IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Cindy Himel, Plaintiff, v. Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka Maryland Medicinal Laboratories, Inc., Defendants.	Civil Action Number 3:16-5529 **JURY TRIAL DEMANDED**

COMPLAINT AND JURY DEMAND

Plaintiff Cindy Himel ("Plaintiff"), through her undersigned counsel, files this Complaint and Jury Demand ("Complaint") against Defendants Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka Maryland Medicinal Laboratories, Inc. (collectively, "Defendants") for compensatory and punitive damages, equitable relief, and any other relief deemed just and proper arising from Plaintiff's injuries from the use of the atypical antipsychotic drug aripiprazole. Aripiprazole is found in the branded drugs Abilify and Abilify Maintena. In support thereof, Plaintiff alleges the following.

INTRODUCTION

1. Abilify and Abilify Maintena (together, "Abilify") are powerful atypical antipsychotics that include aripiprazole as their active drug.

2. Abilify is heavily marketed, sold and distributed in the United States by

Defendants.

3. As a result of Defendants' behavior, Abilify was, and continues to be, prescribed to a significant population of individuals for multiple mental conditions including bipolar disorder and schizophrenia.

4. As a direct and proximate result of the defective nature of Abilify, Plaintiff has suffered and will continue to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

5. These injuries would not have manifested, or risen to the severity experienced, but for Plaintiff's use of Abilify.

6. While on Abilify, Plaintiff suffered from compulsive behavior, including pathological gambling among other issues, caused by the use of Abilify.

7. Plaintiff was unaware that Abilify caused compulsive behavior, and until recently, did not associate past compulsive behavior with Abilify.

8. In stark contrast, Defendants were aware since at least 2010 of the causal link between compulsive behavior and Abilify.

9. Defendants have not taken any steps to alert the Unites States public to this unnecessary danger posed by Abilify. Defendants have not updated Abilify's warning label or packaging instructions to indicate a causal link to compulsive behavior. Defendants have not sent "Dear Doctor" letters to inform the prescribing community about the risks and dangers regarding the use of Abilify. Defendants have sat passively and simply done nothing.

10. Had Plaintiff known the truth and risks related to Abilify and compulsive behavior, which has been known to Defendants for a significant period of time, Plaintiff would not have taken Abilify and consequently suffered serious injuries.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are citizens of states other than the state in which Plaintiff is domiciled.

12. Venue is proper in this District under 28 U.S.C. § 1391 inasmuch as a substantial part of the events or omissions giving rise to the claims occurred in this District.

13. For purposes of venue and a foreign defendant, this District is proper under 28 U.S.C. § 1391(c)(3).

14. At all times herein mentioned, Defendants conducted, and continue to conduct, a substantial amount of business activity and have committed a tort, in whole or in part, in this District. Defendants are registered to conduct business in this District, and engaged in interstate commerce when they advertised, promoted, supplied, and sold pharmaceutical products, including Abilify, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this District.

PARTIES

15. Plaintiff Cindy Himel is domiciled in Lafayette Parish, Louisiana.

16. Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is a Delaware corporation with its principal place of business in New York City, New York.

17. Defendant Otsuka Pharmaceutical Co., Ltd., is a foreign Japanese company, with its principal place of business in Tokyo, Japan.

18. Defendants Otsuka America Pharmaceutical, Inc. ("OAP"), Otsuka Pharmaceutical Development and Commercialization, Inc. ("OPDC"), and Otsuka Maryland Medicinal Laboratories, Inc. ("OMML") are subsidiaries of Otsuka America, Inc., which is a holding

company owned in its entirety by its parent company Defendant Otsuka Pharmaceutical Co., Ltd.

19. Defendant Otsuka America Pharmaceutical, Inc. is a Delaware corporation with its headquarters located in Princeton, New Jersey.

20. Defendant Otsuka Pharmaceutical Development and Commercialization, Inc. is a Delaware corporation with its headquarters located in Princeton, New Jersey.

21. Defendant Otsuka Maryland Medicinal Laboratories, Inc. is a Delaware corporation with its headquarters located in Rockville, Maryland.

FACTUAL BACKGROUND

Relevant Aripiprazole Information

22. Aripiprazole was first approved in November 2002 by the U.S. Food and Drug Administration ("FDA") as part of a co-development and a co-branded effort by Bristol-Myers and Otsuka Pharmaceutical Co., Ltd.[1]

23. Aripiprazole is classified as a partial agonist of the D3 receptor and a full agonist of the D2 receptor, which can also be referred to as a dopamine agonist.[2]

24. An agonist is a chemical that binds to a receptor and induces a biological response. Comparatively, an antagonist is a chemical that binds to a receptor and blocks a biological response.

