

1 ZIMMERMAN REED, LLP
CHRISTOPHER P. RIDOUT (SBN 143931)
2 chritopher.ridout@zimmreed.com
CALEB LH. MARKER (SBN 269721)
3 caleb.marker@zimmreed.com
2381 Rosecrans Ave., Suite 328
4 Manhattan Beach, CA 90245
(877) 500-8780 Telephone
5 (877) 500-8781 Facsimile

6 ZIMMERMAN REED, LLP
GORDON RUDD (MN BN 222082) (*Pro hac* to be filed)
7 gordon.rudd@zimmreed.com
KIRSTEN D. HEDBERG (MN BN 344369) (*Pro hac* to be filed)
8 Kirsten.hedberg@zimmreed.com
1100 IDS Center, 80 South 8th Street
9 Minneapolis, MN 55402
(612) 341-0400 Telephone
10 (612) 341-0844 Facsimile

11 *Attorneys for the Plaintiffs*

12
13 **UNITED STATES DISTRICT COURT**
14 **CENTRAL DISTRICT OF CALIFORNIA**

15 MARSHA GIBSON and R. DALE
16 GIBSON,
17 Plaintiffs,
18 v.
19 BRISTOL-MYERS SQUIBB
20 COMPANY, OTSUKA
21 PHARMACEUTICAL CO., LTD., and
22 OTSUKA AMERICA
23 PHARMACEUTICAL, INC.,
24 Defendants.

Case No.: 2:16-CV-03930

COMPLAINT
DEMAND FOR JURY TRIAL
Complaint Filed: June 3, 2016

1 Plaintiffs, Marsha Gibson and R. Dale Gibson, by and through Plaintiffs'
2 undersigned counsel, bring this civil action against Defendants above-named for personal
3 injuries suffered by Plaintiff Marsha Gibson and for R. Dale Gibson loss of consortium,
4 and allege as follows:

5 **INTRODUCTION**

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

10 2. Defendants manufacture, promote, and sell Abilify as a prescription drug that
11 treats depression, bipolar I disorder, and schizophrenia. Abilify is manufactured as tablets,
12 oral solution, and injection.

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

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 behaviors
19 such as compulsive gambling.

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

22 6. Defendants did not warn, advise, educate, or otherwise inform Abilify users or
23 prescribers in the United States about the risk of compulsive gambling or other compulsive
24 behaviors. Prior to January 2016, the U.S. label made no mention of pathological
25 gambling or compulsive behaviors whatsoever. In January 2016, Defendants simply added
26 "pathological gambling" to the postmarketing experience section of the U.S. label.
27 Defendants did not, however, make any mention of gambling in the patient medication
28 guide, the source of information most likely viewed by physicians and patients. On May 3,

1 2016, the FDA announced that warnings regarding “compulsive or uncontrollable urges to
2 gamble, binge eat, shop, and have sex” would be added to the Abilify label.

3 **PARTIES**

4 7. Plaintiffs are adult residents and citizens of Ventura, California.

5 8. Plaintiff Marsha Gibson was prescribed and took the prescription drug Abilify
6 and as a result developed compulsive gambling behaviors. Plaintiff Marsha Gibson began
7 taking Abilify in or around November 2005, began compulsively gambling shortly
8 thereafter, and stopped compulsively gambling soon after Plaintiff Marsha Gibson had
9 ceased taking Abilify in May 2016. Due to Defendants’ conduct, as detailed herein,
10 Plaintiff’s injuries and their relationship to Abilify were not discovered until 2016.

11 9. By way of example, as a result of Abilify use, Plaintiff Marsha Gibson has
12 suffered the following losses: monetary losses in excess of \$90,000, loss of financial
13 stability, and other mental, physical, and economic losses. The injurious impact of Abilify
14 on Plaintiff’s brain constitutes a physical injury.

15 10. As a result of Abilify use, Plaintiff Marsha Gibson has suffered, and will
16 continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and
17 economic loss as alleged herein.

