Exhibit A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF New York

Cheyenne Beth Confer

Plaintiff(s),

-against-

Bristol-Myers Squibb Company and Otsuka American Pharmaceutical Inc.

Defendant(s).

Index No.

Summons

Date Index No. Purchased: 8/22/14

To the above named Defendant(s)

Bristol-Myers Squibb Company c/o CT Corporation System
111 8th Ave
New York, NY 10011

You are hereby summoned to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's attorney within 20 days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

The basis of venue is Location of defendant and all/part of the causes of action occurred there which is Bristol-Myers Squibb Company, 345 Park Ave., New York, NY

Dated: August 22, 2014

The D'Onofrio Firm, LLC
by _____
Louis F. D'Onofrio, Esquire
Attorneys for Plaintiff
Cheyenne Beth Confer
347 5th Avenue, Suite 1402-215
New York, NY 10016
Telephone: 646-205-8082

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF New York

Cheyenne Beth Confer

Plaintiff(s),

-against-

Bristol-Myers Squibb Company and Otsuka American Pharmaceutical Inc.

Defendant(s).

Index No.

Summons

Date Index No. Purchased: 8/22/14

To the above named Defendant(s)

Otsuka American Pharmaceutical Inc. c/o CT Corporation System
1633 Broadway
New York, NY 10019

You are hereby summoned to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's attorney within 20 days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

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Dated: August 22, 2014

The D'Onofrio Firm, LLC
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New York, NY 10016
Telephone: 646-205-8082

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF New York

---x

Cheyenne Beth Confer

Plaintiff/Petitioner,

- against -

Index No. _____

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

Defendant/Respondent.

---x

NOTICE OF COMMENCEMENT OF ACTION SUBJECT TO MANDATORY ELECTRONIC FILING

PLEASE TAKE NOTICE that the matter captioned above, which has been commenced by filing of the accompanying documents with the County Clerk, is subject to mandatory electronic filing pursuant to Section 202.5-bb of the Uniform Rules for the Trial Courts. This notice is being served as required by Subdivision (b) (3) of that Section.

The New York State Courts Electronic Filing System ("NYSCEF") is designed for the electronic filing of documents with the County Clerk and the court and for the electronic service of those documents, court documents, and court notices upon counsel and self-represented parties. Counsel and/or parties who do not notify the court of a claimed exemption (see below) as required by Section 202.5-bb(e) must immediately record their representation within the e-filed matter on the Consent page in NYSCEF. Failure to do so may result in an inability to receive electronic notice of document filings.

Exemptions from mandatory e-filing are limited to: 1) attorneys who certify in good faith that they lack the computer equipment and (along with all employees) the requisite knowledge to comply; and 2) self-represented parties who choose not to participate in e-filing. For additional information about electronic filing, including access to Section 202.5-bb, consult the NYSCEF website at www.nycourts.gov/efile or contact the NYSCEF Resource Center at 646-386-3033 or efile@courts.state.ny.us.

Dated: 8/22/14

_____ (Signature)

Louis F. D'Onofrio (Name)

The D'Onofrio Firm, LLC (Firm Name)

347 5th Avenue, Suite 1402-215 (Address)
New York, NY 10016

646-205-8082 (Phone)

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To: Bristol-Myers Squibb Company
c/o CT Corporation System
111 8th Ave.
New York NY 10011

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF New York

---x

Cheyenne Beth Confer

Plaintiff/Petitioner,

- against -

Index No. _____

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

Defendant/Respondent.

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Dated: 8/22/14

(Signature)

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To: Otsuka American Pharmaceutical, Inc.
c/o CT Corporation System
1633 Broadway
New York NY 10019

SUPREME COURT OF NEW YORK
NEW YORK COUNTY

CHEYENNE BETH CONFER, Plaintiff, -against- BRISTOL-MYERS SQUIBB COMPANY AND OTSUKA AMERICAN PHARMACEUTICAL INC., Defendants.	Index No. **COMPLAINT**

TO THE SUPREME COURT OF THE STATE OF NEW YORK

The Named Plaintiff, by her attorney Louis F. D'Onofrio of The D'Onofrio Firm LLC, alleges upon knowledge to itself and upon information and belief as to all other matters as follows:

PRELIMINARY STATEMENT

1. This case involves the atypical antipsychotic prescription drug Abilify®, which is manufactured, sold, distributed, and promoted by Defendants.

2. Abilify® was initially approved by the Federal Drug Administration to treat adult schizophrenia and bi-polar disorder, and was later approved by FDA for treatment of schizophrenia in adolescents aged 13 to 17 years, and for treatment of acute manic or mixed episodes associated with Bipolar I Disorder and autism irritability in pediatric patients.

3. Defendants misrepresented the pediatric diabetes mellitus risk profile for Abilify®. Defendants labeling for Abilify® has consistently failed to provide adequate information about the relative risk exposed for the development of Type II diabetes mellitus in children taking the drug.

4. The risk of diabetes in youth taking atypical antipsychotic drugs increases

with dosage: 2.1 times the risk at low doses; 3.4 times the risk at medium doses; and 5.4 times the risk at high doses. The risk associated with average dose for Abilify® increases the diabetes risk 7.72 times above normal.

5. Defendants failed to adequately warn physicians about the magnitude of the risk of development of Type II diabetes mellitus associated with Abilify®, when the drug is used by pediatric patients. If fact, the labeling for Abilify® entirely fails to quantify the risk to pediatric patients.

6. Plaintiff was prescribed Abilify® while she was a child, took the medication as directed by her physician(s) and subsequently developed Type II diabetes mellitus.

JURISDICTION

7. This Court has jurisdiction over the Defendants because the Defendants have at all relevant times transacted business in New York, and/or has committed a tort in whole or in part in New York, and Defendant Bristol-Myers Squibb Company is a resident and citizen of the State of New York. In the instant case, the provision of Section 1441 which prevents removal is triggered because the Defendant Bristol-Myers Squibb Company is a citizen of New York, the Defendant is properly joined, and service has been requested. *See, e.g.*, 28 U.S.C. § 1441(b)(2). This Court also has jurisdiction over the controversy because the damages are above the minimum jurisdictional limits. The Defendants are amenable to service of process by a New York court.

