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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CHRYSTAL AUSTIN,

Plaintiff,

vs.

Bristol-Myers Squibb Company,
Otsuka Pharmaceutical Co., Ltd., and
Otsuka American Pharmaceutical,
Inc.,

Defendants.

Case No.: 3:16-cv-6327

COMPLAINT FOR DAMAGES

- 1. Strict Liability -
Design, Manufacturing and
Warning**
- 2. Breach of Express Warranty
by Defendants**
- 3. Breach of Implied Warranty**
- 4. Negligence**
- 5. Negligence Per Se**
- 6. Negligent Misrepresentation**
- 7. Violation of California Unfair
Competition Law and
Consumers Legal Remedies
Act**
- 8. Fraudulent Concealment**
- 9. Punitive Damages**

DEMAND FOR JURY TRIAL

Plaintiff, CHRYSTAL AUSTIN, by and through Plaintiff's undersigned
counsel, brings this civil action against Defendants above-named for personal injuries
suffered by Plaintiff CHRYSTAL AUSTIN, and allege as follows:

///

INTRODUCTION

1
2 1. This is an action for damages suffered by Plaintiff as a direct and
3 proximate result of Defendants' wrongful conduct in connection with the
4 development, design, testing, labeling, packaging, promoting, advertising, marketing,
5 distribution, and sale of Defendants' prescription drug, Abilify.
6

7
8 2. Defendants manufacture, promote, and sell Abilify as a prescription drug
9 that treats depression, bipolar I disorder, and schizophrenia. Abilify is manufactured
10 in the form of tablets, oral solution, and injections.
11

12 3. Defendants' drug, Abilify, harmed Plaintiff CRYSTAL AUSTIN,
13 having caused harmful compulsive behaviors including compulsive gambling,
14 resulting in substantial financial, mental, and physical damages.
15

16 4. Defendants knew or should have known that Abilify, when taken as
17 prescribed and intended, causes and contributes to an increased risk of serious and
18 dangerous side effects including, without limitation, uncontrollable compulsive
19 behaviors such as compulsive gambling.
20

21 5. Defendants' labeling in Europe and Canada warns about the risk of
22 "pathological gambling."
23

24 6. Defendants did not warn, advise, educate, or otherwise inform Abilify
25 users or prescribers in the United States about the risk of compulsive gambling or
26 other compulsive behaviors. Prior to January 2016, the U.S. label made no mention
27 of pathological gambling or compulsive behaviors whatsoever. In January 2016,
28

1 Defendants simply added “pathological gambling” to the postmarketing experience
2 section of the U.S. label. Defendants did not, however, make any mention of
3 gambling in the patient medication guide, the source of information most likely
4 viewed by physicians and patients. On May 3, 2016, the FDA announced that
5 warnings regarding “compulsive or uncontrollable urges to gamble, binge eat, shop,
6 and have sex” would be added to the Abilify label.
7
8

9 **PARTIES**

10 7. Plaintiff CRYSTAL AUSTIN is an adult resident and citizen of
11 California.
12

13 8. Plaintiff CRYSTAL AUSTIN was prescribed and took the prescription
14 drug Abilify and as a result developed compulsive gambling behaviors. Plaintiff
15 CRYSTAL AUSTIN began taking Abilify in or around 2011, began compulsively
16 gambling shortly thereafter, and stopped compulsively gambling soon after Plaintiff
17 CRYSTAL AUSTIN had ceased taking Abilify in 2015. Plaintiff CRYSTAL
18 AUSTIN was prescribed and purchased Abilify in the State of California. Due to
19 Defendants’ conduct, as detailed herein, Plaintiff’s injuries and their relationship to
20 Abilify were not discovered until a much later date.
21
22

23 9. By way of example, as a result of Abilify use, Plaintiff CRYSTAL
24 AUSTIN has suffered the following losses: monetary losses in excess of \$10,000,
25 loss of financial stability, and other mental, physical, and economic losses. The
26 injurious impact of Abilify on Plaintiff’s brain constitutes a physical injury.
27
28

1 10. As a result of Abilify use, Plaintiff CHRYSTAL AUSTIN has suffered,
2 and will continue to suffer, neuropsychiatric and physical injury, emotional distress,
3 harm, and economic loss as alleged herein.
4

5 11. Defendant Bristol-Myers Squibb Company (“Bristol-Myers”) is
6 incorporated in Delaware, with its principal executive office at 345 Park Avenue,
7 New York, New York. Upon information and belief, Bristol-Myers owns and
8 operates six facilities in the state of New Jersey.
9

10 12. Defendant Otsuka Pharmaceutical Co., Ltd. (“OPC”) is a Japanese
11 company, with its principal office at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo
12 101-8535, Japan, and has a registered agent located at 351 West Camden Street,
13 Baltimore, Maryland per records filed with the Maryland Department of Assessments
14 and Taxation Business Services. Abilify is a trademark of Defendant Otsuka
15 Pharmaceutical Co., Ltd. Defendant Otsuka Pharmaceutical Co. Ltd. wholly owns
16 Otsuka America, Inc. (“OAI”), a holding company established in the United States in
17 or around 1989. OAI is the parent of Defendant Otsuka America Pharmaceutical,
18 Inc. (“OAPI”), Otsuka Pharmaceutical Development & Commercialization, Inc.
19 (“OPDC”), and Otsuka Maryland Medicinal Laboratories, Inc. (“OMML”).
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24 13. Defendant OAPI is incorporated in Delaware, with its principal place of
25 business at 508 Carnegie Center, Princeton, New Jersey. OAPI oversees all
26 pharmaceutical commercial activities in North America. OAPI developed,
27 distributed, and marketed Abilify with OPC.
28

1 14. At all times relevant to this Complaint, Defendant OPC, OAI, OAPI,
2 OPDC, and OMML (the “Otsuka entities”) have operated in concert as it relates to
3 the development, research, distribution, manufacturing, and/or marketing of Abilify.
4 OPC has control over its subsidiaries’ daily affairs and operations with respect to
5 Abilify. The Otsuka entities work in concert as a single operation known as the
6 Otsuka Group.
7

