety Update Report
8 acknowledges a plausible mechanism for pathological gambling. The Report states that
9 an article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to Psychiatric*
10 *Disorders*, "does suggest a possible mechanism by which drugs that act on dopamine
11 neurons, like aripiprazole, might possibly have some effect on behavior related to
12 reward."

13 54. Defendants' September 2011 6-Month Periodic Safety Update Report
14 submitted to the European Medicines Agency acknowledged seven serious reports of
15 pathological gambling, three in the medical literature and four spontaneous reports.
16 The report also noted sixteen cases of pathological gambling in the Bristol-Myers
17 company safety database.

18 55. The Medical Assessment of the pathological gambling cases in Defendants'
19 September 2011 6-Month Periodic Safety Update Report did not exclude Abilify as the
20 cause of the compulsive gambling adverse events. Defendants concluded that "a causal
21 role of aripiprazole could not be excluded" or that "aripiprazole was suggested by the
22 temporal relationship."

23 56. The European Final Assessment Report of the September 2011 6-Month
24 Periodic Safety Update Report concluded that with regard to compulsive gambling "in
25 all of the reported cases we have a (+) temporal; (+) dechallenge and in one case a (+)
26 rechallenge."

27 57. Numerous case reports have been published in the medical literature linking
28 Abilify to compulsive behavior, including at least seventeen cases of compulsive

1 gambling. Gaboriau et al. examined case reports of compulsive gambling and found
2 that the probability that pathological gambling was actually due to Abilify was
3 “possible” in sixteen of the cases and “doubtful” in only one of the cases.

4 58. Several case reports demonstrate what is known as a challenge, de-challenge,
5 and re-challenge.

6 59. Challenge is the administration of a suspect product by any route.

7 60. De-challenge is the withdrawal of the suspected product from the patient’s
8 therapeutic regime. A positive de-challenge is the partial or complete disappearance of
9 an adverse experience after withdrawal of the suspect product. For example, a positive
10 de-challenge occurs when a patient ceases use of Abilify and pathological gambling
11 behaviors cease.

12 61. Re-challenge is defined as a reintroduction of a product suspected of having
13 caused an adverse experience following a positive de-challenge. A positive re-challenge
14 occurs when similar signs and symptoms reoccur upon reintroduction of the suspect
15 product. For example, a positive re-challenge occurs when a patient reintroduces
16 Abilify into her treatment regime and pathological gambling behavior reoccurs in a
17 similar manner as such behaviors had existed when the patient previously used Abilify.

18 62. A positive de-challenge is considered evidence that a drug caused a particular
19 effect, as is a positive re-challenge.

20 63. From May 1, 2009 to May 1, 2011, the FDA received thousands of serious
21 adverse event reports concerning Abilify (n=4599), including over two-thousand serious
22 adverse drug experiences of which 193 involved children (0-16 years old).

23 64. Serious adverse events are drug experiences including the outcomes of death,
24 life-threatening events, hospitalization, disability, congenital abnormality, and other
25 harmful medical events.

26 65. From 2005 to 2013, an FDA report showed that Abilify accounted for at least
27 fifty-four reports of compulsive or impulsive behavior problems, including thirty
28 reports of compulsive gambling, twelve reports of impulsive behavior, nine reports of

1 hypersexuality, and three reports of compulsive shopping.

2 66. A disproportionality study of the FDA Adverse Event Reporting System
3 showed a proportional reporting ratio for compulsivity of 8.6 for Abilify. A ratio of
4 more than three indicates a signal of an adverse event.

5 67. An analysis of the FDA Adverse Event Reporting System shows an escalating
6 number of reports. Twenty-nine reports of gambling behavior were made to the FDA in
7 2014.

8 68. The 2014 FDA Adverse Event Reporting System data shows a proportional
9 reporting ratio for compulsive gambling of 64.3 for Abilify. The same data demonstrates
10 Abilify is unique in this regard and compulsive gambling is not a class-wide problem
11 among anti-psychotic medications.

12 69. Defendants have not adequately studied Abilify. A review of all the
13 randomized clinical trials comparing Abilify to other schizophrenia drugs concluded
14 that the information on comparisons was of limited quality, incomplete, and problematic
15 to apply clinically.

16 70. Despite evidence that Abilify causes compulsive behaviors like pathological
17 gambling and calls from the medical community to conduct further research and warn
18 patients about this possible effect of Abilify, Defendants have either failed to investigate
19 or conduct any studies on the compulsive behavior side effects of Abilify or failed to
20 make public the results of any studies or investigations that they might have done.

21 71. Abilify is not very efficacious. According to a rigorous study by the Cochrane
22 Collaboration, there is limited evidence that Abilify leads to symptom reduction when
23 added to antidepressants and side effects are more frequent under Abilify augmentation
24 treatment.

25 72. The Drug Facts Box for Abilify for major depression includes a “summary” of
26 the combined data from the two identical six week randomized trials that were the basis
27 for FDA drug approval for this indication. The box shows that Abilify has only a
28 modest benefit: on average, patients on Abilify improved by 3 points more (*on a scale of*

1 60) than patients on placebo, and only an additional 11% of patients had a clinically
2 important response as defined in the trial.