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

22 12. Defendant Otsuka Pharmaceutical Co., Ltd. (“OPC”) is a Japanese company,
23 with its principal office at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535,
24 Japan, and has a registered agent located at 351 West Camden Street, Baltimore, Maryland
25 per records filed with the Maryland Department of Assessments and Taxation Business
26 Services. Abilify is a trademark of Defendant Otsuka Pharmaceutical Co., Ltd. Defendant
27 Otsuka Pharmaceutical Co. Ltd. wholly owns Otsuka America, Inc. (“OAI”), a holding
28 company established in the United States in or around 1989. OAI is the parent of

1 Defendant Otsuka. America Pharmaceutical, Inc. (“OAPI”), Otsuka Pharmaceutical
2 Development & Commercialization, Inc. (“OPDC”), and Otsuka Maryland Medicinal
3 Laboratories, Inc. (“OMML”).

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

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

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

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

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 through
23 third parties or related entities, the pharmaceutical drug Abilify, in all states and throughout
24 the United States.

JURISDICTION

1
2 18. This Court has federal subject matter jurisdiction pursuant to 28 U.S.C. §
3 1332 because Plaintiffs and Defendants are citizens of different states and the amount in
4 controversy exceeds \$75,000, exclusive of interest and costs.

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

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

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

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

15 23. This Court has personal jurisdiction over Otsuka Pharmaceutical Co., Ltd.
16 based on its contacts with California relating to the subject matter of this action and
17 because Otsuka Pharmaceutical Co., Ltd. has continuous and systematic contacts with this
18 judicial district. On information and belief, Otsuka Pharmaceutical Co., Ltd. regularly
19 places goods into the stream of commerce for distribution in California and throughout the
20 United States. Members of Otsuka Pharmaceutical Co., Ltd. continuously communicate
21 from Japan with members of Otsuka America Pharmaceutical, Inc. Otsuka Pharmaceutical
22 Co., Ltd sells and markets Abilify in the United States and California.

23 24. Defendants are subject to the *in personam* jurisdiction of this Court, and
24 venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendants did and
25 do business within and have continuous and systematic contacts with the State of
26 California, and have consented to jurisdiction in the State of California and/or committed a
27 tort in whole or in part in the State of California against Plaintiffs, as more fully set forth
28 herein. On information and belief, Defendants also advertised in this district, made

1 material omissions and representations in this district, and breached warranties in this
2 district.

3 25. Jurisdiction is proper under Cal. Civ. Proc. Code § 410.10 and the Due
4 Process Clause of the Constitution because Defendants have sufficient minimum contacts
5 with the State of California related to Abilify and have purposefully directed conduct
6 toward the State of California.

7 **FACTUAL BACKGROUND**

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

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

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

17 **Pathological gambling**

18 **Post-marketing reports of pathological gambling have been**
19 **reported among patients prescribed ABILIFY, regardless of**
20 **whether these patients had a prior history of gambling. Patients**
21 **with a prior history of pathological gambling may be at increased**
22 **risk and should be monitored carefully.**

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

26 **Psychiatric disorders: agitation, nervousness, pathological**
27 **gambling, suicide attempt, suicidal**
28 **ideation, and completed suicide.**

30. In or around November 2015, Canadian regulators concluded that there is “a
link between the use of aripiprazole and a possible risk of pathological gambling or

1 hypersexuality” and found an increased risk of pathological (uncontrollable) gambling and
2 hypersexuality with the use of Abilify.

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

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**
9 **gambling disorder may be at increased risk and should be**
10 **monitored carefully.**

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

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

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

35. Defendant Bristol-Myers touts Abilify as its “2013 largest-selling product”

1 noting sales of \$2.3 billion. Defendant Bristol-Myers recently reported U.S. revenues from
2 Abilify sales of \$417 million over three months ending June 30, 2014, and worldwide
3 revenues of \$555 million over the same time period.