8
9 15. Defendant Bristol-Myers has operated in concert with the other
10 Defendants and jointly marketed, sold, and promoted Abilify in the United States
11 with the Otsuka Group, through Defendant OAPI and otherwise.
12

13 16. Defendants are collectively engaged in the development, design, testing,
14 labeling, packaging, promoting, advertising, marketing, distribution, and selling of
15 pharmaceutical products, including Abilify. Otsuka “discovered” Abilify in 1988,
16 obtained approval in the United States in November 2002 and in Japan in January
17 2006.
18

19
20 17. Defendants Bristol-Myers and Otsuka are and have been engaged in the
21 business of researching, testing, developing, manufacturing, packaging, distributing,
22 licensing, labeling, promoting, marketing and selling, either directly or indirectly
23 through third parties or related entities, the pharmaceutical drug Abilify, in all states
24 and throughout the United States.
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JURISDICTION

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

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

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

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

22. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of marketing, promoting, distributing, and selling prescription drug products, including the Abilify products, within the State of California, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

23. This Court has personal jurisdiction over Otsuka Pharmaceutical Co., Ltd. based on its contacts with California relating to the subject matter of this action and because Otsuka Pharmaceutical Co., Ltd. has continuous and systematic contacts with this judicial district. On information and belief, Otsuka Pharmaceutical Co., Ltd. regularly places goods into the stream of commerce for distribution in California and throughout the United States. Members of Otsuka Pharmaceutical Co., Ltd.

1 continuously communicate from Japan with members of Otsuka America
2 Pharmaceutical, Inc. Otsuka Pharmaceutical Co., Ltd sells and markets Abilify in the
3 United States and California.
4

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

15 25. Jurisdiction is proper under this State's Long Arm Statute and the Due
16 Process Clause of the Constitution because Defendants have sufficient minimum
17 contacts with the State of California related to Abilify and have purposefully directed
18 conduct toward the State of California.
19
20

21 **FACTUAL BACKGROUND**

22 26. Abilify was first introduced to the market in the United States in or
23 around the fall of 2002. Abilify is an atypical anti-psychotic prescription medicine
24 discovered by Defendant Otsuka Pharmaceutical Co., Ltd.
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1 27. In or around October or November of 2012, the European Medicines
2 Agency required that Defendants warn patients and the medical community in
3 Europe that Abilify use included the risk of pathological gambling.
4

5 28. In particular, the European Medicines Agency required the European
6 labeling for Abilify to carry the following language in the Special Warnings and
7 Precautions For Use section of the label:
8

9 **Pathological gambling**

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

14 29. The European labeling for Abilify also carries additional language
15 concerning adverse reactions that have been reported during post-marketing
16 surveillance relating to gambling side effects. Under a section entitled “Undesirable
17 effects,” it provides:
18

19 **Psychiatric disorders: agitation, nervousness, pathological**
20 **gambling, suicide attempt, suicidal ideation,**
21 **and completed suicide.**

22 30. In or around November 2015, Canadian regulators concluded that there
23 is “a link between the use of aripiprazole and a possible risk of pathological gambling
24 or hypersexuality” and found an increased risk of pathological (uncontrollable)
25 gambling and hypersexuality with the use of Abilify.
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1 31. In or about November 2015, the following warning statement for the risk
2 of pathological gambling was added to the Canadian prescribing information for
3 Abilify:
4

5 **Pathological Gambling**

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

10 32. Despite these warnings and advisories in Europe and Canada—for the
11 same drug sold to patients in the United States—the labeling for Abilify in the United
12 States did not adequately warn about the risk of compulsive gambling and contained
13 no mention that pathological gambling has been reported in patients prescribed
14 Abilify. In January 2016, pathological gambling was added only to the
15 Postmarketing Experience section of the label; Defendants did not make any mention
16 of gambling in the patient medication guide, a source of information likely viewed by
17 physicians and patients. On May 3, 2016, the FDA issued a warning that Abilify was
18 associated with “compulsive or uncontrollable urges to gamble, binge eat, shop, and
19 have sex.” The FDA recommended that doctors “make patients and caregivers aware
20 of the risk of these uncontrollable urges,” “closely monitor” patients, and consider
21 reducing or stopping Abilify if compulsivity emerges.
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26 33. The labeling for Abilify in the United States contained no mention of the
27 word “gambling” until January 2016.
28

1 34. Defendants wrongfully and unjustly profited at the expense of patient
2 safety and full disclosure to the medical community by failing to include language
3 about gambling in the United States labeling and by failing to otherwise warn the
4 public and the medical community about Abilify's association with gambling—
5 despite opportunities and a duty to do so. As a result, Defendants have made
6 significantly more revenue from Abilify sales in the United States compared to
7 Europe.
8

9
10 35. Defendant Bristol-Myers touts Abilify as its “2013 largest-selling
11 product” noting sales of \$2.3 billion. Defendant Bristol-Myers recently reported U.S.
12 revenues from Abilify sales of \$417 million over three months ending June 30, 2014,
13 and worldwide revenues of \$555 million over the same time period.
14

15
16 36. Since its introduction to the United States market, Abilify has generally
17 been used to treat patients with schizophrenia, bipolar disorder, as an adjunct for
18 depression, and autism spectrum disorders.
19

20 37. In 2001, Defendant Otsuka Pharmaceutical Co., Ltd. submitted a New
21 Drug Application (“NDA”) to the United States Food and Drug Administration
22 (“FDA”) for Abilify (aripiprazole). This initial NDA sought approval to market
23 Abilify in 2, 5, 10, 15, 20 and 30 mg tablets as a treatment for schizophrenia. The
24 NDA was approved on November 15, 2002.
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1 38. In November 2002, the FDA required Defendants to submit results of
2 Study 138047 to address the longer-term efficacy of Abilify in the treatment of adults
3 with schizophrenia.
4

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
7 longer-term efficacy of Abilify in the treatment of schizophrenia. This application
8 was approved on August 28, 2003.
9

10 40. In June 2003, Otsuka Maryland Research Institute submitted another
11 Supplemental New Drug Application (NDA 21-436/S-002) for Abilify tablets as a
12 treatment for bipolar disorder. This application was approved on September 29,
13 2004.
14