3 73. Despite the risks of serious adverse events, and the lack of adequate testing,
4 Defendants aggressively promoted Abilify, including illegal promotion for off-label use.
5 In 2007, Defendant Bristol-Myers reportedly paid \$515 million to settle federal and state
6 investigations into off-label marketing of Abilify for pediatric use and to treat dementia-
7 related psychosis. Defendant Otsuka American Pharmaceutical, Inc. later paid more
8 than \$4 million to resolve the allegations.

9 74. The FDA issued a letter dated April 17, 2015 finding Abilify promotional
10 material “false or misleading because it makes misleading claims and presentations
11 about the drug.” The FDA found the material “misleading because it implies that
12 Abilify offers advantages over other currently approved treatments for bipolar disorder
13 or MDD when this has not been demonstrated.” The FDA also found the cited
14 references “not sufficient to support claims and presentations suggesting that Abilify has
15 been demonstrated to modulate dopaminergic and serotonergic activity, or modulate
16 neuronal activity in both hypoactive and hyperactive environments in humans.”

17 75. Upon information and belief, Defendants have invested millions of dollars in
18 teams of pharmaceutical sales representatives who visit and contact members of the
19 medical community, including prescribing doctors, purporting to “educate” them about
20 Abilify. Upon information and belief, these pharmaceutical sales representatives have
21 not notified patients, the medical community, or prescribers in the United States that
22 Abilify use causes, is linked to, or might be associated with compulsive gambling,
23 pathological gambling, or gambling addiction.

24 76. Defendants have invested millions of dollars in “Direct to Consumer”
25 advertising. None of the advertising in the United States notifies patients, the medical
26 community, or prescribers that Abilify use causes, is linked to, or might be associated
27 with compulsive gambling, pathological gambling, or gambling addiction.

28 77. Defendants’ Direct to Consumer advertising minimizes risks while over-

1 promoting the drug.

2 78. As a result of Defendants' misleading promotional campaigns, Abilify
3 occupies the top sales position for a prescription drug in the United States (but has only
4 reached seventh place in the global ranking of drug sales).

5 79. Defendants have made payments to doctors to promote Abilify. From August
6 2013 to December 2014, \$10.6 million in payments relating to Abilify were made to
7 21,155 physicians in the United States.

8 80. To date, Defendants have not adequately notified or warned patients, the
9 medical community, or prescribers in the United States that Abilify use causes, is linked
10 to, and is associated with compulsive gambling, pathological gambling, or gambling
11 addiction.

12 81. Prior to May 2016, upon information and belief, Defendants had not sent out
13 any "Dear Doctor" letters to inform the medical community of the risk or association of
14 Abilify use and gambling.

15 82. Under the heading "What are the possible side effects of ABILIFY?" the
16 labeling for Abilify in the United States does not list gambling, pathological or
17 otherwise. Nor does it mention compulsive behaviors.

18 83. Likewise, the labeling for Abilify in the United States lists serious side effects
19 that have been reported with Abilify, but did not list gambling, pathological or
20 otherwise in any form until January 2016 when it was only added to the postmarketing
21 experience section of the label. Prior to May 2016, the label did not mention compulsive
22 behaviors other than pathological gambling or adequately warn patients about the risk
23 of compulsive gambling. Defendants also did not make any mention of gambling in the
24 patient medication guide, the source of information most likely viewed by physicians
25 and patients.

26 84. The labeling in the United States contradicts the labeling in Europe and
27 Canada by not providing adequate warnings and not cautioning that patients should be
28 closely monitored, and does not adequately inform patients and physicians that

1 gambling and other compulsive behaviors have been associated with Abilify use.

2 85. Defendant Otsuka America Pharmaceutical, Inc. maintains a website
3 promoting Abilify, www.abilify.com. The website includes, among other information,
4 “tips for taking Abilify,” links to “a 30-day free trial & savings on refills,” and
5 “important safety information” for Abilify. Although it has sections about “important
6 safety information,” nowhere on the website does it mention the word “gambling.”

7 86. Also, Defendant Otsuka America Pharmaceutical, Inc. operated another
8 website promoting Abilify, www.addabilify.com. Prior to 2015, this website included,
9 among other information, “important safety information,” “tips for family and friends,”
10 “treatment FAQs,” “side effects FAQs,” and “what your doctor needs to know”
11 concerning Abilify. Nowhere on the website did it mention the word “gambling.”

12 87. Defendant Bristol-Myers promotes Abilify on its own website, www.bms.com
13 (“BMS website”), noting it was approved in November 2002 and is “jointly marketed in
14 the U.S. by Bristol-Myers Squibb and Otsuka America Pharmaceutical.” The BMS
15 website also includes a link to the www.abilify.com website. Nowhere on the BMS
16 website does it mention the word “gambling.”