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

7 37. In 2001, Defendant Otsuka Pharmaceutical Co., Ltd. submitted a New Drug
8 Application (“NDA”) to the United States Food and Drug Administration (“FDA”) for
9 Abilify (aripiprazole). This initial NDA sought approval to market Abilify in 2, 5, 10, 15,
10 20 and 30 mg tablets as a treatment for schizophrenia. The NDA was approved on
11 November 15, 2002.

12 38. In November 2002, the FDA required Defendants to submit results of Study
13 138047 to address the longer-term efficacy of Abilify in the treatment of adults with
14 schizophrenia.

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

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

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

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

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

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

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

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

21 47. Defendants had, or should have had, knowledge that Abilify can cause
22 compulsive behaviors like gambling. Despite their significant collective resources, and
23 signals that Abilify is associated with compulsive behaviors such as gambling,
24 Defendant have failed to fully and adequately test or research Abilify and its association
25 with compulsive behaviors to the detriment of Plaintiffs, Abilify users, the public, the
26 medical community, and prescribing doctors.

27 48. Compulsive gambling is a major psychiatric disorder. The American
28 Psychiatric Association’s *Diagnostic and Statistical Manual of Mental Disorders* (“DSM”)

1 first recognized pathological gambling as a psychiatric disorder in 1980.

2 49. Originally, the disorder was classified as an impulse control disorder. The
3 current version of the DSM, the DSM-V, renamed pathological gambling as “gambling
4 disorder.” DSM-V reclassified gambling disorder under the category Substance-Related
5 and Addictive Disorders in order to reflect evidence that gambling behaviors activate or are
6 activated by reward systems similar to those activated by drugs of abuse, and produce
7 some behavioral symptoms comparable to those produced by substance abuse disorders.

8 50. Abilify is a partial and full dopamine agonist. Dopamine is a neurotransmitter
9 that helps control the brain’s reward and pleasure centers.

10 51. Dopamine’s role in compulsive behavior and pathological gambling is well-
11 known. Dopaminergic reward pathways have frequently been implicated in the etiology of
12 addictive behavior. Scientific literature has identified dopamine as a potential cause of
13 pathological gambling for years.

14 52. Abilify’s dopaminergic activity at the mesolimbic circuit, especially at the
15 nucleus accumbens, has been associated with compulsive behavior in Abilify patients.

16 53. Defendants’ September 2011 6-Month Periodic Safety Update Report
17 acknowledges a plausible mechanism for pathological gambling. The Report states that an
18 article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to Psychiatric*
19 *Disorders*, “does suggest a possible mechanism by which drugs that act on dopamine
20 neurons, like aripiprazole, might possibly have some effect on behavior related to reward.”

21 54. Defendants’ September 2011 6-Month Periodic Safety Update Report
22 submitted to the European Medicines Agency acknowledged seven serious reports of
23 pathological gambling, three in the medical literature and four spontaneous reports. The
24 report also noted sixteen cases of pathological gambling in the Bristol-Myers company
25 safety database.

26 55. The Medical Assessment of the pathological gambling cases in Defendants’
27 September 2011 6-Month Periodic Safety Update Report did not exclude Abilify as the
28 cause of the compulsive gambling adverse events. Defendants concluded that “a causal

1 role of aripiprazole could not be excluded” or that “aripiprazole was suggested by the
2 temporal relationship.”

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

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

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

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

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

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

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

28 63. From May 1, 2009 to May 1, 2011, the FDA received thousands of serious

1 adverse event reports concerning Abilify (n=4599), including over two-thousand serious
2 adverse drug experiences of which 193 involved children (0-16 years old).

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

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

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

13 67. An analysis of the FDA Adverse Event Reporting System shows an escalating
14 number of reports. Twenty-nine reports of gambling behavior were made to the FDA in
15 2014.

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

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

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

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

5 72. The Drug Facts Box for Abilify for major depression includes a “summary” of
6 the combined data from the two identical six week randomized trials that were the basis for
7 FDA drug approval for this indication. The box shows that Abilify has only a modest
8 benefit: on average, patients on Abilify improved by 3 points more (*on a scale of 60*) than
9 patients on placebo, and only an additional 11% of patients had a clinically important
10 response as defined in the trial.

