UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

PATRICK PARKS, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, OTSUKA PHARMACEUTICAL CO., LTD., AND OTSUKA AMERICA PHARMACEUTICAL, INC., Defendants.	Civil Action No.: 2:16-cv-1098 **COMPLAINT AND DEMAND FOR JURY TRIAL**

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

INTRODUCTION

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

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

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

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

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

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

7. On May 3, 2016, the FDA announced that warnings regarding "compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex" would be added to the Abilify label. In August 2016, warnings regarding compulsive gambling and other compulsive behaviors were added to the Abilify label. The label now warns that "[b]ecause patients may not recognize these behaviors as abnormal, it is important for

prescribers to ask patients or their caregivers specifically about the development of new or intense gambling urges, compulsive sexual urges, compulsive shopping, binge or compulsive eating, or other urges while being treated with aripiprazole….Compulsive behaviors may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urges."

PARTIES

8. Plaintiff is an adult resident and citizen of Delaware, Ohio.

9. Plaintiff PATRICK PARKS was prescribed and took the prescription drug Abilify and as a result developed compulsive gambling behaviors. Plaintiff began taking Abilify in or around May 2013, began compulsively gambling shortly thereafter, and stopped compulsively gambling soon after Plaintiff had ceased taking Abilify in August, 2014. Plaintiff was prescribed and purchased Abilify in the State of Ohio. Due to Defendants' conduct, as detailed herein, Plaintiff's injuries and their relationship to Abilify were not discovered until sometime on or about November 18, 2014.

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

11. As a result of Abilify use, Plaintiff PATRICK PARKS has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

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

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

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

15. At all times relevant to this Complaint, Defendant OPC, OAI, OAPI, OPDC, and OMML (the "Otsuka entities") have operated in concert as it relates to the development, research, distribution, manufacturing, and/or marketing of Abilify. OPC

has control over its subsidiaries daily affairs and operations with respect to Abilify. The Otsuka entities work in concert as a single operation known as the Otsuka Group.

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

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

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

JURISDICTION

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

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

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

22. 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).

23. 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 Ohio, 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.

24. This Court has personal jurisdiction over Otsuka Pharmaceutical Co., Ltd. based on its contacts with Ohio 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 Ohio and throughout the United States. Members of Otsuka Pharmaceutical Co., Ltd. continuously communicate from Japan with members of Otsuka America Pharmaceutical, Inc. Otsuka Pharmaceutical Co., Ltd sells and markets Abilify in the United States and Ohio.

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

26. Jurisdiction is proper under long arm statute and the Due Process Clause of the Constitution because Defendants have sufficient minimum contacts with the State of Ohio related to Abilify and have purposefully directed conduct toward the State of Ohio.

FACTUAL BACKGROUND

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

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

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

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

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

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

31. 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 hypersexuality" and found an increased risk of pathological (uncontrollable) gambling and hypersexuality with the use of Abilify.

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

Pathological Gambling

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

33. Despite these warnings and advisories in Europe and Canada—for the same drug sold to patients in the United States—the labeling for Abilify in the United States did not adequately warn about the risk of compulsive gambling and contained no mention that pathological gambling has been reported in patients prescribed Abilify. In January 2016, pathological gambling was added only to the Postmarketing Experience section of the label; Defendants did not make any mention of gambling in the patient medication guide, a source of information likely viewed by physicians and patients. On May 3, 2016, the FDA issued a warning that Abilify was associated with "compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex." The FDA recommended that doctors "make patients and caregivers aware of the risk of these uncontrollable

urges," "closely monitor" patients, and consider reducing or stopping Abilify if compulsivity emerges.

34. The labeling for Abilify in the United States contained no mention of the word "gambling" until January 2016.

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

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

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

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

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

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

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

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

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

44. In or around 1999, Defendants Bristol-Myers and Otsuka entered into an agreement to co-develop and "commercialize" Abilify (hereinafter referred to as "Defendants' Marketing Agreement"). Under the terms of Defendants' Marketing Agreement, Defendant Bristol-Myers was to market and promote Abilify in the United

States and the European Union, in collaboration with Defendant Otsuka Pharmaceutical Co., Ltd., and under Defendant Otsuka Pharmaceutical Co., Ltd.'s trademark.

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

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

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

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

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

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

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

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

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

54. Defendants' September 2011 6-Month Periodic Safety Update Report acknowledges a plausible mechanism for pathological gambling. The Report states that an article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to Psychiatric Disorders,* "does suggest a possible mechanism by which drugs that act on dopamine

neurons, like aripiprazole, might possibly have some effect on behavior related to reward."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

71. Despite evidence that Abilify causes compulsive behaviors like pathological gambling and calls from the medical community to conduct further research and warn patients about this possible effect of Abilify, Defendants have either failed to investigate or conduct any studies on the compulsive behavior side effects of Abilify or

failed to make public the results of any studies or investigations that they might have done.

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

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

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

75. The FDA issued a letter dated April 17, 2015 finding Abilify promotional material "false or misleading because it makes misleading claims and presentations about the drug." The FDA found the material "misleading because it implies that Abilify offers advantages over other currently approved treatments for bipolar disorder or MDD when

this has not been demonstrated." The FDA also found the cited references "not sufficient to support claims and presentations suggesting that Abilify has been demonstrated to modulate dopaminergic and serotonergic activity, or modulate neuronal activity in both hypoactive and hyperactive environments in humans."