25. Aripiprazole is chemically unique for an atypical antipsychotic. Specifically, "aripiprazole is chemically different from other atypical agents. It is a quinolinone derivative with a high affinity for dopamine D2 and D3 receptors, as well as serotonin 5-HT1A, 5-HT2A and 5-

[1] https://www.otsuka-us.com/our-history.html#2002
[2] A. Bartolemis, *et al.*, Update on the Mechanism of Action of Aripiprazole: Translational Insights into Antipsychotic Strategies Beyond Dopamine Receptor Antagonism CNS Drugs, 29:773–799 (2015).

HT2B receptors."[3]

26. As early as 2010, studies and case reports identified aripriprazole's ability to cause individuals to manifest compulsive behavior such as hypersexuality and addiction.[4]

27. Similar studies and case reports specific to pathological gambling were published around the same time period. One study observed that "[pathological gambling] appeared between a few days and a few months after aripiprazole was started, – sometimes only after dosage was increased – and it decreased between a few days and a few months after the treatment was stopped, even, in some cases, only after dosage was decreased."[5]

28. In another report, there were documented instances where two schizophrenic individuals developed pathological gambling. The report held "in both our cases, [pathological gambling] rapidly resolved once [the] dopamine partial agonist was discontinued. This close time relationship suggests a causal association."[6]

29. Evidence increasingly emerged supporting that a causal link between dopamine agonists and new-onset gambling exists. In a 2013 analysis of one-hundred seventy-seven patients with Parkinson Disease with new-onset gambling, a staggering 98% of patients were found to be taking a dopamine agonist.[7]

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[3] E. Pessina, *et al.*, Aripiprazole augmentation of serotonin reuptake inhibitors in treatment-resistant obsessive–compulsive disorder: a 12-week open-label preliminary study, Int Clin Psychopharmacol. 265-269 (Sep 24, 2009).
[4] M. Kodama, *et al.*, Aripiprazole-induced behavioural disturbance related to impulse control in a clinical setting, International Journal of Neuropsychopharmacoloy, 549–551 (2010).
[5] L. Gaboriau, C. Victorri-Vigneau, M. Gérardin, G. Allain-Veyrac, P. Jolliet-Evin, M. Grall-Bronnec, Aripiprazole: A new risk factor for pathological gambling? A report of 8 case reports, Addictive Behaviors 562–565 (2014).
[6] Aripiprazole - Pathological gambling: 2 case reports Reactions Weekly May 2011, Volume 1351, Issue 1, pp 11.
[7] R. Khalil, Dopamine D3 Receptor Antagonists in Pathologic Gambling, Journal of Clinical Psychopharmacology, Volume 33, Number 1, (February, 2013).

30. Even with these published reports and studies, Abilify is one of the most prescribed drugs in the United States. Interestingly, aripiprazole has been found to be less effective than olanzapine and no different in its efficacy when compared against risperdone.[8] In other words, Abilify is prescribed more often than cheaper, alternative drugs that are more effective in treating similar conditions.

Pathological Gambling

31. Among known compulsive behaviors caused by Abilify, pathological gambling is the most prevalent condition.

32. Pathological gambling is an identifiable disorder, and was first identified in Diagnostic and Statistical Manual of Mental Disorders – Third Edition ("DSM-III") in 1980.[9] Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition ("DSM-IV") re-classified pathological gambling ("PG") as an Impulse Control Disorder ("ICD") characterized by inadequate, repetitive and persistent gambling with repercussions on family, personal or professional life. DSM-IV established ten possible criteria in classifying PG behaviors, five of which were required to be diagnosed as a pathological gambler.[10]

33. Presently, Diagnostic and Statistical Manual of Mental Disorders, 5th Edition ("DSM-V") updated pathological gambling from an ICD to a diagnosis similar to one with traits and characteristics observed in substance use disorders.

34. The updated classification identifies that the brain's chemistry and impulses that

[8] P. Khanna, *et al.*, Aripiprazole versus other atypical antipsychotics for schizophrenia, Cochrane Database Syst Rev. (2014).
[9] National Research Council, Pathological Gambling: A Critical Review, National Academy Press, (1999).
[10] J. Cohen, Aripiprazole-Induced Pathological Gambling - A Report of 3 Cases, Current Drug Safety, 51-53 (2011).

result in compulsive behavior are the same whether it be for opiate drugs, alcoholism, or in Plaintiff's situation: pathological gambling.

Foreign Countries, Their Abilify Approvals, and
Pathological Gambling Warnings

35. Abilify is available in many countries including within the European Union and Canada.

36. Abilify was approved by the European Union's European Medicines Agency on June 6, 2004.

37. The European Medicines Agency updated Abilify's label on November 19, 2012 to include pathological gambling as a possible adverse effect. The update reflects the post-market reports linking pathological gambling to Abilify. The warning states:

> **"Pathological gambling**
> **Post-marketing reports of pathological gambling have been reported among patients prescribed aripiprazole, 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 (see section 4.8)."**[11]

38. After the European Union, Canada's Health Canada approved Abilify on July 9, 2009.

39. On November 2, 2015, Health Canada updated its Abilify label for issues related to pathological gambling. The update included hypersexuality as another impulse control related risk to Abilify. The warning states:

> **"Health Canada conducted a safety review following product labelling updates in Europe that linked the use of aripiprazole with the risk of uncontrollable gambling (pathological gambling), a type of behaviour where an individual cannot control their urges (impulse control behaviour). Health Canada's safety review showed evidence of a link between the use of Abilify and Abilify Maintena and an increased risk of certain impulse control behaviours: pathological gambling and uncontrollable sexual**

[11] http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000471/WC500020170.pdf

behaviours (hypersexuality). Therefore, Health Canada has updated the Canadian prescribing information for both products. Health Canada has issued an Information Update about these changes.

