# ONTARIO SUPERIOR COURT OF JUSTICE

THE HONOURABLE	)	MONDAY, THE 23 <sup>rd</sup> DAY	
JUSTICE E.M. MORGAN	)	OF DECEMBER, 2024	
(Court Seal)			
BETWEEN:			
		_	
			-
			Plaintiffs
	– and –		

BRISTOL-MYERS SQUIBB, BRISTOL-MYERS SQUIBB CANADA CO./LA SOCIÉTÉ BRISTOL-MYERS SQUIBB, OTSUKA PHARMACEUTICAL CO., LTD., OTSUKA CANADA PHARMACEUTICAL INC., OTSUKA AMERICA PHARMACEUTICAL, INC., OTSUKA AMERICA, INC., OTSUKA MARYLAND MEDICINAL LABORATORIES, INC., and OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC., H. LUNDBECK A/S, and LUNDBECK CANADA INC.

**Defendants** 

Proceeding under the Class Proceedings Act, 1992

#### **ORDER**

# (Motion for Approval of Settlement and Class Counsel Fees)

**THIS MOTION**, made by the Plaintiffs, for an Order approving: (i) the Settlement Agreement reached between the Plaintiffs and the Defendants dated September 3, 2024 ("Settlement Agreement") a copy of which is attached as Schedule "A" to this Order; (ii) the Distribution Protocol attached as Exhibit A to the Settlement Agreement ("Distribution Protocol"); (iii) Class Counsel's

Fees and Disbursements; and (d) honoraria for the Representative Plaintiffs in this action was heard this day.

**ON READING** the materials filed, including the Settlement Agreement entered into between the parties, and on hearing the submissions of Class Counsel and Counsel for the Defendants and any objector who has objected pursuant to the terms of the Settlement Agreement,

**AND ON BEING ADVISED** that the deadline for objecting to the Settlement Agreement has passed;

**AND ON BEING ADVISED** that the Defendants have paid the Settlement Amount into the Escrow Account within 30 days of the Notice of Settlement Approval Hearings Date pursuant to section 4 of the Settlement Agreement;

AND ON BEING ADVISED that while the Settlement Agreement is entered on the basis that the Settlement does not constitute an admission of liability, and the Defendants expressly deny liability and the truth of the Plaintiffs' allegations, the parties having considered the risks and uncertainties associated with further proceedings and have consented to the Order requested;

**AND ON BEING ADVISED** that the Defendants take no position on the appropriateness of the Distribution Protocol and have had no role in its development or the categories of monetary compensation which may be available to Class Members under the Settlement Agreement;

1. **THIS COURT ORDERS** that, except as otherwise stated, the capitalized terms in this Order have the definitions set out in the Settlement Agreement.

- 2. **THIS COURT DECLARES** that the Settlement Agreement is fair, reasonable and in the best interests of the Class Members.
- 3. **THIS COURT ORDERS** that the Settlement Agreement attached as Schedule "A" is hereby approved pursuant to section 29(2) of the *Class Proceedings Act*, S.O. 1992, c. 6 (the "*CPA*").
- 4. **THIS COURT ORDERS** that the Settlement Agreement shall be implemented in accordance with its terms.
- 5. **THIS COURT ORDERS** that the full and final releases which are set out in the Settlement Agreement, including the releases by the Releasors and the Provincial Health Insurers, are approved and granted and shall forever and absolutely release the Releasees from the Released Claims and the claims of the Provincial Health Insurers as set out in the Settlement Agreement.
- 6. **THIS COURT DECLARES** that Class Counsel Fees, expenses, costs, disbursements and applicable taxes in the total amount of \$5,350,697.00 ("Class Counsel Fees and Disbursements") are fair and reasonable.
- 7. **THIS COURT ORDERS** that Class Counsel Fees and Disbursements are hereby approved pursuant to sections 32 and 33 of the *CPA*.
- 8. **THIS COURT ORDERS** that an Honoraria of \$10,000 shall be paid out to each of

who are the Representative Plaintiffs in the Ontario and Quebec proceedings.

- 9. **THIS COURT ORDERS THAT** that the Settlement Approval Notices, substantially in the form attached as Schedules "B" and "C", are hereby approved (the "Settlement Approval Notices").
- 10. **THIS COURT ORDERS THAT** the Settlement Approval Notices shall be disseminated and published in accordance with the Notice Plan.
- 11. **THIS COURT ORDERS** that the Claim Form, substantially in the form attached at Exhibit A to the Settlement Agreement, is hereby approved.
- 12. **THIS COURT ORDERS** that all provisions of the Settlement Agreement (including the Recitals and Definitions) form part of this Order and are binding on the Defendants in accordance with the terms thereof, and upon the Plaintiffs and all Class Members that did not opt out of this Action in accordance with the Order of the Ontario Superior Court of Justice in this Action dated November 4, 2024, including persons that are minors or mentally incapable.
- 13. **THIS COURT ORDERS** that, in the event of a conflict between this Order and the Settlement Agreement, this Order shall prevail.
- 14. **THIS COURT ORDERS** that compliance with requirements of Rules 7.04(1) and 7.08(4) of the *Rules of Civil Procedure*, RRO 1990, Reg. 194 is hereby dispensed with.
- 15. **THIS COURT ORDERS** that the payment of \$368,750.00 (all inclusive) from the Settlement Fund for the benefit of the Public Health Insurers is hereby approved, and that this sum shall be deducted from the Settlement Fund at the start of the Claim Period, to be distributed amongst the provinces and territories proportionately based on population, in full satisfaction of the Public Health Insurers' claims.

- 16. **THIS COURT DECLARES** that the Distribution Protocol, substantially in the form attached to the Settlement Agreement as Schedule B, is fair and appropriate.
- 17. **THIS COURT ORDERS** that should more Class Members than anticipated come forward with claims for Residual Catastrophic Injury, the Distribution Grid may be adjusted to re-allocate up to \$1,000,000 of additional funds for compensation in that category without further Order from the court.
- 18. **THIS COURT ORDERS** that the Distribution Protocol is approved and that the Settlement Amount shall be distributed in accordance with the terms of the Settlement Agreement and the Distribution Protocol following payment of Class Counsel Fees, payment of \$368,750.00 (all inclusive) to the Public Health Insurers, and Claims Administration Expenses.
- 19. **THIS COURT ORDERS** that the Plaintiffs and Defendants may, on notice to the Court, but without the need for further order of the Court, agree to reasonable extensions of time to carry out any provisions of the Settlement Agreement.
- 20. **THIS COURT ORDERS** that in the event that the Settlement Agreement is terminated in accordance with its terms, the Order shall be null and void, *nunc pro tunc*.
- 21. **THIS COURT ORDERS** that upon the Effective Date, the Action shall be dismissed against all Defendants with prejudice and without costs.
- 22. **THIS COURT ORDERS** that the Claims Deadline is set at 240 days from the date the Settlement Approval Notice is first published.

- 23. **THIS COURT ORDERS** that costs of the Notice Plan and of the Claims Administrator are to be paid from the Settlement Fund.
- 24. **THIS COURT ORDERS** that there be no costs on this motion.
- 25. **THIS COURT ORDERS** that the style of cause in this matter is amended to the style of cause below:



BRISTOL-MYERS SQUIBB, BRISTOL-MYERS SQUIBB CANADA CO./LA SOCIÉTÉ BRISTOL-MYERS SQUIBB, OTSUKA PHARMACEUTICAL CO., LTD., OTSUKA CANADA PHARMACEUTICAL INC., OTSUKA AMERICA PHARMACEUTICAL, INC., OTSUKA AMERICA, INC., OTSUKA MARYLAND MEDICINAL LABORATORIES, INC., and OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC., H. LUNDBECK A/S, and LUNDBECK CANADA INC.

**Defendants** 

26. **THIS COURT ORDERS** that the Plaintiffs are granted leave to file the Amended Statement of Claim in the form attached as Schedule "D".



# Schedule "A"

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® CLASS ACTIONS NATIONAL SETTLEMENT AGREEMENT

Made as of September 3, 2024 (the "Execution Date")

Between

(the "Plaintiffs") and

OTSUKA PHARMACEUTICAL CO., LTD., OTSUKA CANADA PHARMACEUTICAL INC., OTSUKA AMERICA PHARMACEUTICAL, INC., OTSUKA AMERICA, INC., OTSUKA MARYLAND MEDICINAL LABORATORIES, INC., OTSUKA PHARMACEUTICALS DEVELOPMENT & COMMERCIALIZATION, INC.

(the "Otsuka Defendants") and

BRISTOL-MYERS SQUIBB, BRISTOL-MYERS SQUIBB CANADA CO./LA SOCIÉTÉ BRISTOL-MYERS SQUIBB

(the "BMS Defendants") and

H. LUNDBECK A/S AND LUNDBECK CANADA INC.

(the "Lundbeck Defendants")

# **Table of Contents**

	BILIFY <sup>®</sup> AND ABILIFY MAINTENA <sup>®</sup> CLASS ACTIONS NATIC AGREEMENT	
	BILIFY® AND ABILIFY MAINTENA® NATIONAL CLASS ACTI AGREEMENT	
RECITALS		4
SECTION 1. D	EFINITIONS	5
SECTION 2. A	GREEMENT FOR SETTLEMENT PURPOSES ONLY	11
1.	No Admission of Liability	11
2.	Settlement Agreement Not Evidence	12
SECTION 3. C	OOPERATION BY THE PARTIES	12
1.	Motions	12
2.	Confidentiality	13
3.	Jurisdiction of the Courts	13
SECTION 4. S	ETTLEMENT BENEFITS	13
1.	Payment of Settlement Fund	13
2.	Interest	14
	LAIMS DEADLINES, CLAIM FORMS, CLAIMS ADMINISTRA	
SECTION 6. P.	AYMENT TO AND RELEASE BY PUBLIC HEALTH INSURERS	17
SECTION 7. O	PTING OUT AND OBJECTING	18
1.	Objections	18
2.	Opt-Outs	18
3.	Opt-Out and Objection Notification and Report	19
_	INAL ORDERS APPROVING THE SETTLEMENT AGREEMENT SETTLEMENT CLASS	
1.	Final Orders Approving the Settlement Agreement	19
2.	Notice of Settlement Approval Hearings	20
3.	Settlement Approval Notice	20
SECTION 9. C	LASS COUNSEL FEES AND HONORARIA	21
1.	Class Counsel Fees	21
2.	Honoraria	21
SECTION 10.	DISTRIBUTION OF THE REMAINING BALANCE	21
SECTION 11.	TERMINATION OF SETTLEMENT AGREEMENT	22
1.	Termination — Absence or Insufficiency of Court Approval	22

2.	Termination — Opt-Out Threshold Exceeded	22
3.	If Settlement Agreement is Terminated	23
4.	Survival of Provisions After Termination	23
SECTION 12.	RELEASES AND DISMISSALS	24
1.	Release of Releasees	24
2.	No Further Claims	24
3.	Dismissal of Other Actions	24
4.	No Further Litigation	24
SECTION 13.	MISCELLANEOUS	25
1.	Motions for Directions	25
2.	Motions on Notice	25
3.	Headings, etc	25
4.	Computation of Time	25
5.	Governing Law	25
6.	Exhibits	26
7.	Waiver	26
8.	Amendments	26
9.	Binding Effect	26
10.	Counterparts	26
11.	Negotiated Agreement	26
12.	Language	27
13.	Transaction	27
14.	Recitals	27
15.	Acknowledgements	27
16.	Authority of Class Counsel	27
17.	Authorized Signatures	28
18.	Date of Execution	29
ROCHON GEN	NOVA LLP	30
CONSUMER L	AW GROUP INC	30
NORTON ROS	E FULBRIGHT CANADA LLP	30
INF S.E.N.C.R.	L LLP ACOCATS BARRISTERS	30
BLAKE, CASS	ELS & GRAYDON LLP	30
MCCARTHY T	TETRAULT LLP	31

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® NATIONAL CLASS ACTIONS SETTLEMENT AGREEMENT

#### RECITALS

WHEREAS the Plaintiffs have commenced class proceedings (the "Proceedings") in Ontario and Québec naming one or more of the Otsuka Defendants, the BMS Defendants and the Lundbeck Defendants (collectively the "Defendants"), in which they seek damages in relation to injuries and economic losses allegedly arising from Compulsive Behaviours and Impulse Control Disorders (as defined herein) resulting from the use of the prescription drug medications ABILIFY® ("Abilify") and ABILIFY MAINTENA® ("Maintena") (collectively the "Abilify Drugs");

WHEREAS on December 12, 2019, the Superior Court of Québec authorized a national class as described herein in relation to alleged claims against certain of the Otsuka Defendants and certain of the BMS Defendants by users of Abilify;

WHEREAS on March 13, 2020, the Ontario Superior Court of Justice certified a national class as described herein in relation to alleged claims against the Defendants by users of the Abilify Drugs;

WHEREAS the Parties have engaged in extensive, arm's-length negotiations through counsel with substantial experience in complex class proceedings and a mediator, which negotiations have resulted in this Settlement Agreement;

WHEREAS the Plaintiffs and Class Counsel have reviewed and fully understand the terms of this Settlement Agreement and based on their analyses of the facts and law applicable to the Plaintiffs' and the Classes' claims, and having regard to the risks and uncertainties associated with trials and appeals, the Plaintiffs and Class Counsel have concluded that this Settlement Agreement is fair, reasonable and in the best interests of the Plaintiffs and of the Classes that they represent;

WHEREAS the Plaintiffs, Class Counsel and the Defendants agree that neither this Settlement Agreement nor any statement made in the negotiation thereof shall be deemed or construed to be an admission by or evidence against the Defendants or evidence of the truth of any of the Plaintiffs' allegations against the Defendants, which the Defendants expressly deny;

WHEREAS although the Defendants deny the Plaintiffs' allegations in the Proceedings, deny any wrongdoing of any kind, and believe that the Proceedings are without merit, the Defendants also have taken into account the uncertainty, risk, and delay inherent in litigation and have agreed to enter into this Settlement Agreement in order to achieve a full and final nation-wide resolution of all claims that were made, or could have been asserted now or in the future against them by the Plaintiffs and the Settlement Class in relation to

the claims made in the Proceedings and to avoid further litigation expense and inconvenience, and to remove the distraction of burdensome and protracted litigation;

WHEREAS the Parties intend and desire to settle, compromise, resolve, dismiss and release all allegations and claims for damages or other relief relating the Abilify Drugs that are set forth in the Proceedings and that have been or could have been brought against any Defendants in the Proceedings, by a Plaintiff, person or entity who is a member of the Settlement Class; and

**WHEREAS** the Parties therefore wish to, and hereby do, finally resolve on a national basis, without admission of liability, all of the Proceedings as against the Defendants.

**NOW THEREFORE**, in consideration of the covenants, agreements and releases set forth herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree on the following terms and conditions, subject to the approval of the Courts:

#### **SECTION 1. DEFINITIONS**

For the purpose of this Settlement Agreement only, including the Recitals and Exhibits hereto, the following terms have the following meanings:

- (1) "Agreement" or "Settlement Agreement" means this Settlement Agreement, including the recitals and all Exhibits attached hereto.
- (2) **"Abilify Drugs"** mean the pharmaceutical medicine aripiprazole distributed and sold in Canada under the brand names ABILIFY® and ABILIFY MAINTENA®.
- (3) "Approved Claimant(s)" means a Settlement Class Member who is approved by the Claims Administrator to receive compensation pursuant to the Settlement Agreement.
- (4) "Claim" means a request for compensation pursuant to this Settlement Agreement submitted by a Settlement Class Member on a Claim Form and filed with the Claims Administrator before the Claim Deadline.
- (5) "Claim Form" means the form to be used by each Settlement Class Member for filing a Claim, substantially in the form attached as "Exhibit A" hereto, which will be submitted to the Courts for approval as part of the Preliminary Motions.
- (6) **"Claim Package"** means all the material required to be submitted in order for a claim for benefits under this Settlement Agreement to be considered.
- (7) "Claims Administration Expenses" means all fees, disbursements, expenses,

costs, taxes and any other amounts incurred or charged by the Claims Administrator in administering the Notice Plan, processing all Claims by Settlement Class Members and Public Health Insurers, and in the distribution of the amounts payable to Settlement Class Members or Public Health Insurers.