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

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

78. Defendants' Direct to Consumer advertising minimizes risks while over-promoting the drug.

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

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

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

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

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

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

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

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

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

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

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

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

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

91. Despite reasonable and diligent investigation by Plaintiff into the causal connection between Plaintiff's injuries and Abilify, the cause and nature of Plaintiff's injuries and their relationship to Abilify was not discovered until on or about November 18, 2014. Therefore, under the appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

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

93. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with use of Abilify as this was non-public information over which Defendants had and continue to have exclusive control, and because Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers

and/or health-care facilities. In addition, Defendants are estopped from relying on any statute of limitation because of their intentional concealment of these facts.

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

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DEFECTIVE MANUFACTURING

95. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

96. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of pharmaceutical products including Abilify.

97. The Abilify manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications posing a serious risk of injury.

98. As a direct and proximate result of Plaintiff's use of Abilify as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

99. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev.

Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECTIVE MANUFACTURING-- PURSUANT TO OHIO REVISED CODE SECTION 2307.74

100. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

101. Plaintiff is a "claimant" as defined at Ohio Rev. Code §§ 2307.71(A)(1)(a) in that Plaintiff is making a "product liability claim," as defined by Ohio Rev. Code §§ 2307.72(A)(13) for damages caused by Plaintiff's use of Abilify, manufactured, designed, sold, distributed, supplied and/or placed this product in the stream of commerce by Defendants who are "manufacturers" as defined by Ohio Rev. Code §§ 2307.71(A)(9) and/or "suppliers" as defined by Ohio Rev. Code §§ 2307.71(A)(15).

102. The Abilify manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of compulsive behaviors, regardless of whether Defendants exercised all possible care in its manufacture or construction.

103. The foregoing acts and/or omissions of Defendants were in violation of Ohio Rev. Code §2307.74 since the Abilify manufactured by Defendants was defective in manufacture or construction.

104. As a direct and proximate result of Plaintiff's use of Abilify as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

105. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DESIGN DEFECT

106. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

107. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of pharmaceutical products including Abilify.

108. The Abilify manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

109. The Abilify that the Plaintiff used had not been materially altered or modified prior to their use.

110. The foreseeable risks associated with the design or formulation of Abilify, include, but are not limited to, the fact that the design or formulation of S Abilify is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

111. As a direct and proximate result of Plaintiff's use of Abilify as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

112. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DESIGN DEFECT PURSUANT TO OHIO REVISED CODE SECTION 2307.75

113. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

114. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of pharmaceutical products including Abilify.

115. The Abilify manufactured and supplied by Defendants were defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with its design or formulation, as defined by Ohio Rev. Code §§ 2307.75(C), or it was more dangerous than an ordinary consumer would expect.

116. As set forth elsewhere in this Complaint, the foreseeable risks of the Abilify, as defined at Ohio Rev. Code §§ 2307.75(B)(1) – (5), include but are not limited to the following:

a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses, as defined at Ohio Rev. Code §§ 2307.75(B)(1);

b. the unlikely awareness to the users of Abilify of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of Abilify, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);

c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as a pharmaceutical product, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);

d. the design or formulation of Abilify produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there

were available, more effective treatment options and pharmaceutical products not as prone to injury including compulsive behaviors, as defined at Ohio Rev. Code §§ 2307.75(B)(4);

e. the design or formulation of Abilify produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using Abilify as a pharmaceutical product, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

117. The Defendants failed to provide an adequate warning as to the risks of Abilify and for this reason Defendants may not claim that Abilify is not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

118. As a direct and proximate result of Plaintiff's use of Abilify as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

119. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to

warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

FIFTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY – DEFECT DUE TO INADEQUATE WARNING

120. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

121. The Abilify manufactured and supplied by Defendants were defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious harm including but not limited to compulsive behavior to consumers and they failed to adequately warn consumers and/or their health care providers of such risks as follows:

a. The Defendants knew or, in the exercise of reasonable care, should have known that a pharmaceutical product such as Abilify through testing, scientific knowledge, advances in the field or otherwise, that the product created a risk of serious compulsive behaviors and harm, and was unreasonably dangerous to Plaintiff and other consumers, about which Defendants failed to warn

b. The Defendants failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning the risk of injury including but not limited to compulsive behavior, in light of the likelihood that Abilify would cause the harm claimed by the Plaintiff and in light of the likely seriousness of that harm.

122. The Defendants, as manufacturers of Abilify, are held to the level of knowledge of an expert in the field of that type of pharmaceutical products, and had a duty to warn its consumers of the dangers associated with Abilify and failed to do so.

123. The Abilify manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious harm, as set forth herein, from the use of Abilify, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury as set forth herein.

124. As a direct and proximate result of Plaintiff's use of Abilify as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

125. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY—DEFECTIVE DUE TO INADEQUATE WARNING--PURSUANT TO OHIO REVISED CODE SECTION 2307.76

126. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

127. The Abilify manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created a risk of serious compulsive behaviors and harm and Defendants failed to adequately warn consumers and/or their health care providers of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

128. In addition to, or in the alternative, the Abilify manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious harm as a result of Abilify, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and that it could cause severe compulsive behavior, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

129. The risks of Abilify were not open and obvious, as defined at Ohio Rev. Code §§ 2307.76(B).

130. As a direct and proximate result of Plaintiff's use of Abilify as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

131. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as

identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY BY DEFENDANTS UNDER OHIO PRODUCTS LIABILITY ACT

132. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

133. Defendants expressly warranted to physicians and consumers, including Plaintiff and/or Plaintiff's physicians, that Abilify was safe and/or well-tolerated.

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

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

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

EIGHTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY BY DEFENDANTS UNDER OHIO PRODUCT LIABILITY ACT

137. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

138. 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.

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

140. Plaintiff 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.

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

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

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

PRAYER FOR RELIEF

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

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

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 the costs and expenses of this litigation to Plaintiff;

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

8. 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 15, 2016

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