Health Canada's current review concludes that there is a link between the use of aripiprazole and a possible risk of pathological gambling or hypersexuality. After the totality of the evidence was considered, and because of the extensive use of Abilify, Health Canada has updated the Canadian prescribing information for Abilify and Abilify Maintena with the addition of a warning statement for the risk of pathological gambling and the inclusion of hypersexuality as a reported side effect (post-market adverse drug reaction). An Information Update has been issued to inform Canadians about these changes."[12]

40. These foreign label updates were done in 2012 and 2015, respectively. Yet, Defendants have failed to update the United States label to include any similar warning.

Abilify Regulatory History in the United States

41. Defendant Otsuka Pharmaceutical Co., Ltd. submitted New Drug Application #21-436. The New Drug Application ("NDA") was for the treatment of schizophrenia. The FDA approved NDA #21-436 on November 15, 2002. According to documented adverse reactions, the most common adverse reactions disclosed include agitation, anxiety, and insomnia.[13]

42. Defendant Otsuka Pharmaceutical Co., Ltd. submitted NDA #21-729 on December 22, 2003 for Abilify disintegrating oral tablets. The FDA approved NDA #21-729 on June 7, 2006.

43. Defendant Otsuka Pharmaceutical Co., Ltd. submitted NDA #21-866 on November 29, 2005 for an Abilify intramuscular injection of 7.5mg/mL. The FDA approved NDA #21-866 on September 20, 2006. The FDA approved NDA #21-866 for the treatment of "agitation associated with schizophrenia or bipolar I disorder, manic or mixed."[14]

44. As more variations of Abilify were approved, the most significant label revisions

[12] http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/abilify-eng.php
[13] http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/21436_Abilify_lbl.pdf
[14] http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/021866s000ltr.pdf

included the addition of a black-box warning for dementia-related issues and suicidal ideations.[15][16]

45. Presently, the following dosage forms and strengths for Abilify are available in the United States:

Tablets: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg

Orally Disintegrating Tablets: 10 mg and 15 mg

Oral Solution: 1 mg/mL

Injection: 9.75 mg/1.3 mL single-dose vial[17]

46. In addition to the various forms of drug delivery and dosage strengths, Abilify is now an acceptable medicine to treat: schizophrenia in adults; schizophrenia in adolescents; bipolar mania in adults as a monotherapy; bipolar mania in adults as an adjunct to lithium or valproate; bipolar mania in adolescents as a monotherapy; bipolar mania in adolescents as an adjunct to lithium or valproate; major depressive orders in adults as an adjunct to anti-depressants; Tourette's syndrome regardless of age; and agitation associated with schizophrenia or bipolar mania in adults.[18]

47. Even though Abilify's mechanism of action is unknown, other foreign, national regulatory agencies changed their warnings to include pathological gambling, but while the evidence overwhelmingly supports a causal link between Abilify and compulsive behavior, Defendants did not update Abilify's FDA label for concerns of pathological gambling until thirty-

[15] February 16, 2006 label revision: "Increased Mortality in Elderly Patients with Dementia-Related Psychosis."
[16] August 14, 2008 label revision: "INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDALITY AND ANTIDEPRESSANT DRUGS."
[17] http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/21436s04021713s03121729s02321866s025lbl.pdf
[18] http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/21436s04021713s03121729s02321866s025lbl.pdf

eight months after the European Union's initial warning for pathological gambling.

48. The FDA label update, however, did not acknowledge any causal link between pathological gambling and Abilify.

49. Interestingly, the supplemental NDA application for the label revision came from Defendant OPDC's Global Regulatory Affairs division, yet no mention is made in the FDA label about the EU or Canadian warnings.

50. Unlike the stronger warnings from foreign countries, on January 15, 2016, an OPDC Assistant Director of Global Regulatory Affairs received a letter approving an update to Abilify's label to include only a reference for pathological gambling. The updated label reads:

> "The following adverse reactions have been identified during post-approval use of ABILIFY. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to establish a causal relationship to drug exposure: occurrences of allergic reaction (anaphylactic reaction, angioedema, laryngospasm, pruritus/urticaria, or oropharyngeal spasm), pathological gambling, hiccups and blood glucose fluctuation."[19]

51. Unlike dementia and suicide-related warnings, the pathological gambling language is not a black-box warning, the FDA label's strongest warning, and does not acknowledge any link between Abilify and pathological gambling.