15 41. In May 2007, Otsuka Pharmaceutical Development &
16 Commercialization, Inc. submitted another Supplemental New Drug Application
17 (NDA 21-436/S-018) for Abilify tablets as an adjunctive treatment for patients with
18 major depressive disorder. This application was approved on November 16, 2007.
19
20

21 42. In contrast, in Europe, Abilify is not indicated to treat depression. The
22 European Medicines Agency declined to approve Abilify as an add-on treatment for
23 depression because of concerns about its efficacy for that indication.
24

25 43. In or around 1999, Defendants Bristol-Myers and Otsuka entered into an
26 agreement to co-develop and “commercialize” Abilify (hereinafter referred to as
27 “Defendants’ Marketing Agreement”). Under the terms of Defendants’ Marketing
28

1 Agreement, Defendant Bristol-Myers was to market and promote Abilify in the
2 United States and the European Union, in collaboration with Defendant Otsuka
3 Pharmaceutical Co., Ltd., and under Defendant Otsuka Pharmaceutical Co., Ltd.'s
4 trademark.
5

6 44. Defendants' Marketing Agreement also provided that Defendants
7 Bristol-Myers and Otsuka Pharmaceutical Co., Ltd. would collaborate to complete
8 clinical studies for schizophrenia, and that Defendant Bristol-Myers would conduct
9 additional studies for new dosage forms and new indications.
10

11 45. Defendant Bristol-Myers began co-promoting Abilify with Defendant
12 Otsuka Pharmaceutical Co., Ltd. in the United States and Puerto Rico in or around
13 November 2002. Defendants' Marketing Agreement was extended in or around
14 2009.
15

16 46. Defendant Bristol-Myers' relationship with Otsuka had been due to
17 expire in or around April 2015, just after the predicted expiration of Abilify's patent
18 protection in the United States. According to a revised marketing agreement,
19 Defendant Bristol-Myers purported to no longer market and promote Abilify as of
20 January 1, 2013, but would continue to carry out its other responsibilities, including
21 manufacturing for sale to third-party customers. Nevertheless, Defendant Bristol-
22 Myers continued to market and promote Abilify, for example, through its website,
23 through September 2015.
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1 47. Defendants had, or should have had, knowledge that Abilify can cause
2 compulsive behaviors like gambling. Despite their significant collective resources,
3 and signals that Abilify is associated with compulsive behaviors such as gambling,
4 Defendants have failed to fully and adequately test or research Abilify and its
5 association with compulsive behaviors to the detriment of Plaintiff CHRYSTAL
6 AUSTIN, Abilify users, the public, the medical community, and prescribing doctors.
7

9 48. Compulsive gambling is a major psychiatric disorder. The American
10 Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*
11 ("DSM") first recognized pathological gambling as a psychiatric disorder in 1980.
12

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

22 50. Abilify is a partial and full dopamine agonist. Dopamine is a
23 neurotransmitter that helps control the brain's reward and pleasure centers.
24

25 51. Dopamine's role in compulsive behavior and pathological gambling is
26 well-known. Dopaminergic reward pathways have frequently been implicated in the
27
28

1 etiology of addictive behavior. Scientific literature has identified dopamine as a
2 potential cause of pathological gambling for years.

3
4 52. Abilify's dopaminergic activity at the mesolimbic circuit, especially at
5 the nucleus accumbens, has been associated with compulsive behavior in Abilify
6 patients.

7
8 53. Defendants' September 2011 6-Month Periodic Safety Update Report
9 acknowledges a plausible mechanism for pathological gambling. The Report states
10 that an article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to*
11 *Psychiatric Disorders*, "does suggest a possible mechanism by which drugs that act
12 on dopamine neurons, like aripiprazole, might possibly have some effect on behavior
13 related to reward."
14

15
16 54. Defendants' September 2011 6-Month Periodic Safety Update Report
17 submitted to the European Medicines Agency acknowledged seven serious reports of
18 pathological gambling, three in the medical literature and four spontaneous reports.
19 The report also noted sixteen cases of pathological gambling in the Bristol-Myers
20 company safety database.
21

22
23 55. The Medical Assessment of the pathological gambling cases in
24 Defendants' September 2011 6-Month Periodic Safety Update Report did not exclude
25 Abilify as the cause of the compulsive gambling adverse events. Defendants
26 concluded that "a causal role of aripiprazole could not be excluded" or that
27 "aripiprazole was suggested by the temporal relationship."
28

1 56. The European Final Assessment Report of the September 2011 6-Month
2 Periodic Safety Update Report concluded that with regard to compulsive gambling
3 “in all of the reported cases we have a (+) temporal; (+) dechallenge and in one case a
4 (+) rechallenge.”
5

6 57. Numerous case reports have been published in the medical literature
7 linking Abilify to compulsive behavior, including at least seventeen cases of
8 compulsive gambling. Gaboriau et al. examined case reports of compulsive
9 gambling and found that the probability that pathological gambling was actually due
10 to Abilify was “possible” in sixteen of the cases and “doubtful” in only one of the
11 cases.
12 cases.
13

14 58. Several case reports demonstrate what is known as a challenge, de-
15 challenge, and re-challenge.
16

17 59. Challenge is the administration of a suspect product by any route.
18

19 60. De-challenge is the withdrawal of the suspected product from the
20 patient’s therapeutic regime. A positive de-challenge is the partial or complete
21 disappearance of an adverse experience after withdrawal of the suspect product. For
22 example, a positive de-challenge occurs when a patient ceases use of Abilify and
23 pathological gambling behaviors cease.
24

25 61. Re-challenge is defined as a reintroduction of a product suspected of
26 having caused an adverse experience following a positive de-challenge. A positive
27 re-challenge occurs when similar signs and symptoms reoccur upon reintroduction of
28

1 the suspect product. For example, a positive re-challenge occurs when a patient
2 reintroduces Abilify into her treatment regime and pathological gambling behavior
3 reoccurs in a similar manner as such behaviors had existed when the patient
4 previously used Abilify.
5

6 62. A positive de-challenge is considered evidence that a drug caused a
7 particular effect, as is a positive re-challenge.
8

9 63. From May 1, 2009 to May 1, 2011, the FDA received thousands of
10 serious adverse event reports concerning Abilify (n=4599), including over two-
11 thousand serious adverse drug experiences of which 193 involved children (0-16
12 years old).
13