11 73. Despite the risks of serious adverse events, and the lack of adequate testing,
12 Defendants aggressively promoted Abilify, including illegal promotion for off-label use.
13 In 2007, Defendant Bristol-Myers reportedly paid \$515 million to settle federal and state
14 investigations into off-label marketing of Abilify for pediatric use and to treat dementia-
15 related psychosis. Defendant Otsuka American Pharmaceutical, Inc. later paid more than
16 \$4 million to resolve the allegations.

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

25 75. Upon information and belief, Defendants have invested millions of dollars in
26 teams of pharmaceutical sales representatives who visit and contact members of the
27 medical community, including prescribing doctors, purporting to “educate” them about
28 Abilify. Upon information and belief, these pharmaceutical sales representatives have not

1 notified patients, the medical community, or prescribers in the United States that Abilify
2 use causes, is linked to, or might be associated with compulsive gambling, pathological
3 gambling, or gambling addiction.

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

8 77. Defendants’ Direct to Consumer advertising minimizes risks while over-
9 promoting the drug.

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

13 79. Defendants have made payments to doctors to promote Abilify. From August
14 2013 to December 2014, \$10.6 million in payments relating to Abilify were made to
15 21,155 physicians in the United States.

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

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

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

26 83. Likewise, the labeling for Abilify in the United States lists serious side effects
27 that have been reported with Abilify, but did not list gambling, pathological or otherwise in
28 any form until January 2016 when it was only added to the postmarketing experience

1 section of the label. Prior to May 2016, the label did not mention compulsive behaviors
2 other than pathological gambling or adequately warn patients about the risk of compulsive
3 gambling. Defendants also did not make any mention of gambling in the patient
4 medication guide, the source of information most likely viewed by physicians and patients.

5 84. The labeling in the United States contradicts the labeling in Europe and
6 Canada by not providing adequate warnings and not cautioning that patients should be
7 closely monitored, and does not adequately inform patients and physicians that gambling
8 and other compulsive behaviors have been associated with Abilify use.

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

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

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

24 88. Likewise, Defendant Otsuka Pharmaceutical Co., Ltd. promotes Abilify on its
25 own website, www.otsuka.co.jp/en/ (“Otsuka website”), noting it was “researched and
26 developed by Otsuka Pharmaceutical” and “launched” in the United States in 2002.
27 Nowhere on the Otsuka website does it mention the word “gambling.”
28

1 **EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

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

5 90. The discovery rule should be applied to toll the running of the statute of
6 limitations until the Plaintiffs discovered or reasonably should have discovered Plaintiff
7 Marsha Gibson's injury and the causal connection between the injury and Defendants'
8 product.

9 91. Despite reasonable and diligent investigation by Plaintiffs into the causal
10 connection between Plaintiffs' injuries and Abilify, the cause and nature of Plaintiffs'
11 injuries and their relationship to Abilify was not discovered until 2016. Therefore, under
12 the appropriate application of the discovery rule, Plaintiffs' suit was filed well within the
13 applicable statutory limitations period.

14 92. Defendants are estopped from asserting a statute of limitations defense
15 because all Defendants fraudulently concealed from Plaintiffs the truth, quality and nature
16 of Plaintiffs' injuries and the connection between the injuries and Defendants' tortious
17 conduct. Defendants, through their affirmative misrepresentations and omissions, actively
18 concealed from Plaintiffs and Plaintiff Marsha Gibson's prescribing physicians the true
19 risks associated with Abilify.

20 93. Defendants were under a duty to disclose the true character, quality and nature
21 of the risks associated with use of Abilify as this was non-public information over which
22 Defendants had and continue to have exclusive control, and because Defendants knew that
23 this information was not available to Plaintiffs, Plaintiff Marsha Gibson, medical providers
24 and/or health-care facilities. In addition, Defendants are estopped from relying on any
25 statute of limitation because of their intentional concealment of these facts.