- (8) "Claims Administrator" means the administrator proposed by Class Counsel and appointed by the Courts to administer the Settlement Agreement and Distribution Protocol by, among other things, overseeing the Notice Plan and Claims process, the administration and processing of Opt-Outs, Objections, and Claims, and the distribution of the Settlement Benefits to Settlement Class Members in accordance with the terms of this Settlement Agreement and Distribution Protocol.
- (9) "Claims Deadline" means 240 days from the date the Settlement Approval Notice is first published, and is the date by which all Claim Forms must be postmarked or received by the Claims Administrator in order to be considered timely. The Claims Deadline shall be clearly set forth in the Final Orders, on the Settlement Website, and the front page of the Claim Form.
- (10) "Claim Period" means the time frame during which Settlement Class Members may submit a Claim, which shall begin on the date the Notice of Settlement Approval Hearings is first published, and will end on the Claims Deadline.
- (11) "Class Counsel" means the law firms of Rochon Genova LLP and Consumer Law Group Inc.
- "Class Counsel Fees" means the amount of fees, disbursements, costs and applicable taxes, including GST, HST, PST or QST, payable to Class Counsel from the Settlement Amount.
- (13) "Compulsive Behaviours", "Impulse Control Behaviours", "Impulse Control Disorders" or "ICDs" shall mean problematic or compulsive gambling or gaming (also known as gambling disorder or pathological gambling); compulsive eating/ binge eating; uncontrollable or compulsive shopping or spending; and/or hypersexual behaviours / sexual addiction.
- "Court(s)" means the Ontario Superior Court of Justice and the Superior Court of Québec.
- (15) "Distribution Protocol" means the plan developed by Class Counsel and approved by the Courts for distributing the monies in the Escrow Account to Approved Claimants substantially in the form attached as Exhibit "B".
- (16) **"Effective Date"** means the date five (5) business days after the date on which there are Final Orders from the Ontario and Quebec Courts approving this

Settlement Agreement.

- (17) **"Escrow Account"** means the interest-bearing trust account with one of the Canadian Schedule 1 banks under the control of the Claims Administrator, for the benefit of Settlement Class Members.
- (18) **"Exhibits"** means the exhibits attached to this Settlement Agreement.
- (19) **"FAAC"** means the "Fonds d'aide aux actions collectives" in the province of Ouébec.
- (20) "Final Order" means a final judgment or final approval order entered by the Courts on each of the Approval Motions, substantially in the form attached as Exhibits "C" and "D" hereto, approving this Settlement Agreement. An Order only becomes a Final Order once the time to appeal such judgment or order (or the time to seek leave to appeal such judgment or order) has expired without any appeal or motion seeking leave to appeal being taken, or if an appeal or motion for leave to appeal from the judgment or order is taken, once there has been affirmation of such final judgment or approval order in its entirety in the form attached as Exhibits "C" and "D", without modification, upon a final disposition of all appeals.
- (21) **"Honorarium"** means a stipend to the Representative Plaintiffs approved and awarded by the Ontario Superior Court of Justice in its discretion and in recognition of their exceptional efforts to advance the Proceedings on behalf of the Settlement Class:
- "Notice Expenses" means the reasonable costs and expenses incurred in connection with preparing, printing, mailing, disseminating, posting, emailing, internet hosting and/or publishing the Notice of Settlement Approval Hearings and Settlement Approval Notice, and all other aspects of administering the Notice Plan, with the exception of expenses relating to the translation of relevant documents from English to French which shall be paid within 30 days of the Execution Date.
- "Notice Plan" means the plan approved by the Courts for disseminating the Notice of Settlement Approval Hearings and the Settlement Approval Notice, substantially in the manner provided for in the Notice Plan which is attached as Exhibit "E".
- (24) **"Objection Deadline"** means the date as approved by the Courts for any objections to be provided to the Administrator, which shall be no less than 45 days from when the Notice of Settlement Approval Hearings is first published or disseminated to the Settlement Class.
- (25) "Ontario Proceeding" means the proceeding commenced by the Plaintiffs

in the Ontario Superior Court of Justice, Court File No. CV-16- 553833-00CP.

- "Ontario Class" means the class defined by the Ontario Superior Court of Justice as including: (i) All persons in Canada, including their estates, who were prescribed and ingested ABILIFY ® between July 9, 2009 and February 23, 2017; (ii) All persons in Canada, including their estates, who were prescribed and used ABILIFY MAINTENA® between February 6, 2014 and December 16, 2016; (iii) All persons resident in Canada who, by virtue of a personal relationship with an Abilify Class Member, are entitled to assert a derivative claim for damages pursuant to Family Law Act, RSO 1990, c. F.3, as amended or equivalent provincial and territorial legislation; and (iv) All persons resident in Canada who, by virtue of a personal relationship with an Abilify Maintena Class Member, are entitled to assert a derivative claim for damages pursuant to Family Law Act, RSO 1990, c. F.3, as amended or equivalent provincial and territorial legislation.
- (27) **"Opt-Out Deadline"** means the date as approved by the Courts for any Opt-Out Forms to be provided to the Administrator, which shall be no less than 45 days from when the Notice of Settlement Approval Hearings is first published or disseminated to the Settlement Class.
- (28) **"Opt-Out Form"** means the form to be completed by Class Members wishing to exclude themselves from the Settlement, substantially in the form attached as "Exhibit "F" hereto, which will be submitted to the Courts for approval as part of the preliminary motions.
- (29) **"Opt-Out Threshold"** means the confidential number of individual class members who may opt-out in addition to those that have already opted out of the Québec Proceeding.
- (30) **"Opt-Out Threshold Letter"** means a confidential letter between the Parties outlining the number of Opt-Outs that may occur before the Defendants have the right to terminate the Settlement.
- (31) "Party" or "Parties" means one or more of the Plaintiffs or the Defendants.
- (32) **"Person"** means any adult individual or minor child or any corporation, trust, partnership, limited liability company or other legal entity, and their respective successors or assigns.
- (33) "Notice of Settlement Approval Hearings" means the portion of the Notice Plan approved by the Courts for (i) disseminating the fact that the Ontario Proceeding has been certified, (ii) providing information about the Settlement Agreement, (iii) providing information about the Settlement Class Members' right to opt out and setting the Opt-Out Deadline, (iv) providing information

regarding the right to object to the Settlement Agreement and setting the Objection Deadline, (v) instructing Class Members on the procedure for making a Claim, and (vi) providing the date of the Settlement Approval Hearings. The proposed Long-Form "Notice of Settlement Approval Hearings" is attached hereto as Exhibit "G" and the Short Form is attached as Exhibit "H". The Press Release is attached as Exhibit "T".

- (34) "Notice of Settlement Approval Hearings Date" means the date on which the Notice of Settlement Approval Hearings is first published or disseminated to the Settlement Class.
- (35) "Proceedings" means the Ontario Proceeding and the Québec Proceeding.
- (36) **"Public Health Insurers"** means all provincial and territorial health insurers.
- (37) **"Public Health Insurance Claims"** means all provincial and territorial health insurance claims pursuant to the provincial public health insurer legislation set out at "Exhibit "I".
- (38) "Québec Court" means the Superior Court of Québec.
- (39) "Québec Proceeding" means the proceeding commenced by the Plaintiff, in the Superior Court of Québec, Court File no. 500-06-00083-160.
- "Québec Class" means the class defined by the Superior Court of Québec as including: all Persons residing in Canada who were prescribed and have ingested and/or used the drug, ABILIFY® (aripiprazole) before February 23, 2017 and who developed one or more of the following impulse control behaviours: pathological gambling (also known as gambling disorder or compulsive gambling); compulsive eating/ binge eating; uncontrollable or compulsive shopping or spending; and/or hypersexual behaviours / sexual addiction; and their successors, assigns, family members, and dependants.
- (41) "Referee" means the individual or individuals proposed by Class Counsel and approved by the Ontario Court and Québec Court responsible for adjudicating challenges made by the Claims Administrator with respect to determinations of eligibility and entitlement to benefits under the Settlement Agreement.
- "Released Claims" means any and all manner of claims, demands, actions, suits, causes of action, whether class, individual or otherwise in nature, whether personal or subrogated, damages whenever incurred, liabilities of any nature whatsoever, including interest, costs, expenses, penalties, and lawyers' fees, known or unknown, suspected or unsuspected, in law, under statute or in equity, that the Releasors, or any of them, whether directly, indirectly, derivatively, or in any other capacity, ever had, now have, or in the future may have, relating to

or arising out of the production, design, sale, marketing, advertising, manufacture, distribution, donation, purchase, sale, possession, handling, ingestion, exposure, or use of the Abilify Drugs provided that they relate to any conduct alleged in the Proceedings including, without limitation, any such claims that have been asserted, whether in Canada or elsewhere, as a result of their past, present or future purchase or use of the Abilify Drugs and any Public Health Insurance Claims.

- "Releasees" or "Released Parties" means the Defendants and any entity or person that manufactured, tested, inspected, audited, certified, purchased, distributed, licensed, transported, marketed, advertised, donated, promoted, prescribed, dispensed, sold or offered for sale any Abilify Drugs to the Releasors, or any part thereof, including all of their respective predecessors, successors, assigns, parents, subsidiaries, divisions, departments, and affiliates, and all of their past, present and future officers, directors, employees, stockholders, partners, agents, servants, successors, attorneys, insurers, representatives, licensees, licensors, customers, subrogees and assigns. It is expressly understood that, to the extent a Releasee is not a Party to the Settlement Agreement, all such Releasees are intended third party beneficiaries of the Settlement Agreement.
- "Releasors" means, jointly and severally, solidarily, individually and collectively, the Plaintiffs, the Settlement Class Members, Class Counsel, and their respective, subsidiaries, affiliates, predecessors, successors, heirs, executors, administrators, insurers and assigns. For greater certainty, a Releasor includes an individual who is a member of the Ontario Class or the Quebec Class and who took one or more of the Abilify Drugs prior to February 23, 2017 (for Abilify) and December 16, 2016 (for Maintena) even if they did not have Compulsive Behaviours as defined in this Settlement Agreement prior to those dates.
- (45) "Representative Plaintiffs" means the Plaintiffs in the Proceedings, specifically:
- (46) "Settlement" means the terms and conditions of this Agreement.
- (47) **"Settlement Amount"** means the all-inclusive amount of CDN \$14,750,000 which will be paid by the Defendants as outlined herein and will be used to pay the Notice Expenses and to fund the Settlement Fund.
- (48) "Settlement Approval Hearings" means the Court-hearings held to determine whether the Agreement should be approved.
- (49) "Settlement Approval Motions" means the motions brought in the Ontario

Superior Court of Justice pursuant to the Ontario *Class Proceedings Act*, 1992, SO 1992, c 6 as amended and the application brought in the Superior Court of Quebec pursuant to the *Code of Civil Procedure*, CQLR c. C-25.01 for the approval of the Notice of Settlement Approval Hearings, the Settlement and the granting of the Releases.

- (50) "Settlement Approval Notice" means the portion of the Notice Plan approved by the Courts which is to be disseminated and published after the Final Orders are entered giving Settlement Class Members notice of the approval of the Agreement and the procedure for making a Claim and includes the Settlement Approval Notice (substantially in the form attached as "Exhibit "J" hereto).
- (51) "Settlement Approval Notice Date" means the date upon which the Settlement Approval Notice is first published or disseminated to the Settlement Class.
- (52) "Settlement Class" means the Québec Class and the Ontario Class.
- (53) "Settlement Class Member" means a member of the Settlement Class, who did not validly opt out of the Settlement.
- (54) "Settlement Consideration" means the consideration exchanged by and between the Defendants and the Settlement Class, as set forth in this Settlement Agreement, including, without limitation, the Settlement Fund.
- (55) "Settlement Fund" means the amount of CDN \$14,750,000, less any Notice Expenses, payable by the Defendants within 30 days of the Notice of Settlement Approval Hearings Date.
- (56) "Settlement Website" means the dedicated website created by the Claims Administrator for the purposes of notifying class members about the settlement and providing a claims portal to facilitate the efficient processing of the claims, located at *Abilifyclassactionsettlement.com*.

#### SECTION 2. AGREEMENT FOR SETTLEMENT PURPOSES ONLY

# 1. No Admission of Liability

a) Whether or not this Settlement Agreement is approved or terminated, this Settlement Agreement and anything contained herein, and any and all negotiations, documents, discussions and proceedings associated with this Settlement Agreement, and any action taken to carry out this Settlement Agreement, shall not be deemed, construed or interpreted to be an admission of any violation of any statute or law, or of any wrongdoing or liability by the Defendants, or of the truth of any of the claims or allegations contained in the Proceedings or any other pleading filed by the Plaintiffs.

# 2. Settlement Agreement Not Evidence

a) The Parties agree that, whether or not the Settlement Agreement is approved or terminated, this Settlement Agreement and anything contained herein, and any and all negotiations, documents, discussions and proceedings associated with this Settlement Agreement, and any action taken to carry out this Settlement Agreement, shall not be referred to, offered as evidence or received in evidence in any pending or future civil, criminal or administrative action or proceeding, except in a proceeding to approve and/or enforce this Settlement Agreement, or to defend against the assertion of Released Claims, or as otherwise required by law.

#### **SECTION 3. COOPERATION BY THE PARTIES**

a) The Parties shall use their best efforts to implement this Settlement in an expedited manner.

#### 1. Motions

- a) At a time mutually agreed to by the Parties after the Settlement Agreement is executed, Class Counsel shall bring a preliminary motion before each of the Ontario and Quebec Superior Courts seeking Orders in substantially the form set out in Exhibits "K" and "L", to (i) approve the form and content of the Notice of Settlement Approval Hearings and its method of dissemination as set out in the Notice Plan, (ii) approve the form and content of the Claim Form and the procedure for submitting Claims, (iii) approve a procedure for submitting objections to the Settlement, (iv) approve the scope of the opt-out rights and the form and content of the Opt-Out Form and set the Opt-Out Deadline, (v) provisionally appoint the Claims Administrator to coordinate the Notice of Settlement Approval Hearings, to oversee the administration of the Settlement if approved and the claims process, (vi) order that the costs of the Notice Plan and of the Claims Administrator be paid from the Settlement Fund, and (vii) set a schedule for proceedings with respect to approval of this Settlement ("**Preliminary Motions**").
- class Counsel shall bring Settlement Approval Motions before each of the Ontario and Quebec Courts seeking Orders in substantially the form set out in Exhibits C and D above seeking to (i) approve the Settlement Agreement as fair, reasonable, and in the best interests of the Settlement Class, (ii) permanently appoint the Claims Administrator to oversee the administration of the Settlement and the claims process, (iii) order that the costs of the Notice Plan and of the Claims Administrator be paid for from the Settlement Fund, and (iv) set the Claims Deadline ("Final Motions").
- c) Class Counsel agree to provide the Defendants with any notice of objection to the Settlement no later than five (5) business days after receipt.

d) If either the Ontario or Quebec Court does not grant the orders sought on the Preliminary Motions or the Settlement Approval Motions either party may terminate the Settlement Agreement upon providing the opposing party with 30 days written notice.

# 2. Confidentiality

a) Save for notification requirements under applicable provincial legislation or regulation, or as may be required to advise the Provincial Health Insurers, or the Courts as to the status of the Canadian litigation, there shall be no public disclosure of the existence or contents of the Settlement Agreement until the signed Settlement Agreement is filed with the Courts as part of the Preliminary Motions.

#### 3. Jurisdiction of the Courts

a) The Parties agree that each of the Ontario and Quebec Courts shall retain continuing jurisdiction over the Proceeding commenced in their respective jurisdictions, the Settlement Agreement, the Parties thereto, the Settlement Class for that jurisdiction as defined herein, and the Claims Administrator, and the Courts retain jurisdiction to interpret and enforce the terms, conditions, and obligations under this Settlement Agreement.

#### **SECTION 4. SETTLEMENT BENEFITS**

# 1. Payment of Settlement Fund

- a) The Defendants will collectively pay CDN \$14,750,000, less any Notice Expenses already paid, into the Escrow Account within 30 days of the Notice of Settlement Approval Hearings Date in full satisfaction of all payment obligations under this Settlement Agreement.
- b) None of the Releasees shall have any obligation to pay any amount other than the Settlement Amount, for any reason, pursuant to or in furtherance of this Settlement Agreement.
- c) The Settlement Amount, which includes the Settlement Fund, the Notice Expenses and the interest accrued thereon, shall be used to pay, *inter alia*, all amounts payable to Settlement Class Members in relation to the Released Claims based on the Distribution Protocol.
- d) The Settlement Fund comprises the total amount that will be paid by the Defendants to Settlement Class Members and the Public Health Insurers in relation to the Released Claims and includes any costs, including any taxes, fees, interests or other charges. The Defendants shall not be liable for any amounts beyond the Settlement Fund.

e) For greater certainty, all compensation to Settlement Class Members, Class Counsel Fees, Honoraria, Claims Administration Expenses, Public Health Insurance Claims, Notice Expenses, and any applicable taxes, shall be paid from the Settlement Amount.