52. The FDA recently made public its concerns about Abilify. Unlike foreign countries, the FDA observed that many compulsive behaviors, not only pathological gambling, are linked to Abilify. The warning came directly from the FDA in the form of a Safety Communication rather than the typical procedure wherein the manufacturer updates the label.

53. The Safety Communication on May 3, 2016 stated in part:

> **"The U.S. Food and Drug Administration (FDA) is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with**

[19]http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/21436s04021713s03121729s023218 66s025lbl.pdf

> **the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized.**
>
> **Although pathological gambling is listed as a reported side effect in the current aripiprazole drug labels, this description does not entirely reflect the nature of the impulse-control risk that we identified. In addition, we have become aware of other compulsive behaviors associated with aripiprazole, such as compulsive eating, shopping, and sexual actions. These compulsive behaviors can affect anyone who is taking the medicine. As a result, we are adding new warnings about all of these compulsive behaviors to the drug labels and the patient Medication Guides for all aripiprazole products**…"[20]

54. Further, the Safety Communication reported that one-hundred sixty-seven individuals reported previously non-existent compulsive behavior after they began Abilify use. One-hundred sixty-four of these individuals identified the compulsive behavior as pathological gambling.[21]

55. Despite evidence that continues to identify a causal link between Abilify and compulsive behavior, which includes pathological gambling, Defendants have not addressed this recent FDA Safety Communication. Defendants have not provided any public statements, any press releases, sent "Dear Doctor" letters, or updated Abilify's warning to address links to compulsive behaviors.

56. Not only have Defendants not addressed the FDA's statement that there is a causal link between Abilify and compulsive behavior, Defendants have not addressed any case report or scientific study related to Abilify and compulsive behavior since they first started to emerge in the last decade.

[20] http://www.fda.gov/Drugs/DrugSafety/ucm498662.htm
[21] *Id.*

Defendants' Abilify History

57. Defendants Bristol-Myers Squibb Company and Otsuka Pharmaceutical Co., Ltd. entered into a co-development and co-commercialization agreement for the United States and European Union in 1999.[22]

58. The co-development and co-commercialization agreement was extended by Bristol-Myers and Otsuka Pharmaceutical Co., Ltd. in 2009.[23]

59. Abilify sales were very strong since its debut in 2002, and were in excess of $20.24 billion for Bristol-Myers during its agreement with Otsuka Pharmaceutical Co., Ltd.

60. Bristol-Myers recognized net sales for Abilify across the United States and the European Union as "$746 million in 2015, $2 billion [in 2014], $2.3 billion in 2013"[24] "$2.8 billion in 2012"[25] "$2.8 billion in 2011 and $2.6 billion in both 2010 and 2009…"[26] "…$2.2 billion in 2008, $1.7 billion in 2007"[27] "$1,282 million in 2006, $912 million in 2005…"[28] "$593 million in 2004, $283 million in 2003 and $25 million in 2002."[29]

61. Comparatively the estimated non-discounted sales in the United States alone were estimated at $4.6 billion in 2010, $5.3 billion in 2011, $5.7 billion in 2012, $6.5 billion in 2013, and $7.8 billion in 2014. The non-discounted sales amount to an estimated $29.9 billion over that five-year period.[30]

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[22] https://www.otsuka.com/en/ir/library/pdf/2014/2014_all.pdf
[23] https://www.otsuka.co.jp/en/company/release/2009/0406_01.html
[24] Bristol-Myers Squibb 10-K Filing February 12, 2016.
[25] Bristol-Myers Squibb 10-K Filing February 13, 2013.
[26] Bristol-Myers Squibb 10-K Filing February 17, 2012.
[27] Bristol-Myers Squibb 10-K Filing February 19, 2010.
[28] Bristol-Myers Squibb 10-K Filing February 26, 2007.
[29] Bristol-Myers Squibb 10-K Filing March 4, 2005.
[30] Medicines Use and Spending Shifts. Report by the IMS Institute for Healthcare Informatics (April 2015).

62. The discrepancy between the net sales and non-discounted sales is explained, in-part, by Defendants' strong marketing for Abilify and expensive cost for the prescription drug. Prices for the drug ranged anywhere from $800 to $1,400 for a one-month supply.

63. In 2012, for example, Defendants marketed and offered a program for adults with major depression to receive a free thirty-day trial and save up to $100 per refill for the next seventeen Abilify refills.

64. A more recent promotion by Defendant OAP offered a savings card for eligible individuals to purchase Abilify. "With this Savings Card, eligible, commercially insured patients can save on their out-of-pocket costs and pay as little as $5 per co-pay for their ABILIFY® (aripiprazole) prescriptions." In the same promotion, the "Ambassador of Savings" displayed for the program is Abraham Lincoln.[31]

65. Yet, according to a study conducted by AARP on rising drug cost, it is noted that "[t]he retail price of a one-year supply of Abilify 20 mg tablets increased by $6,507 in the 8-year period ending in 2013. The retail price for a 1-year supply of this drug rose from $5,247 in 2006 to $11,755 in 2013."[32]

66. Plainly, the incentives provided by Defendants do not help most individuals, however, since Abilify's cost is so high, and therefore these plans do not significantly affect Defendants' Abilify revenue.