26 94. Plaintiffs had no knowledge that Defendants were engaged in the wrongdoing
27 alleged herein. Because of the fraudulent acts of concealment of wrongdoing by
28 Defendants, Plaintiffs could not have reasonably discovered the wrongdoing at any time

1 prior to 2016.

2 **FIRST CAUSE OF ACTION**

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

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

6 96. Defendants had a duty to provide adequate warnings and instructions for
7 Abilify, to use reasonable care to design a product that is not unreasonably dangerous to
8 users, and to adequately test their product.

9 97. The Abilify manufactured and/or supplied to Plaintiff Marsha Gibson by
10 Defendants was defective in design or formulation in that, when it left the hands of the
11 manufacturer and/or supplier, it was in an unreasonably dangerous and a defective
12 condition for its intended use and it posed a risk of serious compulsive behaviors and harm
13 to Plaintiff and other consumers which could have been reduced or avoided, inter alia, by
14 the adoption of a feasible reasonable alternative design.

15 98. The Abilify manufactured and/or supplied to Plaintiff Marsha Gibson by
16 Defendants was defective in design or formulation in that, when it left the hands of the
17 manufacturer and/or supplier, Abilify had not been adequately tested, was in an
18 unreasonably dangerous and a defective condition, and it posed a risk of serious
19 compulsive behaviors and harm to Plaintiff and other consumers.

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

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

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

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

7 103. Defendants failed to provide adequate warnings to users, purchasers, or
8 prescribers of Abilify, including Plaintiff Marsha Gibson and her physicians, and instead
9 continued to sell Abilify in an unreasonably dangerous form without adequate warnings or
10 instructions.

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

21 105. As a direct and proximate result of Defendants' conduct, including the
22 inadequate warnings, dilution or lack of information, lack of adequate testing and research,
23 and the defective and dangerous nature of Abilify, Plaintiffs have suffered, and will
24 continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and
25 economic loss as alleged herein.

26 **SECOND CAUSE OF ACTION**

27 **Breach of Express Warranty by Defendants**

28 106. Plaintiffs incorporate the factual allegations set forth in paragraphs 1 to 94 as

1 if fully set forth herein and further allege as follows:

2 107. Defendants expressly warranted to physicians and consumers, including
3 Plaintiff Marsha Gibson and/or Plaintiff's physicians, that Abilify was safe and/or well-
4 tolerated.

5 108. Abilify does not conform to these express representations because it is not
6 safe and/or well-tolerated because it causes compulsive behaviors such as pathological
7 gambling addiction, which in turn can lead to financial ruin, job loss, familial devastation,
8 and suicide attempts.

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

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

14 **THIRD CAUSE OF ACTION**

15 **Breach of Implied Warranty**

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

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

21 113. Defendants knew, or had reason to know, that Plaintiff Marsha Gibson and
22 Plaintiff's physicians would rely on the Defendants' judgment and skill in providing
23 Abilify for its intended use.

24 114. Plaintiff Marsha Gibson and Plaintiff's physician reasonably relied upon the
25 skill and judgment of Defendants as to whether Abilify was of merchantable quality, safe,
26 and fit for its intended use.

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

1 defective and unfit for the ordinary purposes for which Abilify was used.

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

4 117. As a direct and proximate result of the breach of implied warranty, Plaintiffs
5 have suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional
6 distress, harm, and economic loss as alleged herein.

7 **FOURTH CAUSE OF ACTION**

8 **Negligence**

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

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

19 120. Defendants had a duty to warn Plaintiff Marsha Gibson, Plaintiff's physicians,
20 and the public in general of Abilify's dangers and serious side effects, including serious
21 compulsive behaviors like pathological gambling addiction, since it was reasonably
22 foreseeable that an injury could occur because of Abilify's use.

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

28 122. Also, Abilify's limited and unproven effectiveness did not outweigh the risks

1 posed by the drug.