#### 2. Interest

- a) The Claims Administrator shall set aside an amount needed for Claims Administration Expenses and Notice Costs and the remainder will be invested in a 30-day non-redeemable (cashable) GIC with one of the Canadian Schedule 1 banks. All interest earned on the Settlement Fund shall accrue to the benefit of the Settlement Class Members and shall become and remain part of the Escrow Account.
- b) All taxes payable on any interest which accrues on the Settlement Amount in the Escrow Account or otherwise in relation to the Settlement Amount shall be the responsibility of the Settlement Class Members. Class Counsel or the Claims Administrator shall be responsible to fulfill all tax reporting and payment requirements arising from the Settlement Amount in the Escrow Account, including any obligation to report taxable income and make tax payments. All taxes (including interest and penalties) due with respect to the income earned on the Settlement Amount shall be paid from the Escrow Account.

# SECTION 5. CLAIMS DEADLINES, CLAIM FORMS, CLAIMS ADMINISTRATION AND CHALLENGES TO REFEREE

- a) All Claims must be submitted with a Claim Form and received by the Claims Administrator or postmarked by the Claims Deadline.
- b) The Claims Deadline shall be clearly set forth in the Notice of Settlement Approval Hearings and Settlement Approval Notice, on the Settlement Website, and on the Claim Form. Settlement Class Members who do not timely submit a completed Claim Form shall not be eligible to receive benefits pursuant to this Settlement Agreement, but will be bound by the remaining terms.
- c) Class Members who submit Claim Packages will be sent an Acknowledgement Letter by the Claims Administrator, in the form attached as Exhibit "M", confirming receipt of the Claim Package and any supporting documentation.
- d) Class Members who submit complete Claim Packages will receive a Claim Determination Letter, in the form attached as Exhibit "N", and the Claim Determination Form, in the form attached as Exhibit "O" from the Claims Administrator. Together, these documents will advise Class Members i) whether they have been approved to receive compensation for Psychological Harm, ii) the category of Psychological Harm (Mild, Moderate, Severe) under which they have been

qualified (and the amount of compensation that will be distributed in accordance with the Distribution Protocol), iii) whether they qualify for compensation for Residual Catastrophic Injury, iv) whether they are entitled to receive compensation for Financial Loss, and v) the estimate of recovery for any eligible Financial Loss.

- e) The Claims Administrator shall be responsible for distribution of the Settlement Amount. The Claims Administrator shall permit a Settlement Class Member who makes a timely Claim to remedy deficiencies in such Claim Form or related documentation within thirty (30) days of the Claims Administrator's request for same. To this end, the Claims Administrator shall deliver a Deficiency Letter, substantially in the form attached as Exhibit "P".
- f) Class Members who disagree with their qualification or categorization of their claim for compensable Psychological Harm and/or the determination of the estimated range of compensation they have been approved for with respect to Financial Harm, may submit a Notice of Challenge, in the form attached as Exhibit "Q", and, should they wish, provide written submissions not exceeding five (5) pages in length setting out the reasons why they disagree with the determination(s).
- g) Within ninety (90) days after all Claims have been finally adjudicated, including the resolution of all Challenges, Class Members will be sent a Final Claim Determination Letter, in the form attached as Exhibit "R", which will advise them of the final amount of their Compensatory Payment and enclose a cheque in that amount.
- h) The Claim Forms must be signed by hand or electronically by the Settlement Class Member who must attest to the truth and accuracy of the information provided therein and acknowledge that knowingly submitting a false Claim is illegal and contrary to the Final Order of the Courts.
- i) Claim Forms will be made available for downloading from the Settlement Website. Such Claim Form must include the following information and/or affirmations as it relates to Class Members, where available
  - i. Telephone number or contact information for use, if necessary, in validating Claims;
  - ii. Receipt(s), pharmaceutical records, or medical records, proving the dispensation or prescription of one or more of the Abilify Drugs. Documentation relating to the generic versions of the Abilify Drugs will not be sufficient as this Settlement relates only to users of branded Abilify Drugs;
  - iii. Name(s) and location(s) of pharmacy(s) at which the Abilify Drugs were purchased or, where some of the Class Member's Abilify Drugs were provided as free samples, the name of the healthcare provider that supplied the free samples;

- iv. Name of person for whom the Abilify Drugs were purchased; and
- v. Contemporaneous records, or other evidence including by way of attestation(s), establishing the Compulsive Behaviours or Impulse Control Disorder(s) experienced by the Class Member.
- j) Settlement Class Members may submit completed and signed (either by hand or electronically) Claim Forms to the Claims Administrator by mail, courier, facsimile, online or as an attachment to an email. The Parties agree that information provided by Settlement Class Members on Claim Forms shall be kept confidential, shall be used only for purposes of reviewing or administering the Settlement, and shall not be used for marketing or any other commercial purposes.
- k) The Claims Administrator will be an agent of the Courts, and will be subject to the Courts' supervision and direction as circumstances may require. The Claims Administrator will administer the Notice Plan and Claims process, and oversee the distribution of the Settlement Fund to Settlement Class Members in accordance with the terms of the Settlement and the Final Orders of the Courts.
- 1) The determination of the validity of Claims submitted by Settlement Class Members (or by Persons who purport to be members of the Settlement Class) shall be made by the Claims Administrator in consultation with Class Counsel. The Defendants have not approved, nor have they had input into, the terms of the Distribution Protocol and agree that they will have no role in the determination of the validity of Claims submitted, all of which will be undertaken solely at the direction of Class Counsel with Court-approval.
- m) The Claims Administrator shall administer the terms of this Settlement Agreement by resolving Claims in a cost effective and timely manner and will consult with Class Counsel as required to assist in resolving Claims or categories of Claims.
- n) The Claims Administrator shall maintain records of all Claims submitted. The Claims Administrator shall maintain all such records until the later of 180 days after either the Claims Deadline or all Claims have been finally resolved, and such records will be made available upon request to the Parties' counsel. Claim Forms and supporting documentation will be provided only to a Court upon request and to the Parties upon request. The Claims Administrator also shall provide such reports and such other information to the Courts as they may require.
- o) The Claims Administrator will review and validate all Claims submitted by Settlement Class Members.
- l) The Claims Administrator shall have the right to contact Settlement Class Members and to validate Claims. The validity of a Claim will be assessed based on the totality of the Claim. Issues regarding the validity of Claims that cannot be resolved by the

Claims Administrator shall be submitted to Class Counsel for resolution and, if no resolution is reached, to an independent Referee appointed by the Courts to address such disputes as part of the Distribution Protocol and whose decision will be final and binding.

- m) Any Settlement Class Member who may wish to challenge the determination of eligibility or entitlement to benefits under the Settlement Agreement shall submit to the Referee the originally submitted Claim Package, all documents filed with the Claims Administrator, and brief written submissions, not exceeding 5 pages, in support of their challenge.
- n) The standard of review to be applied by the Referee on a challenge relating to eligibility or relating to the quantum of compensation for a Claim, shall be whether there was a misapprehension of the evidence, an error in principle or the decision was unreasonable.
- o) The Referee's determination shall be set out in brief written reasons, not exceeding one page, and shall be final and binding, and not subject to any further challenge, appeal, or revision, except in the case of a clerical or obvious error.
- p) The Referee will be entitled to compensation of a maximum of \$350.00 per hour, to a maximum per-claim amount of \$1,200.00, not inclusive of taxes. In exceptional cases, where the volume of records submitted with a challenge requires further time for proper review, the Referee shall so advise the Claims Administrator as soon as is reasonably practicable. The Claims Administrator shall then determine whether further reasonable requests for additional fees should be approved for payment, with all such additional fees and applicable taxes to be deducted from the Settlement Amount. Notice of all requests for such further fees shall be provided by the Claims Administrator to Class Counsel.
- q) The cost of creating and maintaining the Settlement Website will be paid from the Settlement Fund.

#### SECTION 6. PAYMENT TO AND RELEASE BY PUBLIC HEALTH INSURERS

- a) At the start of the Claim Period, the Claims Administrator shall deduct the sum of \$368,750.00 from the Settlement Fund for the benefit of the Public Health Insurers, to be distributed amongst the provinces and territories proportionately based on population.
- b) In consideration of the payment set out in this Section, the Public Health Insurers as of the Effective Date, fully and finally release the Released Parties from all Public Health Insurance Claims and undertake not to make any claim or take or continue any action, investigation or other proceeding in any forum against any person, partnership, corporation, or other entity, including without limitation, any health care professionals, hospitals or other health care facilities, who might claim

contribution or indemnity or any other relief of a monetary, declaratory, or injunctive nature from the Released Parties in connection with the Public Health Insurance Claims. Class Counsel will make best efforts to obtain signed releases from the Public Health Insurers in the form attached as Exhibit "S".

#### SECTION 7. OPTING OUT AND OBJECTING

# 1. Objections

- a) Class Members shall have the right to object to the Agreement. They may do so by appearing and stating if they have any reason why the terms of this Agreement should not be granted approval. Objections, including all briefs or other papers or evidence in support, should be in writing and delivered, served, filed and received by the Claims Administrator by the Objection Deadline.
- Any objection regarding or related to the Settlement Agreement should contain: (i) a caption or title that identifies it as Objection to the Settlement; (ii) information sufficient to identify and contact information for the objecting Class Member (or his or her lawyer, if any), such as name, address, email address and telephone number; (iii) a clear statement of the nature and reasons for the Class Member's objection, and documents sufficient to establish the basis for his or her standing as a Class Member; and (iv) a declaration under the penalty of perjury that the foregoing information provided by the objector is true and correct.
- Any objector who wishes to appear before the Court(s) at the Settlement Approval Hearing(s), whether in person or through a lawyer, must send a notice of intention to appear in writing, which should be postmarked, served, filed and be received by the Claims Administrator at least ten (10) days prior to the said Settlement Approval Hearing. Such notice of intention to appear should include the name, address, and telephone number of the Class Member and any lawyer who will appear on his or her behalf, if applicable.
- d) The Claims Administrator shall immediately provide Class Counsel and the Defendants with a copy of the Objection and any accompanying documentation.

# 2. Opt-Outs

a) An individual who is a member of the Ontario Class, but who is not a member of the Quebec Class may opt out of the Settlement by sending a signed Opt-Out Form by mail, courier or facsimile to the Claims Administrator in the form attached above as Exhibit F. A Settlement Class Member who is a member of the Quebec Class may make a request to the Quebec Court to opt out of the Settlement even if they did not previously opt out of the Quebec proceeding. The Defendants reserve the right to challenge an opt out by a member of the Quebec Class given that the deadline for opting out of the Quebec Class has already passed.

- b) An opt-out will only be effective if delivered to the Claims Administrator before the Opt- Out Deadline. An opt-out will only be effective if it is on behalf of a single Person. So- called "mass" or "class" opt-outs shall not be allowed.
- c) If there are more than the number of Class Members specified by the parties in the Opt- Out Threshold Letter whose opt outs are deemed to be valid and effective, the Defendants may terminate this Settlement Agreement.
- d) To the extent that a member of the Quebec Class previously opted out of that proceeding, they will be contacted directly by Class Counsel or the Settlement Administrator to be advised of the Settlement, and the Opt-Out Deadline. Class Members who previously opted out of the Quebec Class will be advised of their ability to "opt into" the Settlement as well as the deadline for them to do so.

# 3. Opt-Out and Objection Notification and Report

- a) The Claims Administrator shall immediately provide the Parties through their respective counsel with any Opt-Out Forms and Objections.
- b) Within five (5) business days after the expiration of the Opt-Out and Objection Deadline, the Claims Administrator shall provide to the Parties through their counsel an Opt-Out and Objection report advising as to the following information in respect of each Person, if any, who has opted out or objected to the Settlement:
  - i. the Person's full name, current address, telephone number and email address;
  - ii. the stated reasons the Person is seeking to opt out or object, if known; and
- iii. a copy of all information provided by that Person in the opting-out or objections process, including the Opt-Out Form or written objection.

# SECTION 8. FINAL ORDERS APPROVING THE SETTLEMENT AGREEMENT AND NOTICES TO SETTLEMENT CLASS

#### 1. Final Orders Approving the Settlement Agreement

- a) Following publication of the Notice of Settlement Approval Hearings, the Plaintiffs shall move for Orders from the Ontario Superior Court of Justice and the Superior Court of Quebec in the forms attached as Exhibits C and D above respectively, which will, among other things:
  - i. Declare that this Settlement is fair, reasonable, and in the best interests of the Class Members;

- ii. approve the Settlement Agreement pursuant to section 29(2) of the *Class Proceedings Act*, 1992 and Article 590 of the *Code of Civil Procedure*, CQLR c. C-25.01 and the releases contained therein; and
- iii. order that Settlement Approval Notice be disseminated in accordance with the Notice Plan set out above as Exhibit E.

# 2. Notice of Settlement Approval Hearings

- a) The Plaintiffs shall move for Orders from the Ontario Superior Court of Justice and the Superior Court of Quebec in the forms attached as Exhibits K and L above, which will, among other things:
  - i. Schedule the Settlement Approval Hearing, approve the form, content and method of dissemination of the Notice of Settlement Approval Hearing and Certification (for the Ontario Action); and
  - ii. Schedule the Settlement Approval Hearing, approve the form, content and method of dissemination of the Notice of Settlement Approval Hearing (for the Quebec Action).
- b) The Settlement Class will be notified of the date of the Settlement Approval Hearings by way of the Notice of Settlement Approval Hearings. Subject to approval of the Courts, the Claims Administrator shall cause the Notice of Settlement Approval Hearings to be published and distributed in the manner described in the Notice Plan attached above as Exhibit E by a date to be set by the Courts.
- c) Before the Settlement is approved, the Defendants will be responsible for the Notice Expenses and Claims Administration Expenses, though it will be paid from the Settlement Amount. In the event that the Settlement is not approved, the Defendants will bear the Notice Expenses as well as all Claims Administration Expenses up until the date of termination of the Settlement, such costs being non-refundable to the Defendants.
- d) The Defendants will be responsible for all Notice Expenses and Claims Administration Expenses if they decide to terminate the Settlement Agreement on the basis that the Opt- Out Threshold has been reached.

#### 3. Settlement Approval Notice

a) The Settlement Class shall be notified of the approval of the Settlement by way of the Settlement Approval Notice substantially in the form attached as Exhibit J above. Subject to approval of the Courts, the Claims Administrator shall cause the Settlement Approval Notice to be published and distributed in the manner described in the Notice Plan attached as Exhibit E above. The publication and

distribution of the Settlement Approval Notices shall begin within the thirty (30) day period commencing on the Effective Date.

#### SECTION 9. CLASS COUNSEL FEES AND HONORARIA

#### 1. Class Counsel Fees

- a) Class Counsel shall bring motions before the Courts for approval of Class Counsel Fees. Such Class Counsel Fees will be paid from the Escrow Account to Class Counsel upon receipt of a written direction from Class Counsel within 5 business days after the Effective Date.
- b) The Releasees hereby acknowledge and agree that they have no standing in relation to any motions for approval of Class Counsel Fees and they will have no involvement in the approval process to determine the amount of Class Counsel Fees.

#### 2. Honoraria

c) As part of the Ontario Settlement Approval Motion, Class Counsel will seek an award of \$60,000 to be divided equally amongst Matthew Kirsh, Gabriel Critchfield, Suerekha Ramdeo, Mohan Seenauth, Diana Senis, and Steven Scheer, as a service award for their exceptional effort and contribution in advancing the Proceedings on behalf of the Settlement Class. Such Honoraria as approved by the Ontario Superior Court of Justice will be paid within five (5) business days after the Effective Date. The Releasees will not oppose the application for Honoraria.