67. During the same time period, Defendant Otsuka American Pharmaceutical Inc. made paid over $10,300,000 in payments for Abilify and over $13,300,000 for Abilify Maintena

[31] http://www.abilify.com/using-the-savings-card.aspx
[32]http://www.aarp.org/content/dam/aarp/ppi/2014-11/rx-price-watch-report-AARP-ppi-health.pdf

to physicians and hospitals while promoting the drug.[33]

68. Unsurprisingly, Defendants' Abilify marketing and promotions did not avoid scrutiny and possibly violated state and federal laws.

69. In 2006, for example, California subpoenaed Bristol-Myers about Abilify to understand how the company marketed the drug.

70. In 2007, the Department of Justice then settled with Bristol-Myers for over $515 million, in part, because "from 2002 through the end of 2005, BMS knowingly promoted the sale and use of Abilify, an atypical antipsychotic drug, for pediatric use and to treat dementia-related psychosis, both "off-label" uses."[34] This settlement included payments to many states as well to resolve litigation for off-label marketing allegations.

71. In 2008, the Department of Justice settled with Otsuka American Pharmaceutical Inc. to resolve off-label marketing "allegations that, from 2002 through the end of 2005, Otsuka knowingly promoted the sale and use of Abilify for pediatric use and to treat dementia-related psychosis."[35]

72. In 2011, California joined a whistle blower suit against Bristol-Myers wherein then California Insurance Commissioner Dave Joes estimated that the Bristol-Myers spent at least $3.5 billion in his state alone from 1999 until 2006 to persuade doctors to promote their drugs.

73. On April 17, 2015, the FDA sent an untitled warning letter Lois M. Jessen, MS, PharmD, Associate Director at OPDC because certain Abilify promotional materials were "false

[33] https://projects.propublica.org/docdollars/company/otsuka-america-pharmaceutical-inc
[34] https://www.justice.gov/archive/opa/pr/2007/September/07_civ_782.html
[35] https://www.justice.gov/archive/opa/pr/2008/March/08_civ_244.html

or misleading because it makes misleading claims and presentations about the drug."[36]

> **"These references are 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. If you have data to support these claims, please submit them to FDA for review. We acknowledge that the bolded headline claims on pages one through three and six include a footnote more accurately describing what is known about the mechanism of action5 for Abilify. However, this footnote does not mitigate the misleading nature of the claims and presentations described above.**
>
> **Furthermore, the totality of these claims and presentations is also misleading because it implies that Abilify offers advantages over other currently approved treatments for bipolar disorder or MDD when this has not been demonstrated."**

Plaintiff's Abilify Exposure

74. Plaintiff was prescribed 2mg daily of Abilify in or about February 2013.

75. Plaintiff's Abilify prescription strength was increased to 5mg in or about June 2013.

76. Plaintiff continues to take Abilify, or its generic equivalent, to this day.

77. Prior to being placed on Abilify, Plaintiff rarely gambled. Plaintiff's gambling was limited to approximately once or twice a year.

78. While on Abilify, Plaintiff developed a dangerous compulsive gambling habit that she could not control.

79. Plaintiff would play exclusively at the Evangeline Downs Casino located near Lafayette, Louisiana.

80. As a result of the effects of Abilify, Plaintiff began to lose large amounts of money. This was money that she could not afford to spend – let alone lose while gambling.

81. From approximately September 16, 2013 to September 18, 2013, for example,

[36]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM443935.pdf

Plaintiff withdrew in excess of $3,300 from the Evangeline Downs Casino ATMs.

82. On another occasion between approximately October 18, 2013 and October 24, 2013, Plaintiff withdrew an additional amount in excess of $5,500 from the Evangeline Downs Casino ATMs.

83. When Plaintiff withdrew funds, it was done in a compulsive manner that she could not stop or control.

84. Plaintiff's behavior on or about October 21, 2013 is a further example of her uncontrollable urges to pathologically gamble while on Abilify. On this date, Plaintiff made at three separate withdrawals of $300 at 11:03 AM; $300 at 11:15 AM; and $400 at 11:42 AM. Plaintiff compulsively gambled away $1,000 within approximately thirty-nine minutes.

85. As a result of Plaintiff's pathological gambling compulsion, Plaintiff lost tens of thousands of dollars at Evangeline Downs Casino.

86. Through the intervention and support of her husband, Plaintiff sought treatment for gambling.

87. Presently, Plaintiff sees a counselor each week, attends weekly Gambler Anonymous meetings, and is a part of a state-funded program to help individuals with gambling problems.