17 88. Likewise, Defendant Otsuka Pharmaceutical Co., Ltd. promotes Abilify on its
18 own website, www.otsuka.co.jp/en/ (“Otsuka website”), noting it was “researched and
19 developed by Otsuka Pharmaceutical” and “launched” in the United States in 2002.
20 Nowhere on the Otsuka website does it mention the word “gambling.”

21 **EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

22 89. Plaintiffs assert all applicable state statutory and common law rights and
23 theories related to the tolling or extension of any applicable statute of limitations,
24 including the discovery rule and/or fraudulent concealment.

25 90. The discovery rule should be applied to toll the running of the statute of
26 limitations until the Plaintiffs discovered or reasonably should have discovered Plaintiff
27 Travis Vickers’ injury and the causal connection between the injury and Defendants’
28 product.

1 91. Despite reasonable and diligent investigation by Plaintiffs into the causal
2 connection between Plaintiffs' injuries and Abilify, the cause and nature of Plaintiffs'
3 injuries and their relationship to Abilify was not discovered until 2014. Therefore, under
4 the appropriate application of the discovery rule, Plaintiffs' suit was filed well within the
5 applicable statutory limitations period.

6 92. Defendants are estopped from asserting a statute of limitations defense
7 because all Defendants fraudulently concealed from Plaintiffs the truth, quality and
8 nature of Plaintiffs' injuries and the connection between the injuries and Defendants'
9 tortious conduct. Defendants, through their affirmative misrepresentations and
10 omissions, actively concealed from Plaintiffs and Plaintiff Travis Vickers' prescribing
11 physicians the true risks associated with Abilify.

12 93. Defendants were under a duty to disclose the true character, quality and
13 nature of the risks associated with use of Abilify as this was non-public information over
14 which Defendants had and continue to have exclusive control, and because Defendants
15 knew that this information was not available to Plaintiffs, Plaintiff Travis Vickers'
16 medical providers and/or health-care facilities. In addition, Defendants are estopped
17 from relying on any statute of limitation because of their intentional concealment of
18 these facts.

19 94. Plaintiffs had no knowledge that Defendants were engaged in the wrongdoing
20 alleged herein. Because of the fraudulent acts of concealment of wrongdoing by
21 Defendants, Plaintiffs could not have reasonably discovered the wrongdoing at any time
22 prior to 2014.

23
24 **FIRST CAUSE OF ACTION**
Strict Liability - Design, Manufacturing and Warning

25 95. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
26 fully set forth herein and further allege as follows:

27 96. Defendants had a duty to provide adequate warnings and instructions for
28 Abilify, to use reasonable care to design a product that is not unreasonably dangerous to

1 users, and to adequately test their product.

2 97. The Abilify manufactured and/or supplied to Plaintiff Travis Vickers by
3 Defendants was defective in design or formulation in that, when it left the hands of the
4 manufacturer and/or supplier, it was in an unreasonably dangerous and a defective
5 condition for its intended use and it posed a risk of serious compulsive behaviors and
6 harm to Plaintiff and other consumers which could have been reduced or avoided, *inter*
7 *alia*, by the adoption of a feasible reasonable alternative design.

8 98. The Abilify manufactured and/or supplied to Plaintiff Travis Vickers by
9 Defendants was defective in design or formulation in that, when it left the hands of the
10 manufacturer and/or supplier, Abilify had not been adequately tested, was in an
11 unreasonably dangerous and a defective condition, and it posed a risk of serious
12 compulsive behaviors and harm to Plaintiff and other consumers.

13 99. Also, Abilify's limited and unproven effectiveness did not outweigh the risks
14 posed by the drug.

15 100. The Abilify manufactured and/or supplied to Plaintiff Travis Vickers by
16 Defendants was defective due to inadequate warnings or instructions concerning the
17 true risks of its use.

18 101. Defendants knew or should have known through testing, scientific
19 knowledge, advances in the field or otherwise, that the product created a risk of serious
20 compulsive behaviors and harm, and was unreasonably dangerous to Plaintiff Travis
21 Vickers and other consumers, about which Defendants failed to warn.

22 102. The Abilify manufactured and/or supplied to Plaintiff Travis Vickers by
23 Defendants was defective, dangerous, and had inadequate warnings or instructions at
24 the time it was sold, and Defendants also acquired additional knowledge and
25 information confirming the defective and dangerous nature of Abilify. Despite this
26 knowledge and information, Defendants failed and neglected to issue adequate
27 warnings or post-sale warnings that Abilify causes serious compulsive behaviors and
28 harm.

1 103. Defendants failed to provide adequate warnings to users, purchasers, or
2 prescribers of Abilify, including Plaintiff Travis Vickers and his physicians, and instead
3 continued to sell Abilify in an unreasonably dangerous form without adequate warnings
4 or instructions.

5 104. By failing to adequately test and research compulsive behaviors and harms
6 associated with Abilify use, and by failing to provide appropriate warnings about
7 Abilify use and associations with compulsive behaviors such as gambling, patients and
8 the medical community, including prescribing doctors, were inadequately informed
9 about the true risk-benefit profile of Abilify and were not sufficiently aware that
10 compulsive behaviors such as gambling might be associated with Abilify use. As such,
11 the medical community was not learned on the true risk-benefit profile of Abilify. Nor
12 was the medical community, patients, patients' families, or regulators appropriately
13 informed that compulsive behaviors such as gambling might be a side effect of Abilify
14 use and should or could be reported as an adverse event.