14 64. Serious adverse events are drug experiences including the outcomes of
15 death, life-threatening events, hospitalization, disability, congenital abnormality, and
16 other harmful medical events.
17

18 65. From 2005 to 2013, an FDA report showed that Abilify accounted for at
19 least fifty-four reports of compulsive or impulsive behavior problems, including
20 thirty reports of compulsive gambling, twelve reports of impulsive behavior, nine
21 reports of hypersexuality, and three reports of compulsive shopping.
22

23 66. A disproportionality study of the FDA Adverse Event Reporting System
24 showed a proportional reporting ratio for compulsivity of 8.6 for Abilify. A ratio of
25 more than three indicates a signal of an adverse event.
26
27
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1 67. An analysis of the FDA Adverse Event Reporting System shows an
2 escalating number of reports. Twenty-nine reports of gambling behavior were made
3 to the FDA in 2014.
4

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

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

15 70. Despite evidence that Abilify causes compulsive behaviors like
16 pathological gambling and calls from the medical community to conduct further
17 research and warn patients about this possible effect of Abilify, Defendants have
18 either failed to investigate or conduct any studies on the compulsive behavior side
19 effects of Abilify or failed to make public the results of any studies or investigations
20 that they might have done.
21
22

23 71. Abilify is not very efficacious. According to a rigorous study by the
24 Cochrane Collaboration, there is limited evidence that Abilify leads to symptom
25 reduction when added to antidepressants and side effects are more frequent under
26 Abilify augmentation treatment.
27
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1 72. The Drug Facts Box for Abilify for major depression includes a
2 “summary” of the combined data from the two identical six week randomized trials
3 that were the basis for FDA drug approval for this indication. The box shows that
4 Abilify has only a modest benefit: on average, patients on Abilify improved by 3
5 points more (*on a scale of 60*) than patients on placebo, and only an additional 11%
6 of patients had a clinically important response as defined in the trial.
7

8
9 73. Despite the risks of serious adverse events, and the lack of adequate
10 testing, Defendants aggressively promoted Abilify, including illegal promotion for
11 off-label use. In 2007, Defendant Bristol-Myers reportedly paid \$515 million to
12 settle federal and state investigations into off-label marketing of Abilify for pediatric
13 use and to treat dementia-related psychosis. Defendant Otsuka American
14 Pharmaceutical, Inc. later paid more than \$4 million to resolve the allegations.
15

16
17 74. The FDA issued a letter dated April 17, 2015 finding Abilify
18 promotional material “false or misleading because it makes misleading claims and
19 presentations about the drug.” The FDA found the material “misleading because it
20 implies that Abilify offers advantages over other currently approved treatments for
21 bipolar disorder or MDD when this has not been demonstrated.” The FDA also
22 found the cited references “not sufficient to support claims and presentations
23 suggesting that Abilify has been demonstrated to modulate dopaminergic and
24 serotonergic activity, or modulate neuronal activity in both hypoactive and
25 hyperactive environments in humans.”
26
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1 75. Upon information and belief, Defendants have invested millions of
2 dollars in teams of pharmaceutical sales representatives who visit and contact
3 members of the medical community, including prescribing doctors, purporting to
4 “educate” them about Abilify. Upon information and belief, these pharmaceutical
5 sales representatives have not notified patients, the medical community, or
6 prescribers in the United States that Abilify use causes, is linked to, or might be
7 associated with compulsive gambling, pathological gambling, or gambling addiction.
8

9
10 76. Defendants have invested millions of dollars in “Direct to Consumer”
11 advertising. None of the advertising in the United States notifies patients, the
12 medical community, or prescribers that Abilify use causes, is linked to, or might be
13 associated with compulsive gambling, pathological gambling, or gambling addiction.
14

15
16 77. Defendants’ Direct to Consumer advertising minimizes risks while over-
17 promoting the drug.
18

19 78. As a result of Defendants’ misleading promotional campaigns, Abilify
20 occupies the top sales position for a prescription drug in the United States (but has
21 only reached seventh place in the global ranking of drug sales).
22

23 79. Defendants have made payments to doctors to promote Abilify. From
24 August 2013 to December 2014, \$10.6 million in payments relating to Abilify were
25 made to 21,155 physicians in the United States.
26

27 80. To date, Defendants have not adequately notified or warned patients, the
28 medical community, or prescribers in the United States that Abilify use causes, is

1 linked to, and is associated with compulsive gambling, pathological gambling, or
2 gambling addiction.

3
4 81. Prior to May 2016, upon information and belief, Defendants had not sent
5 out any “Dear Doctor” letters to inform the medical community of the risk or
6 association of Abilify use and gambling.

7
8 82. Under the heading “What are the possible side effects of ABILIFY?” the
9 labeling for Abilify in the United States does not list gambling, pathological or
10 otherwise. Nor does it mention compulsive behaviors.

11
12 83. Likewise, the labeling for Abilify in the United States lists serious side
13 effects that have been reported with Abilify, but did not list gambling, pathological or
14 otherwise in any form until January 2016 when it was only added to the
15 postmarketing experience section of the label. Prior to May 2016, the label did not
16 mention compulsive behaviors other than pathological gambling or adequately warn
17 patients about the risk of compulsive gambling. Defendants also did not make any
18 mention of gambling in the patient medication guide, the source of information most
19 likely viewed by physicians and patients.