8. There is no basis for federal court jurisdiction over this matter:

a. Plaintiff has not pleaded nor does Plaintiff intend to plead any claim cognizable under federal law or any federal code, regulation, rule, statute, or otherwise;

b. There is an in-state or local defendant and service has been requested. Pursuant to 28 U.S.C. § 1441(b)(2), this case cannot be properly removed to federal court.

9. Venue is proper in New York County because the Defendants transacts business in New York County, New York and all or part of the causes of action occurred or accrued in New York County, New York.

THE PARTIES

10. Plaintiff Cheyenne Beth Confer is a natural person who was born on September 1, 1994, and who is a citizen and resident of the State of Pennsylvania.

11. Defendant Bristol-Myers Squibb Company, is incorporated in Delaware and has its principle place of business at 345 Park Avenue, New York, New York. Service of process on Bristol-Myers Squibb Company, may be made by serving its agents for service:

Bristol-Myers Squibb Company
c/o CT CORPORATION SYSTEM
111 8th Ave.
New York, NY 10011

At all relevant times Bristol-Myers Squibb Company was in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting,

packaging, and/or advertising for sale or selling the prescription drug Abilify® throughout the United States.

12. Defendant Otsuka American Pharmaceutical Inc., is the American subsidiary of Japanese pharmaceutical manufacturer Otsuka Pharmaceutical Co., Ltd., and is incorporated in Delaware and has its principle place of business at Otsuka America Pharmaceutical, Inc. Rockville, MD 20850. Service of process on Otsuka American Pharmaceutical Inc., may be made by serving its registered agent for service:

Otsuka American Pharmaceutical Inc.
c/o CT CORPORATION SYSTEM
1633 Broadway
New York, NY 10019

At all relevant times, Otsuka American Pharmaceutical Inc., was in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising for sale or selling the prescription drug Abilify® throughout the United States.

FACTS

13. At all times herein mentioned, the Defendants were engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising for sale or selling the prescription drug Abilify® for the use and application by psychiatric patients, including, but not limited to, Plaintiff.

14. Abilify® was first marketed in the United States in 2002.

15. Bristol-Myers Squibb Company has a worldwide commercialization agreement with Otsuka Pharmaceutical Co., Ltd. to co-develop and co-promote Abilify®, for the treatment of schizophrenia, bipolar mania disorder, and major depressive disorder.

16. Bristol-Myers Squibb Company and Otsuka American Pharmaceutical Inc. co-promote and co-market Abilify® in the United States.

Development of Antipsychotic Drugs for the Treatment of Schizophrenia

17. Schizophrenia is a serious and debilitating mental disease affecting approximately one percent of the human population.

18. Despite extensive research, the cause, mechanism, and etiology of schizophrenia were unknown in 2002 and remain unknown today.

19. Researchers believe that both genetic and environmental factors may play a role in the cause of the illness. Individuals with schizophrenia suffer from positive symptoms, negative symptoms, and cognitive deficits. Positive symptoms include hallucinations and delusions, while negative symptoms include flat affect, poverty of speech, inability to experience pleasure, lack of desire to form relationships, and lack of motivation.

20. The first antipsychotic drug, chlorpromazine, was discovered by accident in the early 1950s. After chlorpromazine was discovered, researchers determined that its antipsychotic properties were due to its antagonism, or blocking, of dopamine receptors in the brain.

21. That key finding led to the development of other "typical" antipsychotics, including haloperidol, thiothixene, trifluoperazine, fluphenazine, thioridazine, mesoridazine, loxapine, molindone, perphenazine, and pentoxide.

22. Typical antipsychotic drugs treat the positive symptoms of schizophrenia, but not the negative symptoms.

23. Typical antipsychotic drugs also have problematic side effects, including extrapyramidal symptoms, tardive dyskinesia, prolactin elevation (hyperprolactinemia), and sudden decrease in blood pressure (orthostatic hypotension). Despite these various drawbacks, the typical antischizophrenic drugs are still used today. Loxapine was the last of the typical antipsychotics to be approved by the FDA, in 1975.

24. The adverse side effects of the first-generation typical antipsychotics led researchers to seek alternatives with a better side effect profile, particularly with regard to extrapyramidal symptoms.

25. Clozapine discovered in the early 1960s, was the first "atypical" antipsychotic drug in that it had diminished propensity to cause extrapyramidal symptoms.

26. Clozapine also differed from typical antipsychotics in that it was useful in treating both positive and negative symptoms of schizophrenia. However, clozapine has several potential adverse side effects including agranulocytosis, a life-threatening decrease in white blood cells; orthostatic hypotension; and frank hypotension.

27. Because of its side effect profile, clozapine was withdrawn from clinical trials in the 1970s and not approved by the FDA for treatment of schizophrenia until 1990, and then only for treatment-resistant or treatment-intolerant patients, subject to rigorous blood testing.

28. Scientists have been attempting since the early 1970s to discover an atypical antipsychotic treatment for schizophrenia that would be similar to clozapine in

efficacy, but without the toxicity and significant side effects. These efforts, however, were largely unsuccessful, and the FDA approved no new antipsychotic drugs between 1976 and 1989.

29. Risperidone was the first post-clozapine atypical antipsychotic approved by the FDA, in 1994. While clozapine remains the "gold standard" with respect to efficacy, a total of nine atypical antipsychotics, including aripiprazole, have now been approved by the FDA and are considered at least as effective as typical antipsychotic drugs in treating the positive symptoms of schizophrenia and also have shown superiority over typical antipsychotic drugs in improving the negative symptoms of schizophrenia.

30. The FDA-approved atypical antipsychotics are clozapine (1990), risperidone (approved in 1993 and first marketed in 1994), olanzapine (1996), quetiapine (1997), ziprasidone (2001), aripiprazole (2002), paliperidone (2007), asenapine (2009), and iloperidone (2009).

31. With the exception of aripiprazole, all FDA-approved atypical antipsychotics are structurally related to either clozapine or risperidone.

32. Aripiprazole is a carbostyril derivative with a butoxy linker at the 7-position of the carbostyril core. The butoxy linker consists of four methylene (CH) units, whereas a propoxy linker consists of three methylene units. Because aripiprazole has two hydrogens at positions 3 and 4 of the carbostyril ring, it is referred to as a "dihydrocarbostyril."