15 105. As a direct and proximate result of Defendants' conduct, including the
16 inadequate warnings, dilution or lack of information, lack of adequate testing and
17 research, and the defective and dangerous nature of Abilify, Plaintiff Travis Vickers has
18 suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional
19 distress, harm, and economic loss as alleged herein.

20
21 **SECOND CAUSE OF ACTION**
Breach of Express Warranty by Defendants

22 106. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
23 fully set forth herein and further allege as follows:

24 107. Defendants expressly warranted to physicians and consumers, including
25 Plaintiff Travis Vickers and/or Plaintiff's physicians, that Abilify was safe and/or well-
26 tolerated.

27 108. Abilify does not conform to these express representations because it is not safe
28 and/or well-tolerated because it causes compulsive behaviors such as pathological

1 gambling addiction, which in turn can lead to financial ruin, job loss, familial
2 devastation, and suicide attempts.

3 109. Also, Abilify's limited and unproven effectiveness did not outweigh the risks
4 posed by the drug.

5 110. As a direct and proximate result of the breach of Defendants' warranties,
6 Plaintiff Travis Vickers has suffered, and will continue to suffer, neuropsychiatric and
7 physical injury, emotional distress, harm, and economic loss as alleged herein.

8
9 **THIRD CAUSE OF ACTION**
Breach of Implied Warranty

10 111. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
11 fully set forth herein and further allege as follows:

12 112. At the time Defendants marketed, sold, and distributed Abilify, Defendants
13 knew of the use for which Abilify was intended and impliedly warranted Abilify to be of
14 merchantable quality, safe and fit for such use.

15 113. Defendants knew, or had reason to know, that Plaintiff Travis Vickers and
16 Plaintiff's physicians would rely on the Defendants' judgment and skill in providing
17 Abilify for its intended use.

18 114. Plaintiff Travis Vickers and Plaintiff's physician reasonably relied upon the
19 skill and judgment of Defendants as to whether Abilify was of merchantable quality,
20 safe, and fit for its intended use.

21 115. Contrary to such implied warranty, Abilify was not of merchantable quality or
22 safe or fit for its intended use, because the product was, and is, unreasonably dangerous,
23 defective and unfit for the ordinary purposes for which Abilify was used.

24 116. Also, Abilify's limited and unproven effectiveness did not outweigh the risks
25 posed by the drug.

26 117. As a direct and proximate result of the breach of implied warranty, Plaintiff
27 Travis Vickers has suffered, and will continue to suffer, neuropsychiatric and physical
28 injury, emotional distress, harm, and economic loss as alleged herein.

FOURTH CAUSE OF ACTION
Negligence

1
2 118. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
3 fully set forth herein and further allege as follows:

4 119. At all times material herein, Defendants had a duty to exercise reasonable care
5 and the duty of an expert in all aspects of the design, formulation, manufacture,
6 compounding, testing, inspection, packaging, labeling, distribution, marketing,
7 promotion, advertising, sale, warning, and post-sale warning, testing, and research to
8 assure the safety of the product when used as intended or in a way that Defendants
9 could reasonably have anticipated, and to assure that the consuming public, including
10 Plaintiff Travis Vickers and Plaintiff's physicians, obtained accurate information and
11 adequate instructions for the safe use or non-use of Abilify.

12 120. Defendants had a duty to warn Plaintiff Travis Vickers, Plaintiff's physicians,
13 and the public in general of Abilify's dangers and serious side effects, including serious
14 compulsive behaviors like pathological gambling addiction, since it was reasonably
15 foreseeable that an injury could occur because of Abilify's use.

16 121. At all times material herein, Defendants failed to exercise reasonable care and
17 the duty of an expert and knew, or in the exercise of reasonable care should have
18 known, that Abilify was not properly manufactured, designed, compounded, tested,
19 inspected, packaged, labeled, warned about, distributed, marketed, advertised,
20 formulated, promoted, examined, maintained, sold, and/or prepared.

21 122. Also, Abilify's limited and unproven effectiveness did not outweigh the risks
22 posed by the drug.

23 123. Each of the following acts and omissions herein alleged was negligently and
24 carelessly performed by Defendants, resulting in a breach of the duties set forth above.
25 These acts and omissions include, but are not restricted to:

- 26 a. Negligent and careless research and testing of Abilify;
27 b. Negligent and careless design or formulation of Abilify;
28

- 1 c. Negligent and careless failure to give adequate warnings that would
- 2 attract the attention of Plaintiff Travis Vickers, Plaintiff's physicians, and
- 3 the public in general of the potentially dangerous, defective, unsafe, and
- 4 deleterious propensity of Abilify and of the risks associated with its use;
- 5 d. Negligent and careless failure to provide instructions on ways to safely use
- 6 Abilify to avoid injury;
- 7 e. Negligent and careless failure to explain the mechanism, mode, and types
- 8 of adverse events associated with Abilify;
- 9 f. Negligent representations that Abilify was safe and/or well-tolerated; and
- 10 g. Negligent and careless failure to issue adequate post-sale warnings that
- 11 Abilify causes an increased risk of compulsive behaviors, including
- 12 pathological gambling.