20
21
22 84. The labeling in the United States contradicts the labeling in Europe and
23 Canada by not providing adequate warnings and not cautioning that patients should
24 be closely monitored, and does not adequately inform patients and physicians that
25 gambling and other compulsive behaviors have been associated with Abilify use.
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1 85. Defendant Otsuka America Pharmaceutical, Inc. maintains a website
2 promoting Abilify, www.abilify.com. The website includes, among other
3 information, “tips for taking Abilify,” links to “a 30-day free trial & savings on
4 refills,” and “important safety information” for Abilify. Although it has sections
5 about “important safety information,” nowhere on the website does it mention the
6 word “gambling.”
7

8
9 86. Also, Defendant Otsuka America Pharmaceutical, Inc. operated another
10 website promoting Abilify, www.addabilify.com. Prior to 2015, this website
11 included, among other information, “important safety information,” “tips for family
12 and friends,” “treatment FAQs,” “side effects FAQs,” and “what your doctor needs to
13 know” concerning Abilify. Nowhere on the website did it mention the word
14 “gambling.”
15
16

17 87. Defendant Bristol-Myers promotes Abilify on its own website,
18 www.bms.com (“BMS website”), noting it was approved in November 2002 and is
19 “jointly marketed in the U.S. by Bristol-Myers Squibb and Otsuka America
20 Pharmaceutical.” The BMS website also includes a link to the www.abilify.com
21 website. Nowhere on the BMS website does it mention the word “gambling.”
22
23

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

3
4 **EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

5 89. Plaintiff asserts all applicable state statutory and common law rights and
6 theories related to the tolling or extension of any applicable statute of limitations,
7 including the discovery rule and/or fraudulent concealment.

8
9 90. The discovery rule should be applied to toll the running of the statute of
10 limitations until Plaintiff discovered or reasonably should have discovered Plaintiff
11 CHRYSTAL AUSTIN’s injury and the causal connection between the injury and
12 Defendants’ product.

13
14 91. Despite reasonable and diligent investigation by Plaintiff into the causal
15 connection between Plaintiff’s injuries and Abilify, the cause and nature of Plaintiff’s
16 injuries and their relationship to Abilify was not discovered until a significant time
17 after Plaintiff experienced injuries from Abilify. Therefore, under the appropriate
18 application of the discovery rule, Plaintiff’s suit was filed well within the applicable
19 statutory limitations period.

20
21
22 92. Defendants are estopped from asserting a statute of limitations defense
23 because all Defendants fraudulently concealed from Plaintiff the truth, quality and
24 nature of Plaintiff’s injuries and the connection between the injuries and Defendants’
25 tortious conduct. Defendants, through their affirmative misrepresentations and
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27
28

1 omissions, actively concealed from Plaintiff and Plaintiff CHRYSTAL AUSTIN's
2 prescribing physicians the true risks associated with Abilify.

3
4 93. Defendants were under a duty to disclose the true character, quality and
5 nature of the risks associated with use of Abilify as this was non-public information
6 over which Defendants had and continue to have exclusive control, and because
7 Defendants knew that this information was not available to Plaintiff, Plaintiff
8 CHRYSTAL AUSTIN's medical providers and/or health-care facilities. In addition,
9 Defendants are estopped from relying on any statute of limitation because of their
10 intentional concealment of these facts.
11
12

13 94. Plaintiff had no knowledge that Defendants were engaged in the
14 wrongdoing alleged herein. Because of the fraudulent acts of concealment of
15 wrongdoing by Defendants, Plaintiff could not have reasonably discovered the
16 wrongdoing at any time prior.
17

18 **FIRST CAUSE OF ACTION**

19 **Strict Liability – Design, Manufacturing and Warning**

20 95. Plaintiff incorporates by reference all previous and subsequent
21 paragraphs of this Complaint as if fully set forth here and further alleges as follows:
22

23 96. Defendants had a duty to provide adequate warnings and instructions for
24 Abilify, to use reasonable care to design a product that is not unreasonably dangerous
25 to users, and to adequately test their product.
26
27
28

1 97. The Abilify manufactured and/or supplied to Plaintiff CHRYSTAL
2 AUSTIN by Defendants was defective in design or formulation in that, when it left
3 the hands of the manufacturer and/or supplier, it was in an unreasonably dangerous
4 and a defective condition for its intended use and it posed a risk of serious
5 compulsive behaviors and harm to Plaintiff and other consumers which could have
6 been reduced or avoided, inter alia, by the adoption of a feasible reasonable
7 alternative design.
8

9
10 98. The Abilify manufactured and/or supplied to Plaintiff CHRYSTAL
11 AUSTIN by Defendants was defective in design or formulation in that, when it left
12 the hands of the manufacturer and/or supplier, Abilify had not been adequately tested,
13 was in an unreasonably dangerous and a defective condition, and it posed a risk of
14 serious compulsive behaviors and harm to Plaintiff and other consumers.
15
16

17 99. Also, Abilify's limited and unproven effectiveness did not outweigh the
18 risks posed by the drug.
19

20 100. The Abilify manufactured and/or supplied to Plaintiff CHRYSTAL
21 AUSTIN by Defendants was defective due to inadequate warnings or instructions
22 concerning the true risks of its use.
23

24 101. Defendants knew or should have known through testing, scientific
25 knowledge, advances in the field or otherwise, that the product created a risk of
26 serious compulsive behaviors and harm, and was unreasonably dangerous to Plaintiff
27 CHRYSTAL AUSTIN and other consumers, about which Defendants failed to warn.
28

1 102. The Abilify manufactured and/or supplied to Plaintiff CHRYSTAL
2 AUSTIN by Defendants was defective, dangerous, and had inadequate warnings or
3 instructions at the time it was sold, and Defendants also acquired additional
4 knowledge and information confirming the defective and dangerous nature of
5 Abilify. Despite this knowledge and information, Defendants failed and neglected to
6 issue adequate warnings or post-sale warnings that Abilify causes serious compulsive
7 behaviors and harm.
8
9

10 103. Defendants failed to provide adequate warnings to users, purchasers, or
11 prescribers of Abilify, including Plaintiff CHRYSTAL AUSTIN and her physicians,
12 and instead continued to sell Abilify in an unreasonably dangerous form without
13 adequate warnings or instructions.
14
15

16 104. By failing to adequately test and research compulsive behaviors and
17 harms associated with Abilify use, and by failing to provide appropriate warnings
18 about Abilify use and associations with compulsive behaviors such as gambling,
19 patients and the medical community, including prescribing doctors, were
20 inadequately informed about the true risk-benefit profile of Abilify and were not
21 sufficiently aware that compulsive behaviors such as gambling might be associated
22 with Abilify use. As such, the medical community was not learned on the true risk-
23 benefit profile of Abilify. Nor was the medical community, patients, patients'
24 families, or regulators appropriately informed that compulsive behaviors such as
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26
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28

1 gambling might be a side effect of Abilify use and should or could be reported as an
2 adverse event.