EQUITTABLE TOLLING OF CLAIMS

88. The statute of limitations in this action is tolled due to Defendants' fraudulent concealment of the dangerous side effects of Abilify. Plaintiff did not know and could not have known of the causal link between Abilify and compulsive behaviors, including, without limitation, pathological gambling. Plaintiff did not learn about the causal connection between Abilify and compulsive behaviors until June 2016. The facts concealed by Defendants prevented Plaintiff from

exercising ordinary diligence that he was injured due to the fault of Defendants.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
Strict Products Liability

89. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

90. Abilify was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants.

91. At the time Abilify left Defendants' control and into the stream of commerce, it was defective in that, without limitation, the required drug label and literature failed to include adequate warnings, instructions, and directions related to risks associated with Abilify use and compulsive behavior.

92. Safe and more effective products were and are available for the same psychological conditions Abilify was marketed, and neither the safety nor the efficacy of Abilify for these conditions have been established.

93. Abilify was not reasonably fit, suitable or safe for its intended purpose because it failed to contain adequate warning or instructions about the dangers related to compulsive behavior, and because it was designed in a defective manner.

94. Defendants failed to provide adequate warnings to users, purchasers, or prescribers, including Plaintiff, about the increased risk of compulsive behavior with Abilify and promoted the product off-label to doctors and to hospitals.

95. Defendants failed to provide adequate warnings to users, purchasers, or prescribers of Abilify, including Plaintiff, and continues to sell Abilify without adequate warnings or

instructions that are statutorily required.

96. Defendants had a duty to exercise reasonable care, and comply with existing standards of care, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of Abilify into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

97. Patients, including Plaintiff, neither knew, nor had reason to know, at the time of their Abilify use, of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which Abilify failed to include appropriate warnings, and which Defendants have completely ignored while they continue to aggressively promote the drug.

98. At all times herein mentioned, due to Defendants' marketing of Abilify, the drug was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

99. Defendants' negligence was the proximate cause of Plaintiff's neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

100. Defendants' negligence, as the proximate cause of Plaintiff's neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life, will continue to cause these injuries.

101. As a direct and proximate result of the defective nature of Abilify, Plaintiff suffered neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

102. As a direct and proximate result of the defective nature of Abilify, Plaintiff will continue to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

SECOND CAUSE OF ACTION
Strict Liability - Design Defect

103. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

104. Abilify is further defective in its design because there is a foreseeable risk of harm posed by the drug, especially since its mechanism of action is unknown, that could have been reduced or eliminated through a reasonable alternative design.

105. Abilify was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants.

106. At the time Abilify left Defendants' control and entered the stream of commerce, it was defective in that, without limitation, the required drug label and literature failed to include adequate warnings, instructions, and directions related to risks associated with Abilify use and compulsive behavior.

107. Abilify was not reasonably fit, suitable or safe for its intended purpose because it was designed in a defective manner.

108. Defendants knew, or should have known, the product was not reasonably safe, and therefore should have provided a practical and feasible alternative design that would have reduced or prevented harm to the Plaintiff.

109. As a direct and proximate result of the defective nature of Abilify, Plaintiff suffered neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

110. As a direct and proximate result of the defective nature of Abilify, Plaintiff will continue to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

THIRD CAUSE OF ACTION
Strict Liability – Failure to Warn

111. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

112. Abilify is further defective in its design because there is a foreseeable risk of harm posed by the drug, especially since its mechanism of action is unknown, that could have been reduced or eliminated through a reasonable alternative design.

113. Abilify was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants.

114. At the time Abilify left Defendants' control and entered the stream of commerce, it was defective in that, without limitation, the required drug label and literature failed to include adequate warnings, instructions, and directions related to risks associated with Abilify use and compulsive behavior.

115. Abilify was not reasonably fit, suitable or safe for its intended purpose because Defendants failed to provide a warning or instruction on Abilify's label.

116. Defendants' warning was, and continues to be, inadequate because Defendants failed, and continue to fail, to act in a reasonably prudent manner to provide an adequate warning.

117. As a direct and proximate result of the defective nature of Abilify, Plaintiff suffered neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

118. As a direct and proximate result of the defective nature of Abilify, Plaintiff will

continue to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

FOURTH CAUSE OF ACTION
Negligence *Per Se*

119. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

120. Defendants, their agents, servants, and/or employees, failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201, in particular.

121. Defendants had a duty to exercise reasonable care, and observe and comply with existing laws, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of Abilify into the stream of commerce.

122. Defendants had a duty to ensure that Abilify would not cause users to suffer unreasonable, dangerous side effects.

123. Defendants failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Abilify into interstate commerce in that Defendants knew or should have known that using Abilify created an unreasonable risk of compulsive behaviors.

124. Defendants violated laws designed to protect Plaintiff against the risks in this immediate action. Therefore, Defendants' conduct constitutes negligence *per se*.

125. These actions were taken when Defendants knew or should have known that Abilify increased compulsive behavior risk, and Defendants continue to negligently and misleadingly market, manufacture, distribute and/or sell Abilify.

126. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as described above.

127. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered and/or will continue to suffer.

128. Plaintiff would not have suffered the injuries and damages as described herein if Plaintiff did not take Abilify.

129. As a result of Defendants' previous acts and omissions, Plaintiff suffered neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

130. Defendants' previous acts and omissions will cause Plaintiff further neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

FIFTH CAUSE OF ACTION
Fraudulent Misrepresentation

131. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

132. Defendants falsely and fraudulently represented to the general public, the medical profession, and the healthcare community, including Plaintiff and Plaintiff's providers, that:

a. Abilify was safe and effective for the treatment of bipolar disorder;

b. Abilify was adequately tested and studied for adverse effects;

c. Abilify use did not increase risks of compulsive behavior; and

d. Recent updates to Abilify's label were of sufficient scope and truthfully disclosed to the general public, the medical profession, and the healthcare community, including Plaintiff and Plaintiff's providers, that Abilify was

not causally linked to pathological gambling.

133. Defendants' representations were material.

134. Defendants' representations were false.

135. Defendants' representations were misleading.

136. Defendants knew these representations to be false and misleading.

137. Defendants made the representations with the intent to defraud and deceive the general public, the medical profession, and the healthcare community, including Plaintiff and Plaintiff's providers.

138. Defendants' representations were made to induce the general public, the medical profession, and the healthcare community, including Plaintiff and Plaintiff's providers, to not only recommend Abilify, but also prescribe Abilify, dispense Abilify and/or purchase Abilify to treat bipolar disorder, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff herein.

139. At the time the representations were made by Defendants and when Plaintiff used Abilify, Plaintiff was unaware of the devious falsity of said representations and reasonably believed them to be true.

140. In reliance upon these representations, Plaintiff's physicians or prescribers were induced to prescribe Abilify to Plaintiff, and Plaintiff was induced to and did, in fact, use Abilify to treat bipolar disorder.

141. Defendants knew that Abilify's unknown mechanism of action created a complete inability to sufficiently test for dopaminergic activity and Abilify's affinity for specific dopamine receptors therefore unable to provide any warning.

142. Defendants knew or should have known that Abilify use increases compulsive

behavior.

143. Defendants' acts and omissions caused Plaintiff to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

144. Defendants' acts and omissions will cause Plaintiff to continue to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

SIXTH CAUSE OF ACTION
Fraudulent Concealment

145. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

146. Defendants' representations to the FDA, healthcare providers, medical providers, and possible users of Abilify including Plaintiff, fraudulently concealed and intentionally omitted the following material facts:

a. Defendants previously illegally paid and offered to pay pediatricians and long-term care facilities for the elderly to promote and prescribe Abilify;

b. Abilify, at the time, included a black-box warning for dementia-related psychosis yet Defendants approached elder care facilities to promote Abilify off-label; and

c. Presently, Defendants have concealed and intentionally omitted information related to compulsive behavior, including, without limitation, compulsive gambling.

147. Defendants' concealment and omissions of material facts concerning, among other issues, the causal link between Abilify and compulsive behavior, is willfully, wantonly, and/or recklessly, done to mislead the general public, the medical profession, and the healthcare community, including Plaintiff and Plaintiff's providers, to continue to use Abilify, and to further

promote, purchase, prescribe, and/or dispense Abilify.

148. Defendants' knew that the general public, the medical profession, and the healthcare community, including Plaintiff and Plaintiff's providers had no way to determine Defendants' deceptive concealment and material omissions of facts about Abilify.

149. Plaintiff and Plaintiff's providers reasonably relied on Defendants' promotional statements that asserted Abilify as safe and effective yet Defendants' negligently, fraudulently and/or purposefully omitted material facts including the risk of compulsive behavior and Abilify use.

150. As a result, Defendants' acts and omissions caused Plaintiff to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

151. Defendants' acts and omissions will cause Plaintiff to suffer further neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

SEVENTH CAUSE OF ACTION
Breach of Express Warranty

152. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

153. Defendants expressly warranted that:

a. Abilify was safe and effective;

b. Abilify was adequately tested and studied; and

c. Abilify does not have a causal link with pathological gambling.

154. Abilify does not conform to these express representations because Abilify is not safe, and Defendants lack adequate tests to support that the drug has been adequately studied.

155. Defendants' lack of adequate tests makes any assertion, denial, or statement related to the safety, efficacy, or risks related to Abilify a breach of said express warranties.

156. Defendants made these affirmations of fact, promise, and description as part of the bargain for the purchase of Abilify.

157. Abilify did not conform with Defendants' affirmations of fact, promise, and description.

158. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm, mental anguish and economic loss.

159. Plaintiff and Plaintiff's physicians relied on Defendants' express warranties.

160. Members of the medical community, including physicians and other healthcare professionals, relied upon Defendants' representations and warranties for use of Abilify in recommending, prescribing, and/or dispensing for bipolar disorder.