# SECTION 10. DISTRIBUTION OF THE REMAINING BALANCE

- a) The Settlement Benefits as set forth in the Distribution Protocol are all subject to *pro rata* distribution downwards if there are insufficient funds in the Escrow Account to pay all Approved Claimants and *pro rata* distribution upwards in the event that more than sufficient funds are available in the Escrow account to pay all Approved Claimants. Consequently, while the Settlement Agreement provides for collective recovery, it is the intention that the entire Settlement Amount be distributed to Settlement Class Members and that there will be no remaining balance.
- b) If, within six (6) months of the payments being issued by the Claims Administrator to pay Approved Claimants, a balance exists in the Escrow Account as a result of uncashed distributions or any other surplus monies, any remaining funds ("Surplus Funds") shall be paid as follows:

- i. The FAAC will be entitled to claim the percentage provided for at s. 1(1) of the *Regulation respecting the percentage withheld by the Fonds d'aide aux actions collectives*, RLRQ c F-3.2.0.1.1, r.2, on the Québec resident portion of the remaining funds. The Quebec resident portion will correspond to 22.98% of the Surplus Funds;
- ii. The balance will be donated to a charity chosen by Class Counsel and approved by the Courts which has a focus on mental health.

# SECTION 11. TERMINATION OF SETTLEMENT AGREEMENT

# 1. Termination — Absence or Insufficiency of Court Approval

- a) In the event that:
  - i. any Court declines to approve this Settlement Agreement or any part hereof;
  - ii. any Court approves this Settlement Agreement in a materially modified form; or
  - iii. any orders approving this Settlement Agreement made by any Court do not become Final Orders,

this Settlement Agreement shall be terminated and, except as provided for in Section 11(4) it shall be null and void and have no further force or effect, shall not be binding on the Parties, and shall not be used as evidence or otherwise in any litigation.

b) It is expressly agreed that the failure or refusal of a Court to grant or approve, in whole or in part, the request for Class Counsel Fees as provided herein shall not be deemed to be a refusal or failure by the Courts to approve this Settlement Agreement or any material part hereof nor be deemed to be a material modification of all, or a part, of this Settlement Agreement, and shall not provide any basis for the termination of this Settlement Agreement.

#### 2. Termination — Opt-Out Threshold Exceeded

- a) In the event that the number of members of the Settlement Class who exercise their rights to opt out under this Settlement Agreement exceeds the number set forth in the Opt-Out Threshold Letter between the Parties, the Defendants may, at their sole discretion, terminate this Settlement Agreement by serving written notice upon Class Counsel within fourteen (14) business days of receiving the Opt-Out report from the Claims Administrator.
- b) The Opt-Out Threshold Letter shall be made available to the Courts but shall not be filed with the Courts or otherwise disclosed to any Person other than Class

Counsel, the Defendants' Counsel and the Defendants. To the extent that a Court requests a copy of the Opt-Out Threshold Agreement, the Parties shall request that the document be filed under seal.

### 3. If Settlement Agreement is Terminated

- a) If this Settlement Agreement is terminated:
  - i. Within ten (10) days of such termination having occurred, Class Counsel shall destroy all documents or other materials provided by the Defendants or containing or reflecting information derived from such documents or other materials received from the Defendants as part of the settlement and mediation process and, to the extent Class Counsel has disclosed any documents or information provided by the Defendants to any other Person, Class Counsel shall recover and destroy such documents or information. Class Counsel shall provide the Defendants with a written certification by Class Counsel of such destruction.
  - ii. Nothing contained in this Section shall be construed to require Class Counsel to destroy any of their work product. However, any documents or information provided by the Defendants, or received from the Defendants in connection with this Settlement Agreement, may not be disclosed to any Person in any manner or used, directly or indirectly, by Class Counsel or any other Person in any way for any reason, without the express prior written permission of the Defendants. Class Counsel shall take appropriate steps and precautions to ensure and maintain the confidentiality of such documents, information and any work product of Class Counsel.
  - iii. Within ten (10) days of such termination having occurred, the Claims Administrator shall return to the Defendants the Settlement Amount, including any interest earned on the Settlement Amount from the date of deposit into the Escrow Account, less the Notice Expenses and Claim Administration Expenses.

#### 4. Survival of Provisions After Termination

- a) If this Settlement Agreement is terminated the provisions of Sections 2 and 11 and the Definitions (in Section 1 herein), shall survive the termination and continue in full force and effect.
- b) The Definitions shall survive only for the limited purpose of the interpretation and implementation of the remaining provisions within the meaning of this Settlement Agreement, but for no other purposes.
- c) All other provisions of this Settlement Agreement and all other obligations pursuant to this Settlement Agreement shall cease immediately. The Parties expressly reserve all of their respective rights if this Settlement Agreement does not become

effective or if this Settlement Agreement is terminated.

#### SECTION 12. RELEASES AND DISMISSALS

# 1. Release of Releasees

a) Upon the Effective Date, and in consideration of the Settlement Consideration, the Releasors forever and absolutely release the Releasees from the Released Claims.

#### 2. No Further Claims

a) The Releasors shall not now or hereafter institute, continue, maintain or assert, either directly or indirectly, whether in Canada or elsewhere, on their own behalf or on behalf of any class or any other Person, any action, suit, cause of action, claim or demand against any Releasee or any other Person who may claim contribution or indemnity from any Releasee in respect of any Released Claim or any matter related thereto.

#### 3. Dismissal of Other Actions

- a) Ontario Class Counsel confirms that they have entered into an agreement with counsel in the proposed class action filed by Siobhan Snyder and Kristina Milisic in Alberta, bearing Court File Number 1701-03651 for the dismissal, with prejudice and without costs, of that proceeding upon approval of the Settlement by the Courts and the dismissal of the proposed class action in Alberta is a requirement of this Settlement.
- b) The Defendants are responsible for seeking dismissal of any other individual action commenced by any Settlement Class Member in Canada, and acknowledge that Class Counsel have no control or responsibility over the commencement, prosecution, continuation, discontinuance, or dismissal of those actions.

### 4. No Further Litigation

- a) Class Counsel, and anyone currently or hereafter employed by, associated with, or in partnership with Class Counsel, may not directly or indirectly participate or be involved in or in any way assist with respect to any claim made or action commenced by any Person which relates to or arises from the Released Claims. However, this section shall not be operative to the extent that it is inconsistent with applicable rules of professional conduct under Rule 3.2-10 of the Code of Professional Conduct for British Columbia.
- b) Moreover, these Persons may not divulge to anyone for any purpose any information obtained in the course of the Proceedings or the negotiation and preparation of this Settlement Agreement, except to the extent such information is otherwise publicly available or unless ordered to do so by a court.

#### SECTION 13. MISCELLANEOUS

#### 1. Motions for Directions

a) Class Counsel, the Defendants or the Claims Administrator may apply to one or more of the Courts for directions in respect of the implementation and administration of this Settlement Agreement.

#### 2. Motions on Notice

a) All motions or applications contemplated by this Settlement Agreement shall be on notice to the Parties in the proceeding in which the motion or application is brought and on a without costs basis.

# 3. Headings, etc.

- a) In this Settlement Agreement:
  - i. the division of the Settlement Agreement into sections and the insertion of headings are for convenience of reference only and shall not affect the construction or interpretation of this Settlement Agreement; and
  - ii. the terms "this Settlement Agreement", "hereof", "herein", and similar expressions refer to this Settlement Agreement and not to any particular section or other portion of this Settlement Agreement unless such section or portion is expressly specified.

#### 4. Computation of Time

- a) In the computation of time in this Settlement Agreement, except where a contrary intention appears,
  - i. where there is a reference to a number of days between two events, the number of days shall be counted by excluding the day on which the first event happens and including the day on which the second event happens, including all calendar days; and
  - ii. only in the case where the time for doing an act expires on a holiday, the act may be done on the next day that is not a holiday.

# 5. Governing Law

a) This Settlement Agreement shall be governed by and construed and interpreted in accordance with the laws of the Province of Ontario with respect to the Ontario Class and governed, construed, and interpreted in accordance with the laws of Quebec with respect to the Quebec Class.

#### 6. Exhibits

- a) All Exhibits to this Settlement Agreement are material and integral parts hereof, and are incorporated by reference as if fully rewritten herein. In the event of any variance between the terms of this Settlement Agreement and any of the Exhibits hereto, the terms of this Settlement Agreement shall govern and supersede the Exhibit(s).
- b) The parties agree to act reasonably as it relates to any modifications to the Exhibits that may be necessary to implement the terms of the Settlement.

#### 7. Waiver

a) The waiver by one Party of any provision or breach of the Settlement Agreement shall not be deemed a waiver of any other provision or any other breach of the Settlement Agreement.

#### 8. Amendments

a) This Settlement Agreement may not be modified or amended except in writing and on consent of all of the Parties and any such modification or amendment must be approved by the Court(s) with jurisdiction over the matter to which the amendment relates.

# 9. Binding Effect

a) This Settlement Agreement shall be binding upon, and enure to the benefit of, the Plaintiffs, the Defendants, the Releasees and all of their successors and assigns. Without limiting the generality of the foregoing, each and every covenant and agreement made herein by the Plaintiffs shall be binding upon all Releasors.

### 10. Counterparts

a) This Settlement Agreement may be executed in counterparts, all of which taken together will be deemed to constitute one and the same agreement, and a facsimile signature or signature sent by e-mail shall be deemed an original signature for purposes of executing this Settlement Agreement and shall be binding.

# 11. Negotiated Agreement

a) This Settlement Agreement has been the subject of negotiations and discussions among the undersigned, each of which has been represented and advised by competent counsel, so that any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter of this Settlement Agreement shall have no force and effect.

b) The Parties further agree that the language contained in or not contained in previous drafts of this Settlement Agreement, or any agreement in principle, shall have no bearing upon the proper interpretation of this Settlement Agreement.

### 12. Language

a) The Parties acknowledge that they have required and consented that this Settlement Agreement and all related documents be prepared in English; *les Parties reconnaissent avoir exigé que la présente convention et tous les documents connexes soient rédigés en anglais.* The Defendants have agreed to translate from English to French all settlement related materials, including, but not limited to the Settlement Agreement and all attached Exhibits, at their own expense. In the event of any dispute as to the interpretation or application of this Settlement Agreement, the English version shall prevail.

#### 13. Transaction

a) This Settlement Agreement constitutes a transaction in accordance with Articles 2631 and following of the *Civil Code of Québec*, CQLR c CCQ-1991 and the Parties are hereby renouncing to any errors of fact, of law and/or of calculation.

#### 14. Recitals

a) The recitals to this Settlement Agreement are true and form part of the Settlement Agreement.

#### 15. Acknowledgements

- a) Each of the Parties hereby affirms and acknowledges that:
  - i. he, she or a representative of the Party with the authority to bind the Party with respect to the matters set forth herein has read and understood the Settlement Agreement;
  - ii. the terms of this Settlement Agreement and the effects thereof have been fully explained to him, her or the Party's representative by his, her or its counsel;
  - iii. he, she or the Party's representative fully understands each term of the Settlement Agreement and its effect; and
  - iv. other than what is expressly set forth in the Settlement Agreement, no Party has relied upon any statement, representation or inducement (whether material, false, negligently made or otherwise) of any other Party with respect to the first Party's decision to execute this Settlement Agreement.

#### 16. Authority of Class Counsel

a) To the extent that any provision or term of this Settlement Agreement expressly provides for the consent, agreement or approval of the Plaintiffs, the Parties or Class Counsel, the Plaintiffs acknowledge and agree that Class Counsel is authorized to give such consent, agreement or approval on behalf of the Plaintiffs and that the Plaintiffs will be bound by such consent, agreement or approval.

# 17. Authorized Signatures

- a) Each of the undersigned represents that he or she is fully authorized to enter into the terms and conditions of, and to execute, this Settlement Agreement.
- b) Where this Settlement Agreement requires a Party to provide notice or any other communication or document to another, such notice, communication or document shall be provided by email, facsimile or letter by overnight delivery to the representatives for the Party to whom notice is being provided, as identified below:

#### For the Plaintiffs:

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Rochon Genova LLP

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#### For Otsuka Defendants:

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#### For Lundbeck Defendants:

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Fax: 416.868.0673 fmclaugh@mccarthy.ca

# 18. Date of Execution

a) The Parties have executed this Settlement Agreement as of the date on the cover page.

# **ROCHON GENOVA LLP**

Rochon Genova LLP For the Plaintiffs Matthew Kirsh, Gayle Kirsh, Gabriel Critchfield, Diana Senis, Sureka Ramdeo, Mohan Seenauth, and Dhanesri Persaud

velm

# CONSUMER LAW GROUP INC.

Consumer Law Group Inc.
Per: Jeff Orenstein

For the Plaintiff Steven Scheer

# NORTON ROSE FULBRIGHT CANADA LLP

Khin

Norton Rose Fulbright Canada LLP For the Otsuka Defendants

# INF S.E.N.C.R.L LLP

# INF S.E.N.C.R.L./LLP

INF S.E.N.C.R.L. LLP Lawyers For Otsuka Canada

# **BLAKE, CASSELS & GRAYDON LLP**

Blake, Cassels & Graydon LLP For the BMS

Defendants

MCCARTHY TETRAULT LLP

McCarthy Tétrault LLP

For the Lundbeck Defendants

#### Exhibit "A"

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® CLASS ACTION SETTLEMENT

### Claim Package

This Claim Package contains:

- a Privacy Statement;
- instructions for Class Members and their legal representatives (if applicable); and
- a Claim Form.

#### PRIVACY STATEMENT

Personal Information regarding Class Members is collected, used, and retained by the Claims Administrator pursuant to the *Personal Information Protection and Electronics Documents Act*, S.C. 2000, c.5 ("PIPEDA"):

- for the purpose of operating and administering the Canadian ABILIFY® and ABILIFY MAINTENA® Settlement Agreement ("Settlement");
- to evaluate and consider the Class Member's eligibility under the Settlement; and
- is strictly private and confidential and will not be disclosed without the express written consent of the Class Member except as provided for in the Settlement.

#### INSTRUCTIONS FOR CLASS MEMBERS

If you are completing this Claim Package PRIOR to the Courts' approval of the Settlement, PLEASE NOTE that no Claims will be processed unless and until the Settlement has been approved by both the Ontario and Québec Courts.

Unless otherwise indicated in this document, capitalized terms have the meanings set out in the Settlement.

These instructions provide basic guidelines for submitting claims under the Settlement. In the event of any disagreement between these instructions and the Settlement, the Settlement shall prevail. For more detailed information, please refer to the Settlement Agreement that can be

viewed or downloaded at <u>abilifyclassactionsettlement.com</u> or the website of Class Counsel, Rochon Genova LLP and Consumer Law Group Inc.

To establish your right to benefits under the terms and conditions of the Settlement, a completed Claim Package must be submitted to the Claims Administrator, which shall consist of:

- a completed and signed Claim Form;
- prescription records and/or medical records;
- Documentation relevant to Compulsive Behaviours or Impulse Control Behaviours where a claim for Psychological Harm, Severe and/or Residual Catastrophic Injury is made;
- Gambling Records and/or Financial Records where a claim for financial loss is made;
- Family Class Member(s)' records where Family Class Members claims are made; and
- all other required documentation as described in this document.

All completed Claim Packages must be submitted to the Claims Administrator or postmarked no later than DATE, at the following address:

## Attention: Canadian ABILIFY® and ABILIFY MAINTENA®

#### **Class Action Settlement**

MNP Ltd. – Class Actions Claims Administration 2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3 abilifysettlement@mnp.ca

Toll-Free: 1 (855) 653-0027

Class Members who have not opted out and who do not submit a completed Claim Package to the Claims Administrator on or before **DATE** shall forever forfeit their rights to benefits from the Settlement and will be precluded from ever bringing an action against any of the Defendants or other Released Parties with respect to any alleged Compulsive Behaviours or Impulse Control Disorders caused by ABILIFY® and ABILIFY MAINTENA® and any other Released Claim.

If you require assistance or advice regarding completion of the Claim Package or have any questions related to your claim, you may contact Class Counsel or the Claims Administrator:

Class Counsel	Claims Administrator
ROCHON GENOVA LLP	
	MNP Ltd. – Class Actions Claims

Tel: (416) 363-1867 1-800-462-3864

contact@rochongenova.com

CONSUMER LAW GROUP INC.

Tel: 1 (888) 909-7863 (514) 266-7863 (613) 627-4894

abilify@clg.org

#### Administration

1-800-538-0009

abilifysettlement@mnp.ca.

Alternatively, you may retain legal counsel at your own expense. <u>Class Members who retain lawyers or agents in making their claims under the Settlement shall be solely responsible for the fees and expenses of such lawyers or agents.</u>

Class Members may communicate with the Claims Administrator and obtain forms in either English or French. Class Members (or their lawyers/agents) should advise the Claims Administrator of any changes or corrections in the address, name, phone number or legal representation.