3
4 105. As a direct and proximate result of Defendants' conduct, including the
5 inadequate warnings, dilution or lack of information, lack of adequate testing and
6 research, and the defective and dangerous nature of Abilify, Plaintiffs have suffered,
7 and will continue to suffer, neuropsychiatric and physical injury, emotional distress,
8 harm, and economic loss as alleged herein.
9

10
11 **SECOND CAUSE OF ACTION**
Breach of Express Warranty by Defendants

12 106. Plaintiff incorporates by reference all previous and subsequent
13 paragraphs of this Complaint as if fully set forth here and further alleges as follows:
14

15 107. Defendants expressly warranted to physicians and consumers, including
16 Plaintiff CRYSTAL AUSTIN and/or Plaintiff's physicians, that Abilify was safe
17 and/or well-tolerated.
18

19 108. Relying upon these warranties, Plaintiff was prescribed and took Abilify.

20 109. Defendants' representations formed the basis of the bargain.
21

22 110. Abilify does not conform to these express representations because it is
23 not safe and/or well-tolerated because it causes compulsive behaviors such as
24 pathological gambling addiction, which in turn can lead to financial ruin, job loss,
25 familial devastation, and suicide attempts.
26
27
28

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

112. As a direct and proximate result of the breach of Defendants' warranties, Plaintiffs have suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

THIRD CAUSE OF ACTION
Breach of Implied Warranty

113. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

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

115. Defendants knew, or had reason to know, that Plaintiff CHRYSTAL AUSTIN and Plaintiff's physicians would rely on the Defendants' judgment and skill in providing Abilify for its intended use.

116. Plaintiff CHRYSTAL AUSTIN and Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether Abilify was of merchantable quality, safe, and fit for its intended use.

117. Contrary to such implied warranty, Abilify was not of merchantable quality or safe or fit for its intended use, because the product was, and is,

1 unreasonably dangerous, defective and unfit for the ordinary purposes for which
2 Abilify was used.

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

6
7 119. As a direct and proximate result of the breach of implied warranty,
8 Plaintiff has suffered, and will continue to suffer, neuropsychiatric and physical
9 injury, emotional distress, harm, and economic loss as alleged herein.

10
11 **FOURTH CAUSE OF ACTION**
Negligence

12 120. Plaintiff incorporates by reference all previous and subsequent
13 paragraphs of this Complaint as if fully set forth here and further alleges as follows:

14
15 121. At all times material herein, Defendants had a duty to exercise
16 reasonable care and the duty of an expert in all aspects of the design, formulation,
17 manufacture, compounding, testing, inspection, packaging, labeling, distribution,
18 marketing, promotion, advertising, sale, warning, and post-sale warning, testing, and
19 research to assure the safety of the product when used as intended or in a way that
20 Defendants could reasonably have anticipated, and to assure that the consuming
21 public, including Plaintiff and Plaintiff's physicians, obtained accurate information
22 and adequate instructions for the safe use or non-use of Abilify.

23
24 122. Defendants had a duty to warn Plaintiff CRYSTAL AUSTIN,
25 Plaintiff's physicians, and the public in general of Abilify's dangers and serious side
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1 effects, including serious compulsive behaviors like pathological gambling addiction,
2 since it was reasonably foreseeable that an injury could occur because of Abilify's
3 use.
4

5 123. At all times material herein, Defendants failed to exercise reasonable
6 care and the duty of an expert and knew, or in the exercise of reasonable care should
7 have known, that Abilify was not properly manufactured, designed, compounded,
8 tested, inspected, packaged, labeled, warned about, distributed, marketed, advertised,
9 formulated, promoted, examined, maintained, sold, and/or prepared.
10

11 124. Also, Abilify's limited and unproven effectiveness did not outweigh the
12 risks posed by the drug.
13

14 125. Each of the following acts and omissions herein alleged was negligently
15 and carelessly performed by Defendants, resulting in a breach of the duties set forth
16 above. These acts and omissions include, but are not restricted to:
17

- 18 a. Negligent and careless research and testing of Abilify;
- 19 b. Negligent and careless design or formulation of Abilify;
- 20 c. Negligent and careless failure to give adequate warnings that would
21 attract the attention of Plaintiff CRYSTAL AUSTIN, Plaintiff's
22 physicians, and the public in general of the potentially dangerous,
23 defective, unsafe, and deleterious propensity of Abilify and of the risks
24 associated with its use;
25
26
27
28

- 1 d. Negligent and careless failure to provide instructions on ways to safely
2 use Abilify to avoid injury;
3
4 e. Negligent and careless failure to explain the mechanism, mode, and
5 types of adverse events associated with Abilify;
6
7 f. Negligent representations that Abilify was safe and/or well-tolerated;
8 and
9
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.

13 126. As a direct and proximate result of Defendants' negligence, Plaintiff has
14 suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional
15 distress, harm, and economic loss as alleged herein.
16

17 **FIFTH CAUSE OF ACTION**

18 **Negligence Per Se**

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

20 127. Plaintiff incorporates by reference all previous and subsequent
21 paragraphs of this Complaint as if fully set forth here and further alleges as follows:

22 128. At all times herein mentioned, Defendants had an obligation to abide by
23 the law, including the Federal Food, Drug and Cosmetic Act and the applicable
24 regulations, in the manufacture, design, formulation, compounding, testing,
25 production, processing, assembling, inspection, research, promotion, advertising,
26 distribution, marketing, labeling, packaging, preparation for use, consulting, sale,
27
28

1 warning, and post-sale warning, and other communications of the risks and dangers
2 of Abilify.

3
4 129. By reason of its conduct as alleged herein, Defendants violated
5 provisions of statutes and regulations, including, but not limited to, the following:

- 6 a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21
7 U.S.C. §§ 331 and 352, by misbranding Abilify;
8
9 b. Defendants failed to follow the “[g]eneral requirements on content and
10 format of labeling for human prescription drugs” in violation of 21
11 C.F.R. § 201.56;
12
13 c. Defendants failed to follow the “[s]pecific requirements on content and
14 format of labeling for human prescription drugs” in violation of 21
15 C.F.R. § 201.57;
16
17 d. Defendants advertised and promoted Abilify in violation of 21 C.F.R. §
18 202.1; and
19
20 e. Defendants violated 21 C.F.R. § 201.57(e) by failing to timely and
21 adequately change the Abilify label to reflect the evidence of an
22 association between Abilify and the serious compulsive behaviors
23 suffered by Plaintiff CHRYSTAL AUSTIN.
24

25 130. These statutes and regulations impose a standard of conduct designed to
26 protect consumers of drugs, including Plaintiff CHRYSTAL AUSTIN.
27
28

1 131. Defendants' violations of these statutes and regulations constitute
2 negligence per se.