33. Dihydrocarbostyrils and carbostyrils are carbostyril derivatives. A dihydrocarbostyril has a single bond between positions 3 and 4 whereas a carbostyril has a double bond.

34. Aripiprazole has a piperazine ring connected to the butoxy linker. The other side of the piperazine ring is connected to a phenyl ring. The phenyl ring includes chlorine substituents attached at both the 2 position and 3 position of the phenyl ring. This substitution of chlorine at the 2 position and the 3 position of the phenyl ring is referred to as a "2,3 dichloro substitution" or a "2,3 dichlorophenyl substitution."

35. Aripiprazole is marketed by Defendants as Abilify® and has been commercially successful. By the end of 2009, sales of Abilify® were $3.3 billion annually, and from 2005 onward, sales of Abilify® have exceeded a billion dollars each year, qualifying it as a "blockbuster drug."

36. According to the Defendants, Aripiprazole has a number of unexpected therapeutic benefits that could not have been originally predicted including its broad efficacy in treating the positive symptoms of schizophrenia and low propensity to cause the serious side effects associated with typical antipsychotic drugs such as extrapyramidal symptoms, tardive dyskinesia, sedation, weight gain or other metabolic effects, prolactin elevation, and orthostatic hypotension.

37. Abilify® has received acclaim from others in the industry. In 2004, Frost & Sullivan[1] awarded its Product Innovation Award for the U.S. antipsychotic medications market to Otsuka for Abilify®. The award was described as being bestowed on the company that successfully develops and commercializes a medication which is believed to provide a unique set of benefits over existing products in the market. In its report covering the award, Frost & Sullivan stated: "With a comparable efficacy and

[1] Frost & Sullivan is a market research firm that examines a wide range of industries, including the pharmaceutical industry.

superior side effect profile, Abilify® may become the new standard against which all new antipsychotics are judged."

38. Abilify® has won a number of other awards throughout the world over the years. Among those awards, Abilify® won the Prix Galien award in 2006 (France) for being the most innovative pharmaceutical product on the market, the Pharmaceutical Executive Magazine Central Nervous System Compound of the Year for 2004 (United States), and a variety of other awards in Germany, Japan, France, and Spain.

Abilify® Aggressively Promoted For Off Label Use

39. On September 28, 2007, the United States Department of Justice announced that Bristol-Myers Squibb Company had agreed to pay over $515 million to resolve a broad array of civil allegations involving its drug marketing and pricing practices, including illegal marketing and pricing practices from approximately 2000 through mid-2003, during which the company "knowingly and willfully" paid illegal remuneration to physicians and other health care providers to induce them to purchase Bristol-Myers Squibb Company drugs. Bristol-Myers Squibb Company paid the illegal remuneration in the form of consulting fees and expenses to physicians and other health care providers to participate in various consulting programs, advisory boards, and preceptorships. Some of these programs involved travel to luxurious resorts.

40. The United States Government further alleged that, from 2002 through the end of 2005, Bristol-Myers Squibb Company "knowingly promoted the sale and use of Abilify®, for pediatric use," which was "off-label". The Food and Drug Administration had approved Abilify® to treat adult schizophrenia and bi-polar disorder, but at the time had not approved the use of Abilify® for children and adolescents. Nonetheless,

Bristol-Myers Squibb Company directed its sales force to call on child psychiatrists and other pediatric specialists, and the sales force then urged physicians and others providers to prescribe Abilify® for pediatric patients. As part of the settlement, Bristol-Myers Squibb Company entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services.

41. On March 27, 2008, Otsuka American Pharmaceutical Inc., agreed to pay over $4 million to resolve allegations of off-label marketing with respect to Abilify®. Otsuka actually developed Abilify® in Japan and then entered into an agreement with Bristol-Myers Squibb to co-promote sales of the drug in the United States. Under that agreement, Otsuka American Pharmaceutical Inc. sales representatives worked on sales teams led primarily by Bristol-Myers Squibb Company sales managers. The Otsuka American Pharmaceutical Inc. settlement resolved government allegations that from 2002 through the end of 2005 Otsuka "knowingly" promoted the sale and use of Abilify® for pediatric use and participated in directing its sales force to call on child psychiatrists and other pediatric specialists, and urge those physicians and others providers to prescribe Abilify® for pediatric patients. As part of the settlement, Otsuka American Pharmaceutical Inc. entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services.

The Abilify® Labeling And Diabetes

42. Type II diabetes mellitus, was once known as adult-onset or noninsulin-dependent diabetes, and used to be a relatively rare condition in children. However, the disease has become much more prevalent among children in recent years.

43. Today, over 500,000 children are being prescribed atypical antipsychotic drugs for a host of conditions, including but not limited to: Attention Deficit Hyperactivity Disorder, Attention Deficit Disorder, Depression, Anxiety, Obsessive Compulsive Disorder, Bipolar Disorder, Autism Irritability, Mania, Psychosis, and Schizophrenia. There have even been some documented cases of children under the age of 1 years old being treated with antipsychotics.

44. The rise in prescriptions for atypical antipsychotic drugs in the United States to children virtually parallels the rise in childhood obesity and the early onset of Type II diabetes. Although the use of atypical antipsychotic drugs is not the only single cause of the increase in childhood obesity rates and Type II diabetes rates among children in the United States, it is a contributing factor.

45. The increase in pediatric use of atypical antipsychotics is driven in part by the recent tendency of including extreme levels of mood volatility and irritability in the diagnostic construct of bipolar disorder, together with the concomitant regulatory approval of some atypical antipsychotic drugs for the treatment of bipolar disorder in both adults and adolescents, has likely contributed to increase the pediatric use of these medications in the U.S. However, there are other well-recognized alternative medications for these psychiatric conditions. *See* Maglione M, Maher AR, Hu J, et al., *Off-label use of atypical antipsychotics: an update* http://www.ncbi.nlm.nih.gov/books/NBK66081/; AHRQ Comparative Effectiveness Reviews. 2011; No. 43.15; Alexander GC, Gallagher SA, Mascola A, Moloney RM, Stafford RS. *Increasing off-label use of antipsychotic medications in the United States, 1995–2008*, Pharmacoepidemiol Drug Saf., 2011;20(2):177–184; Kutcher S, Aman M,

Brooks SJ, et al., *International consensus statement on attention-deficit/hyperactivity disorder (ADHD)and disruptive behaviour disorders (DBDs): clinical implications and treatment practice suggestions.* Eur Neuropsychopharmacol, 2004;14(1):11–28; Kowatch RA, Fristad M, Birmaher B,Wagner KD, Findling RL, Hellander M; *Child Psychiatric Workgroup on Bipolar Disorder, Treatment guidelines for children and adolescents with bipolar disorder*, J AmAcad Child Adolesc Psychiatry, 2005;44(3):213–35.