Please keep copies of all documentation you send to the Claims Administrator. Completing the documentation process takes time. ACT NOW. Do not wait until the last few weeks before the Claim Period expires.

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® SETTLEMENT CLAIM FORM

#### **Strictly Private and Confidential**

#### Section 1 – Class Member Identification

I am making a claim as a:

Class Member (the person who used ABILIFY® and/or ABILIFY MAINTENA®)

**Representative of a Class Member** (a person who is the representative of a Class Member who is deceased, a minor and/or otherwise under a legal disability, including an individual with legal control over the Class Member's financial and property interest)

Lawyer or agent for the Class Member

#### Section 2 – Class Member Identification

This section is to be completed by or on behalf of the Class Member. Please NOTE: If someone else has legal control over your property or finances, they MUST complete and submit Section 3 for your Claim to be processed.

Class Membe	ass Member Last Name:First Name			
Address				_P.O. Box
City		Province	Postal Code_	
Birth Date:	Year:	Month:	Day:	_
Date of Death	ı (if applicable):	Year	MonthDay	_
	Official Death certifi	cate attached		
Home Phone_			Work Phone	
Fax		E-mail		

## Section 3 – Representative of Class Member – Identification

This section is to be completed <u>only</u> if you are submitting a claim as the Representative of a Class Member. You MUST provide proof of your authority to act as the Representative of a Class Member. <u>Before completing this section</u>, you MUST complete Sections 1 and 2 to identify yourself and the Class Member that you are representing.

I am applying	g on behalf of a Class Member	/ho is:
	A minor (under 18 years of Please enclose a copy of your certificate, court order or other	authority to act (i.e., long-form birth certificate, baptismal
	A person under legal disabi Please enclose a copy of your	authority to act (i.e., power of attorney, etc.)
	Deceased Please enclose a copy of your etc.)	authority to act (i.e., will, death certificate, probate order,
Legal Repres	entative's Last Name:	First Name
Address		P.O. Box
City	Provin	ePostal Code
Birth Date:	Year:Month	Day:
Home Phone		Work Phone
Fax	E-mai	

#### Section 4 – Family Class Member Claims

This section is to be completed by eligible Family Class Members. Eligible Family Class Members are spouses, children, parents, grandparents, brothers, and sisters of a Class Member by or for whom a claim is being advanced under the Settlement. If the Family Class Member is a minor, under a legal disability or deceased, this section may be completed by someone with authority to act on their behalf.

Please note that a Family Class Member is only entitled to claim compensation if the Class Member has not opted out of the class action **and** is submitting a claim to receive benefits under the Settlement.

Please include document(s) demonstrating proof of each Family Class Member's relationship to the Class Member and, where the Family Class Member is a minor, under a legal disability or deceased, please include document(s) demonstrating proof of your authority to act (e.g., marriage certificate, long-form birth certificate, baptismal papers, separation agreement, custody judgment, divorce judgment or affidavit, will or other document confirming your authority to act).

Before completing this section, you MUST complete Sections 1 and 2 to identify the Class Member who is entitled to make a claim. If there is/are more than one Family Class Member making a claim, please copy this section and have each eligible Family Class Member provide the requested information and submit this information along with your Claim Package.

Relationship to Class Member:		
Family Class Member Last Name:		First Name:
Address_		P.O. Box
City	Province	Postal Code
Birth Date: Year Month_	Day	
Home Phone	Work Phone	
Fax	E-mail	
Signature of Family Class Memb	er:	

## **Section 5 – Legal Representative Identification**

This section is to be completed ONLY IF a lawyer or agent is representing the Class Member.

Name of Law Firm or Agency		
Lawyer's or Agent's Last Name:_		First Name:
Address		P.O. Box
City	Province	Postal Code
Phone - Fax_		<u> </u>
E-mail		
Provincial Law Society Number (i	f applicable)	

NOTE: If you complete Section 5 above, all correspondence will be sent to the Class Member's legal representative, who must notify the Claims Administrator of any change in mailing address. If you change your legal representation or cease to retain your legal representative, you must notify your former legal representative and the Claims Administrator in writing.

#### Section 6 – Products Prescribed and Used

Please indicate whether the Class Member was prescribed or provided with free sample packages of any or all of the following:

ABILIFY <sup>®</sup>	YES	NO
ABILIFY MAINTENA®	YES	NO

You must provide all available prescription records and/or medical records for the period of the Class Members' usage of ABILIFY<sup>®</sup> and/or of ABILIFY MAINTENA<sup>®</sup> to prove that the Class Member was prescribed and/or provided ABILIFY<sup>®</sup> and/or ABILIFY MAINTENA<sup>®</sup>. You must provide one or more of the following forms of documentary support set out below:

a) pharmacy records reflecting the dispensing of ABILIFY® and/or ABILIFY MAINTENA® to the Class Member, including the dosage and date(s) of same;

#### AND/OR

b) all insurance records reflecting the Class Member's purchase of ABILIFY® and/or ABILIFY MAINTENA®, including the dosage and dates of same, if available;

#### AND/OR

c) medical records reflecting the prescription and/or provision (samples) of ABILIFY® and/or ABILIFY MAINTENA® to the Class Member, along with the dosage and dates of same;

#### OR

d) in extraordinary circumstances only, to be determined by the Claims Administrator, if none of the above records are available, a declaration signed by the Class Member's physician attesting to the Class Member having been prescribed and/or provided with ABILIFY® and/or ABILIFY MAINTENA®, including the dosage and dates of same, **AND** a declaration by the Class Member (or the Class Member's representative) that the Class Member was prescribed and/or provided with ABILIFY® and/or ABILIFY MAINTENA®, along with the dosage and dates of same, and attesting that they have made reasonable best efforts to obtain the above records and providing the reason why such records could not be obtained.

#### Section 7 – Psychological Harm

Please indicate the Class Member's alleged Compensable Injury which forms the basis of this claim along with date(s) of diagnosis and/or treatment (you may check all that apply but note that compensation is only available once per claim, at the highest confirmed injury level, regardless of the number of potential Compensable Injuries). Please note that this information is intended to assist with the review of your Claim Package. The Claims Administrator is entitled to make any and all determinations in respect of the appropriate Compensable Injury following its review of the Class Member's Mandatory medical records:

#### 1) **Mild:**

MAINTENA® for 1-6 months and experienced one	or more of the following
Compulsive Behaviours or Impulse Control Disorders while	le on or within 3 months of
discontinuing their use of ABILIFY® and/or receiving MAINTENA® (check all that apply):	g injections of ABILIFY
☐ Compulsive gambling	☐ Compulsive or
☐ Hypersexuality	Uncontrollable shopping
☐ Binge eating	snopping
DATES DURING WHICH BEHAVIOURS OCCURRED:	

The Class Member took ABILIFY® and/or received injections of ABILIFY

A signed attestation (Section 7A) that the Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for 1-6 months and experienced one or more of the above Compulsive Disorders or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® and/or receiving injections of ABILIFY MAINTENA®.

## 2) Moderate:

MAINTENA® for more than 6 months and experience Compulsive Behaviours or Impulse Control Disorders after taking ABILIFY® and/or receiving injections of A	ed one or more of the following (check all that apply) while or
☐ Compulsive gambling	☐ Compulsive on
☐ Hypersexuality	Uncontrollable shopping
☐ Binge eating	snopping
DATES DURING WHICH BEHAVIOURS OCCURRI	ED:
A signed attestation (Section 7A) from the Class Mem and/or received injections of ABILIFY MAINTENA® experienced one or more Compulsive Behaviours or Imon or within 3 months of discontinuing their use of ABI of ABILIFY MAINTENA®.	for more than 6 months and pulse Control Disorders while
OR	
The Class Member took ABILIFY® and/or recei MAINTENA® for <b>1-6 months</b> and, while on or with their use of ABILIFY® and/or receiving injections experienced one or more of the following Compulsive ID Disorders of such severity that treatment or counselling Behaviours or Impulse Control Disorders in question (control Disorders in question (control Disorders in question)	hin 3 months of discontinuing of ABILIFY MAINTENA® Behaviours or Impulse Contro was sought for the Compulsive
☐ Compulsive gambling	☐ Binge eating
☐ Hypersexuality	☐ Uncontrollable shopping
Please identify and attach medical records specifying counselling sought or provided and the specific Common Control Disorders for which treatment or counselling treatment in question was not covered by provincial here or confirmation of payment. Check all forms of applications of applications are confirmation of payment.	pulsive Behaviour or Impulse was sought or provided. If the ealth insurance, attach receipts
☐ Gambling counselling	☐ Binge eating clinic
☐ Hypersexuality clinic	☐ Uncontrollable shopping clinic

DATES DURING WHICH BEHAVIOURS	OCCURRED:
DATES DURING WHICH SPECIALIZED (SOUGHT OR RECEIVED:	COUNSELLING OR TREATMENT WAS
A signed attestation (Section 7A) from the Cand/or received injections of ABILIFY MAIN within 3 months of discontinuing their use ABILIFY MAINTENA®, they experienced Impulse Control Disorders of such severity that the Compulsive Behaviours or Impulse Control	TENA® for <b>1-6 months</b> and, while on or of ABILIFY® or receiving injections of one or more Compulsive Disorders or at treatment or counselling was sought for
3) Severe:	
The Class Member took ABILIFY® and MAINTENA® for more than 6 months and Compulsive Behaviours or Impulse Control I discontinuing their use of ABILIFY® MAINTENA® (check all that apply):	d experienced one or more of the below Disorders while on or within 3 months of
☐ Gambling counselling	☐ Binge eating clinic
☐ Hypersexuality clinic	☐ Uncontrollable shopping clinic
AND	
The Class Member experienced bankruptcy and/or criminal prosecution for fraud, the experiencing Compulsive Behaviours and/or apply:	eft, etc. contemporaneous to or after
☐ Declaration of Bankruptcy	☐ Re-mortgaging a property
☐ Divorce	☐ Criminal prosecution
☐ Other	

Identify and attach records demonstrating that you experienced the Compulsive Behaviours or Impulse Control Behaviours (e.g. gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, medical records referencing the Compulsive Behaviors, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours or Impulse Control Disorders), together with a signed attestation available under **Section 7A** that you experienced the Compulsive Behaviours or Impulse Control Disorders and experienced bankruptcy, divorce, remortgaging of a property, and/or criminal prosecution for fraud, theft, etc. contemporaneous to or after experiencing the Compulsive Behaviours and/or Impulse Control Disorders

#### **AND**

Documentary evidence of bankruptcy, divorce, re-mortgaging of a property, and/or criminal prosecution for fraud, theft, etc. contemporaneous to or after experiencing Compulsive Behaviours and/or Impulse Control Disorders, check all that apply:

☐ Declaration of Bankruptcy
☐ Divorce
☐ Re-mortgaging a property
☐ Criminal prosecution
□ Other
DATES DURING WHICH BEHAVIOURS OCCURRED:
DATES OF BANKRUPTCY, DIVORCE, RE-MORTGAGING OF A PROPERTY, AND/OR CRIMINAL PROSECUTION FOR FRAUD, THEFT, ETC.:
OR/ AND (if applicable)

The Class Member experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders for **more than 6 months** while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, and the Compulsive Behaviours or Impulse Control Disorder were of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question **for more than 6 months** (check all that apply):

☐ Compulsiv	e gambling	□ H	ypersexuality

☐ Binge eating	shoppin
☐ Uncontrollable	
Identify and attach records demonstrating Compulsive Behaviours or Impulse Control D ATM withdrawals at casinos, self-exclusion statements showing payments for gamblin compulsive behaviors, or medical records or treatment was sought for Compulsive Behaviogether with a signed attestation, available up the Compulsive Behaviours or Impulse Contreatment or counselling was sought for the Compulsional Control of the Co	isorders (e.g. gambling records, such as from a casino, credit card or banking ag, medical records referencing the counselling records documenting that viours or Impulse Control Disorders), ander <b>Section 7A</b> , that you experienced antrol Disorders of such severity that impulsive Behaviours or Impulse Control
☐ Gambling counselling	☐ Compulsive or Uncontrollable
☐ Hypersexuality clinic	shopping clinic
☐ Binge eating clinic	
Identify and attach medical records specifyin sought or provided and the specific Comp Disorders for which treatment or counselling vin question was not covered by provincial confirmation of payment. Check all forms of a	ulsive Behaviour or Impulse Control was sought or provided. If the treatment health insurance, attach receipts or
☐ Gambling counselling	
☐ Hypersexuality clinic	
☐ Binge eating clinic	
☐ Uncontrollable shopping clinic	
DATES DURING WHICH BEHAVIOURS O	CCURRED:
DATES DURING WHICH SPECIALIZED CO SOUGHT OR RECEIVED:	OUNSELLING OR TREATMENT WAS

4)	ado		Catastrophic Injury (compensation available for catastrophic injury <u>in</u> <u>to</u> compensation available for Mild, Moderate and Severe Psychological
			Members claiming in this category must also claim for compensation under the Moderate, or Severe Psychological Harm category, above, and must provide mentary evidence demonstrating they:
		i)	experienced catastrophic physical or psychological consequences of Compulsive Behaviours or Impulse Control Disorders alleged to have been caused by the use of ABILIFY® and/or ABILIFY MAINTENA®, including but not limited to: contracting HIV, Hepatitis, or a non-treatable STI (sexually transmitted infection) as a result of hypersexuality, suicidality and related hospitalization related to Compulsive Behaviours or Impulse Control Disorders and their consequences. Specifically, they experienced (attach additional sheets if needed):

## 7A – CLASS MEMBER'S ATTESTATION

## MILD:

MA Co mo	e Class Member took ABILIFY® and/or received injections of ABILIFY AINTENA® for <b>1-6 months</b> and experienced one or more of the following mpulsive Behaviours or Impulse Control Disorders while on or within 3 on this of discontinuing their use of ABILIFY® or receiving injections of BILIFY MAINTENA® (check all that apply):
	☐ Compulsive gambling
	☐ Hypersexuality
	☐ Binge eating
	☐ Compulsive or Uncontrollable shopping
MODERA	ΓΕ:
MA fol tha	e Class Member took ABILIFY® and/or received injections of ABILIFY AINTENA® for <b>more than 6 months and</b> experienced one or more of the lowing Compulsive Behaviours or Impulse Control Disorders (check all t apply) while on or within 3 months of discontinuing their use of BILIFY® or receiving injections of ABILIFY MAINTENA®:
	☐ Compulsive gambling
	☐ Hypersexuality
	☐ Binge eating
	☐ Compulsive or Uncontrollable shopping
MA dis MA Bel	e Class Member took ABILIFY® and/or received injections of ABILIFY AINTENA® for <b>1-6 months</b> and, while on or within 3 months of continuing their use of ABILIFY® or receiving injections of ABILIFY AINTENA®, experienced one or more of the following Compulsive haviours or Impulse Control Disorders of such severity that treatment or unselling was sought for the Compulsive Behaviours or Impulse Control sorders in question (check all that apply):
	☐ Gambling counselling
	☐ Hypersexuality clinic
	☐ Binge eating clinic
	☐ Uncontrollable shopping clinic

## **SEVERE:**

	Th Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for <b>more than 6 months and</b> experienced one or more of the below Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA® (check all that apply):
	☐ Compulsive gambling
	☐ Hypersexuality
	☐ Binge eating
	☐ Uncontrollable shopping
AND	
	The Class Member experienced bankruptcy, divorce, re-mortgaging of a property, and/or criminal prosecution for fraud, theft, etc. contemporaneous to or after experiencing Compulsive Behaviours and/or Impulse Control Disorders (check all that apply):
	☐ Declaration of Bankruptcy
	☐ Divorce
	☐ Re-mortgaging a property
	☐ Criminal prosecution
	☐ Other
OR/AND (if ap	oplicable)
	While on or within 3 months of discontinuing my use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, the Class Member experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders for more than 6 months of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question for more than 6 months (check all that apply):
	☐ Compulsive gambling
	☐ Hypersexuality
	☐ Binge eating

☐ Uncontrollable shopping

## **Attestation**

The undersigned attests, under penalty of law, that the information provided in this Claim Form is true and correct to the best of his/her knowledge, information and belief.		
	Date:	
Signature of Class Member or their Representative	DD/MM/YYYY	

#### **Section 8 – Financial Loss**

This section <u>only</u> applies if you are submitting a claim for a Class Member's alleged financial loss. A total of \$1.5 million dollars has been set aside to compensate eligible Class Members for their financial losses, and will be distributed *pro rata* among Class Members who submit claims with priority given to those who submit documentation in support of their claims relating to gambling losses.