13 124. As a direct and proximate result of Defendants' negligence, Plaintiff Travis
14 Vickers has suffered, and will continue to suffer, neuropsychiatric and physical injury,
15 emotional distress, harm, and economic loss as alleged herein.

16 **FIFTH CAUSE OF ACTION**

17 Negligence Per Se

18 (Violations of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)

19 125. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
20 fully set forth herein and further allege as follows:

21 126. At all times herein mentioned, Defendants had an obligation to abide by the
22 law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations,
23 in the manufacture, design, formulation, compounding, testing, production, processing,
24 assembling, inspection, research, promotion, advertising, distribution, marketing,
25 labeling, packaging, preparation for use, consulting, sale, warning, and post-sale
26 warning, and other communications of the risks and dangers of Abilify.

27 127. By reason of its conduct as alleged herein, Defendants violated provisions of
28 statutes and regulations, including, but not limited to, the following:

- 1 a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C.
2 §§ 331 and 352, by misbranding Abilify;
- 3 b. Defendants failed to follow the “[g]eneral requirements on content and
4 format of labeling for human prescription drugs” in violation of 21 C.F.R.
5 § 201.56;
- 6 c. Defendants failed to follow the “[s]pecific requirements on content and
7 format of labeling for human prescription drugs” in violation of 21 C.F.R.
8 § 201.57;
- 9 d. Defendants advertised and promoted Abilify in violation of 21 C.F.R.
10 § 202.1; and
- 11 e. Defendants violated 21 C.F.R. § 201.57(e) by failing to timely and
12 adequately change the Abilify label to reflect the evidence of an association
13 between Abilify and the serious compulsive behaviors suffered by Plaintiff
14 Travis Vickers.

15 128. These statutes and regulations impose a standard of conduct designed to
16 protect consumers of drugs, including Plaintiff Travis Vickers.

17 129. Defendants’ violations of these statutes and regulations constitute negligence
18 per se.

19 130. As a direct and proximate result of Defendants’ statutory and regulatory
20 violations, Plaintiff, a member of the class of persons protected by the above-mentioned
21 statutes, has suffered, and will continue to suffer, neuropsychiatric and physical injury,
22 emotional distress, harm, and economic loss as alleged herein.

23 **SIXTH CAUSE OF ACTION**
24 **Negligent Misrepresentation**

25 131. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
26 fully set forth herein and further allege as follows:

27 132. Defendants misrepresented to consumers and physicians, including Plaintiff
28 Travis Vickers and/or Plaintiff’s physicians and the public in general, that Abilify was

1 safe and/or well-tolerated when used as instructed, and that Abilify was safe and/or
2 well-tolerated, when, in fact, Abilify was dangerous to the well-being of patients.

3 133. Also, Abilify's limited and unproven effectiveness did not outweigh the risks
4 posed by the drug.

5 134. At the time Defendants promoted Abilify as safe and/or well-tolerated, they
6 did not have adequate proof upon which to base such representations, and, in fact, knew
7 or should have known that Abilify was dangerous to the well-being of Plaintiff Travis
8 Vickers and others.

9 135. Defendants failed to exercise reasonable care and competence in obtaining
10 and/or communicating information regarding the safe use of Abilify and otherwise
11 failed to exercise reasonable care in transmitting information to Plaintiff Travis Vickers,
12 Plaintiff's physicians, and the public in general.

13 136. Defendants made the aforesaid representations in the course of Defendants'
14 business as designers, manufacturers, and distributors of Abilify despite having no
15 reasonable basis for their assertion that these representations were true and/or without
16 having accurate or sufficient information concerning the aforesaid representations.
17 Defendants were aware that without such information they could not accurately make
18 the aforesaid representations.

19 137. At the time the aforesaid representations were made, Defendants intended to
20 induce Plaintiff Travis Vickers and/or Plaintiff's physicians to rely upon such
21 representations.

22 138. At the time the aforesaid representations were made by Defendants, and at the
23 time Plaintiff Travis Vickers received Abilify, Plaintiff and/or Plaintiff's physicians, and
24 the public in general, reasonably believed them to be true. In reasonable and justified
25 reliance upon said representations, Plaintiff used Abilify.

26 139. As a direct and proximate result of reliance upon Defendants'
27 misrepresentations, Plaintiff Travis Vickers has suffered, and will continue to suffer,
28 neuropsychiatric and physical injury, emotional distress, harm, and economic loss as

1 alleged herein.