46. The atypical antipsychotic drugs were introduced into the adult pharmacopoeia with the expectation that they would be safer, better tolerated, and therefore more clinically versatile than the first-generation antipsychotics. However, with perhaps the exception of clozapine, the atypical antipsychotic drugs have not consistently demonstrated better efficacy than first-generation antipsychotics.

47. For adults, there is considerable evidence linking antipsychotic use to increased risk of type 2 diabetes. Several antipsychotics have metabolic effects, such as weight gain, increased glucose level, and insulin resistance that are thought to be precursors to diabetes. Epidemiologic studies have confirmed an increased risk for type 2 diabetes for individuals using some types of antipsychotics, particularly the atypical antipsychotic drugs. *See* Kessing LV, Thomsen AF, Mogensen UB, Andersen PK. *Treatment with antipsychotics and the risk of diabetes in clinical practice*, Br J Psychiatry, 2010;197(4):266–71; Lambert BL, Cunningham FE, Miller DR, Dalack GW, Hur K., *Diabetes risk associated with use of olanzapine, quetiapine, and risperidone in veterans health administration patients with schizophrenia*, Am J Epidemiol. 2006;164(7):672–81; Nielsen J, Skadhede S, Correll CU. *Antipsychotics associated with*

the development of type 2 diabetes in antipsychotic-naïve schizophrenia patients, Neuropsychopharmacology. 2010;35(9):1997–2004; Chae B-J, Kang B-J. *The effect of clozapine on blood glucose metabolism*, Hum Psychopharmacol 2001; 16: 265–71; Miller MJ, Molla PM. *Prevalence of diabetes mellitus in patients receiving depot neuroleptics or clozapine*, Arch Psychiatr Nurs 2005; 19: 30–4; Mackin P, Watkinson HM, Young AH., *Prèvalence of obesity, glucose homeostasis disorders and metabolic syndrome in psychiatric patients taking typical or atypical antipsychotic drugs: a cross-sectional study*, Diabetologia 2005; 48: 215–21; Jin H, Meyer JM, Jeste DV. *Phenomenology of and risk factors for new-onset diabetes mellitus and diabetic ketoacidosis associated with atypical antipsychotics: an analysis of 45 published cases*, Ann Clin Psychiatry 2002;14: 59–64.

48. In children, few controlled studies have directly compared the effects of first- and second-generation antipsychotics. Although clozapine has shown some superiority over other atypical antipsychotic drugs in children and adolescents with schizophrenia, no evidence of differences in efficacy among the remaining antipsychotics has emerged.

49. The steep increase in pediatric use of the atypical antipsychotics stands in stark contrast with the relative paucity of data from controlled investigations in the age group, especially given that much of the use of the medication is for the management of non-psychotic conditions, such as aggression, disruptive behavior, and mood dysregulation. Olfson, M., Blanco, C., Liu, L., Moreno, C., Laje, G., 2006. *National trends in the outpatient treatment of children and adolescents with antipsychotics.* Arch. Gen. Psychiatry 63, 679–85.

50. Nevertheless, a major contributor to the popularity of the atypical antipsychotics among clinicians is the belief that the atypical antipsychotic drugs are safer than first generation antipsychotics. Further, due to the perceived ease of use, treatment with atypical antipsychotic drugs has become more accepted also for non-psychotic conditions, including mood disorders and aggression, both in adults and children. Further still, the rise of the use of atypical antipsychotics in children occurred at a time when the availability of inpatient services for mental health treatment has been, at least in the U.S., greatly curtailed, with consequent pressure on clinicians to stabilize patient behavior expeditiously and cheaply.

51. Although the increased use of atypical antipsychotics in adult populations, has been profound, the increased use has actually occurred at a greater rate in youth. *See* Olfson M, Marcus SC, Weissman MM, Jensen PS: *National trends in the use of psychotropic medications by children.* J Am Acad Child AdolescPsychiatry 41:514–21, 2002; Zito JM, Bureu M, Ibe A, Safer DJ, Magder LS: *Antipsychotic use by Medicaid-insured youths: Impact of eligibility and psychiatric diagnosis across a decade.* Psychiatr Serv 64:223–29, 2013; Patel NC, Crismon ML, Hoagwood K, Johnsrud MT, Rascati KL, Wilson JP, Jensen PS: *Trends in the use of typical and atypical antipsychotics in children and adolescents*, J Am Acad Child Adolesc Psychiatry 44:548–56, 2005; Matone M, Localio R, Huang YS, dosReis S, Feudtner C, Rubin D: *The relationship between mental health diagnosis and treatment with second-generation antipsychotics over time: A national study of U.S. Medicaid-enrolled children.* Health Serv Res 47:1836–60, 2012; Olfson M, Blanco C, Liu SM, Wang S, Correll CU: *National trends in the office-based*

treatment of children, adolescents, and adults with antipsychotics, Arch Gen Psychiatry 69:1247–56, 2012.