If you are claiming compensation for financial harm relating to compensable gambling losses or a loan relating to gambling losses, please complete this section and attach the requested Gambling Records and Financial Records.

#### 1) Compensable gambling losses

Please attach **all available** Gambling Records for all venues at which gambling took place. This documentation must show the gambling activities at each venue. Gambling venues include casinos, online gambling websites, and any other venue in which the at issue gambling occurred whether in person or virtually. Supportive documentation may include, but is not limited to, records of gambling counselling, ATM withdrawal at casinos, credit card or banking statements showing payments for gambling, together with a signed attestation by the Class Member or their legal representative, available at **Section 8A**, of the net amount of any gambling losses.

Please indicate if the Class Member was taking any other prescription medications with dopamine agonist properties while the at issue gambling occurred. Such medications include, but are not limited to, the following (please check all that you were taking when the at issue gambling occurred):

Pramipexole (Mirapex)
Ropinirole (Requip)
Pergolide (Permax)
Other (please fill in):

#### 2) Compensable income loss

Please attach

i) documentation to demonstrate that the Class Member experienced the Compulsive Behaviours (gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours, together with a signed attestation that you

experienced the Compulsive Behaviours);

#### <u>and</u>

records of any income loss if your Compulsive Behaviours or Impulse Control Disorders resulted in termination or loss of employment, including: the applicable employment agreement and income tax returns for the two years preceding the termination. Please also submit the Class Member Attestation <a href="mailto:and/or">and/or</a> the Employer's Attestation available below under **Section 8B**, describing the reason for termination of employment.

#### 3) Compensable loan losses

Please attach:

i) documentation to demonstrate that the Class Member experienced the Compulsive Behaviours (gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours, together with a signed attestation that you experienced the Compulsive Behaviours);

#### and

ii) all available financial records related to any loan for which compensation is sought. If the loan is from a financial institution, this must include a current statement of account for the loan. If the loan is from a private lender, friend, or family member, please provide an attestation from the lender, under penalty of law, confirming: the balance of the loan outstanding, the loan principal, accrued interest to date, and an account of all payments toward the loan received to date.

## Section 8A – Class Member's Attestation Regarding Gambling Losses

## **Attestation**

their Representative

The undersigned attests, under penalty of law, that the Class Member

a)	experienced	IFY® and/or Compulsive C ABILIFY® or	Sambling w	hile on	or within	3 month	s of discontin	
AN	ND							
b)	Suffered approximate	gambling ly	losses	in ·	the	net	amount	of
Signature	e of Class Mer	mber or			Date:	DD/MM	I/YYY	

#### **Section 8B – Compensable Income Loss**

This section <u>only</u> applies if you are submitting a claim for a Class Member's compensable income loss.

If you are claiming compensation for a Class Member's income loss if their Compulsive Behaviours or Impulse Control Disorders resulted in their termination or loss of employment, please complete the Class Member and/or the Employer's Attestation below and attach the requested documents.

i) attach **complete** records of any income loss if the Class Member's Compulsive Behaviours or Impulse Control Disorders resulted in termination or loss of employment, including: the applicable employment agreement and income tax returns for the two years preceding the termination;

#### **AND**

ii) have the Class Member and/or the Class Member's Representative fill out the attestation below confirming termination of employment and the reason for termination, **or** provide the Employer's Attestation.

## **CLASS MEMBER'S ATTESATION**

## **Information About Employer**

Business Name:		
Address:		P.O. Box
City	Province	Postal Code
Phone	E-mail	
Information About Cla	ss Members' Employment	
Duration (Dates) of Clas	s Member's Employment	
		tion:
		·
Date of Termination:		
Reason(s) for Termination	on:	

## Attestation

The undersigned attests, under penalty of law, that the Cla	ass Member's Compulsive Behaviours			
or Impulse Control Disorders and resulting behaviour was the cause of their termination.				
of impulse Control Disorders and resulting behaviour was the cause of their termination.				
	Date:			
Signature of Class Member or their Representative	DD/MM/YYYY			

#### **EMPLOYER'S ATTESATION**

Should the Class Member elect to submit the Employer Attestation, and if the Class Member experienced termination or loss of employment by more than one employer, this section should be completed separately by each employer.

## **Information About Employer**

Last Name:	First Name	
Business Name:		
Relationship to Class Member:		
Address:		P.O. Box
City	Province	Postal Code
Phone	E-mail	
Information About Class Member		
Duration (Dates) of Class Member	's Employment	
Description of Class Member's Job	Duties and Renumeration	on:
Date of Termination:		
Reason(s) for Termination:		

Attestation	
The undersigned attests, under penalty of la	aw, that that the information provided in this Attest
The undersigned attests, under penalty of la	
The undersigned attests, under penalty of la	vledge, information and belief.
The undersigned attests, under penalty of la	

#### **Section 9 – Class Member Declaration**

This Section is to be completed by the Class Member, the Representative of the Class Member or the Legal Representative of the Class Member.

The undersigned hereby consent(s) to the disclosure of the information contained herein to the extent necessary to process this claim for benefits. The undersigned acknowledges and understands that this Claim Form is an official Court document approved by the Ontario and Québec Courts that preside over the Settlement, and submitting this Claim Form to the Claims Administrator is equivalent to filing it with a Court.

After reviewing the information that has been supplied on this Claim Form, the undersigned declares under penalty of law that the information provided in this Claim Form is true and correct to the best of his/her knowledge, information and belief.

	Date	
Signature		DD/MM/YYYY

#### Section 10 - Physician Declaration

This Section is to be completed ONLY if you were UNABLE to obtain and provide the prescription records and/or medical records required by Section 6 above.

I solemnly declare that: 1. I am a physician licensed to practice medicine in the province of \_\_\_\_\_\_. I am/was a treating physician for (Class 2. Member) and I hereby attest that the Class Member was prescribed and/or provided with ABILIFY® and or ABILIFY MAINTENA® as follows: **ABILIFY®** YES NO Date(s), duration and dosage(s):\_\_\_\_\_ ABILIFY MAINTENA® YES NO Date(s), duration and dosage(s):\_\_\_\_\_ Signature of Physician Date Name of Physician\_\_\_\_ CPSO# (or equivalent) Address:

Telephone Number:

## Section 11 – Class Member Declaration – Missing Product Identification Documentation

This Section is to be completed ONLY if you were UNABLE to obtain and provide the prescription records and/or medical records required by Section 6 above.

The undersigned hereby declares under penalty of law that the Class Member was prescribed and/or provided with ABILIFY® and/or ABILIFY MAINTENA® as follows:

ABILIF		YES	NO		
Date(s),	duration and dosage(	(s):			
					_
					_
ABILIF	Y MAINTENA®	YES	NO		
	duration and dosage(		1.0		
-					
					_
TT1 1 1	1	1.1 1			
				otain the required med WHY such documenta	
	tained and provided (				11011
					_
					_
					_
					_
					_
					_
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			D /		
			Date		
Signature of Cla	ass Member or their F	Representative	e	DD/MM/YYYY	-

#### Exhibit "B"

#### **DISTRIBUTION PROTOCOL**

Under the Settlement, Class Members may be entitled to compensation for Compensable Injury, including eligible Psychological Harm and Financial Loss. Eligibility to receive compensation under the Settlement, including the specific category or categories of Compensable Injury for which a Class Member qualifies, will be determined by the Claims Administrator. The Settlement Fund Less Class Counsel Fees, Disbursements, Payment to Public Health Insurance Claims, Claims Administration Expenses, Honoraria, Referee Fees and Applicable Taxes is to be distributed per category is detailed in the Distribution Grid set out below, and is subject to a *pro rata* adjustment based on the number of Class Members who qualify for compensation in each category.

The categories of compensation and their requirements are as follows:

## Psychological Harm

1)	Mi	ild:		
	☐ The Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for <b>1-6 months</b> and experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®:			nore of the following or within 3 months of
		☐ Compulsive gambling		Binge eating
		☐ Hypersexuality		Uncontrollable shopping
		The Class Member provided a signed attestation that they took ABILIFY® and/oreceived injections of ABILIFY MAINTENA® for <b>1-6 months</b> and experienced or or more of the above Compulsive Disorders or Impulse Control Disorders while on within 3 months of discontinuing their use of ABILIFY® or receiving injections ABILIFY MAINTENA®.		
2)	Mo	oderate:		
	☐ The Class Member took ABILIFY® and/or received injections of ABILIF MAINTENA® for <b>more than 6 months and</b> experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders (check all that apply) while or within 3 months of discontinuing their use of ABILIFY® or receiving injections ABILIFY MAINTENA®:			or more of the following all that apply) while on
		☐ Compulsive gambling		Binge eating
	☐ Hypersexuality ☐ Uncontrollable shopping			Uncontrollable shopping

	The Class Member provided a signed attestation (Section 7.4 took ABILIFY® and/or received injections of ABILIFY M months and experienced one or more Compulsive Be Disorders while on or within 3 months of discontinuing their injections of ABILIFY MAINTENA®.	AINTENA® for more than 6 chaviours or Impulse Control		
	OR			
	The Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for <b>1-6 months and</b> , while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question:			
	☐ Compulsive gambling	☐ Binge eating		
	☐ Hypersexuality	☐ Uncontrollable shopping		
The Class Member attached medical records specifying the following forms treatment or counselling were sought or provided. If the treatment in question was covered by provincial health insurance, the Class Member attached receipts confirmation of payment for:				
	☐ Gambling counselling	☐ Binge eating clinic		
	☐ Hypersexuality clinic	☐ Uncontrollable shopping clinic		
	The Class Member provided a signed attestation (Section 7A) that the Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for 1-6 months and, while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, experienced one or more Compulsive Disorders or Impulse Control Disorders of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question.			

#### 3) Severe:

a) The Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for **more than 6 months and** experienced one or more of the below Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA® (check all that apply), and experienced bankruptcy, divorce, remortgaging of a property, and/or criminal prosecution for fraud, theft, termination or loss of employment, contemporaneous to experiencing Compulsive Behaviours and/or

Impulse Control Disorders				
☐ Compulsive gambling	☐ Binge eating			
☐ Hypersexuality	☐ Uncontrollable shopping			
☐ The Class Member attached records demonstrating they experienced the Compulsive Behaviours or Impulse Control Disorders (e.g. gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours or Impulse Control Disorders).				
mortgaging of a property, and/or crimina	s demonstrating bankruptcy, divorce, re- al prosecution for fraud, theft, termination or ous to experiencing Compulsive Behaviours k all that apply:			
☐ Declaration of Bankruptcy	☐ Re-mortgaging a property			
☐ Divorce	☐ Criminal prosecution			
Other				
The Class Member provided a signed attestation (Section 7A of the Claim Form) that they took ABILIFY® and/or received injections of ABILIFY MAINTENA® for more than 6 months, experienced one or more Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, and experienced bankruptcy, divorce, re-mortgaging of a property, and/or criminal prosecution for fraud, theft, etc. contemporaneous to or after experiencing Compulsive Behaviours and/or Impulse Control Disorders				
OR/ AND (if applicable)				
b) While on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, the Class Member experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders for more than 6 months of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question for more than 6 months:				
☐ Compulsive gambling				
☐ Hypersexuality				
☐ Binge eating				
☐ Uncontrollable shopping				

	Composite such as or ban counse	Class Member attached records demonstrating they experienced the ulsive Behaviours or Impulse Control Disorders (e.g. gambling records, s ATM withdrawals at casinos, self-exclusion from a casino, credit card king statements showing payments for gambling, or medical records or elling records documenting that treatment was sought for Compulsive iours or Impulse Control Disorders).
	counse	Class Member attached records specifying the form of treatment or elling sought or provided. If the treatment in question was not covered vincial health insurance, the Class Member attached receipts of same:
		Gambling counselling
		Hypersexuality clinic
		Binge eating clinic
		Uncontrollable shopping
	Form MAI of dis MAI Impu soug	Class Member provided a signed attestation (Section 7A of the Claim n) that they took ABILIFY® and/or received injections of ABILIFY NTENA® for more than 6 months and, while on or within 3 months scontinuing their use of ABILIFY® or receiving injections of ABILIFY NTENA®, experienced one or more of the Compulsive Behaviours or alse Control Disorders of such severity that treatment or counselling was the for the Compulsive Behaviours or Impulse Control Disorders in tion for more than 6 months.
Re	sidual	Catastrophic Injury:
	addit	Class Member provided documentary evidence demonstrating that, in ion to claiming under the Mild, Moderate or Severe Psychological Harm gories they:
	i)	experienced catastrophic physical or psychological consequences of Compulsive Behaviours or Impulse Control Disorders alleged to have been caused by the use of ABILIFY® and/or ABILIFY MAINTENA®, including but not limited to: contracting HIV, Hepatitis, or a non-treatable STI (sexually transmitted infection) as a result of hypersexuality, suicidality and related hospitalization related to Compulsive Behaviours or Impulse Control Disorders and their consequences.

## Financial Harm

4)

## 1) Compensable gambling losses

☐ The Class Member provided all available documentation capable of showing gambling activity at each venue where gambling took place. In the aggregate between these venues, the Class Member suffered a net gambling loss of an amount specified.
☐ The Class Member confirmed that when the at issue gambling occurred, they were not taking any other dopamine agonist medications, including but not limited to:
☐ Pramipexole (Mirapex)
☐ Ropinirole (Requip)
☐ Pergolide (Permax)
□ Other
2) Compensable income loss
☐ The Class Member provided documentation for entitlement to compensation for termination or loss of employment.
3) Compensable loan losses
☐ The Class Member provided documentation for entitlement to compensation for compensable loan losses.
☐ The Class Member provided complete Financial Records from relevant lenders, including the specific amounts borrowed.
Family Class Member Claims:
☐ The Family Class Member provided records demonstrating they are entitled to settlement benefits, including their relationship to the Class Member and the percentage of their entitlement.
Unless otherwise indicated herein, all capitalized terms have the meanings set out in the

Settlement Agreement.

Distribution Grid: Estimated Settlement Fund Less Class Counsel Fees, Disbursements, Payment to Public Health Insurance Claims, Claims Administration Expenses, Honoraria, Referee Fees and Applicable Taxes, 900 Class Members<sup>1</sup>

Categories <sup>2</sup>	Estimated Number	Estimated Individual	Estimated Aggregate	Estimated Cap of
0	of Class Members	Claim Value	Claim Value	Net Settlement
Psychological: Mild	(% of 10tal) 720 (80.0%)	\$3, 246.53	\$ 2,337,500	Funds 27.5%
Psychological: Moderate	144 (16%)	\$14,756.94	\$ 2,125,000	25%
Psychological: Severe	36 (4%)	\$42,500	\$ 1,530,000	18%
Compensation available for Catastrophic Injury: in addition to compensation available for Mild, Moderate, and Severe Psychological Harm: HIV Infection and incurable STIs, attempted suicide and hospitalization <sup>3</sup>	5 of 900	\$42,500	\$ 212,500	2.5%
Eligible financial losses <sup>4</sup>	N/A	N/A	\$1,700,000	20%
Family Class Members (available to Family Members of Class Members who qualify for Psychological: Moderate and Severe)			\$595,000	7%
Total	900 (100.0%)	N/A	\$8,500,000 max	100.0%

<sup>&</sup>lt;sup>1</sup> Class Counsel may apply to the Courts for any substantial variations to the distribution protocol.

<sup>&</sup>lt;sup>2</sup> If there is under subscription to the settlement, excess funds will be distributed pro rata. If there is over subscription, claim values will be deducted from claimants

<sup>&</sup>lt;sup>3</sup> If one or more such claimants with verifiable claims come forward and the settlement is fully or over subscribed, other claims will be reduced pro rata to compensate these claimants.

<sup>&</sup>lt;sup>4</sup> Any excess funds will be distributed to eligible claimants pro rata.

# Exhibit "C"

Court File No. CV-16-553833-00CP

# ONTARIO SUPERIOR COURT OF JUSTICE

BETWEEN:

**Plaintiffs** 

- and -

BRISTOL-MYERS SQUIBB, BRISTOL-MYERS SQUIBB CANADA CO./LA SOCIÉTÉ BRISTOL-MYERS SQUIBB, OTSUKA PHARMACEUTICAL CO., LTD., OTSUKA CANADA PHARMACEUTICAL INC., OTSUKA AMERICA PHARMACEUTICAL, INC., OTSUKA AMERICA, INC., OTSUKA MARYLAND MEDICINAL LABORATORIES, INC., and OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC., H. LUNDBECK A/S, and LUNDBECK CANADA INC.