2 123. Each of the following acts and omissions herein alleged was negligently and
3 carelessly performed by Defendants, resulting in a breach of the duties set forth above.

4 These acts and omissions include, but are not restricted to:

- 5 a. Negligent and careless research and testing of Abilify;
- 6 b. Negligent and careless design or formulation of Abilify;
- 7 c. Negligent and careless failure to give adequate warnings that would
8 attract the attention of Plaintiff Marsha Gibson, Plaintiff's physicians,
9 and the public in general of the potentially dangerous, defective, unsafe,
10 and deleterious propensity of Abilify and of the risks associated with its
11 use;
- 12 d. Negligent and careless failure to provide instructions on ways to safely
13 use Abilify to avoid injury;
- 14 e. Negligent and careless failure to explain the mechanism, mode, and
15 types of adverse events associated with Abilify;
- 16 f. Negligent representations that Abilify was safe and/or well-tolerated;
17 and
- 18 g. Negligent and careless failure to issue adequate post-sale warnings that
19 Abilify causes an increased risk of compulsive behaviors, including
20 pathological gambling.

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

24 **FIFTH CAUSE OF ACTION**

25 **Negligence Per Se**

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

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

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

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

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

21 128. These statutes and regulations impose a standard of conduct designed to
22 protect consumers of drugs, including Plaintiff Marsha Gibson.

23 129. Defendants’ violations of these statutes and regulations constitute negligence
24 per se.

25 130. As a direct and proximate result of Defendants’ statutory and regulatory
26 violations, Plaintiffs, members of the class of persons protected by the above-mentioned
27 statutes, have suffered, and will continue to suffer, neuropsychiatric and physical injury,
28 emotional distress, harm, and economic loss as alleged herein.

SIXTH CAUSE OF ACTION

Negligent Misrepresentation

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

5 132. Defendants misrepresented to consumers and physicians, including Plaintiff
6 Marsha Gibson and/or Plaintiff's physicians and the public in general, that Abilify was safe
7 and/or well-tolerated when used as instructed, and that Abilify was safe and/or well-
8 tolerated, when, in fact, Abilify was dangerous to the well-being of patients.

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

11 134. At the time Defendants promoted Abilify as safe and/or well-tolerated, they
12 did not have adequate proof upon which to base such representations, and, in fact, knew or
13 should have known that Abilify was dangerous to the well-being of Plaintiff Marsha
14 Gibson and others.

15 135. Defendants failed to exercise reasonable care and competence in obtaining
16 and/or communicating information regarding the safe use of Abilify and otherwise failed to
17 exercise reasonable care in transmitting information to Plaintiff Marsha Gibson, Plaintiff's
18 physicians, and the public in general.

19 136. Defendants made the aforesaid representations in the course of Defendants'
20 business as designers, manufacturers, and distributors of Abilify despite having no
21 reasonable basis for their assertion that these representations were true and/or without
22 having accurate or sufficient information concerning the aforesaid representations.
23 Defendants were aware that without such information they could not accurately make the
24 aforesaid representations.

25 137. At the time the aforesaid representations were made, Defendants intended to
26 induce Plaintiff Marsha Gibson and/or Plaintiff's physicians to rely upon such
27 representations.

28 138. At the time the aforesaid representations were made by Defendants, and at the

1 time Plaintiff Marsha Gibson received Abilify, Plaintiff and/or Plaintiff's physicians, and
2 the public in general, reasonably believed them to be true. In reasonable and justified
3 reliance upon said representations, Plaintiff used Abilify.

4 139. As a direct and proximate result of reliance upon Defendants'
5 misrepresentations, Plaintiffs have suffered, and will continue to suffer, neuropsychiatric
6 and physical injury, emotional distress, harm, and economic loss as alleged herein.