52. The most dramatic increase the use of atypical antipsychotic drugs has been among publicly insured children and for off-label behavioral conditions, such as attention-deficit/hyperactivity disorder and other disruptive behavior disorders. *See* Crystal S, Olfson M, Huang C, Pincus H, Gerhard T: *Broadened use of atypical antipsychotics: safety, effectiveness, and policy challenges.* Health Aff (Millwood) 28:w770–w781, 2009; Cooper WO, Hickson GB, Fuchs C, Arbogast PG, Ray WA: *New users of antipsychotic medications among children enrolled in TennCare.* Arch Pediatr Adolesc Med 158:753–59, 2004; Constantine RJ, Jentz S, Bengtson M, McPherson M, Andel R, Jones MB, *Exposure to antipsychotic medications over a 4-year period among children who initiated antipsychotic treatment before their sixth birthday.*, Pharmacoepidemiol Drug Saf 21:152–60, 2012; Constantine RJ, Tandon R,McPherson M, Andel R, *Early diagnoses and psychotherapeutic treatment experiences of a cohort of children under 6 years old who received antipsychotic treatment in Florida's Medicaid program*, J Child Adolesc Psychopharmacol 21:79–84, 2011; Zito JM, Burcu M, Ibe A, Safer DJ, Magder LS, *Antipsychotic use by Medicaid-insured youths: Impact of eligibility and psychiatric diagnosis across a decade*, Psychiatr Serv 64:223–29, 2013.

53. Compared with privately insured youth, youth in state Medicaid systems had five to six fold greater antipsychotic use, Crystal S, Olfson M, Huang C, Pincus H, Gerhard T: *Broadened use of atypical antipsychotics: safety, effectiveness, and policy challenges.* Health Aff (Millwood) 28:w770–w781, 2009, and by 2006–2007. Medicaid-insured youth diagnosed with externalizing behavioral disorders by far

represented the largest group of youth receiving antipsychotic medications. Matone M, Localio R, Huang YS, dosReis S, Feudtner C, Rubin D: *The relationship between mental health diagnosis and treatment with second-generation antipsychotics over time: A national study. of U.S. Medicaid-enrolled children,* Health Serv Res 47:1836–60, 2012; Zito JM, Burcu M, Ibe A, Safer DJ, Magder LS, *Antipsychotic use by Medicaid-insured youths: Impact of eligibility and psychiatric diagnosis across a decade*, Psychiatr Serv 64:223–29, 2013.

54. The data in children over the last several years demonstrate that children are more sensitive than adults to the metabolic adverse effects of atypical antipsychotics. Children tend to gain proportionately more weight and do so more rapidly during treatment than adults. *See* Correll, C.U., Carlson, H.E., 2006. *Endocrine and metabolic adverse effects of psychotropic medications in children and adolescents*, J. Am. Acad. Child. Adolesc. Psychiatry 45, 771–91. Because drug-induced metabolic changes can persist over time and may not be fully reversible upon drug discontinuation, the implications for future health outcomes can be profound.

55. The metabolic changes in children have included the early onset of Type II diabetes mellitus. Panagiotopoulos C, Ronsley R, Davidson J., *Increased prevalence of obesity and glucose intolerance in youth treated with second-generation antipsychotic medications*, Can J Psychiatry. 2009;54(11):743–49; Hammerman A, Dreiher J, Klang SH, Munitz H, Cohen AD, Goldfracht M. *Antipsychotics and diabetes: an age-related association,* Ann Pharmacother. 2008;42(9):1316–22; Andrade SE, Lo JC, Roblin D, et al. *Antipsychotic medication use among children and risk of diabetes mellitus*, Pediatrics. 2011;128(6):1135–41; Correll CU, Manu P, Olshanskiy V, Napolitano B, Kane JM,

Malhotra AK. *Cardiometabolic risk of second-generation antipsychotic medications during first-time use in children and adolescents,* JAMA. 2009;302(16):1765–73; Correll CU, *Weight gain and metabolic effects of mood stabilizers and antipsychotics in pediatric bipolar disorder: a systematic review and pooled analysis of short-term trials*, J AmAcad Child Adolesc Psychiatry, 2007;46(6):687–700.

56. The epidemiological data indicates that children and adolescents taking atypical antipsychotic drugs have a 3-fold increased risk for Type II diabetes. Bobo WV, Cooper WO, Stein CM, Olfson M, Graham D, Daugherty J, Fuchs DC, Ray WA, *Antipsychotics and the Risk of Type 2 Diabetes Mellitus in Children and Youth, JAMA Psychiatry.* 2013;70(10):1067–75. doi:10.1001/jamapsychiatry.2013.2053, August 21, 2013. The increased risk is often apparent within the first year after drug initiation, and the risk does not vary significantly according to baseline dose but did increase with cumulative dose during follow-up. *Id.* Given that the risk of diabetes in children taking atypical antipsychotic drugs increases with dosage, the science demonstrates that children are at: 2.1 times the risk of developing diabetes at low doses; 3.4 times the risk of developing diabetes at medium doses; and 5.4 times the risk of developing diabetes at high doses. *Id.* (supplemental content at jamapsychiatry.com). **The risk associated with average dose for Abilify® increases the diabetes risk 7.72 times.** *Id.* (supplemental content at jamapsychiatry.com).

57. In 2004, the Federal Food And Drug Administration required the Defendants to provide the following language in the "Warnings" portion of the Abilify® label:

Hyperglycemia and Diabetes Mellitus

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia in patients treated with ABILIFY. Although fewer patients have been treated with ABILIFY, it is not known if this more limited experience is the sole reason for the paucity of such reports. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies which did not include ABILIFY suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics included in these studies. Because ABILIFY was not marketed at the time these studies were performed, it is not known if ABILIFY is associated with this increased risk. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

58. Despite being on the United States market for twelve years, the current labeling for Abilify® entirely fails to provide accurate and meaningful information to physicians or anyone else about the potential relative risk to children taking Abilify® for the development of Type II diabetes. Specifically, the Abilify® labeling under "Warnings" and "Adverse Reactions" states the following with respect to diabetes:

Warnings

• *Metabolic Changes:* Atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, dyslipidemia, and body weight gain (5.5)
o *Hyperglycemia/Diabetes Mellitus:* Monitor glucose regularly in patients with and at risk for diabetes (5.5)
o *Dyslipidemia:* Undesirable alterations in lipid levels have been observed in patients treated with atypical antipsychotics (5.5)
o *Weight Gain:* Weight gain has been observed with atypical antipsychotic use. Monitor weight (5.5)

5.5 Metabolic Changes

Atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, dyslipidemia, and body weight gain. While all drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Hyperglycemia/Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with ABILIFY *[see ADVERSE REACTIONS (6.2, 6.3)]*. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Because ABILIFY was not marketed at the time these studies were performed, it is not known if ABILIFY is associated with this increased risk. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (eg, obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with

atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Adults

In an analysis of 13 placebo-controlled monotherapy trials in adults, primarily with schizophrenia or bipolar disorder, the mean change in fasting glucose in aripiprazole-treated patients (+4.4 mg/dL; median exposure 25 days; N=1057) was not significantly different than in placebo-treated patients (+2.5 mg/dL; median exposure 22 days; N=799). Table 5 shows the proportion of aripiprazole-treated patients with normal and borderline fasting glucose at baseline (median exposure 25 days) that had treatment-emergent high fasting glucose measurements compared to placebo-treated patients (median exposure 22 days).