Defendants

Proceeding under the Class Proceedings Act, 1992

# ORDER

THIS MOTION, made by the Plaintiffs, for an Order approving: (i) the Settlement Agreement reached between the Plaintiffs and the Defendants dated X ("Settlement Agreement") a copy of which is attached as Schedule "X" to this Order; (ii) the Distribution Protocol attached as Schedule X to the Settlement Agreement ("Distribution Protocol"); (iii) Class Counsel's Fees and Disbursements; and (d) honoraria for the Representative Plaintiffs in this action was heard this day.

**ON READING** the materials filed, including the Settlement Agreement entered into between the parties and on hearing the submissions of Class Counsel and Counsel for the Defendants and any objector who has objected pursuant to the terms of the Settlement Agreement,

AND ON BEING ADVISED that the deadline for objecting to the Settlement Agreement has passed;

**AND ON BEING ADVISED** that the Defendants have paid the Settlement Amount into the Escrow Account within 30 days of the Notice of Settlement Approval Hearings Date pursuant to section 4 of the Settlement Agreement;

AND ON BEING ADVISED that while the Settlement Agreement is entered on the basis that the settlement does not constitute an admission of liability, and the Defendants expressly deny liability and the truth of the Plaintiffs allegations, the parties having considered the risks and uncertainties associated with further proceedings and have consented to the Order requested;

**AND ON BEING ADVISED** that the Defendants take no position on the appropriateness of the Distribution Protocol and have had no role in its development or the categories of monetary compensation which may be available to Class Members under the Settlement Agreement;

- 1. **THIS COURT ORDERS** that, except as otherwise stated, the capitalized terms in this Order have the definitions set out in the Settlement Agreement;
- 2. **THIS COURT DECLARES THAT** the Settlement Agreement is fair, reasonable and in the best interests of the Class Members;
- 3. **THIS COURT ORDERS THAT** the Settlement Agreement is hereby approved pursuant to section 29(2) of the *Class Proceedings Act*, S.O. 1992, c. 6 (the "*CPA*");
- 4. **THIS COURT ORDERS THAT** the full and final releases which are set out in the Settlement Agreement, including the releases by the Releasors and the Provincial Health Insurers

are approved and granted and shall forever and absolutely release the Releasees from the Released Claims and the claims of the Provincial Health Insurers as set out in the Settlement Agreement.

- 5. **THIS COURT ORDERS** that the Settlement Agreement shall be implemented in accordance with its terms;
- 6. **THIS COURT DECLARES** that Class Counsel Fees in the amount of \$X plus applicable taxes of \$X plus \$X in incurred disbursements, inclusive of applicable taxes ("Class Counsel Fees and Disbursements"), are fair and reasonable;
- 7. **THIS COURT ORDERS** that Class Counsel Fees and Disbursements are hereby approved pursuant to sections 32 and 33 of the *CPA*;
- 8. **THIS COURT ORDERS** that an Honoraria of \$10,000 shall be paid out of the Settlement Amount to each of the Representative Plaintiffs for the Abilify Class and the Abilify Maintena Class in this action;
- 9. **THIS COURT ORDERS THAT** that the Settlement Approval Notice (Press Release), substantially in the form attached at Schedule X to the Settlement Agreement, is hereby approved;
- 10. **THIS COURT ORDERS THAT** the Settlement Approval Notice, attached at Schedule X to the Settlement Agreement, shall be disseminated and published in accordance with the Notice Plan, attached at Schedule X to the Settlement Agreement.
- 11. **THIS COURT ORDRES THAT** the Claim Form, substantially in the form attached at Schedule X to the Settlement Agreement, is hereby approved;

- 12. **THIS COURT ORDERS** that all provisions of the Settlement Agreement (including the Recitals and Definitions) form part of this Order and are binding on the Defendants in accordance with the terms thereof, and upon the Plaintiffs and all Class Members that did not opt out of this Action in accordance with the Order of the Ontario Superior Court of Justice in this Action dated X, including persons that are minors or mentally incapable;
- 13. **THIS COURT ORDERS** that in the event of a conflict between this Order and the Settlement Agreement, this Order shall prevail;
- 14. **THIS COURT ORDERS** that compliance with requirements of Rules 7.04(1) and 7.08(4) of the *Rules of Civil Procedure*, RRO 1990, Reg. 194 is hereby dispensed with;
- 15. **THIS COURT ORDERS** that the payment of \$368,750.00 (all inclusive) from the Settlement Fund for the benefit of the Public Health Insurers is hereby approved, and that this sum shall be deducted from the Settlement Fund at the start of the Claim Period, to be distributed amongst the provinces and territories proportionately based on population, in full satisfaction of the Public Health Insurers' claims;
- 16. **THIS COURT DECLARES** that the Distribution Protocol, in substantially the form attached to the Settlement Agreement as Schedule X, is fair and appropriate;
- 17. **THIS COURT ORDERS** that the Distribution Protocol is approved and that the Settlement amount shall be distributed in accordance with the terms of the Settlement Agreement and the Distribution Protocol following payment of Class Counsel Fees, payment of \$368,750.00 (all inclusive) to the Public Health Insurers, and Claims Administration Expenses;

- 18. **THIS COURT ORDERS** that the Plaintiffs and Defendants may, on notice to the Court, but without the need for further order of the Court, agree to reasonable extensions of time to carry out any provisions of the Settlement Agreement;
- 19. **THIS COURT ORDERS** that in the event that the Settlement Agreement is terminated in accordance with its terms, the Order shall be null and void, *nunc pro tunc*;
- 20. **THIS COURT ORDERS** that upon the Effective Date, the Action shall be dismissed against all Defendants with prejudice and without costs;

21.	THIS COURT ORDERS that there be no costs on this motion.	

THE HONOURABLE JUSTICE MORGAN

et al.

**Plaintiffs** 

BRISTOL-MYERS SQUIBB, et al.

Defendants

Court File No.: CV-16-553833-00CP

# SUPERIOR COURT OF JUSTICE ONTARIO

# PROCEEDING COMMENCED IN TORONTO

# ORDER

# ROCHON GENOVA LLP

Barristers • Avocats

121 Richmond Street West, Suite 900 Toronto, ON M5H 2K1

Golnaz Nayerahmadi (LSO #: 68204C) Joel P. Rochon (LSO #: 28222Q)

Sarah J. Fiddes (LSO #: 84897H)

Tel: 416.363.1867

Fax: 416.363.0263

Lawyers for the Plaintiffs

# SUPERIOR COURT

(Class Action)

CANADA
PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

N<sup>O</sup>: 500-06-000831-160

DATE: , 2024

BY: THE HONOURABLE PIERRE NOLLET, J.S.C.

Plaintiff

٧.

BRISTOL-MYERS SQUIBB CANADA CO.

and

OTSUKA CANADA PHARMACEUTICALS INC.

Defendants

# JUDGMENT (SETTLEMENT APPROVAL)

- [1] **CONSIDERING** Plaintiff's Application for Approval of: (a) the Settlement Agreement; (b) the Distribution Protocol; and (c) Class Counsel's Fees and Disbursements (the "Application");
- [2] **CONSIDERING** the materials filed, including the Settlement Agreement entered into by the Parties as at August , 2024;
- [3] **CONSIDERING** the submissions of counsel for the Plaintiff and counsel for the Defendants;

500-06-000831-160 PAGE: 2

[4] **CONSIDERING** that by Judgment rendered on , 2024, this Court approved the Notice of Settlement Approval Hearings, both in English and in French, and the said notices were disseminated and published as ordered by this Court;

- [5] **CONSIDERING** that the time for opting out has passed and there were optouts;
- [6] **CONSIDERING** that the deadline for objecting to the Settlement Agreement has passed and there were objections to the Settlement Agreement;
- [7] **CONSIDERING** that the Defendants have paid the Settlement Amount into the Escrow Account;
- [8] **CONSIDERING** that the Application has been notified to the *Fonds d'aide aux actions collectives*;
- [9] **CONSIDERING** that the Defendants take no position on the appropriateness of the Distribution Protocol and have had no role in its development or the categories of monetary compensation which may be available to Class Members under the Settlement Agreement;
- [10] **CONSIDERING** that while the Settlement Agreement is entered on the basis that the settlement does not constitute an admission of liability, and the Defendants expressly deny liability and the truth of the Plaintiff's allegations, the parties having considered the risks and uncertainties associated with further proceedings and have consented to the Judgment requested;
- [11] **CONSIDERING** article 590 of the *Code of Civil Procedure*;

POUR CES MOTIFS, LE TRIBUNAL :	FOR THESE REASONS, THE COURT:
[12] <b>ACCUEILLE</b> la présente Demande ;	GRANTS the present Application;
[13] <b>DÉCLARE</b> que, sauf indication contraire, les termes commençant par une majuscule dans le présent Jugement ont la définition qui leur est donnée dans l'Entente de règlement;	Judgment, the definitions set out in the Settlement Agreement apply to and are
[14] <b>DÉCLARE</b> que l'Entente de règlement est juste, raisonnable et dans le meilleur intérêt des Membres du groupe ;	<b>DECLARES</b> that the Settlement Agreement is fair, reasonable and in the best interests of Class Members;

500-06-000831-160 PAGE: 3

[15] APPROUVE l'Entente de Règlement APPROVES the Settlement Agreement en vertu de l'article 590 C.p.c.; pursuant to article 590 C.C.P.: [16] **DÉCLARE** que l'Entente de règlement **DECLARES** that the Settlement Agreement constitue une transaction au sens de constitutes a transaction within the meaning l'article 2631 du Code civil du Québec : of article 2631 of the Civil Code of Quebec: [17] **ORDONNE** que l'Entente de règlement **ORDERS** that the Settlement Agreement soit mise en œuvre conformément à ses shall be implemented in accordance with its termes; terms; [18] **DÉCLARE** que les Honoraires des **DECLARES** that Class Counsel Fees in the avocats du groupe d'un montant de X \$ plus amount of \$X plus applicable taxes of \$X les taxes applicables de X \$ plus X \$ de plus \$X in incurred disbursements, inclusive débours encourus, y compris les taxes of applicable taxes ("Class Counsel Fees applicables (« Honoraires et débours des and Disbursements"), as and avocats du groupe »), sont justes et reasonable; raisonnables; [19] APPROUVE les Honoraires et débours | APPROVES | Class | Counsel | Fees | and des avocats du groupe en vertu de l'article Disbursements pursuant to article 593 C.C.P.; 593 C.p.c.; [20] **APPROUVE** la forme et le contenu de **APPROVES** the form and content of the l'Avis d'approbation du règlement | Settlement Approval (Press Notice (Communiqué de presse), essentiellement Release), substantially in the form attached dans la forme iointe à l'Annexe « X » de las Schedule "X" to the Settlement l'Entente de règlement : Agreement: [21] **ORDONNE** que l'Avis d'approbation du **ORDERS** that the Settlement Approval rèalement soit publié Notice shall be published and disseminated et diffusé conformément au Plan de diffusion des in accordance with the Notice Plan, avis, joint à Annexe X de l'Entente de attached at Schedule X to the Settlement règlement; Agreement; [22] **ORDONNE** que toutes les dispositions **ORDERS** that all provisions of the de l'Entente de règlement (y compris les Settlement Agreement (including the Attendus et les Définitions) fassent partie de Recitals and Definitions) form part of this ce Jugement et soient contraignantes pour Judgment and are binding les Défendeurs conformément aux termes Defendants in accordance with the terms de celui-ci, et pour le Demandeur et tous les thereof, and upon the Plaintiff and all Class Membres du groupe qui ne se sont pas Members that did not opt out of this Action exclus de cette Action conformément au in accordance with the Judgment of this 500-06-000831-160 PAGE: 4

compris les personnes mentalement inaptes;

Jugement de ce Tribunal daté du X, y Court dated X , including persons that are mineures ou minors or mentally incapable;

[23] **ORDONNE** gu'en cas de conflit entre le **ORDERS** that in the event of a conflict présent Jugement et l'Entente règlement, le présent Jugement prévaudra ;

de between this Judgment and the Settlement Agreement, this Judgment shall prevail;

[24] **ORDONNE** que le paiement de 368 750,00 \$ (tout compris) du Fonds de (all inclusive) from the Settlement Fund for règlement au profit des Assureurs de soins the benefit of the Public Health Insurers is de santé publics soit par la présente hereby approved, and that this sum shall be approuvé, et que cette somme soit déduite deducted from the Settlement Fund at the du Fonds de règlement au début de la start of the Claim Period, to be distributed Période de réclamation, pour être distribuée amongst the provinces and territories provinces entre les et proportionnellement à la population, en satisfaction of the Public Health Insurers' pleine satisfaction des Réclamations des claims; assureurs de soins de santé publics ;

**ORDERS** that the payment of \$368,750.00 territoires proportionately based on population, in full

[25] ORDONNE que les complètes et finales prévues à l'Entente de which are set out in the Settlement règlement, y compris les guittances des Agreement, including the releases by the Renonciateurs et des Assureurs de soins de Releasors and the Public Health Insurers santé publics. sont accordées approuvées et qu'elles libèrent à tout jamais and absolutely release the Releasees from Renonciataires des faisant l'objet d'une quittance et des Public Health Insurers as set out in the Réclamations des assureurs de soins de Settlement Agreement; santé publics, tel que prévu à l'Entente de règlement ;

quittances **ORDERS** that the full and final releases et are approved and granted and shall forever Réclamations the Released Claims and the claims of the

[26] **DÉCLARE** que le Protocole règlement, est équitable et approprié;

de **DECLARES** that the Distribution Protocol. distribution, essentiellement dans la forme in substantially the form attached as jointe à l'Annexe X de l'Entente de Schedule X to the Settlement Agreement, is fair and appropriate;

[27] APPROUVE le Protocole distribution et **ORDONNE** que le Montant du **ORDERS** that the Settlement Amount shall règlement soit distribué conformément aux be distributed in accordance with the terms termes de l'Entente de règlement et du of the Settlement Agreement and the des Honoraires et débours des avocats du Class Counsel Fees and Disbursements.

de APPROVES the Distribution Protocol and Protocole de distribution après le paiement Distribution Protocol following payment of groupe, le paiement de 368 750,00 \$ (tout payment of \$368,750.00 (all inclusive) to the 500-06-000831-160 PAGE: 5

inclus) aux Assureurs de soins de santé Public Health Claims Insurers, and publics, et les Frais d'administration des Administration Expenses; réclamations : [28] **ORDONNE** gue le Demandeur et les **ORDERS** that the Plaintiffs and Defendants Défendeurs puissent, sur notification au may, on notice to the Court, but without the Tribunal, mais sans avoir besoin d'une autre need for further order of the Court, agree to ordonnance du Tribunal, convenir de reasonable extensions of time to carry out prolongations raisonnables de délai pour provisions of the Settlement anv mettre en œuvre toute disposition de Agreement; l'Entente de règlement ; [29] **DÉCLARE** que le pourcentage prélevé **DECLARES** that the percentage withheld par le Fonds d'aide aux actions collectives by the Fonds d'aide aux actions collectives sera calculé conformément à l'article 1(1) shall be calculated in accordance with du Règlement sur le pourcentage prélevé section 1 (1) of the Regulation respecting par le Fonds d'aide aux actions collectives the percentage withheld by the Fonds d'aide uniquement sur la partie québécoise de tout aux actions collectives only on the Quebec reliquat du Fonds de règlement, cette partie portion of any remaining funds in the québécoise correspondant à 23,2 % de ce Settlement Fund, such Quebec portion reliquat, et **ORDONNE** que ce montant sera corresponding to 23.2%<sup>2</sup> of said remaining remis conformément à l'article 42 de la Loi funds, and ORDERS that this amount shall sur le Fonds d'aide aux actions collectives : be remitted in accordance with article 42 of the Act respecting the Fonds d'aide aux actions collectives: ORDERS that in the event that the [30] **ORDONNE** qu'en cas de résiliation de l'Entente de règlement conformément à ses Settlement Agreement is terminated in termes, le présent Jugement sera nul et non accordance with its terms, this Judgment avenu, nunc pro tunc; shall be null and void, nunc pro tunc; [31] **ORDONNE** qu'à la Date de prise **ORDERS** that upon the Effective Date, the d'effet, l'Action soit réglée à l'encontre de Action shall be settled against tous les Défendeurs conformément à Defendants according to the Settlement l'Entente de règlement et sans frais ; Agreement and without costs; [32] **ORDONNE** que le présent Jugement **ORDERS** that this Judgment is contingent est subordonné à une ordonnance parallèle upon a parallel order being made by the rendue par la Cour supérieure de justice de Ontario Superior Court of Justice and the l'Ontario et que les termes de ce Jugement | terms of this Judgment shall not be effective

<sup>&</sup>lt;sup>1</sup> Selon le Recensement du Canada 2016, la population québécoise représente 23,2 % de l'ensemble de la population canadienne.