3
4 132. As a direct and proximate result of Defendants' statutory and regulatory
5 violations, Plaintiff, members of the class of persons protected by the above-
6 mentioned statutes, has suffered, and will continue to suffer, neuropsychiatric and
7
8 physical injury, emotional distress, harm, and economic loss as alleged herein.

9 **SIXTH CAUSE OF ACTION**
10 **Negligent Misrepresentation**

11 133. Plaintiff incorporates by reference all previous and subsequent
12 paragraphs of this Complaint as if fully set forth here and further alleges as follows:

13
14 134. Defendants misrepresented to consumers and physicians, including
15 Plaintiff CHRYSTAL AUSTIN and/or Plaintiff's physicians and the public in
16 general, that Abilify was safe and/or well-tolerated when used as instructed, and that
17 Abilify was safe and/or well-tolerated, when, in fact, Abilify was dangerous to the
18 well-being of patients.

19
20 135. Also, Abilify's limited and unproven effectiveness did not outweigh the
21 risks posed by the drug.

22
23 136. At the time Defendants promoted Abilify as safe and/or well-tolerated,
24 they did not have adequate proof upon which to base such representations, and, in
25 fact, knew or should have known that Abilify was dangerous to the well-being of
26 Plaintiff CHRYSTAL AUSTIN and others.
27
28

1 137. Defendants failed to exercise reasonable care and competence in
2 obtaining and/or communicating information regarding the safe use of Abilify and
3 otherwise failed to exercise reasonable care in transmitting information to Plaintiff
4 CHRYSTAL AUSTIN, Plaintiff's physicians, and the public in general.
5

6 138. Defendants made the aforesaid representations in the course of
7 Defendants' business as designers, manufacturers, and distributors of Abilify despite
8 having no reasonable basis for their assertion that these representations were true
9 and/or without having accurate or sufficient information concerning the aforesaid
10 representations. Defendants were aware that without such information they could not
11 accurately make the aforesaid representations.
12
13

14 139. At the time the aforesaid representations were made, Defendants
15 intended to induce Plaintiff CHRYSTAL AUSTIN and/or Plaintiff's physicians to
16 rely upon such representations.
17

18 140. At the time the aforesaid representations were made by Defendants, and
19 at the time Plaintiff CHRYSTAL AUSTIN received Abilify, Plaintiff and/or
20 Plaintiff's physicians, and the public in general, reasonably believed them to be true.
21 In reasonable and justified reliance upon said representations, Plaintiff used Abilify.
22
23

24 141. As a direct and proximate result of reliance upon Defendants'
25 misrepresentations, Plaintiffs have suffered, and will continue to suffer,
26 neuropsychiatric and physical injury, emotional distress, harm, and economic loss as
27 alleged herein.
28

SEVENTH CAUSE OF ACTION
Violation of California Unfair Competition Law and Consumers Legal Remedies Act

142. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

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

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

145. By reason of such violations and pursuant to Cal. Bus. & Prof. Code § 17200 et seq. and Cal. Civ. Code § 1750 et seq., Plaintiff CHRYSTAL AUSTIN is entitled to recover all of the monies paid for Abilify; to be compensated for the cost of the medical care arising out of the use of Abilify; and to recover any and all

1 consequential damages recoverable under the law including, but not limited to,
2 gambling losses, both past and future medical expenses, past wage loss, loss of future
3 earning capacity, past and future pain, suffering, disability, and emotional distress.
4 Plaintiff is entitled to seek compensatory damages, attorney's fees, and other
5 remedies as determined by the Court pursuant to Cal. Bus. & Prof. Code § 17200 et
6 seq. and Cal. Civ. Code § 1750 et seq.
7
8

9 **EIGHTH CAUSE OF ACTION**
10 **Fraudulent Concealment**

11 146. Plaintiff incorporates by reference all previous and subsequent
12 paragraphs of this Complaint as if fully set forth here and further alleges as follows:
13

14 147. Throughout the relevant time period, Defendants knew that Abilify was
15 defective and unreasonably unsafe for its intended purpose.

16 148. Defendants fraudulently concealed from or failed to disclose or to warn
17 Plaintiff CRYSTAL AUSTIN, Plaintiff's physicians, and the medical community
18 that Abilify was defective, unsafe, unfit for the purposes intended, and was not of
19 merchantable quality.
20

21 149. Defendants were under a duty to Plaintiff CRYSTAL AUSTIN to
22 disclose and warn of the defective nature of Abilify because:
23

- 24 a. Defendants were in a superior position to know the true quality, safety
25 and efficacy of Abilify;
26
27
28

1 b. Defendants knowingly made false claims about the safety and quality of
2 Abilify in the documents and marketing materials Defendants provided
3 to the FDA, physicians, and the general public; and
4

5 c. Defendants fraudulently and affirmatively concealed the defective nature
6 of Abilify from Plaintiff.
7

8 150. Defendants were under a duty to Plaintiff CHRYSTAL AUSTIN to
9 disclose and warn of the defective nature of Abilify because the facts concealed or
10 not disclosed by Defendants to Plaintiff were material facts that a reasonable person
11 would have considered to be important in deciding whether or not to purchase or use
12 the product.
13

14 151. Defendants intentionally concealed or failed to disclose the true
15 defective nature of Abilify so that Plaintiff CHRYSTAL AUSTIN would request and
16 purchase Abilify, and that their healthcare providers would dispense, prescribe, and
17 recommend Abilify, and Plaintiff justifiably acted or relied upon, to Plaintiff's
18 detriment, the concealed or non-disclosed facts as evidenced by her purchase and use
19 of Abilify.
20

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

7
8 153. As a result of Defendants' foregoing acts and omissions, Plaintiff
9 CHRYSTAL AUSTIN was and still is caused to suffer and is at a greater increased
10 risk of serious and dangerous side effects including compulsive gambling, and other
11 severe and personal injuries, physical pain and mental anguish, diminished enjoyment
12 of life, any and all life complications.
13

14
15 154. As a direct and proximate result of the foregoing acts and omissions,
16 Plaintiff CHRYSTAL AUSTIN has required and will require healthcare and services,
17 and has incurred financial loss, medical, health care, incidental, and related expenses.
18

19
20 155. As a direct and proximate result of reliance upon Defendants'
21 misrepresentations, Plaintiffs have suffered, and will continue to suffer,
22 neuropsychiatric and physical injury, emotional distress, harm, and economic loss as
23 alleged herein.