Table 5: Changes in Fasting Glucose From Placebo-Controlled Monotherapy Trials in Adult Patients

	Category Change (at least once) from Baseline	**Treatment Arm**	**n/N**	**%**
Fasting Glucose	Normal to High (<100 mg/dL to ≥126 mg/dL)	Aripiprazole	31/822	3.8
		Placebo	22/605	3.6
	Borderline to High (≥100 mg/dL and <126 mg/dL to ≥126 mg/dL)	Aripiprazole	31/176	17.6
		Placebo	13/142	9.2

At 24 weeks, the mean change in fasting glucose in aripiprazole-treated patients was not significantly different than in placebo-treated patients [+2.2 mg/dL (n=42) and +9.6 mg/dL (n=28), respectively].

The mean change in fasting glucose in adjunctive aripiprazole-treated patients with major depressive disorder (+0.7 mg/dL; median exposure 42 days; N=241) was not significantly different than in placebo-treated patients (+0.8 mg/dL; median exposure 42 days; N=246). Table 6 shows the proportion of adult patients with changes in fasting glucose levels from two placebo-controlled, adjunctive trials (median exposure 42 days) in patients with major depressive disorder.

Table 6: Changes in Fasting Glucose From Placebo-Controlled Adjunctive Trials in Adult Patients with Major Depressive Disorder

	Category Change (at least once) from Baseline	Treatment Arm	n/N	%
Fasting Glucose	Normal to High (<100 mg/dL to ≥126 mg/dL)	Aripiprazole	2/201	1.0
		Placebo	2/204	1.0
	Borderline to High (≥100 mg/dL and <126 mg/dL to ≥126 mg/dL)	Aripiprazole	4/34	11.8
		Placebo	3/37	8.1

Pediatric Patients and Adolescents

In an analysis of two placebo-controlled trials in adolescents with schizophrenia (13 to 17 years) and pediatric patients with bipolar disorder (10 to 17 years), the mean change in fasting glucose in aripiprazole-treated patients (+4.8 mg/dL; with a median exposure of 43 days; N=259) was not significantly different than in placebo-treated patients (+1.7 mg/dL; with a median exposure of 42 days; N=123). In an analysis of two placebo-controlled trials in pediatric and adolescent patients with irritability associated with autistic disorder (6 to 17 years) with median exposure of 56 days, the mean change in fasting glucose in aripiprazole-treated patients (–0.2 mg/dL; N=83) was not significantly different than in placebo-treated patients (–0.6 mg/dL; N=33). Table 7 shows the proportion of patients with changes in fasting glucose levels from the pooled adolescent schizophrenia and pediatric bipolar patients (median exposure of 42-43 days) as well as from two placebo-controlled trials in pediatric patients (6 to 17 years) with irritability associated with autistic disorder (median exposure of 56 days).

Table 7: Changes in Fasting Glucose From Placebo-Controlled Trials in Pediatric and Adolescent Patients

Category Change (at least once) from Baseline	Indication	Treatment Arm	n/N	%
Fasting Glucose				
Normal to High		Aripiprazole	2/236	0.8

(<100 mg/dL to ≥126 mg/dL)	Pooled Schizophrenia and Bipolar Disorder	Placebo	2/110	1.8
	Irritability Associated With Autistic Disorder	Aripiprazole	0/73	0
		Placebo	0/32	0
Fasting Glucose				
Borderline to High (≥100 mg/dL and <126 mg/dL to ≥126 mg/dL)	Pooled Schizophrenia and Bipolar Disorder	Aripiprazole	1/22	4.5
		Placebo	0/12	0
	Irritability Associated With Autistic Disorder	Aripiprazole	0/9	0
		Placebo	0/1	0

At 12 weeks in the pooled adolescent schizophrenia and pediatric bipolar disorder trials, the mean change in fasting glucose in aripiprazole-treated patients was not significantly different than in placebo-treated patients [+2.4 mg/dL (n=81) and +0.1 mg/dL (n=15), respectively].

ADVERSE REACTIONS

Other Adverse Reactions Observed During the Premarketing Evaluation of Aripiprazole

Adults - Oral Administration

Metabolism and Nutrition Disorders:
≥1/1000 patients and <1/100 patients - hyperlipidemia, anorexia, diabetes mellitus (including blood insulin increased, carbohydrate tolerance decreased, diabetes mellitus non-insulin-dependent, glucose tolerance impaired, glycosuria, glucose urine, glucose urine present), hyperglycemia, hypokalemia, hyponatremia, hypoglycemia, polydipsia; *<1/1000 patients* - diabetic ketoacidosis

Pediatric Patients - Oral Administration
Most adverse events observed in the pooled database of 920 pediatric patients, aged 6 to 17 years, were also observed in the adult population. Additional adverse reactions observed in the pediatric population are listed below.

Gastrointestinal Disorders:
≥1/1000 patients and <1/100 patients - tongue dry, tongue spasm
Investigations:
≥1/100 patients - blood insulin increased
Nervous System Disorders:
≥1/1000 patients and <1/100 patients - sleep talking
Skin and Subcutaneous Tissue Disorders:
≥1/1000 patients and <1/100 patients - hirsutism

59. Defendants' labeling for Abilify® entirely omits more than 12 years of scientific evidence with respect to the relative risk to children of developing diabetes associated with the ingestion of Abilify®. Significantly, the labeling is outdated, incomplete, and materially false and misleading as it pertains to the diabetes risk to children and adults.

The Ravages Of Diabetes

60. Type II diabetes is a chronic condition that affects the way the body metabolizes sugar (glucose). The body either resists the effects of insulin—a hormone that regulates the movement of sugar into cells—or doesn't produce enough insulin to maintain a normal glucose level. There's no cure for type II diabetes

61. Some individuals may be able to manage type II diabetes by diet and exercise. Others require diabetes medications or insulin therapy.

62. Symptoms usually develop slowly over time, and include: increased thirst and frequent urination caused by excess sugar building up in the bloodstream causing fluid to be pulled from the tissues; increased hunger due to lack of insulin to move sugar into cells, muscles and organs depleting them of energy; weight loss caused by loss of the ability to metabolize glucose requiring the body uses alternative fuels stored in muscle and fat; extreme fatigue because the cells are deprived of sugar; blurred vision caused by blood sugar being too high, and fluid may being pulled from the lenses of the eyes

affecting the ability to focus; slow-healing sores or frequent infections; areas of darkened skin—a condition called acanthosis nigricans—which for some people suffering from diabetes presents as patches of dark, velvety skin in the folds and creases of their bodies—usually in the armpits and neck.

63. The long-term complications of diabetes can be disabling or even life-threatening. Some of the potential complications of diabetes include:

- **Premature death**. Life expectancy is reduced, on average, more than 20 years in people who develop diabetes at a younger age.
- **Heart and blood vessel disease.** Diabetes dramatically increases the risk of various cardiovascular problems, including coronary artery disease with chest pain (angina), heart attack, stroke, narrowing of arteries (atherosclerosis) and high blood pressure.
- **Kidney damage (nephropathy).** The kidneys contain millions of tiny blood vessel clusters that filter waste from the blood. Diabetes can damage this delicate filtering system. Severe damage can lead to kidney failure or irreversible end-stage kidney disease, which often eventually requires dialysis or a kidney transplant.
- **Nerve damage (neuropathy).** Excess sugar can injure the walls of the tiny blood vessels (capillaries) that nourish the nerves, especially in the legs. This can cause tingling, numbness, burning or pain that usually begins at the tips of the toes or fingers and gradually spreads upward. Poorly controlled blood sugar can eventually cause the loss of all sense of feeling in the affected limbs. Damage to the nerves that control digestion can cause problems with nausea, vomiting, diarrhea or constipation. For men, erectile dysfunction may be an issue.
- **Foot damage and amputation.** Nerve damage in the feet or poor blood flow to the feet increases the risk of various foot complications. Left untreated, cuts and blisters can become serious infections, which may heal poorly. Severe damage might require toe, foot or leg amputation.
- **Alzheimer's disease.** Type II diabetes may increase the risk of Alzheimer's disease. The poorer blood sugar control, the greater the risk appears to be.
- **Eye damage.** Diabetes can damage the blood vessels of the retina (diabetic retinopathy), potentially leading to blindness. Diabetes also increases the risk of other serious vision conditions, such as cataracts and glaucoma.
- **Hearing impairment.** Hearing problems are more common in people with diabetes.
- **Skin conditions.** Diabetes may leave a person more susceptible to skin problems, including bacterial and fungal infections.

- **Sexual Dysfunction**. Men with diabetes are 2 to 3 times more likely to have erectile dysfunction, and to begin experiencing dysfunction 10–15 years earlier than healthy men.
- **Pregnancy Complications**. including miscarriage and birth defects

64. Further, the average American annual healthcare expense is $6,815, but the average diabetic annual healthcare expenses is more than double that amount, $13,700. Diabetics also earn $160,000 less over their lifetime, on average due to being more likely to drop out of school, more likely to be unemployed, missing more time from work due to illness and/or premature death.

The Plaintiff Developed Type II Diabetes After Ingesting Abilify®

65. Cheyenne Beth Confer was 15 years old when she was prescribed Abilify® "off-label" for depression in May 2009. Cheyenne's healthcare is provided through the Medicaid program. By November 2009 she had gained approximately 30 pounds and had developed Type II diabetes. Cheyenne had no prior history of diabetes or impaired glucose tolerance. She is now taking Metformin to treat her Type II diabetes.

COUNT I
Strict Products Liability—Failure to Warn

66. Plaintiff incorporates by reference the previous allegations as if they were fully set forth herein.

67. The Defendants are liable under the theory of product liability as set forth in Sections 402A and 402B of the Second Restatement of Torts.

68. Abilify® was defective in design or formulation in that, when it left the hands of the Defendants, it was unreasonably dangerous for use by a reasonably prudent

consumer or patient when using it as intended or in a reasonably foreseeable manner, because the foreseeable risks of Abilify® exceeded the benefits associated with the design and/or the formulation of the product.

69. Further the product failed to contain adequate warnings or instructions about the latent dangers resulting from foreseeable uses of the product of which the Defendants knew or should have known. Further, the product created significant risks of serious bodily harm to consumers ingesting it, and it failed to adequately warn consumers, patients and/or their health care providers, including the Plaintiff's physician, of such risks.

70. Defendants failed to adequately warn consumers, patients and/or their health care providers, including the Plaintiff's physician, that Abilify® could cause the early onset of Type II diabetes mellitus in children.

71. Defendants failed to adequately warn consumers, patients, and/or their health care providers, including the Plaintiff's physician, about the potential relative risk for children taking Abilify® of developing Type II diabetes.

72. Defendants failed to adequately warn consumers, patients, and/or their health care providers. including the Plaintiff's physician, that that children who take atypical antipsychotic drugs, the class of drugs that Abilify® is in, are at: 2.1 times the risk of developing diabetes at low doses; 3.4 times the risk of developing diabetes at medium doses; and 5.4 times the risk of developing diabetes at high doses.

73. Defendants failed to adequately warn consumers, patients, and/or their health care providers, including the Plaintiff's physician, that children who take Abilify®, at the average recommended dose, are exposed to an increased diabetes risk that is more

than triple the risk for those not taking Abilify®, and which may be as high 7.72 times above the background rate.

74. Abilify® manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm to children from the use of Abilify®, Defendants failed to provide an adequate warning to consumers, patients and/or health care providers, including the Plaintiff's physician, of the substantial Type II diabetes risk with the product.

75. The labeling for Abilify® was not correct, fully descriptive, or complete and it failed to convey to health care providers, including the Plaintiff's physician, updated information as to the known side effects of Abilify®.

76. Plaintiff was an Abilify® consumer or patient. As a direct and proximate result of Plaintiff's reasonably anticipated and proper use of Abilify® as manufactured, designed, sold, supplied, marketed, and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages, and losses in the future.

Count II
Negligence

77. Plaintiff incorporates by reference the previous allegations as if they were fully set forth herein.

78. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, and adequately warn of the risks and dangers of Abilify®.

79. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use, and sold Abilify® and failed to adequately test and warn of the risks and dangers of Abilify®.

80. Despite the fact that Defendants knew or should have known that Abilify® caused unreasonable, dangerous side effects, Defendants continued to market Abilify® to consumers, patients, and health care professionals, including the Plaintiff's physician, without proper and adequate warnings that were correct, fully descriptive, or complete and which failed to convey to health care providers, including the Plaintiff's physician, updated information as to the known side effects of Abilify®.

81. Plaintiff was an Abilify® consumer and patient. 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.

82. Defendants' negligence was a proximate cause of the Plaintiff's injuries.

83. As a direct and proximate result of the Defendants' negligent acts and omissions, the Plaintiff has suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages, and losses in the future.

Count III
Breach of Implied Warranty

84. Plaintiff incorporates by reference the previous allegations as if they were fully set forth herein.

85. Prior to the time that the aforementioned products were used by the Plaintiff, Defendants impliedly warranted to Plaintiff, Plaintiff's agents, and/or

physicians that Abilify® was of merchantable quality and safe and fit for the use for which it was intended.

86. Plaintiff was and is unskilled in the research, design, and manufacture of medical drugs, including Abilify®, and reasonably relied entirely on the skill, judgment, and implied warranty of the Defendants in using Abilify®.

87. Abilify® was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Abilify® has dangerous propensities when used as intended, the labeling contained material misrepresentations and/or omitted material information and the product has the potential to cause severe injuries to users.

88. As a direct and proximate result of Abilify®, and relying upon the implied warranties for Abilify®, which was at all times defective and unfit for its intended purpose, and which contained such defects when it left the hands of the Defendants, the Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages, and losses in the future.

Count IV
Breach of Express Warranty

89. Plaintiff incorporates by reference the previous allegations as if they were fully set forth herein.

90. At all times mentioned, Defendants expressly represented and warranted to Plaintiff, Plaintiff's agents, and/or physicians, by and through statements made by Defendants or its authorized agents or sales representatives, orally and in publications, package inserts and/or other written materials intended for physicians, medical patients

and the general public, that Abilify® is safe, effective, fit and proper for its intended use. Plaintiff or Plaintiff's agent purchased Abilify® relying upon these warranties.

91. In utilizing Abilify®, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that Abilify® is unsafe and unfit for its intended uses.

92. As a direct and proximate result of Abilify®, and relying upon the express warranties for Abilify®, which was at all times defective and unfit for its intended purpose, and which contained such defects when it left the hands of the Defendants, the Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages, and losses in the future.

Count V
Defendants' Malicious, Wanton, Or Reckless Conduct

93. Plaintiff incorporates by reference the previous allegations as if they were fully set forth herein.

94. Since at least 2005, Defendants have had actual knowledge based upon scientific studies, post marketing data, and clinical experience that their product Abilify® was and is improperly labeled and as a result created an unreasonable risk of serious bodily injury to consumers.

95. Defendants made fraudulent misrepresentations to Plaintiff, Plaintiff's physicians, and the general public by allowing inaccurate outdated information to persist in the Abilify® labeling and by omitting material information in the labeling, marketing promotions, and advertising, and Defendants instead labeled, promoted, and advertised its

product as being safe, fit, and effective for human consumption in order to avoid losses and sustain profits in sales to consumers.

96. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale of Abilify® and to misrepresent to Plaintiff, Plaintiff's physicians, and the general public as to the health risks and consequences of the use of Abilify®.

97. The Defendants made the foregoing representations and omissions without any reasonable ground for believing them to be true. These representations and omissions were made directly by Defendants through its labeling for Abilify®, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients, and the public, with the intention of inducing reliance and the prescription, purchase, and use of Abilify®.

98. The representations by the Defendants were made maliciously, wantonly, or recklessly, and were in fact false, because Abilify® is not safe, fit and effective for human consumption as labeled, and Abilify® has a high propensity to cause serious injuries to pediatric users, including but not limited to the injuries suffered by Plaintiff.

99. The foregoing representations and omissions by Defendants were each made with the intention of inducing reliance and the prescription, purchase, and use of Abilify® for pediatric patients. Further, a superior officer for each of the Defendants in the course of employment ordered, participated in, or ratified the conduct giving rise to the Defendants oppressive conduct related to Abilify®.

100. In reliance on the misrepresentations and omissions by Defendants, Plaintiff was prescribed Abilify®, induced to take Abilify®, and induced to purchase Abilify®.

101. As a direct and proximate result of the foregoing conduct, omissions, and affirmative misrepresentations by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages, and losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Cheyenne Beth Confer seeks the following relief:

(1) Actual damages;
(2) Past and future physical pain and suffering;
(3) Past and future mental anguish;
(4) Past and future physical disfigurement;
(5) Past and future physical impairment;
(6) Medical expenses in the past and future;
(7) Lost Wages and/or loss of earning capacity;
(8) Past and future inconvenience;
(9) Exemplary or Punitive damages;
(10) Court costs;
(11) Attorney's fees;
(12) Pre-judgment interest and post-judgment interest; and
(13) Together with such other and further relief the Court may deem appropriate.

DATED: August 22, 2014

New York, New York

Respectfully submitted,

THE D'ONOFRIO FIRM, LLC

By: _____

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ATTORNEYS FOR PLAINTIFF

VERIFICATION

I, Louis F. D'Onofrio, Esquire, am an attorney of record for Plaintiff, Cheyenne Beth Confer, and hereby state under oath that I am familiar with the facts set forth in the foregoing Complaint and that the same are true and correct to the best of my knowledge, information and belief. This statement is made subject to the penalties relating to unsworn falsification to authorities.

LOUIS F. D'ONOFRIO, ESQUIRE
ATTORNEY FOR PLAINTIFF

Dated: 8/22/2014