2 **SEVENTH CAUSE OF ACTION**
3 **Violation of California Unfair Competition Law**
4 **and Consumers Legal Remedies Act**

5 140. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
6 fully set forth herein and further allege as follows:

7 141. By reason of the conduct as alleged herein, and by inducing Plaintiff Travis
8 Vickers and Plaintiff's physicians to use Abilify through the use of deception, fraud,
9 false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices,
10 and the concealment and suppression of material facts including, but not limited to,
11 fraudulent statements, concealments, and misrepresentations identified herein and
12 above, Defendants violated the provisions of Cal. Bus. & Prof. Code § 17200 *et seq.* and
13 Cal. Civ. Code § 1750 *et seq.*

14 142. As a direct and proximate result of Defendants' statutory violations, Plaintiff
15 Travis Vickers was damaged by Abilify which would not have occurred had Defendants
16 not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair
17 and/or deceptive practices, and the concealment and suppression of material facts to
18 induce Plaintiff and Plaintiff's physicians to use this product.

19 143. By reason of such violations and pursuant to Cal. Bus. & Prof. Code § 17200 *et*
20 *seq.* and Cal. Civ. Code § 1750 *et seq.*, Plaintiff Travis Vickers is entitled to recover all of
21 the monies paid for Abilify; to be compensated for the cost of the medical care arising
22 out of the use of Abilify; and to recover any and all consequential damages recoverable
23 under the law including, but not limited to, gambling losses, both past and future
24 medical expenses, past wage loss, loss of future earning capacity, past and future pain,
25 suffering, disability, and emotional distress. Plaintiff is entitled to seek compensatory
26 damages, attorney's fees, and other remedies as determined by the Court pursuant to
27 Cal. Bus. & Prof. Code § 17200 *et seq.* and Cal. Civ. Code § 1750 *et seq.*
28

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EIGHTH CAUSE OF ACTION
Fraudulent Concealment

1
2 144. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
3 fully set forth herein and further allege as follows:

4 145. Throughout the relevant time period, Defendants knew that Abilify was
5 defective and unreasonably unsafe for its intended purpose.

6 146. Defendants fraudulently concealed from or failed to disclose or to warn
7 Plaintiff Travis Vickers, Plaintiff's physicians, and the medical community that Abilify
8 was defective, unsafe, unfit for the purposes intended, and was not of merchantable
9 quality.

10 147. Defendants were under a duty to Plaintiff Travis Vickers to disclose and warn
11 of the defective nature of Abilify because:

- 12 a. Defendants were in a superior position to know the true quality, safety and
13 efficacy of Abilify;
- 14 b. Defendants knowingly made false claims about the safety and quality of
15 Abilify in the documents and marketing materials Defendants provided to
16 the FDA, physicians, and the general public; and
- 17 c. Defendants fraudulently and affirmatively concealed the defective nature
18 of Abilify from Plaintiff.

19 148. Defendants were under a duty to Plaintiff Travis Vickers to disclose and warn
20 of the defective nature of Abilify because the facts concealed or not disclosed by
21 Defendants to Plaintiff were material facts that a reasonable person would have
22 considered to be important in deciding whether or not to purchase or use the product.

23 149. Defendants intentionally concealed or failed to disclose the true defective
24 nature of Abilify so that Plaintiff Travis Vickers would request and purchase Abilify,
25 and that their healthcare providers would dispense, prescribe, and recommend Abilify,
26 and Plaintiff justifiably acted or relied upon, to Plaintiff's detriment, the concealed or
27 non-disclosed facts as evidenced by his purchase and use of Abilify.
28

1 150. Defendants, by concealment or other action, intentionally prevented Plaintiff
2 Travis Vickers and Plaintiff's physicians from acquiring material information regarding
3 the lack of safety and effectiveness of Abilify, and are subject to the same liability to
4 Plaintiff for Plaintiff's pecuniary losses, as though Defendants had stated the non-
5 existence of such material information regarding Abilify's lack of safety and
6 effectiveness and dangers and defects, and as though Defendants had affirmatively
7 stated the non-existence of such matters that Plaintiff was thus prevented from
8 discovering the truth. Defendants therefore have liability for fraudulent concealment
9 under all applicable law, including, *inter alia*, Restatement (Second) of Torts § 550 (1977).

10 151. As a result of Defendants' foregoing acts and omissions, Plaintiff Travis
11 Vickers was and still is caused to suffer and is at a greater increased risk of serious and
12 dangerous side effects including compulsive gambling, and other severe and personal
13 injuries, physical pain and mental anguish, diminished enjoyment of life, any and all life
14 complications.

15 152. As a direct and proximate result of the foregoing acts and omissions, Plaintiff
16 Travis Vickers has required and will require healthcare and services, and has incurred
17 financial loss, medical, health care, incidental, and related expenses.

18 153. As a direct and proximate result of reliance upon Defendants'
19 misrepresentations, Plaintiff Travis Vickers has suffered, and will continue to suffer,
20 neuropsychiatric and physical injury, emotional distress, harm, and economic loss as
21 alleged herein.

22 **NINTH CAUSE OF ACTION**
23 **Loss of Consortium**

24 154. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth
25 herein and further allege as follows:

26 155. Plaintiffs are husband and wife.

27 156. Plaintiff Travis Vickers' spouse has incurred financial loss as a result of
28 Defendants' conduct.