161. Defendants knew or should have known that said representations and warranties were false, misleading and untrue because Abilify was not safe or fit for the purpose promoted, expressly warranted and intended by Defendants.

162. As a result, Defendants' acts and omissions caused Plaintiff to suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

163. Defendants' acts and omissions will cause Plaintiff to further suffer neurological injury, physical injury, emotional distress, emotional harm, economic loss, economic distress, and a diminished enjoyment of life.

EIGHTH CAUSE OF ACTION
Redhibition, La. Civ. Code art. 2520

164. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

165. Under Louisiana law, a seller "warrants the buyer against redhibitory defects, or vices, in the thing sold." La. Civ. Code art. 2520.

166. Defendants manufactured, distributed, marketed, sold and/or otherwise released into the stream of commerce Abilify, and directly marketed the product to healthcare professionals and consumers.

167. Abilify contains a redhibitory defect in that it induces pathological and compulsory behavior in some patients, causing out-of-character, deleterious behavior. This defect renders Abilify so dangerous that buyers would not have purchased it, had they known about said defect.

168. Plaintiff is thus entitled to obtain a rescission of the sale of Abilify.

169. Defendants knew that Abilify was defective when it left their control and entered the stream of commerce. They are thus “liable for the return of the price with interest from the time it was paid, for the reimbursement of the reasonable expenses occasioned by the sale and those incurred for the preservation of the thing, and also for damages and reasonable attorney fees.” La. Civ. Code Ann. § art. 2545.

NINTH CAUSE OF ACTION
Punitive Damages

170. Plaintiff re-alleges each allegation of this Complaint contained in the previous paragraphs as if fully set forth herein.

171. Plaintiff requests punitive damages against Defendants as Defendants were aware of Abilify’s unnecessary risk of injury.

172. Plaintiff requests punitive damages against Defendants as Defendants were culpably indifferent to Abilify's unnecessary risk of injury.

173. Although Defendants were aware and/or culpably indifferent, Defendants refuse to take steps to reduce Abilify's danger to an acceptable level.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action as follows:

a. For general damages in a sum in excess of the jurisdictional minimum of this Court;

b. For all medical, psychiatric, incidental, and hospital expenses according to proof;

c. For pre-judgment and post-judgment interest as provided by law;

d. For full refund of all purchase costs of Abilify;

e. For consequential damages in excess of the jurisdictional minimum of this Court;

f. For compensatory damages in excess of the jurisdictional minimum of this Court;

g. For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish Defendants for the conduct described herein;

h. For attorneys' fees, expenses and costs of this action; and

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

JURY DEMAND

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

Dated: September 12, 2016

Respectfully submitted,

By: /s/Alexandra K. Piazza
Alexandra K. Piazza
Shanon J. Carson*
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Telephone: (215) 875-3000
Facsimile: (215) 875-4604
Email: apiazza@bm.net
Email: scarson@bm.net

Greg F. Coleman*
Adam A. Edwards*
GREG COLEMAN LAW P.C.
800 S. Gay Street, Suite 1100
Knoxville, TN 37929
Telephone: 865-247-0080
Facsimile: 865-522-0049
Email: greg@gregcolemanlaw.com
Email: adam@gregcolemanlaw.com

Counsel for Plaintiff

**Motions for Pro Hac Vice forthcoming*

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
Cindy Himel

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alexandra K. Piazza
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103 215-875-3000

DEFENDANTS
Bristol-Myers Squibb Company, et al.

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

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. § 1332 - Diversity
Brief description of cause:
Pharmaceutical Products Liability Action

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND $ 75,001.00
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:
JUDGE _____ DOCKET NUMBER _____

DATE 09/12/2016
SIGNATURE OF ATTORNEY OF RECORD Alexandra K. Piazza

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

New Jersey

Cindy Himel

Plaintiff(s)

v.

Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka Maryland Medicinal Laboratories, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bristol-Myers Squibb Company
The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Alexandra K. Piazza
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

New Jersey

Cindy Himel

Plaintiff(s)

v.

Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka Maryland Medicinal Laboratories, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Otsuka America Pharmaceutical, Inc.
The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Alexandra K. Piazza
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

New Jersey

Cindy Himel

Plaintiff(s)

v.

Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka Maryland Medicinal Laboratories, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Otsuka Maryland Medicinal Laboratories, Inc.
The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Alexandra K. Piazza
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

New Jersey

Cindy Himel

Plaintiff(s)

v.

Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka Maryland Medicinal Laboratories, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Otsuka Pharmaceutical Co., Ltd.
2-9, Kanda Tsukasa-machi, Chiyoda-ku
Tokyo 101-8535, Japan

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Alexandra K. Piazza
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

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Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

New Jersey

Cindy Himel

Plaintiff(s)

v.

Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka Maryland Medicinal Laboratories, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Otsuka Pharmaceutical Development and Commercialization, Inc.
The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Alexandra K. Piazza
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: