CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000831-160

(Class Action)
SUPERIOR COURT

S. SCHEER

Petitioner

-vs.-

BRISTOL-MYERS SQUIBB CANADA CO., legal person duly constituted, having its head office at 2344 Boul. Alfred-Nobel, City of Saint-Laurent, Province of Quebec, H4S 0A4

and

OTSUKA CANADA PHARMACEUTICAL INC., legal person duly constituted, having its head office at 301-2250 Boul. Alfred-Nobel, City of Saint-Laurent, Province of Quebec, H4S 2C9

and

LUNDBECK CANADA INC., legal person duly constituted, having its head office at 500-1000 rue de la Gauchetière West, City of Montreal, Province of Quebec, H3B 4W5

Respondents

APPLICATION TO AUTHORIZE THE BRINGING OF A CLASS ACTION & TO APPOINT THE PETITIONER AS REPRESENTATIVE PLAINTIFF (Art. 574 C.C.P and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PETITIONER STATES AS FOLLOWS:

I. GENERAL PRESENTATION

A) The Action

1. Petitioner wishes to institute a class action on behalf of the following class, of which he is a member, namely:

    - All persons residing in Canada who were prescribed and have ingested and/or injected the drug(s), ABILIFY® and/or ABILIFY MAINTENA® (aripiprazole) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

    Alternatively (or as a subclass)

    - All persons residing in Quebec who were prescribed and have ingested and/or injected the drug(s), ABILIFY® and/or ABILIFY MAINTENA® (aripiprazole) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

2. "ABILIFY" and "ABILIFY MAINTENA" (collectively, "ABILIFY Products") are the brand names of the atypical antipsychotic[1] medication, aripiprazole, which is prescribed to patients in order to *inter alia* treat symptoms of schizophrenia, to treat manic or mixed episodes in bipolar I disorder (manic depression), and to treat symptoms of major depressive disorder (in combination with antidepressants);

3. The Respondents developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the ABILIFY Products as safe and/or effective despite a wealth of existing knowledge that the drugs had dangerous side effects including uncontrollable impulses, such as pathological gambling, binge eating, uncontrollable spending or shopping and hypersexual behaviour;

4. The Petitioner contends that Respondents represented to the medical and healthcare community, to Health Canada, and to the Class Members that they had developed, designed, manufactured, and tested the ABILIFY Products and that they had been found to be safe and/or effective for their intended use. In addition, the Respondents concealed their knowledge of the ABILIFY Products' defects from the medical and healthcare community, Health Canada and from Class Members;

5. In short, the Respondents' liability rests on (i) inadequate warning about the risk of developing compulsive behaviours, (ii) failure to notify of the full scope of risks known to be associated with and caused by the ABILIFY Products, and (iii) safety misrepresentations;

6. Respondents continue to market, label, package, promote, advertise, import, distribute, and/or sell the ABILIFY Products throughout Canada, including within the

[1] Antipsychotics also known as neuroleptics or major tranquilizers, are a class of psychiatric medication primarily used to manage psychosis (including delusions, hallucinations, paranoia or disordered thought), principally in schizophrenia and bipolar disorder – the word atypical indicates that it is a second generation antipsychotic developed to produce less side effects that its predecessors.

province of Quebec, with inadequate warnings as to its serious and adverse side effect of compulsive behaviour;

B) The Respondents

8. Respondent Bristol-Myers Squibb Canada Co. ("Bristol-Myers") is a Canadian pharmaceutical corporation, with its head office in Saint-Laurent, Quebec. Bristol-Myers is and was at all relevant times involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of pharmaceutical products including ABILIFY. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* and from a copy of an extract from Respondent Bristol-Myers' website at www.bmscanada.ca, produced herein *en liasse* as **Exhibit R-1**;

9. Respondent Otsuka Canada Pharmaceutical Inc. ("Otsuka") is a Canadian pharmaceutical corporation, with its head office in Saint-Laurent, Quebec. Otsuka is and was at all relevant times involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of pharmaceutical products including the ABILIFY Products. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises*, produced herein as **Exhibit R-2**;

10. Respondents Otsuka and Bristol-Myers co-promote ABILIFY in Canada; as sponsors for ABILIFY in Canada, they are responsible for the Product Monographs, which are the primary source of information for healthcare professionals and patients, setting out the uses, dosage, and risks associated with the drug, the whole as appears more fully from a copy of an extract from Respondent Otsuka's website at www.otsukacanada.com and from a copy of Respondent Bristol-Myers' News Release entitled "Newest Treatment for Schizophrenia & Related Psychotic Disorders now Available to all Quebecers" dated October 26, 2010, produced herein *en liasse* as **Exhibit R-3**;

11. Respondent Lundbeck Canada Inc. ("Lundbeck") is a Canadian pharmaceutical corporation, with its head office in Montreal, Quebec. Lundbeck is and was at all relevant times involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of pharmaceutical products including ABILIFY MAINTENA. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* and from a copy of an extract from Respondent Lundbeck's website at www.lundbeck.com.ca, produced herein *en liasse* as **Exhibit R-4**;

12. On November 11, 2011, the parent companies of Respondents Otsuka and Lundbeck, namely, Otsuka Pharmaceutical Co., Ltd. and Lundbeck A/S, entered into a

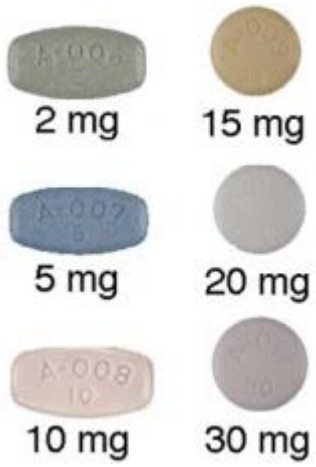
development and commercialisation agreement to develop and commercialize up to five medicines, included ABILIFY MAINTENA – thereafter, Respondents Otsuka and Lundbeck launched ABILIFY MAINTENA in Canada (Exhibit R-3), the whole as appears more fully from a copy of the Press Release entitled “Lundbeck and Otsuka Pharmaceutical sign historic agreement to deliver innovative medicines targeting psychiatric disorders worldwide” dated November 11, 2011, produced herein as **Exhibit R-5**;

13. Respondents Otsuka and Lundbeck, as sponsors for ABILIFY MAINTENA in Canada, are responsible for its Product Monographs, which are the primary source of information for healthcare professionals and patients, setting out the uses, dosage, and risks associated with the drug;

14. All Respondents have either directly or indirectly developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the ABILIFY Products to distributors and retailers for resale to or, directly to physicians, hospitals, medical practitioners and to the general public throughout Canada, including within the province of Quebec;

15. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other;

C) <u>The Situation</u>



I. What are the ABILIFY Products?

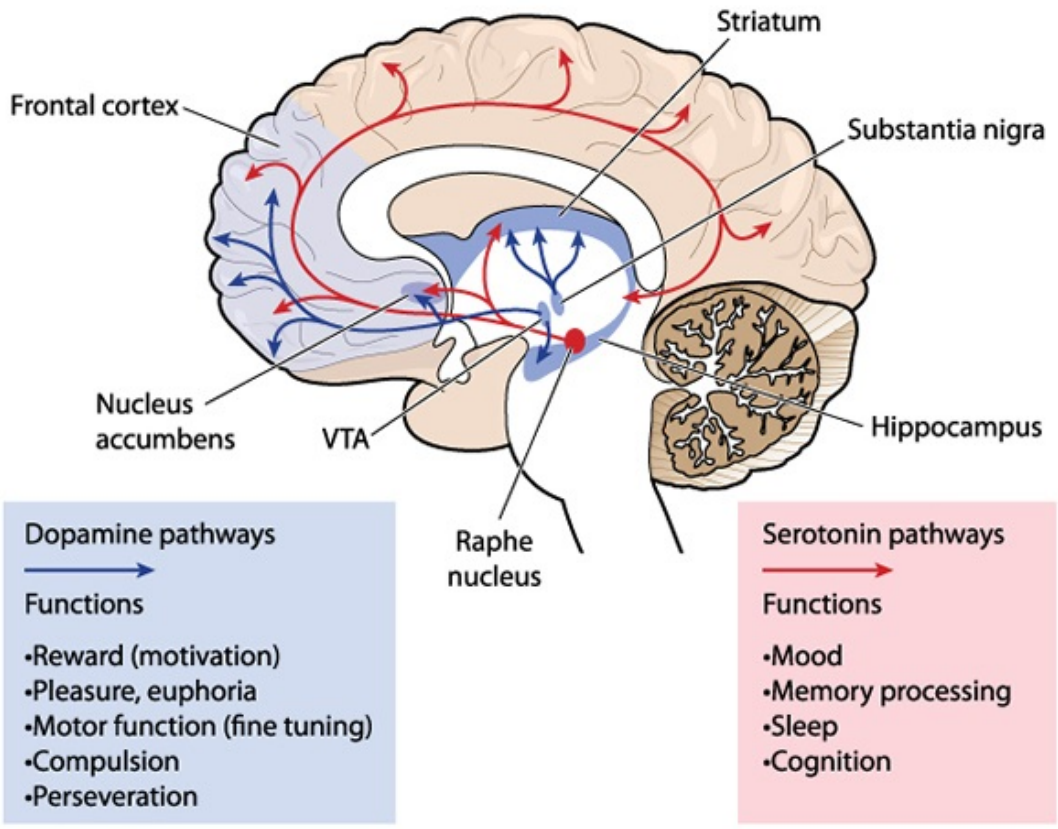
16. The ABILIFY Products belong to a group of medicines called atypical antipsychotics. Atypical antipsychotics (also known as second generation antipsychotics) are a group of antipsychotic drugs used to treat psychiatric conditions. Both generations of medication (typical and atypical antipsychotics) block receptors in the brain's dopamine pathways. Atypicals are less likely to cause extrapyramidal motor control disabilities such as unsteady Parkinson's disease-type movements, body rigidity, and involuntary tremors;

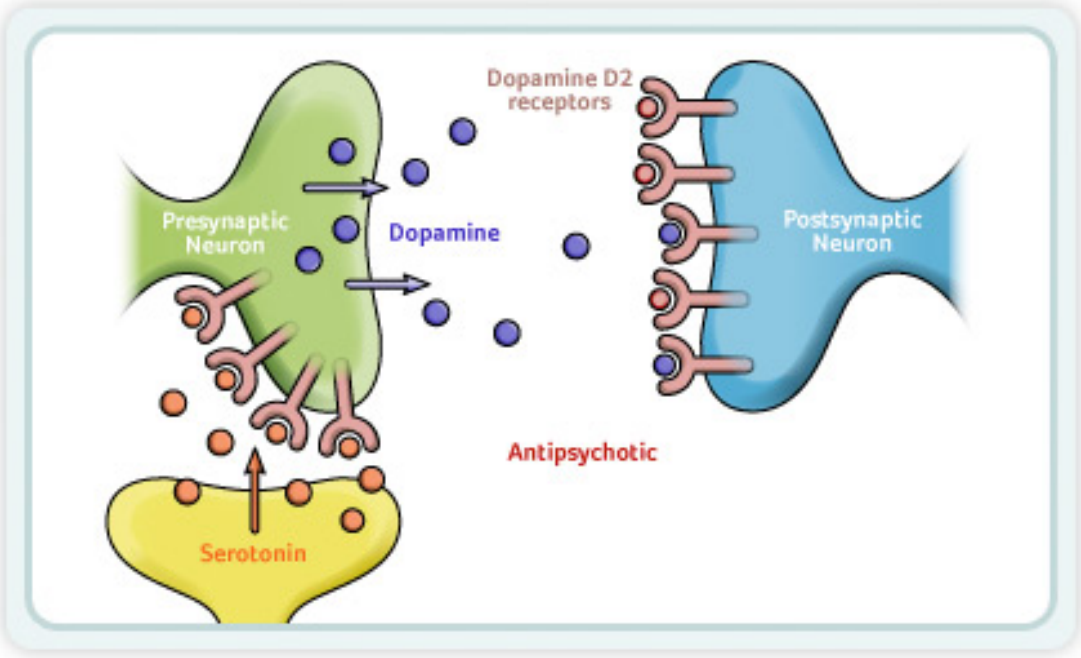
17. Like other atypical antipsychotics, the ABILIFY Products bind to several different neurotransmitter receptors, but unlike others in its class, it doesn't block dopamine[2] (specifically, dopamine D2) or serotonin[3] (specifically, 5-HT1A) receptors. Instead, it's a partial agonist[4] at those receptors – it can activate those receptors, but not to the full biological effect. In lay terms, it can both enhance dopamine and serotonin signaling where those transmitters are deficient, and inhibit signaling where they are in excess;

[2] Dopamine is a compound present in the body as a neurotransmitter and a precursor of other substances including epinephrine. It helps control the brain's reward and pleasure centers and helps regulate movement and emotional responses, and it enables us not only to see rewards, but to take action to move toward them.

[3] Serotonin is a compound present in blood platelets and serum that constricts the blood vessels and acts as a neurotransmitter. It is thought that *serotonin* can affect mood and social behaviour, appetite and digestion, sleep, memory and sexual desire and function.

[4] In pharmacology, partial agonists are drugs that bind to and activate a given receptor, but have only partial efficacy at the receptor relative to a full agonist.





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

of pathological gambling for years, the whole as appears more fully from a copy of the Frontiers in Behavioral Science article entitled “How central is dopamine to pathological gambling or gambling disorder?” dated December 23, 2013, from a copy of the Frontiers in Behavioral Science article entitled “What motivates gambling behavior? Insight into dopamine’s role” dated December 2, 2013, from a copy of the Scientific American article entitled “How the Brain Gets Addicted to Gambling”, and from a copy of the Gambling Research Exchange Ontario article entitled “Dopamine release in ventral striatum of pathological gamblers losing money” dated 2010, produced herein *en liasse* as **Exhibit R-6**;

19. The ABILIFY Products are available in following forms:

    (a) ABILIFY is available in the oral tablet form in six strengths (2 mg, 5 mg, 10 mg, 20 mg, and 30 mg) usually to be taken daily and

    (b) ABILIFY MAINTENA is available in the prolonged release syringe and/or vial in four strengths (300 mg vial, 400 mg vial, 300 mg dual chamber syringe, and 400 mg dual chamber syringe) for intra-muscular injection usually to be administered monthly;

II. <u>The Psychiatric Conditions – Explained</u>

(a) <u>Schizophrenia</u>

20. Schizophrenia is a severe mental disorder characterized by abnormal social behaviour and a failure to comprehend what is real. Common symptoms include false beliefs or suspicions, unclear or confused thinking, hallucinations, delusions, reduced social engagement and emotional expression, and a lack of motivation. People with schizophrenia often have additional mental health problems such as anxiety disorders, major depressive illness, or substance use disorders. Symptoms typically come on gradually, begin in young adulthood, the whole as appears more fully from a copy of the World Health Organization Fact Sheet and from a copy of an extract from the Schizophrenia Society of Canada at <u>www.schizophrenia.ca</u>, produced herein as **Exhibit R-7**;

21. Schizophrenia affects approximately 1 percent of the Canadian Population, the whole as appears more fully from a copy of an extract from the Public Health Agency of Canada - A Report on Mental Illness in Canada: Chapter 3 Schizophrenia and from a copy of the Statistics Canada publication at Section G – Schizophrenia, produced herein *en liasse* as **Exhibit R-8**;

22. Treatment for schizophrenia is antipsychotic medication (such as the ABILIFY Products) along with counselling, job training and social rehabilitation;

(b) <u>Bipolar I Disorder and Depression</u>

23. Bipolar I disorder is a bipolar spectrum disorder characterized by the occurrence of at least one manic or mixed episode[5]. Most patients also, at other times, have one or more depressive episodes, and all experience a hypomanic stage before progressing to full mania, the whole as appears more fully from a copy of the Psych Central article entitled "The Two Types of Bipolar Disorder", from a copy of the Canadian Mental Health Association article entitled "Bipolar Disorder", from a copy of the Canadian Mental Health Association brochure for Depression and Bipolar Disorder, dated 2014, and from a copy of the Pubic Health Agency of Canada article entitled "What Should I Know about Bipolar Disorder (Manic-Depression)?" dated April 23, 2009, produced herein *en liasse* as **Exhibit R-9**;

24. Approximately 1 percent of Canadians will experience bipolar disorder;

III. Approval of the ABILIFY Products in Canada

25. On July 9, 2009, Respondent Bristol-Myers obtained approval for ABILIFY from Health Canada in the 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg tablet form for the "treatment of schizophrenia and related psychotic disorders" and for the "acute treatment of manic or mixed episodes in Bipolar I Disorder…with lithium or divalproex sodium when there is an insufficient acute response to these agents alone". Thereafter:

(a) On May 12, 2011, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada "[t]o use as cotherapy with lithium or divalproex sodium for maintaining clinical improvement for up to 1 year in patients with manic or mixed episodes associated with Bipolar I Disorder",

(b) On November 21, 2011, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada for the "treatment of schizophrenia in adolescents 15-17 years of age",

(c) On March 13, 2012, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada for the "acute treatment of manic or mixed episodes in bipolar 1 disorder as monotherapy in adolescent patients 13-17 years of age", and

(d) On May 29, 2013, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada for the "use as an adjunct to antidepressants for the treatment of Major Depressinve *[sic]* Disorder (MDD) in adult patients who had an inadequate reponse *[sic]* to prior antidepressant treatments during the current episode",

the whole as appears more fully from copies of the five (5) Notices of Compliance obtained from Respondent Bristol-Myers from Health Canada dated July 9, 2009, May 12, 2011, November 21, 2011, March 13, 2012, and May 29, 2013 and from

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a copy of the Health Canada Summary Basis of Decision (SBD) for ABILIFY dated July 9, 2009, produced herein *en liasse* as **Exhibit R-10**;

26. Accordingly, ABILIFY was launched in Canada in 2009 in the 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths as a prescription medication;

27. On February 10, 2014, non-party Otsuka Pharmaceutical Co., Ltd. obtained approval for ABILIFY MAINTENA from Health Canada in the 300 mg and in the 400 mg vial form for the intramuscular injection in the dosage form "kit, suspension". On August 20, 2015, non-party Otsuka Pharmaceutical Co Ltd. obtained approval for ABILIFY MAINTENA from Health Canada in the same strengths, but in the dosage forms of "kit, powder for suspension, sustained-release". Lastly, on September 16, 2015, non-party Otsuka Pharmaceutical Co Ltd. obtained approval for ABILIFY MAINTENA from Health Canada in the same strengths and in the dosage forms, but added the indication of "treatment of acute episodes of schizophrenia", the whole as appears more fully from copies of three (3) Notices of Compliance dated February 10, 2014, August 20, 2015, and September 16, 2015, from a copy of the Regulatory Decision Summary for ABILIFY MAINTENA dated September 16, 2015 and from a copy of the Press Release entitled "The Otsuka and Lundbeck Alliance Announces Once-Monthly ABILIFY MAINTENA™ (ARIPIPRAZOLE for prolonged release injectable suspension) Now Approved in Canada for the Maintenance Treatment of Schizophrenia in Stabilized Adult Patients" dated February 12, 2014, produced herein *en liasse* as **Exhibit R-11**;

28. On or about February 12, 2014, ABILIFY MAINTENA was launched in Canada, the whole as appears more fully from a copy of an extract from Respondent Otsuka's website at www.otsukacanada.com, produced herein as **Exhibit R-12**;

IV. The U.S. Experience

29. ABILIFY was launched in the United States in or around the fall of 2002 and ABILIFY MAINTENA was launched in the United States in March 2013;

30. On October 31, 2001, non-party Otsuka Pharmaceutical Co., Ltd. submitted a New Drug Application to the United States Food and Drug Administration ("US FDA") for ABILIFY. Approval was sought to market ABILIFY in 2, 5, 10, 15, 20 and 30 mg tablets as a treatment for schizophrenia. It was approved on November 15, 2002, the whole as appears more fully from a copy of the Approval Letter – Application 21-436, produced herein as **Exhibit R-13**;

31. The US FDA required that the results of Study 138047 to address the longer-term efficacy of ABILIFY in the treatment of adults with schizophrenia be submitted;

32. On December 3, 2002, non-party Otsuka America Pharmaceutical, Inc., submitted a Supplemental New Drug Application (NDA 21-436/S-001) on the longer-term efficacy of ABILIFY in the treatment of schizophrenia. This application was approved on

August 28, 2003, the whole as appears more fully from a copy of the Approval Package Application Number NDA 21-436/S-001 dated August 28, 2003, produced herein as **Exhibit R-14**;

33. In June 2003, non-party Otsuka Maryland Research Institute submitted another Supplemental New Drug Application (NDA 21-436/S-002) for ABILIFY tablets as a treatment for bipolar disorder. This application was approved on September 29, 2004, the whole as appears more fully from a copy of the Approval Letter and Package for Application Number NDA 21-436/S-002 dated September 29, 2004, produced herein as **Exhibit R-15**;

34. In May 2007, non-party Otsuka Pharmaceutical Development & Commercialization, Inc., submitted another Supplemental New Drug Application (NDA 21-436/S-018) for ABILIFY tablets as an adjunctive treatment for patients with major depressive disorder. This application was approved on November 16, 2007, the whole as appears more fully from a copy of the Approval Letter from the Department of Health & Human Services dated November 16, 2007, produced herein as **Exhibit R-16**;

35. In Europe, ABILIFY is not indicated to treat depression. The European Medicines Agency declined to approve ABILIFY as an add-on treatment for depression because of concerns about its efficacy for that indication, the whole as appears more fully from a copy of the Withdrawal Assessment Report for ABILIFY dated January 20, 2010, produced herein as **Exhibit R-17**;

V. <u>Pathological/ Compulsive Gambling and Dopamine</u>

36. Pathological gambling is a major psychiatric disorder and is considered to be the most extreme form of "disordered gambling". It may be defined as an addictive urge to gamble continuously despite harmful negative consequences or a desire to stop, the whole as appears more fully from a copy of the Journal of Gambling Studies article entitled "Pathologic Gambling and Impulse Control Disorders" dated March 2005, produced herein as **Exhibit R-18**;

37. Dopamine's role in compulsive behaviour and pathological gambling is well-known. Dopaminergic reward pathways have frequently been implicated in the cause of addictive behaviour. Scientific literature has identified dopamine as a potential cause of pathological gambling for years (as appears in the proceeding section);

38. The ABILIFY Products are dopamine agonists and they have been scientifically linked to a higher chance of compulsive behaviours like binge-eating, hypersexuality, compulsive spending or shopping, and gambling;

39. Bristol-Myers Squibb Company's September 2011 6-Month Periodic Safety Update Report submitted to the European Medicines Agency acknowledges a plausible mechanism for pathological gambling. The Report states that an article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to Psychiatric Disorders* (Exhibit R-

21), “does suggest a possible mechanism by which drugs that act on dopamine neurons, like aripiprazole, might possibly have some effect on behavior related to reward”, the whole as appears more fully from a copy of Bristol-Myers Squibb Company’s September 1, 2011 6-Month Periodic Safety Update Report dated September 1, 2011, produced herein as **Exhibit R-19**;

40. The Safety Update Report (Exhibit R-19) acknowledged seven serious reports of pathological gambling, three in the medical literature and four spontaneous reports. The report also noted sixteen cases of pathological gambling in the Bristol-Myers Squibb company safety database;

41. The Medical Assessment of the pathological gambling cases in Respondents’ Safety Update Report (Exhibit R-19) did not exclude ABILIFY as the cause of the compulsive gambling adverse events. The Respondents concluded that “a causal role of aripiprazole could not be excluded” or that “aripriprazole was suggested by the temporal relationship”;

42. The European Final Assessment Report of the Safety Update Report (Exhibit R-19) concluded that with regard to compulsive gambling “in all of the reported cases we have a (+) temporal; (+) dechallenge and in one case a (+) rechallenge”, the whole as appears more fully from a copy of the Final Assessment Report on the 15th Periodic Safety Update Report dated December 5, 2011, produced herein as **Exhibit R-20**;

VI. <u>The Scientific Studies Behind the Drug(s)</u>

43. ABILIFY emulates dopamine, a chemical that is critical for controlling the pleasure and reward centers in the brain. It is also a chemical that has often been implicated in relation to addiction. Researchers argue that dopamine has two key effects on patients: (i) it can impair decision-making and (ii) create urges that must be rewarded. The drug can minimize cognitive control while, at the same time stimulate the brain’s reward system. The studies and case reports that follow demonstrate that ingesting and/or injecting the ABILIFY Products causes an increased risk of compulsive or pathological gambling;

44. In 2004, the complex nature of reward processing in the brain and the role of the brain’s reward circuitry in several psychiatric disorders including substance use disorders, schizophrenia, pathologic gambling, major depressive disorder, and attention-deficit/hyperactivity disorder was investigated. The report concluded that more research would be beneficial on the relationship between dopamine and various disorders including pathological gambling, the whole as appears more fully from a copy of the Current Psychiatry Reports report entitled “The neural circuitry of reward and its relevance to psychiatric disorders” dated November 2004, produced herein as **Exhibit R-21**;

45. In April 2007, a case report was published detailing the exacerbation of obsessive-compulsive disorder (OCD) during treatment with atypical antipsychotics (such as the

ABILIFY Products), the whole as appears more fully from a copy of the Journal of Clinical Psychopharmacology Letters to the Editors entitled “Worsening of Obsessive-Compulsive Symptoms After Treatment With Aripiprazole” dated April 2007, produced herein as **Exhibit R-22**;

46. In October 2008, a case report was published detailing an uncontrollable increase in sexual desire following the ingestion of aripiprazole (the ABILIFY Products). ABILIFY’S dopaminergic activity at the mesolimbic circuit, especially at the nucleus accumbens, was associated with compulsive behaviour, the whole as appears more fully from a copy of the Journal of Clinical Psychopharmacology Letters to the Editors entitled “Aripiprazole Induced Hypersexuality in a 24-Year-Old Female Patient With Schizoaffective Disorder?” dated October 2008, produced herein as **Exhibit R-23**;

47. In March 2010, an article was published detailing the experience of a 64-year old woman who after being prescribed aripiprazole, she experienced an irresistible urge to gamble and compulsion to eat – these urges stopped one month after switching medications, the whole as appears more fully from a copy of the Australian & New Zealand Journal of Psychiatry correspondence entitled “Pathological Gambling and Compulsive Eating Associated with Aripiprazole” dated March 2010, produced herein as **Exhibit R-24**;

48. In November 2010, a case report was published in which two patients with schizophrenia, previously treated with anti-psychotic drugs and no history of pathological gambling, who within a short time after starting aripiprazole, developed pathological gambling symptoms and criminal behaviour, which totally resolved after stopping the drug, the whole as appears more fully from a copy of the Journal of Forensic Sciences article Case Report entitled “Partial Agonist Therapy in Schizophrenia: Relevance to Diminished Criminal Responsibility” dated November 2010, produced herein as **Exhibit R-25**;

49. In 2010, two case reports were published in which two patients experienced adverse behavioural changes related to impulse control and addictions such as hypersexuality and excessive shopping after administration of aripiprazole, the whole as appears more fully from a copy of the International Journal of Neuropsychopharmacology Letter to the Editor entitled “Aripiprazole-induced behavioural disturbance related to impulse control in a clinical setting” dated 2010, produced herein as **Exhibit R-26**;

50. In 2011, three case reports were published that suggested that pathological gambling may have been caused following treatment with aripiprazole. All three subjects reported an escalation of gambling and uncontrollable urges upon being administered ABILIFY and all three reported these urges normalizing upon cessation of the drug, the whole as appears more fully from a copy of report from the British Journal of Psychiatry entitled “Pathological gambling and the treatment of psychosis with aripiprazole: case reports” dated 2011, produced herein as **Exhibit R-27**;

51. In 2011, three cases of pathological gambling induced by Aripiprazole were reported whereby there was no prior history of pathological gambling and they started gambling after initiating treatment with Aripiprazole. The pathological behaviour disappeared when the medication ended, the whole as appears more fully from a copy the Current Drug Safety article entitled “Aripiprazole-Induced Pathological Gambling: A Report of 3 Cases” dated 2011, produced herein as **Exhibit R-28**;

52. In 2013, two cases of hypersexuality were reported in patients receiving treatment with aripiprazole, the whole as appears more fully from a copy of the Case Report entitled “Two Cases of Hypersexuality Probably Associated with Aripiprazole” dated 2013, produced herein as **Exhibit R-29**;

53. In December 2014, a study was published that analyzed the records of 1,580 patients who had reported adverse drug effects involving compulsive gambling and other impulse behaviour issues. The researchers conducting the study reported that they found a “significant” link between use of ABILIFY and gambling, the whole as appears more fully from a copy of the JAMA Internal Medicine article entitled “Reports of Pathological Gambling, Hypersexuality, and Compulsive Shopping Associated With Dopamine Receptor Agonist Drugs” dated 2014, produced herein as **Exhibit R-30**;

54. In March 2014, a study was published that involved eight people who were being treated for compulsive gambling. A direct link between the use of aripiprazole and the disorder was present in 7 of the patients. The researchers reported those patients could once again control their impulse to gamble after they were taken off of the medication, the whole as appears more fully from a copy of the Addictive Behaviors “Aripiprazole: a new risk factor for pathological gambling? A report of 8 case reports” dated March 2014, produced herein as **Exhibit R-31**;

55. Several of these studies demonstrate what is known as a challenge, de-challenge, and re-challenge (see, for example, Exhibits R-21, R-26, and R-27):

    (a) Challenge is the administration of a suspect product by any route,

    (b) De-challenge is the withdrawal of the suspected product from the patient’s therapeutic regime. A positive de-challenge is the partial or complete disappearance of an adverse experience after withdrawal of the suspect product. For example, a positive de-challenge occurs when a patient ceases use of ABILIFY and pathological gambling behaviours cease,

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

The whole as appears more fully from a copy of the US FDA draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biologic Products Including Vaccines dated 2001, produced herein as **Exhibit R-32**;

56. A positive de-challenge is considered evidence that a drug caused a particular effect, as is a positive re-challenge, the whole as appears more fully from a copy of the USFDA Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment dated March 2005 and from a copy of the Federal Judicial Center's Reference Manual on Scientific Evidence – Third Edition, dated 2011, produced herein *en liasse* as **Exhibit R-33**;

57. These studies serve to indicate the importance of informing both patients and healthcare professionals of these adverse side-effects so that they may make informed decisions regarding this medication. In addition, should the patient make an informed decision to take ABILIFY in spite of the serious risks, knowledge of these risks would have allowed them to, at the very least, know what was causing their pathological behaviours;

58. The Respondents, in failing to advise doctors and patients of the increased risks associated with ABILIFY, effectively usurped their ability to make informed decisions regarding its use and removed their ability to limit and/or control the risk through engaging in precautionary monitoring measures;

59. On November 19, 2009, the first adverse event was reported to Health Canada, whereby a 56-year-old female suffered palpitations while taking ABILIFY. Thereafter, 597 adverse events reported up until June 20, 2016, the whole as appears from a copy of Health Canada's adverse reaction reports, produced herein as **Exhibit R-34**;

60. Of these adverse events reported, 10 included gambling, the first having been reported on August 25, 2014, the whole as appears more fully from a copy of Health Canada's list of adverse reaction reports and from a copy of the actual reports, produced herein *en liasse* as **Exhibit R-35**;

61. In the United States, from May 1, 2009 to May 1, 2011, the US FDA received thousands of serious adverse event reports concerning ABILIFY (n=4599), including over two-thousand serious adverse drug experiences of which 193 involved children (0-16 years old), the whole as appears more fully from a copy of the slides from the US FDA "Pediatric Focused Safety Review: Abilify® (aripiprazole) to May 1, 2011" dated September 22, 2011, produced herein as **Exhibit R-36**;

62. Since its introduction in the U.S. in November 2002 until mid-January 2016,184 case reports were identified indicating an association between the ABILIFY Products and impulse-control problems. The specific impulse-control problems reported include: pathological gambling (n=164); compulsive sexual behaviour (n=9); compulsive buying (n=4); compulsive eating (n=3); and multiple impulse-control problems (n=4).

These urges began only after starting to take the ABILIFY Products and were resolved after reducing the dosage or discontinuing the treatment altogether, the whole as appears more fully from a copy of the US FDA Drug Safety Communications Safety Announcement entitled "FDA Drug Safety Communication: FDA warns about new impulse-control problems associated with mental health drug aripiprazole (Abilify, Abilify Maintena, Aristada)" dated May 3, 2016, produced herein as **Exhibit R-37**;

63. A disproportionality study of the US FDA Adverse Event Reporting System showed a proportional reporting ratio for compulsivity of 8.6 for ABILIFY (Exhibit R-30). A ratio of more than three indicates a signal of an adverse event, the whole as appears more fully from a copy of the International Journal of Medical Sciences article entitled "Data Mining of the Public Version of the FDA Adverse Event Reporting System" dated April 25, 2013, produced herein as **Exhibit R-38**;

VII. <u>Governmental Regulation of the ABILIFY Products</u>

64. In October 2012, the European Medicines Agency required that the Respondents warn patients and the medical community in Europe of the risk of pathological gambling associated with the use of ABILIFY, the whole as appears more fully from a copy of the European Medicines Agency document for ABILIFY and from a copy of the European Medicines Agency's Annex I – Summary of Product Characteristics, produced herein *en liasse* as **Exhibit R-39**;

65. Specifically, the European Medicines Agency required the following labelling change in Europe in the "Special warnings and precautions" for use section of the label:

> <u>Pathological gambling</u>
> 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),

66. In addition, the risk of pathological gambling was included in the section entitled "Undesirable effects" along with agitation, nervousness, suicide attempt, suicidal ideation, and completed suicide;

67. On November 2, 2015, Health Canada concluded that there is "a link between the use of aripiprazole and a possible risk of pathological gambling or hypersexuality" and found an increased risk of pathological (uncontrollable) gambling and hypersexuality with the use of the ABILIFY Products, the whole as appears more fully from a copy of the Health Canada Information Update entitled "Safety information for antipsychotic drug Abilify and risk of certain impulse-control behaviours" dated November 2, 2015, from a copy of the Health Canada Summary Safety Review - ABILIFY and ABILIFY MAINTENA (aripiprazole) - Evaluating the Risk of Certain Impulse Control Behaviours" dated November 2, 2015, and from a copy of the CTV News article

entitled “Health Canada updates list of possible side effects for 2 antipsychotic drugs” dated November 2, 2015, produced herein *en liasse* as **Exhibit R-40**;

68. It was not until June 22, 2015 and September 15, 2015 respectively, that the Respondents finally did include pathological gambling as a potential side effect of ingesting and/or injecting the ABILIFY Products on the Product Monograph (as will be outlined in more detail below);

VIII. The Respondents’ Marketing Practices

69. Despite the risks of serious adverse events, and the lack of adequate testing, that Respondents aggressively promoted ABILIFY, including illegal promotion for off-label use. In the United States, in 2007, Bristol-Myers reportedly paid $515 million to settle federal and state investigations into off-label marketing of Abilify for pediatric use and to treat dementia-related psychosis. Otsuka American Pharmaceutical, Inc., later paid more than $4 million to resolve the allegations, the whole as appears more fully from a copy of the United States Department of Justice Press Release entitled “Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing” dated September 28, 2007 and from a copy of the United States Department of Justice Press Release entitled “Otsuka to Pay More than $4 Million to Resolve off-label Marketing Allegations Involving Abilify” dated March 27, 2008, produced herein *en liasse* as **Exhibit R-41**;

70. The US FDA issued a letter dated April 17, 2015 finding ABILIFY promotional material “false or misleading because it makes misleading claims and presentations about the drug.” The US FDA found the material “misleading because it implies that Abilify offers advantages over other currently approved treatments for bipolar disorder or MDD when this has not been demonstrated.” The US FDA also found the cited references “not sufficient to support claims and presentations suggesting that Abilify has been demonstrated to modulate dopaminergic and serotonergic activity, or modulate neuronal activity in both hypoactive and hyperactive environments in humans”, the whole as appears more fully from a copy of the letter from the US FDA Department of Health & Human Services to Otsuka Pharmaceutical Development & Commercialization, Inc. dated April 17, 2015 and from a copy of the PLoS Medicine article entitled “Questionable Advertising of Psychotropic Medications and Disease Mongering” dated July 2006, produced herein *en liasse* as **Exhibit R-42**;

71. The Respondents have invested millions of dollars in teams of pharmaceutical sales representatives who visit and contact members of the medical community, including prescribing doctors, purporting to “educate” them about ABILIFY. These pharmaceutical sales representatives have not notified patients, the medical community, or prescribers that ABILIFY use causes, is linked to, or might be associated with compulsive gambling, pathological gambling, or gambling addiction;

72. The Respondents have made payments to doctors to promote ABILIFY. For example, from August 2013 to December 2014, $10.6 million in payments relating to ABILIFY

were made to 21,155 physicians in the United States, the whole as appears more fully from a copy of the Pro Publica webpage entitled “Has Your Doctor Received Drug or Device Company Money?” for ABILIFY, produced herein as **Exhibit R-43**;

73. ABILIFY generated $5.501 billion in sales worldwide in 2013, being the tenth best-selling drug worldwide, the whole as appears more fully from a copy of an extract from the FiercePharma article for ABILIFY, produced herein as **Exhibit R-44**;

74. Bristol-Myers touted ABILFY as its “largest-selling product” in 2012, 2013 and 2014, the whole as appears more fully from copies of extracts from Bristol-Myers website at www.bms.com, produced herein *en liasse* as **Exhibit R-45**;

75. Bristol-Myers reported worldwide revenues from sales of ABILIFY of $2.020 billion in 2014, $2.289 billion in 2013, $2.827 in 2012, and $2.758 in 2011, the whole as appears more fully from a copy of Bristol-Myers’ Annual Reports dated 2014 and 2013, produced herein *en liasse* as **Exhibit R-46**;

76. Lundbeck reported worldwide revenues from sales of ABILFY MAINTENA of $209 million in 2014, the whole as appears more fully from a copy of Lundbeck’s Annual Report dated 2014, produced herein as **Exhibit R-47**;

77. According to Otsuka’s Annual Report for the year 2014, sales of their “top-selling pharmaceutical product ABILIFY constitute approximately 40% of [their] total consolidated net sales”. In 2013, Otsuka reported that it constituted over 30% of sales, the whole as appears more fully from copies of Otsuka’s Annual Reports dated 2013 and dated 2014, produced herein *en liasse* as **Exhibit R-48**;

78. As stated above in the section entitled “B) The Respondents”, Respondent Bristol-Myers and Otsuka entered into an agreement to co-market and promote ABILIFY in Canada (Exhibit R-3). Under the terms of this agreement, ABILIFY was to be marketed by Bristol-Myers under license by non-party Otsuka Pharmaceutical Co., Ltd. This agreement was originally formed for the marketing of ABILIFY in the U.S. in 1999 whereby it was agreed that Bristol-Myers and Otsuka would collaborate to complete clinical studies for schizophrenia, and that Bristol-Myers would conduct additional studies for new dosage forms and new indications, the whole as appears more fully from a copy of the Press Release entitled “Bristol-Myers Squibb And Otsuka Announce Commercialization Agreement For Aripiprazole” dated September 21, 1999, produced herein as **Exhibit R-49**;

79. In spite of the strong indication that ABILIFY was causing pathological gambling and other pathological behaviours, the Respondents failed to timely inform consumers, health care professionals, Health Canada and the scientific community and they failed to perform further investigation into its safety;

80. This important information is hardly present in the eighty-four-page Product Monograph of ABILIFY and in the 52-page Product Monograph for ABILIFY

MAINTENA at present as it is only mentioned three times; one in the "Warnings and Precautions" section as follows:

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

Under the section entitled "Post-Market Adverse Drug Reactions" the word "gambling" again appears as follows: "*Unknown*: Pathological gambling, Hypersexuality" and lastly in the Consumer Information section for ABILIFY, "an urge to gamble" appears under "side effects and what to do about them" and under for ABILIFY MAINTENA it simply says to advise your doctor, nurse or pharmacist of you "have a history of gambling",

The whole as appears more fully from a copy of the Product Monograph for ABILIFY last revised on June 22, 2015 and from a copy of the Product Monograph for ABILIFY MAINTENA dated September 15, 2015, produced herein *en liasse* as **Exhibit R-50**;

81. Previous versions of the Product Monographs for ABILIFY and ABILIFY MAINTENA, which make no mention whatsoever about gambling, pathological or otherwise, are produced herein *en liasse* as **Exhibit R-51**;

82. There are many feasible alternatives to ABILIFY in the form of antipsychotics and/or atypical antipsychotics which do not cause uncontrollable impulses such as compulsive or pathological gambling. The serious side effects of the ABILIFY Products rendered their design defective, which was a substantial factor in causing the Petitioner's and Class Members' injuries;

83. Despite various warning changes, the Respondents' marketing of ABILIFY continues to fail to adequately warn consumers, healthcare professionals and the public of the serious risk of experiencing uncontrollable urges including compulsive or pathological gambling;

IX. <u>The Respondents' Liability</u>

84. The Respondents have not adequately studied ABILIFY. A review of all the randomized clinical trials comparing ABILIFY to other schizophrenia drugs concluded that the information on comparisons was of limited quality, incomplete, and problematic to apply clinically, the whole as appears more fully from a copy of the Cochrane Library Database of Systematic Reviews article entitled "Aripiprazole versus other atypical antipsychotics for schizophrenia (Review)" dated 2016, produced herein as **Exhibit R-52**;

85. Despite evidence that ABILIFY causes compulsive behaviours such as pathological gambling and calls from the medical community to conduct further research and warn

patients about this possible effect of ABILIFY, the Respondents have either failed to investigate or conduct any studies on the compulsive behaviour side effects of ABILIFY and/or failed to make public the results of any studies or investigations that they might have conducted;

86. A reasonably prudent drug developer, designer, manufacturer, tester, marketer, labeller, packager, promotor, advertiser, distributer, and/or seller in the Respondents' positions would have adequately warned both doctors and patients of the risks associated with the use of the ABILIFY Products;

87. Despite a clear signal, the Respondents failed to either alert the public and the scientific and medical community or to perform further investigation into the safety of the ABILIFY Products;

88. The Respondents were negligent in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, distribution, and/or sale of the ABILIFY Products in one or more of the following respects:

    a. They knew or should have known that the ABILIFY Products increased the risk of the adverse side effect of uncontrollable impulses including compulsive and/or pathological gambling;

    b. They failed to ensure that ABILIFY was not dangerous to consumers;

    c. They failed to conduct appropriate testing to determine whether and to what extent the ingestion and/or injection of the ABILIFY Products pose serious risks, including the uncontrollable impulses of compulsive and/or pathological gambling;

    d. They failed to adequately test the products prior to placing them on the market;

    e. They failed to adequately test the ABILIFY Products in a manner that would fully disclose the side effect of uncontrollable impulses including compulsive and/or pathological gambling;

    f. They failed to use care in developing, designing and manufacturing their products so as to avoid posing unnecessary health risks to users of such products;

    g. They failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the drugs;

    h. They failed to advise that the ingestion and//or injection of the ABILIFY Products could result in severe side effects, including but not limited to, uncontrollable impulses including compulsive and/or pathological gambling;

i. They failed to advise the medical and scientific communities of the potential to increase the risk of uncontrollable impulses including compulsive and/or pathological gambling;

j. They failed to provide adequate and timely warnings or sufficient indications about the increased potential health risks associated with the use of the ABILIFY Products;

k. They failed to provide Class Members and their physicians with adequate warnings or sufficient indications of inherent risks associated with the ABILIFY Products;

l. They failed to provide adequate warnings regarding the need to assess impulse control and gambling activity prior to starting a patient on the ABILIFY Products and to continue with periodic testing and monitoring while the patient is taking the ABILIFY Products;

m. They failed to provide adequate updated and current information to Class Members and their physicians respecting the risks of the ABILIFY Products as such information became available;

n. They failed to provide prompt warnings of potential hazards of the ABILIFY Products in the products' monographs and in the products' labelling;

o. They failed to warn that Class Members and their physicians that the risks associated the ABILIFY Products would exceed the risks of other available antipsychotic and atypical antipsychotic medications;

p. After receiving actual or constructive notice of the problems associated with the ABILIFY Products, they failed to issue adequate warnings, to publicize the problem and otherwise act properly and in a timely manner to alert the public, the Class Members and their physicians, of the drugs' inherent dangers;

q. They failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the risks associated with the drugs;

r. They falsely stated and/or implied that the ABILIFY Products were safe when they knew or ought to have known that this representation was false;

s. They disregarded reports of uncontrollable impulses including compulsive and/or pathological gambling among patients;

t. They failed to accurately and promptly disclose to Health Canada information relating to uncontrollable impulses including compulsive and/or pathological gambling associated with the ABILIFY Products and to modify the ABILIFY

Products' product monographs and product labelling accordingly in a timely manner;

u. They failed to monitor and to initiate a timely review, evaluation and investigation of reports of uncontrollable impulses including compulsive and/or pathological gambling associated with the ABILIFY Products in Canada and around the world;

v. They failed to properly investigate cases of uncontrollable impulses including compulsive and/or pathological gambling caused by the ABILIFY Products;

w. They deprived patients of a chance for safe, effective and/or successful alternative treatments; and

x. In all circumstances of this case, they applied callous and reckless disregard for the health and safety of their consumers;

89. Despite the vast availability of knowledge clearly indicating that ABILIFY Product use is causally-related to uncontrollable impulses including compulsive and/or pathological gambling, the Respondents not only failed to provide adequate labelling to warn Class Members of the risks associated with the use of the ABILIFY Products, but instead incongruously promoted and marketed the ABILIFY Products as a safe and effective drug, effectively appropriating the ability of doctors and patients to make informed decisions regarding their health;

90. The Respondents concealed and failed to completely disclose their knowledge that the ABILIFY Products were associated with or could cause uncontrollable impulses including compulsive and/or pathological gambling as well as their knowledge that they had failed to fully test or study said risk;

91. The Respondents ignored the association between the use of the ABILIFY Products and the risk of uncontrollable impulses including compulsive and/or pathological gambling;

92. The Respondents' failure to disclose information that they possessed regarding the failure to adequately test and study the ABILIFY Products for uncontrollable impulses including compulsive and/or pathological gambling risk further rendered warnings for this medication inadequate;

II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

93. In late 2010, early 2011, the Petitioner was prescribed ABILIFY by his physician in the 10-mg dosage[6], which was intended to treat his severe anxiety associated with his Obsessive-Compulsive Disorder (OCD) and to help boost his mood to prevent depressive episodes;

[6] The Petitioner was weaned onto the medication, starting first with a lower dose for a very short period of time.

94. The Petitioner filled his prescription at the Uniprix located at 5443 Rue Bannantyne, in Verdun, Quebec and he took the medication as directed, namely, once daily in the mornings. Thereafter, he switched pharmacies several times depending on where he was living;

95. Within a few months' time, the Petitioner began experiencing urges to gamble for the first time and he started gambling with small sums of money in slot machines at various bars. At first, he would gamble once a week with $20.00, then with $50.00, but the urges escalated, rapidly becoming uncontrollable and he began regularly gambling at the slot machines, losing thousands of dollars within a short period of time;

96. The Petitioner's gambling became so uncontrollable and compulsive that he would to do anything he could to find cash to gamble at the slot machines including, but not limited to the following:

    (a) Withdrawing his RRSPs at the Laurentian Bank in the amount of $2,500.00,

    (b) Selling his 2006 Pontiac G6 GT Coupe for $850.00 (approximately 10 to 15 percent of its worth at the time),

    (c) Selling his Canada Goose jacket in the middle of winter for $60.00 (approximately 10 percent of its worth at the time),

    (d) Accruing liabilities on various credit cards (owned by himself and by close friends and family) by purchasing new merchandise from stores on credit and then pawning them at pawn shops for a fraction of their value, and

    (e) Pawning all the gold he could find, including sentimental family pieces;

97. The Petitioner's anxiety about his urges and about where he was going to find money to gamble with became unbearable. He lost interest in everything except gambling and he could not stop the cravings and urges so he checked himself into a rehab centre, Pavillon Foster at 6 Rue Foucreault, in Saint-Philippe, Quebec;

98. He stayed at the rehab centre on two occasions for three-week periods, where he was administered ABILIFY every day, but when he was released, he would continue compulsively gambling;

99. His urges and compulsions, and the accompanying anxiety, became so bad that he attempted suicide by taking all the medication that he found in his mother's medicine cabinet. He was taken by ambulance to the Hôpital de Verdun at 4000 Boulevard LaSalle, in Verdun, Quebec, where he was administered charcoal to make him throw up the medications that he had taken;

100. Thereafter, he registered with another rehab centre, Portage Quebec Adult Day Centre Montreal, at 1640, rue Saint-Antoine West, in Montreal, Quebec, where he was an out-patient on Tuesdays, Wednesdays, and Thursdays from 10:00 A.M. to 4:00 P.M. The idea was to wait for an opening at their in-patient facility at 1790 Chemin du Lac Écho, in Prévost, Quebec;

101. Throughout this time period, the Petitioner would continue to compulsively gamble, including on the way to and from the rehab centre;

102. On or about September 3, 2014, the Petitioner was admitted to the Portage Quebec in-patient centre in Prévost, Quebec where he was administered ABILIFY and where his uncontrollable and unbearable gambling urges continued;

103. The Petitioner's urges to gamble became so intense that he had to check himself out of the rehab centre after approximately three months to gamble – after temporarily satiating his urges, the Petitioner checked himself back into the centre the following week;

104. The Petitioner's gambling compulsions continued unabated for another three months while at the centre until his cravings again forced him to check himself out again at which point he travelled directly to the Casino de Montreal to gamble all the money in his bank account at the time;

105. The Petitioner continued gambling five to six days a week and losing approximately $1,000.00 to $1,500.00 each time;

106. This dismal situation continued until on or about August 2016 when his girlfriend's sister saw a commercial about ABILIFY and how it may cause gambling problems. The Petitioner stopped taking ABILIFY immediately upon learning that his compulsive gambling may be related to the medication that he was taking;

107. About one month after stopping to take ABILIFY, the Petitioner's compulsive gambling problems were completely gone;

108. The Petitioner lost between $50,000.00 and $60,000.00 while taking ABILIFY over the course of approximately five years;

109. The Petitioner had no gambling problems prior to taking ABILIFY and his gambling problems ended upon stopping to take ABILIFY;

110. At no time was the Petitioner made aware of the risks of suffering from uncontrollable impulses including compulsive and/or pathological gambling associated with taking ABILIFY;

111. Had the Respondents properly disclosed the risks associated with ABILIFY, Petitioner would have avoided the risk of suffering from uncontrollable impulses,

including compulsive and/or pathological gambling by not ingesting ABILIFY at all. Further, had the Petitioner been made aware of the risks of suffering from uncontrollable impulses, including compulsive and/or pathological gambling, he would not have had to suffer injury for five long years without any explanation of the cause, and instead would have simply discontinued his use of ABILIFY at the first sign of the uncontrollable urges;

112. Petitioner is aware that several lawsuits were filed in the United States due to the defects associated with ABILIFY and due to the Respondents' conduct related thereto, as appears more fully from a copy of the U.S. Complaints, produced herein *en liasse* as **Exhibit R-53**;

113. As a result of the Respondents' conduct, the Petitioner suffered damages including, but not limited to physical and mental/emotional injuries, including pain, suffering, anxiety (the very problem he was trying to resolve), fear, loss of quality and enjoyment of life, damage to or loss of reputation, extensive financial losses (including the loss of sentimental family jewelry pieces), loss of income, expenses relating to his treatment in the rehab centres, and the apportioned cost of ABILIFY;

114. Petitioner's damages are a direct and proximate result of his use of the drug ABILIFY, Respondents' negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of the ABILIFY Products;

115. In consequence of the foregoing, the Petitioner is justified in claiming damages;

III. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP

116. Every member of the Class has purchased and/or ingested/injected the ABILIFY Products or is the successor, family member, assign, and/or dependant of a person who purchased, ingested, and/or injected the ABILIFY Products;

117. The Class Members' damages would not have occurred, but for the acts, omissions and/or negligence of the Respondents in failing to ensure that the ABILIFY Products were safe to use, for failing to provide adequate warning of the unreasonable risks associated with using the drug, for false or misleading representations and for omitting to disclose important information to Class Members, to their physicians, and to Health Canada;

118. In consequence of the foregoing, each member of the Class is justified in claiming at least one or more of the following as damages:

a. Physical and mental/emotional injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life, increased risk of mental problems, damage to and/or loss of reputation;

b. Out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of the compulsive behaviours;

c. Extensive financial losses (such as from gambling or spending) and out-of-pocket expenses, including loss of income and loss of future income;

d. Refund of the purchase price of the ABILIFY Products or alternatively, the incremental costs of the ABILIFY Products as paid for by the class members and/or by the *Régie de l'assurance maladie du Québec*, the Ontario Health Insurance Plan, and other provincial health insurers; and

e. Punitive damages;

119. As a direct result of the Respondents' conduct, the users' family members and dependants have, had, and/or will suffer damages and loss including:

a. Out-of-pocket expenses, including debts accrued and/or paying or providing nursing, housekeeping and other services;

b. Loss of income and loss of future income; and

c. Loss of support, guidance, care, consortium, and companionship that they might reasonably have expected to receive if the injuries had not occurred;

120. All of these damages to the Class Members are a direct and proximate result of the use of the ABILIFY Products and the Respondents' conduct, negligence and reckless failure to adequately disclose necessary information and the risks associated with the drug;

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

A) The composition of the Class makes it difficult or impracticable to apply the rules for mandates to sue on behalf of others or for consolidation of proceedings

121. The Petitioner is unaware of the specific number of persons who ingested, injected and/or purchased ABILIFY, which information is confidential; however, it is safe to estimate that it is in the hundreds of thousands;

122. Class Members are numerous and are scattered across the entire province and country;

123. In addition, given the costs and risks inherent in an action before the courts, many people will hesitate to institute an individual action against the Respondents. Even if

the Class Members themselves could afford such individual litigation, it would place an unjustifiable burden on the courts. Furthermore, individual litigation of the factual and legal issues raised by the conduct of the Respondents would increase delay and expense to all parties and to the court system;

124. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory judgments on questions of fact and law that are similar or related to all members of the Class;

125. These facts demonstrate that it would be impractical, if not impossible, to contact each and every member of the Class to obtain mandates and to join them in one action;

126. In these circumstances, a class action is the only appropriate procedure for all of the members of the Class to effectively pursue their respective rights and have access to justice;

B) <u>The claims of the members of the Class raise identical, similar or related issues of law or fact</u>

127. Individual issues, if any, pale by comparison to the numerous common issues that are significant to the outcome of the litigation;

128. The damages sustained by the Class Members flow, in each instance, from a common nucleus of operative facts, namely, Respondents' misconduct;

129. The claims of the members raise identical, similar or related issues of fact or law, namely:

a) Do the ABILIFY Products cause, exacerbate or contribute to an increased risk of having uncontrollable impulses, including compulsive and/or pathological gambling?

b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to warn/inform imposed upon them as developers, designers, researchers, manufacturers, testers, marketers, labellers, packagers, promotors, advertisers, distributers, and/or sellers of the ABILIFY Products?

c) Were the ABILIFY Products developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, distributed, and/or sold with defects that increase a patient's risk of having uncontrollable impulses, including compulsive and/or pathological gambling?

d) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for the ABILIFY Products?

e) Did the Respondents fail to adequately and properly test the ABILIFY Products before and/or after placing them on the market?

f) Did the Respondents know or should have known about the risks associated with the use of the ABILIFY Products?

g) Did the Respondents knowingly, recklessly or negligently misrepresent to Class Members, Health Canada, and/or their physicians the risks of harm from the use/ingestion of the ABILIFY Products?

h) Did the Respondents knowingly fail to disclose and warn of the ABILIFY Product defects?

i) Did the Respondents adequately and sufficiently warn the Class Members and/or their physicians of the Class Members about the risks associated with the use of the ABILIFY Products?

j) Should the ABILIFY Products have been sold with more appropriate warnings?

k) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that the ABILIFY Products were safe or omitted to disclose material facts regarding the ABILIFY Products' safety?

l) Were the members of the Class prejudiced by taking the ABILIFY Products instead of other antipsychotic medications, which have similar benefits, but do not pose such an increased risk of having uncontrollable impulses, including compulsive and/or pathological gambling?

m) In the affirmative to any of the above questions, did the Respondents' conduct engage their solidary liability toward the members of the Class?

n) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the Class can claim from the Respondents?

o) Are members of the Class entitled to bodily, moral, and material damages?

p) Are members of the Class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking the ABILIFY Products?

q) Are the members of the Class entitled to recover as damages an amount equal to the purchase price of the ABILIFY Products or any part of the purchase price?

r) Are members of the Class entitled to aggravated or punitive damages?

130. The interests of justice favour that this motion be granted in accordance with its conclusions;

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

131. The action that the Petitioner wishes to institute on behalf of the members of the Class is an action in damages, injunctive relief, and declaratory judgment;

132. The conclusions that the Petitioner wishes to introduce by way of a motion to institute proceedings are:

GRANT the class action of the Petitioner and each of the members of the Class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of the ABILIFY Products;

RESERVE the right of each of the members of the Class to claim future damages related to the use of the ABILIFY Products;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the Class;

CONDEMN the Defendants to pay to each member of the Class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the Class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

A) The Petitioner requests that he be attributed the status of representative of the Class

133. Petitioner is a member of the Class;

134. Petitioner is ready and available to manage and direct the present action in the interest of the members of the Class that he wishes to represent and is determined to lead the present dossier until a final resolution of the matter, the whole for the benefit of the Class, as well as, to dedicate the time necessary for the present action before the Courts and the *Fonds d'aide aux actions collectives*, as the case may be, and to collaborate with his attorneys;

135. Petitioner has the capacity and interest to fairly, properly, and adequately protect and represent the interest of the members of the Class;

136. Petitioner has given the mandate to his attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

137. Petitioner, with the assistance of his attorneys, is ready and available to dedicate the time necessary for this action and to collaborate with other members of the Class and to keep them informed;

138. Petitioner has given instructions to his attorneys to put information about this class action on its website and to collect the coordinates of those Class Members that wish to be kept informed and participate in any resolution of the present matter, the whole as will be shown at the hearing;

139. Petitioner is in good faith and has instituted this action for the sole goal of having his rights, as well as the rights of other Class Members, recognized and protected so that they may be compensated for the damages that they have suffered as a consequence of the Respondents' conduct;

140. Petitioner understands the nature of the action;

141. Petitioner's interests are not antagonistic to those of other members of the Class;

142. Petitioner is prepared to be examined out-of-court on his allegations (as may be authorized by the Court) and to be present for Court hearings, as may be required and necessary;

143. Petitioner has spent time researching this issue on the internet and meeting with his attorneys to prepare this file. In so doing, he is convinced that the problem is widespread;

B) The Petitioner suggests that this class action be exercised before the Superior Court of Justice in the district of Montreal

144. A great number of the members of the Cass reside in the judicial district of Montreal and in the appeal district of Montreal;

145. The Petitioner's attorneys practice their profession in the judicial district of Montreal;

146. The present motion is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present motion;

AUTHORIZE the bringing of a class action in the form of a motion to institute proceedings in damages, injunctive relief, and declaratory relief;

ASCRIBE the Petitioner the status of representative of the persons included in the class herein described as:

- All persons residing in Canada who were prescribed and have ingested and/or injected the drug(s), ABILIFY® and/or ABILIFY MAINTENA® (aripiprazole) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

Alternatively (or as a subclass)

- All persons residing in Quebec who were prescribed and have ingested and/or injected the drug(s), ABILIFY® and/or ABILIFY MAINTENA® (aripiprazole) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

IDENTIFY the principle issues of fact and law to be treated collectively as the following:

a) Do the ABILIFY Products cause, exacerbate or contribute to an increased risk of having uncontrollable impulses, including compulsive and/or pathological gambling?

b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to warn/inform imposed upon them as developers, designers, researchers, manufacturers, testers, marketers, labellers, packagers, promotors, advertisers, distributers, and/or sellers of the ABILIFY Products?

c) Were the ABILIFY Products developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, distributed, and/or sold with defects that increase a patient's risk of having uncontrollable impulses, including compulsive and/or pathological gambling?

d) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for the ABILIFY Products?

e) Did the Respondents fail to adequately and properly test the ABILIFY Products before and/or after placing them on the market?

f) Did the Respondents know or should have known about the risks associated with the use of the ABILIFY Products?

g) Did the Respondents knowingly, recklessly or negligently misrepresent to Class Members, Health Canada, and/or their physicians the risks of harm from the use/ingestion of the ABILIFY Products?

h) Did the Respondents knowingly fail to disclose and warn of the ABILIFY Product defects?

i) Did the Respondents adequately and sufficiently warn the Class Members and/or their physicians of the Class Members about the risks associated with the use of the ABILIFY Products?

j) Should the ABILIFY Products have been sold with more appropriate warnings?

k) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that the ABILIFY Products were safe or omitted to disclose material facts regarding the ABILIFY Products' safety?

l) Were the members of the Class prejudiced by taking the ABILIFY Products instead of other antipsychotic medications, which have similar benefits, but do not pose such an increased risk of having uncontrollable impulses, including compulsive and/or pathological gambling?

m) In the affirmative to any of the above questions, did the Respondents' conduct engage their solidary liability toward the members of the Class?

n) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the Class can claim from the Respondents?

o) Are members of the Class entitled to bodily, moral, and material damages?

p) Are members of the Class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking the ABILIFY Products?

q) Are the members of the Class entitled to recover as damages an amount equal to the purchase price of the ABILIFY Products or any part of the purchase price?

r) Are members of the Class entitled to aggravated or punitive damages?

IDENTIFY the conclusions sought by the class action to be instituted as being the following:

GRANT the class action of the Petitioner and each of the members of the Class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of the ABILIFY Products;

RESERVE the right of each of the members of the Class to claim future damages related to the use of the ABILIFY Products;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the Class;

CONDEMN the Defendants to pay to each member of the Class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the Class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

DECLARE that all members of the Class that have not requested their exclusion, be bound by any judgment to be rendered on the class action to be instituted in the manner provided for by the law;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the Class Members, date upon which the members of the Class that have not exercised their means of exclusion will be bound by any judgment to be rendered herein;

ORDER the publication of a notice to the members of the group in accordance with article 579 C.C.P. within sixty (60) days from the judgment to be rendered herein in the Globe and Mail, the National Post, La Presse, and the Montreal Gazette;

ORDER that said notice be available on the Respondents' websites, Facebook page(s), and twitter accounts with a link stating "Notice to ABILIFY and ABILIFY MAINTENA prescribers and users";

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

THE WHOLE with costs, including all publication fees.

Montreal, December 12, 2016

(s) Andrea Grass

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CONSUMER LAW GROUP INC.
Per: Me Andrea Grass
Attorneys for the Petitioner