24 **NINTH CAUSE OF ACTION**
25 **Punitive Damages**

26
27 156. Plaintiff incorporates by reference all previous and subsequent
28 paragraphs of this Complaint as if fully set forth here and further alleges as follows:

1 157. Plaintiff is entitled to an award of punitive and exemplary damages
2 based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts,
3 omissions, and conduct, and Defendants' reckless disregard for the public's safety
4 and welfare. Defendants intentionally and fraudulently misrepresented facts and
5 information to both the medical community and the general public, including Plaintiff
6 CHRYSTAL AUSTIN, by making intentionally false and fraudulent
7 misrepresentations about the safety and efficacy of Abilify. Defendants intentionally
8 concealed the true facts and information regarding the serious risks of harm
9 associated with the ingestion of Abilify, and intentionally downplayed the type,
10 nature, and extent of the adverse side effects of ingesting Abilify, despite Defendants'
11 knowledge and awareness of the serious side effects and risks associated with
12 Abilify.

13 158. Defendants had knowledge of, and were in possession of evidence
14 demonstrating that Abilify caused serious side effects including compulsive
15 gambling. Notwithstanding Defendants' knowledge of the serious side effects of
16 Abilify, Defendants continued to market the drug by providing false and misleading
17 information with regard to the product's safety and efficacy to the regulatory
18 agencies, the medical community, and consumers of Abilify.

19 159. Although Defendants knew or recklessly disregarded the fact that
20 Abilify cause debilitating compulsive behavior side effects including compulsive
21 gambling, Defendants continued to market, promote, and distribute Abilify to
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1 consumers, including Plaintiff CHRYSTAL AUSTIN, without disclosing these side
2 effects when there were safer alternative methods for treating Plaintiff's underlying
3 condition.
4

5 160. Defendants failed to provide warnings that would have dissuaded
6 physicians from prescribing Abilify and consumers from purchasing and ingesting
7 Abilify, thus depriving both from weighing the true risks against the benefits of
8 prescribing, purchasing or consuming Abilify.
9

10 161. Defendants knew of Abilify's defective nature as set forth herein, but
11 continued to design, manufacture, market, distribute, sell and/or promote the drug as
12 to maximize sales and profits at the expense of the health and safety of the public,
13 including Plaintiff CHRYSTAL AUSTIN in a conscious or negligent disregard of the
14 foreseeable harm caused by Abilify.
15
16

17 162. The aforementioned conduct of Defendants was committed with
18 knowing, conscious, and deliberate disregard of the rights and safety of consumers
19 such as Plaintiffs, thereby entitling Plaintiffs to punitive damages in the amount
20 appropriate to punish Defendants and deter them from similar conduct in the future.
21

22 **PRAYER FOR RELIEF**

23 WHEREFORE, Plaintiff seeks judgment in Plaintiff's favor as follows:
24

25 1. Awarding actual damages to Plaintiff incidental to the purchase and
26 ingestion of Abilify in an amount to be determined at trial;
27
28

2. Awarding the costs of treatment for Plaintiff's injuries caused by
Abilify;

3. Awarding damages for Plaintiff's neuropsychiatric, mental, physical,
and economic pain and suffering;

4. Awarding damages for Plaintiff's mental and emotional anguish;

5. Awarding pre-judgment and post-judgment interest to Plaintiff;

6. Awarding punitive damages;

7. Awarding the costs and expenses of this litigation to Plaintiff;

8. Awarding reasonable attorneys' fees and costs to Plaintiff as provided
by law; and

9. For such further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

DATED: November 1, 2016

NAPOLI SHKOLNIK, PLLC

By: /s/ Jennifer Liakos
Jennifer Liakos (CA SBN 207487)
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(310) 331-8224 (Phone)
(646) 843-7603 (Facsimile)
jliakos@napolilaw.com

Attorneys for Plaintiff

CIVIL COVER SHEET

The JS-CAND 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 in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Chrystal Austin

(b) County of Residence of First Listed Plaintiff
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Jennifer Liakos (CA SBN 207487)
Napoli Shkolnik PLLC
525 South Douglas Street, Suite 260
El Segundo, CA 90245
Telephone: (310) 331-8224
Email: jliakos@napolilaw.com

DEFENDANTS

Bristol-Meyers Squibb Company, Otsuka Pharmaceutical Co., Ltd., and Otsuka American Pharmaceutical, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.
Attorneys (If Known)

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)

- | | PTF | DEF |
|---|---------------------------------------|--|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 Incorporated or Principal Place of Business In This State |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 Incorporated and Principal Place of Business In Another State |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 Foreign Nation |

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment Of Veteran's Benefits <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC § 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC § 158 <input type="checkbox"/> 423 Withdrawal 28 USC § 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC § 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC § 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities-Employment <input type="checkbox"/> 446 Amer. w/Disabilities-Other <input type="checkbox"/> 448 Education PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee-Conditions of Confinement			

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-Transfer ☐ 8 Multidistrict Litigation-Direct File

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:
Product Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, Fed. R. Civ. P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S),

IF ANY (See instructions):

JUDGE Chief Judge M. Casey Rodgers, Magistrate Judge Gary Jones

DOCKET NUMBER 3:16-md-2734

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)

(Place an "X" in One Box Only)

☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA-MCKINLEYVILLE

DATE: 11/01/2016

SIGNATURE OF ATTORNEY OF RECORD: /s/ Jennifer Liakos