1 157. As a result of Defendants' conduct, Plaintiffs were caused to suffer, and will
2 continue to suffer in the future, loss of consortium, loss of society, affection, assistance,
3 and conjugal fellowship, all to the detriment of their marital relationship.

4 **TENTH CAUSE OF ACTION**
5 **Punitive Damages**

6 158. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as if
7 fully set forth herein and further allege as follows:

8 159. Plaintiffs are entitled to an award of punitive and exemplary damages based
9 upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions,
10 and conduct, and Defendants' reckless disregard for the public's safety and welfare.
11 Defendants intentionally and fraudulently misrepresented facts and information to both
12 the medical community and the general public, including Plaintiff Travis Vickers, by
13 making intentionally false and fraudulent misrepresentations about the safety and
14 efficacy of Abilify. Defendants intentionally concealed the true facts and information
15 regarding the serious risks of harm associated with the ingestion of Abilify, and
16 intentionally downplayed the type, nature, and extent of the adverse side effects of
17 ingesting Abilify, despite Defendants' knowledge and awareness of the serious side
18 effects and risks associated with Abilify.

19 160. Defendants had knowledge of, and were in possession of evidence
20 demonstrating that Abilify caused serious side effects including compulsive gambling.
21 Notwithstanding Defendants' knowledge of the serious side effects of Abilify,
22 Defendants continued to market the drug by providing false and misleading
23 information with regard to the product's safety and efficacy to the regulatory agencies,
24 the medical community, and consumers of Abilify.

25 161. Although Defendants knew or recklessly disregarded the fact that Abilify
26 cause debilitating compulsive behavior side effects including compulsive gambling,
27 Defendants continued to market, promote, and distribute Abilify to consumers,
28 including Plaintiff Travis Vickers, without disclosing these side effects when there were

1 safer alternative methods for treating Plaintiff's underlying condition.

2 162. Defendants failed to provide warnings that would have dissuaded physicians
3 from prescribing Abilify and consumers from purchasing and ingesting Abilify, thus
4 depriving both from weighing the true risks against the benefits of prescribing,
5 purchasing or consuming Abilify.

6 163. Defendants knew of Abilify's defective nature as set forth herein, but
7 continued to design, manufacture, market, distribute, sell and/or promote the drug as to
8 maximize sales and profits at the expense of the health and safety of the public,
9 including Plaintiff Travis Vickers in a conscious or negligent disregard of the foreseeable
10 harm caused by Abilify.

11 164. The aforementioned conduct of Defendants was committed with knowing,
12 conscious, and deliberate disregard of the rights and safety of consumers such as
13 Plaintiffs, thereby entitling Plaintiffs to punitive damages in the amount appropriate to
14 punish Defendants and deter them from similar conduct in the future.

15 **PRAYER FOR RELIEF**

16 WHEREFORE, Plaintiffs seeks judgment in Plaintiffs' favor as follows:

- 17 1. Awarding actual damages to Plaintiffs incidental to the purchase
18 and ingestion of Abilify in an amount to be determined at trial;
- 19 2. Awarding the costs of treatment for Plaintiffs' injuries caused by
20 Abilify;
- 21 3. Awarding damages for Plaintiffs' neuropsychiatric, mental,
22 physical, and economic pain and suffering;
- 23 4. Awarding damages for Plaintiffs' mental and emotional anguish;
- 24 5. Awarding pre-judgment and post-judgment interest to Plaintiffs;
- 25 6. Awarding punitive damages;
- 26 7. Awarding the costs and expenses of this litigation to Plaintiffs;
- 27
- 28

CIVIL COVER SHEET

Case 1:16-at-00390 Document 1-1 Filed 05/27/16 Page 1 of 5

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings 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 in September 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
Travis Vickers and Stacey Vickers,
(b) County of Residence of First Listed Plaintiff Kings
(c) Attorneys (Firm Name, Address, and Telephone Number)
Gary Wilson 612-349-8500
Robins Kaplan LLP
800 LaSalle Avenue, Suite 2800
Minneapolis, MN 55402

DEFENDANTS
Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., and Otsuka America Pharmaceutical, Inc.
County of Residence of First Listed Defendant New York
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.
Attorneys (If Known)
Barry Thompson, Esq.
Hogan Lovells US LLP
1999 Avenue of the Stars, Suite 1400
Los Angeles, CA 90067
Matthew Campbell, Esq.
Winston & Strawn LLP
1700 K Street, NW
Washington, DC 20006-3817

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)
1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
1 1 Incorporated or Principal Place of Business In This State
2 2 Incorporated and Principal Place of Business In Another State
3 3 Foreign Nation
4 4
5 5
6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various legal categories and checkboxes.