7 **SEVENTH CAUSE OF ACTION**

8 **Violation of California Unfair Competition Law and**
9 **Consumers Legal Remedies Act**

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

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

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

23 143. By reason of such violations and pursuant to Cal. Bus. & Prof Code §17200 *et*
24 *seq.* and Cal. Civ. Code §1750 *et seq.*, Plaintiff Marsha Gibson is entitled to recover all of
25 the monies paid for Abilify; to be compensated for the cost of the medical care arising out
26 of the use of Abilify; and to recover any and all consequential damages recoverable under
27 the law including, but not limited to, gambling losses, both past and future medical
28 expenses, past wage loss, loss of future earning capacity, past and future pain, suffering,

1 disability, and emotional distress. Plaintiff is entitled to seek compensatory damages,
2 attorney's fees, and other remedies as determined by the Court pursuant to Cal. Bus. &
3 Prof Code §17200 *et seq.* and Cal. Civ. Code §1750 *et seq.*

4 **EIGHTH CAUSE OF ACTION**

5 **Fraudulent Concealment**

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

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

10 146. Defendants fraudulently concealed from or failed to disclose or to warn
11 Plaintiff Marsha Gibson, Plaintiff's physicians, and the medical community that Abilify
12 was defective, unsafe, unfit for the purposes intended, and was not of merchantable quality.

13 147. Defendants were under a duty to Plaintiff Marsha Gibson to disclose and warn
14 of the defective nature of Abilify because:

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

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

26 149. Defendants intentionally concealed or failed to disclose the true defective
27 nature of Abilify so that Plaintiff Marsha Gibson would request and purchase Abilify, and
28 that their healthcare providers would dispense, prescribe, and recommend Abilify, and

1 Plaintiff justifiably acted or relied upon, to Plaintiff's detriment, the concealed or non-
2 disclosed facts as evidenced by his purchase and use of Abilify.

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

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

17 152. As a direct and proximate result of the foregoing acts and omissions, Plaintiff
18 Marsha Gibson has required and will require healthcare and services, and has incurred
19 financial loss, medical, health care, incidental, and related expenses.

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

23 **NINTH CAUSE OF ACTION**

24 **Loss of Consortium**

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

27 155. Plaintiffs are husband and wife.

28 156. Plaintiff Marsha Gibson's spouse has incurred financial loss as a result of

1 Defendants' conduct.

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

5 **TENTH CAUSE OF ACTION**

6 **Punitive Damages**

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

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

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

26 161. Although Defendants knew or recklessly disregarded the fact that Abilify
27 causes debilitating compulsive behavior side effects including compulsive gambling,
28 Defendants continued to market, promote, and distribute Abilify to consumers, including

1 Plaintiff Marsha Gibson, without disclosing these side effects when there were safer
2 alternative methods for treating Plaintiff's underlying condition.

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

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

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

16 **PRAYER FOR RELIEF**

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

- 18 1. Awarding actual damages to Plaintiffs incidental to the purchase and ingestion
19 of Abilify in an amount to be determined at trial;
- 20 2. Awarding the costs of treatment for Plaintiffs' injuries caused by Abilify;
- 21 3. Awarding damages for Plaintiffs' neuropsychiatric, mental, physical, and
22 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 8. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by
28 law; and

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

2 **DEMAND FOR JURY TRIAL**

3 Plaintiffs hereby demand a trial by jury as to all issues.

4
5 Date: June 3, 2016

ZIMMERMAN REED, LLP

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7 By: /s/ Christopher P. Ridout
8 Christopher P. Ridout
9 Caleb LH Marker
10 2381 Rosecrans Ave., Suite 328
11 Manhattan Beach, CA 90245
12 (877) 500-8780 Telephone
13 (877) 500-8781 Facsimile

ZIMMERMAN REED, LLP

14 Gordon Rudd (*Pro hac* to be filed)
15 Kirsten D. Hedberg (*Pro hac* to be filed)
16 1100 IDS Center, 80 South 8th Street
17 Minneapolis, MN 55402
18 (612) 341-0400 Telephone
19 (612) 341-0844 Facsimile

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Attorneys for Plaintiffs