V. ORIGIN (Place an "X" in One Box Only)
1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District (specify)
6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. § 1332
Brief description of cause:
Products liability action regarding prescription drug Abilify

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND \$ over \$75,000
CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY
(See instructions):
JUDGE See attachment; Lawrence J. O'Neill
DOCKET NUMBER 1:16-cv-00065-LJO-BAM

DATE 05/27/2016
SIGNATURE OF ATTORNEY OF RECORD /s/ Gary L. Wilson

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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 in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I. (a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an "X" in one of the six boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

ATTACHMENT FOR CIVIL COVER SHEET

Attorneys for Plaintiff(s):

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Munir R. Meghjee
Megan L. McKenzie
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800 LaSalle Avenue
Suite 2800
Minneapolis, MN 55402-2015
Telephone: (612) 349-8500

Related Cases

No.	Case	Case Docket	Judge	Date Terminated
1	Daniel Thomas v. Bristol-Myers Squibb Company, et al.	2:16-cv-00326-PA-AGR (C.D. Cal.)	District Judge Percy Anderson and Magistrate Judge Alicia G. Rosenberg	n/a
2	Stephanie Pamintuan v. Bristol-Myers Squibb Company, et al.	4:16-cv-00254-DMR (N.D. Cal.)	District Judge Haywood S Gilliam, Jr. and Magistrate Judge Donna M. Ryu	n/a
3	Brenda Sears v. Bristol-Myers Squibb Company, et al.	1:16-cv-00065-LJO-BAM (E.D. Cal)	District Judge Lawrence J. O'Neill and Magistrate Barbara A. McAuliffe	n/a
4	Karen Reynolds v. Bristol-Myers Squibb Company, et al.	1:16-cv-00357-LJO-BAM (E.D. Cal)	District Judge Lawrence J. O'Neill and Magistrate Barbara A. McAuliffe	n/a
5	Denise Miley v. Bristol-Myers Squibb Company, et al.	0:16-cv-00067-MJD-JSM (D. Minn.)	Judge Patrick J. Schiltz and Magistrate Judge Janie S. Mayeron	n/a
6	Sean Brazil v. Bristol-Myers Squibb Company, et al.	1:16-cv-00271 (S.D.N.Y.)	Judge Naomi Reice Buchwald and Magistrate Judge Sarah Netburn	n/a

No.	Case	Case Docket	Judge	Date Terminated
7	Marc Tripler v. Bristol-Myers Squibb Company, et al.	2:16-cv-00244-PBT (E.D. Pa.)	Chief Judge Petrese Tucker	n/a
8	Ben Bowman v. Bristol-Myers Squibb Company, et al.	8:16-cv-00117-JDW-JSS (M.D. Fla.)	District Judge James D. Whittemore and Magistrate Judge Julie S. Sneed	n/a
9	Wilette Reese v. Bristol-Myers Squibb Company, et al.	8:16-cv-00116-SDM-MAP (M.D. Fla.)	District Judge Steven D. Merryday and Magistrate Judge Mark A. Pizzo	n/a
10	Nicholas Meyer v. Bristol-Myers Squibb Company, et al.	1:16-cv-00191-SEB-MJD (S.D. Ind.)	District Judge Sarah Evans Barker and Magistrate Mark J. Dinsmore	n/a
11	Thomas LeLand v. Bristol-Myers Squibb Company, et al.	16-cv-03023-S-MDH (W.D. Mo)	District Judge M. Douglas Harpool	n/a
12	Stephan Butler v. Bristol-Myers Squibb Company, et al.	1:16-cv-00173-ELH (D. Md.)	District Judge Ellen L. Hollander	n/a
13	James Davis v. Bristol-Myers Squibb Company, et al.	1:16-cv-00171-ELH (D. Md.)	District Judge Ellen L. Hollander	n/a
14	Diana Kinder v. Bristol-Myers Squibb Company, et al.	1:16-cv-00170-ELH (D. Md.)	District Judge Ellen L. Hollander	n/a
15	Matthew Schaap v. Bristol-Myers Squibb Company, et al.	1:16-cv-00172-ELH (D. Md.)	District Judge Ellen L. Hollander	n/a
16	Angel Clark v. Bristol-Myers Squibb Company, et al.	3:16-cv-01313-MAS-TJB (D.N.J.)	District Judge Michael A. Shipp and Magistrate Judge Tonia J. Bongiovanni	n/a
17.	Athalean Harper-Mosley v. Bristol-Myers Squibb Company, et al.	1:16-cv-00609-LJO-BAM (E.D. Cal.)	District Judge Lawrence J. O'Neill and Magistrate Barbara A. McAuliffe	n/a
18.	Joseph Edgar v. Bristol-Myers Squibb Company, et al.	1:16-cv-00654-CCC	District Judge Christopher C. Conner and Magistrate Judge	n/a

No.	Case	Case Docket	Judge	Date Terminated
19.	*Debra Cottrell v. Bristol-Myers Squibb Company, et al.	3:16-cv-01802-MAS-TJB (D.N.J.)	District Judge Michael A. Shipp and Magistrate Judge Tonianne J. Bongiovanni	n/a
20.	*Geneva Johnson v. Bristol-Myers Squibb Company, et al.	3:16-cv-01841-MAS-TJB (D.N.J.)	District Judge Michael A. Shipp and Magistrate Judge Tonianne J. Bongiovanni	n/a

* Plaintiff will be filing a Motion to Remand to Superior Court of New Jersey Law Division, Bergen County shortly.