<sup>&</sup>lt;sup>2</sup> According to Census Canada 2016, the Quebec population makes up 23.2% of the Canadian population as a whole.

500-06-000831-160 PAGE: 6

ne seront pas en vigueur tant qu'une telle ordonnance n'aura pas été rendue par la Cour supérieure de justice de l'Ontario ;	
après le jour où les fonds de règlement seront entièrement distribués, l'Administrateur des réclamations déposera auprès de la Cour un rapport contenant les	shall file with the Court a report setting out the information required under art. 59 of the Regulation of the Superior Court of Québec
[34] <b>LE TOUT</b> sans frais de justice.	THE WHOLE without legal costs.
	PIERRE NOLLET, J.S.C.

Me Jeff Orenstein Me Lawrence David CONSUMER LAW GROUP INC. Attorneys for the Plaintiff

Me Robert Torralbo Me Ariane Bisaillon BLAKES LLP Attorneys for Defendant Bristol-Myers Squibb Canada Co.

Me Marianne Ignacz INF LLP Attorneys for Defendant Otsuka Canada Pharmaceutical Inc.



# NATIONAL ABILIFY & ABILIFY MAINTENA NATIONAL CLASS ACTIONS NOTICE PLAN NOTICE OF SETTLEMENT APPROVAL HEARINGS IN ONTARIO AND QUEBEC AND CERTIFICATION OF THE ONTARIO ACTION

# **OBJECTIVES**

To effect adequate notice to the Class Members of the Settlement Approval Hearings before the Ontario Superior Court of Justice and the Superior Court of Québec (the "Courts") and certification of the class action in Ontario.

### Reasonable notification entails:

- achieving broad reach of the target group;
- in all regions of the country; and
- in English and French

All communications will comply with the provisions of the Class Proceedings legislation in all the jurisdictions involved in the action, as follows:

- Class Proceedings Act, SA 2003, c C-16 (Alberta);
- Class Proceedings Act, RCBC 1996 c 50 (British Columbia);
- *The Class Proceedings Act*, SM 2002, c 14 (Manitoba);
- Class Actions Act. 2001 c C-18.1, s. 1 (Newfoundland); and
- New Brunswick Class Proceedings Act, RSNB 2011, c 125 (New Brunswick);
- Class Proceedings Act, 2007, c. 28, s. 1 (Nova Scotia);
- Class Proceedings Act, 1992, SO 1992, c 6 (Ontario);
- Class Proceedings Act, R.S.P.E.I. 1988, c C-9.01 (Prince Edward Island);
- Code of Civil Procedure, CQLR c C-25.01 (Quebec)An Act Representing the Class Action, RSQ, c R-2.1 (Quebec); and
- *The Class Actions Act*, SS 2001, c C-12.01 (Saskatchewan).



# **OBJECTIVES**

The objectives of this Notice Plan are to advise Class Members of:

- the proposed Canadian settlement agreement that has been reached for both the certified Ontario action and the authorized Quebec Action;
- the certification of the national Abilify and Abilify Maintena class action by the Ontario Superior Court of Justice on March 13, 2020;
- the settlement approval hearings in Ontario and Quebec;
- the eligibility criteria for receiving compensation, and the benefits available, under the Settlement;
- the Class Members' right to object to the Settlement;
- the right of Abilify Maintena Class Members in the national Ontario Abilify and Abilify Maintena class action to opt out of the Settlement;
- the requirement for Abilify Class Members to make a request to the Superior Court of Quebec if they wish to opt out of the Settlement; and
- Class Counsel's request to the Courts to appoint MNP as Claims Administrator;

Following the settlement approval hearing, there will be further notice, specifically digital notice and press releases in English and French, to inform the class of any settlement approval.

# **COMMUNICATIONS STRATEGY**

A combination of direct mail, indirect notification via print and digital media, and paid advertising in digital media, together with neutrally worded press releases in English and French will be used in an effort to reach as large a percentage of Class Members as feasible.

Planned communications include:

- Press release to be issued via Canada Newswire in both English and French, in the form set out in Schedules "B" and "C";
- Publication of the Long Form Notice in both English and French to known Class Members and posted on Class Counsel's website, in the form set out in Schedule "D" and "E";



- Publication of the Short Form Notice in print form in national and regional newspapers in English or French listed in Schedule "A", in the form set out in Schedules "F" and "G";
- Direct mailing by Class Counsel to all Class Members on Class Counsel's distribution list, enclosing a copy of the Short and Long Form Certification Notice in English or French, depending on the language in which the Class Member has communicated with Class Counsel. Direct mailing will be effected by e-mail, where e-mail addresses are known, and by regular mail otherwise, with follow-up (best efforts) for any undeliverable e-mails and/or returned mail;
- Publication of an abbreviated version of the Short Form Notice for use in digital media listed in Schedule "A", including on the PostMedia Digital Network;
- Paid Google search engine advertising as well advertising on Instagram, Facebook and X (formerly Twitter). These advertisements will contain links to the Settlement Website, which will be maintained by the Claims Administrator;
- Publication of the Short and Long Form Notice, in both English and French, by Class Counsel on Class Counsel's website; specifically, the dedicated webpage relating to the National Abilify and Abilify Maintena Class Action;
- Publication of the Short and Long Form Notice, in both English and French, on the Settlement Website administered by the Claims Administrator; and
- Notice posted on Class Counsel's social media (Twitter) accounts.

# TARGET AUDIENCE

For the purposes of paid media selection, the target audience is defined as:

- adults 18 years of age or older;
- split evenly between males and females;
- in all geographic regions of Canada; and
- Communicating in both English and French,

# FORM OF PROPOSED NOTICES

Unless the Courts order otherwise, the Notice is to be delivered to known Class Members and will also be posted on Class Counsel's website.

With respect to the Notices to be published in print media, it may be necessary to make slight typesetting revisions in order to accommodate the different sizes of each publication; however, the wording will not change, and the overall page layout will remain as consistent as possible in each.



# 1) DIRECT NOTICE – MAILING TO REGISTERED CLASS MEMBERS

Class Counsel will deliver the Long Form Notice (along with an abbreviated description of the proceeding and instructions for opting out) by email to all Class Members for whom an e-mail address is available, in the language used in their correspondence with Class Counsel.

Class Counsel will deliver letters (which will contain an abbreviated description of the proceeding and instructions for opting out and will enclose the Long Form Notice and Opt Out Form) only to those Class Members in Class Counsel's database for whom an e-mail address is not available or an email correspondence is returned as undeliverable.

To date, 478 individuals have contacted Class Counsel in Ontario regarding this class action. Of the 478, Class Counsel has email addresses for the majority of these individuals.

# 2) INDIRECT NOTICE – NEWSPAPER NOTICES

To broaden the program's reach and provide unknown Class Members with an opportunity to learn about and participate in the National Abilify and Abilify Maintena Class Action, the Short Form Notice will be published in the national and regional newspapers set out in Schedule A. This list of newspapers addresses the need for widespread national and regional reach.

The newspapers listed in Schedule A have been selected based on the breadth of coverage, economical reach, and flexibility of timing they provide. (It is estimated that average daily newspaper reach in Canada ranges between 61% and 78%, depending on region, with an average of 69% nationally (Source: Statista, in cooperation with Vividata. September 2020).

A 1/4-page, black & white notice, containing a detailed description of the class action and the procedures and dates for opting out and objecting will be run in each of the newspapers in Schedule A.

Estimated cost (ex. HST):

\$73,796.68.

# 3) INDIRECT NOTICE – DIGITAL AND SOCIAL MEDIA ADVERTISING

# **Notice of Settlement Approval Hearings and Certification**

Paid ads on the PostMedia Digital News Network will be used to supplement notices published in printed newspapers. All digital ads will contain abbreviated messages with links to the Settlement Website. Target: 500,000 impressions.



Paid ads on Google, Instagram, Facebook, an X (formerly Twitter) will also be used and will run for four weeks. All digital ads will contain abbreviated messages with links to the Settlement Website. Target: 3,500,000 impressions

Estimated cost (ex. HST):

\$54,710.00

# **Notice of any Settlement Approval**

Following the settlement approval hearings, paid ads will run on Google, Instagram, Facebook, and X (formerly Twitter) to inform the class of any settlement approval. All digital ads will contain abbreviated messages with links to the Claims Website. Campaign duration will be 4 weeks, with a target of delivering: 750,000 impressions.

Estimated cost (ex. HST):

\$12,325.00

# 4) INDIRECT NOTICE – CLASS COUNSEL'S WEBSITES AND DEDICATED SETTLEMENT WEBSITE

The Long Form Notice, Short Form Notice, and the Opt-Out Form will be posted, in both English and French, by the Claims Administrator on the Settlement Website.

Class Counsel maintains dedicated webpages on their firms' websites in relation to the National Abilify and Abilify Maintena Class Action. Class Counsel will publish the Short and Long Form Notice of Certification, in both French and English, on the following webpages:

www.clg.org/Class-Action/List-of-Class-Actions/Abilify-Compulsive-Gambling-Side-Effects-National-Class-Action www.rochongenova.com/Current-Class-Action-Cases/Abilify-National-Class-Action.shtml

# 5) INDIRECT NOTICE – PRESS RELEASES

# **Notice of Settlement Approval Hearings and Certification**

Press releases will be issued in English and French via Cision (formerly Canada Newswire.)

Estimated Cost (ex. HST):

\$5,200.00

# NOTICE OF SETTLEMENT APPROVAL



Press releases will be issued in English and French via Cision (formerly Canada Newswire.)

Estimated Cost (ex. HST):

\$5,200.00

# ESTIMATED REACH

While it is not possible to provide an accurate reach number for this Notice Plan, the combination of direct notice to known Class Members, supplemented by paid advertising in a broad range of mass market media in print and digital formats, plus search engine advertising, provides Class Members with multiple opportunities for obtaining information about the National Abilify and Abilify Maintena Class Action. This increases their chances of seeing a notice and maximizes the effectiveness of the funds allocated to the notification program.

Estimated total cost, exclusive of HST: \$151,231.68

HST: \$19,660.12

Estimated total cost, including HST: \$170,891.80

# **ADMINISTRATION**

Dewar Communications will be responsible for the administration of the Notice Plan. The Claims Administrator will be responsible for receiving Objections and Opt-Outs, if any, in accordance with the deadlines set by the Courts.

### Exhibit "F"

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® CLASS ACTION SETTLEMENT

# **OPT-OUT FORM**

This is NOT a Claim Form. If you were prescribed<sup>1</sup> and received injections of ABILIFY MAINTENA® between February 6, 2014 and December 16, 2016, completing this Form will EXCLUDE you and members of your family from participating in the Canadian Settlement.<sup>2</sup>

If you were prescribed and ingested ABILIFY® tablets before February 23, 2017, you must seek permission of the Québec Court to opt out late from the Settlement. Please see further below under "ABILIFY® Class Member".

If you used both ABILIFY® and ABILIFY MAINTENA® during the time periods indicated and wish to opt out of the Settlement, please consult with Class Counsel below, prior to completing this form.

DO NOT complete this Form if you wish to seek compensation under the Canadian ABILIFY® and ABILIFY MAINTENA® Settlement.

To be effective as an election to opt-out of the Proceedings, this Opt-Out Form must be completed, signed **and received** by the Claims Administrator **no later than [Opt-Out Deadline].** 

Please read the entire form and follow the instructions carefully. Only completed Opt-Out Forms postmarked or received by the Claims Administrator by [Opt-Out Deadline] will be considered valid.

SECTION 1 – IDENTIFICATION OF THE PERSON SIGNING THIS OPT OUT FORM (SELECT ONLY <u>ONE</u> OPTION):

ABILIFY MAINTENA® Class Member – I was prescribed and received injections of
ABILIFY MAINTENA® between February 6, 2014 and December 16, 2016. By completing
and signing this Opt Out Form, I am excluding myself from participating in the Canadian
Settlement. I understand that by opting out of the Settlement, I EXCLUDE myself and any
eligible Family Class Member from receiving benefits under the Settlement Agreement.

<sup>&</sup>lt;sup>1</sup> The terms "prescribe" and "prescription" include receipt of samples of ABILIFY® from healthcare professionals.

<sup>&</sup>lt;sup>2</sup> Unless otherwise indicated herein, capitalized terms have the meanings set out in the Settlement Agreement.

	<b>ABILIFY® Class Member</b> – I was prescribed and ingested ABILIFY® before February 23, 2017. By completing and signing this Opt Out Form, I am indicating my intention to request to opt-out late from the previously authorized Québec Class Action. I understand that completion of this form does not entitle me to opt out, and that I must make a request to the Québec Court to do so, which may or may not be granted by the Québec Court. I understand that if the Québec Court allows me to opt out of the Settlement, I will be EXCLUDING myself and any eligible Family Class Member from receiving benefits under the Settlement and if the Québec Court does not grant my request, I will be bound by the Settlement, including the release of my claim.
	<b>Legal representative</b> – I am the legal representative for the above identified Settlement Class Member. By completing and signing this Opt Out Form, I am excluding the Settlement Class Member from participation in the Canadian ABILIFY® and ABILIFY MAINTENA® Settlement Agreement. I understand that by opting the Settlement Class Member out of the Settlement Agreement, I exclude both them and any eligible Family Class Member from receiving benefits under the Settlement Agreement.
	TION 2 – REASON FOR OPT OUT (OPTIONAL INFORMATION) – If you wish to your reason for excluding yourself from the Settlement Agreement, please write it out below:
your	TION 3 – PERSONAL INFORMATION – Please provide the following information about self, or, if you are filing this Opt-Out Form as the legal representative of a Settlement Class aber, please provide the following information about the Settlement Class Member.
First	Name Last Name
Date	of Birth (DD/MM/YYYY)
Stree	t Address

City	
Province	
Postal Code	
Telephone (Daytime) _	
Telephone (Alternate)	
Email	
Health Card Number	
Date of Death (if applica	ble) Death Certificate Attached
	f a court order or other official document(s) demonstrating that you are the epresentative of the Class Member and check the box below describing the :
	minor (court order appointing guardian or property or custody order, if any, or sworn affidavit of the person with custody of the minor);
	a mentally incapable person (copy of a continuing power of attorney for property, or a Certificate of statutory guardianship);
	the estate of a deceased person (Letters Probate, Letters of Administration or Certificate of Appointment as Estate Trustee).
Class Member, has hire	YER INFORMATION (IF APPLICABLE) – If you, or the Settlement ed a lawyer in connection with a claim arising from the Class Member's use LIFY MAINTENA® please provide the following information about the
Lawyer's First and Las	t Name
Law Firm	
Lawyer's Phone Numb	per
Lawver's F-mail Addr	ess

# **SECTION 5 – SIGNATURE**

Date	
DD/MM/YYYY	
Name of Settlement Class Member	
Signature of Settlement Class Member	
Name of Legal Representative (if applicable)	_
Signature of Legal Representative (if applicable)	_
Name of Lawyer (if applicable)	
Signature of Lawyer (if applicable)	

# The deadline to submit an Opt Out Form is MONTH DAY 2024

To be effective as an election to Opt Out of the proceedings, this Form must be completed, signed, sent to the Claims Administrator at the address listed below, by regular mail, courier or fax and must be received by the Claims Administrator no later than [Opt Out Deadline] at:

MNP Ltd. – Class Actions Claims Administration 2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3
<a href="mailto:abilifysettlement@mnp.ca">abilifysettlement@mnp.ca</a>
Toll-Free: 1 (855) 653-0027

If you have questions about using or completing this Opt Out Form, please contact Class Counsel, your lawyer, or the Claims Administrator.

# **CLASS COUNSEL**

ROCHON GENOVA LLP	CONSUMER LAW GROUP INC.
900-121 Richmond St. W.	1030 rue Berri, Suite 102
Toronto, Ontario, M5H 2K1	Montreal (Québec) H2L 4C3
Joel P. Rochon	Jeff Orenstein
Golnaz Nayerahmadi	Tel: 1 (888) 909-7863
Sarah J. Fiddes	(514) 266-7863
Tel: (416) 363-1867	(613) 627-4894
contact@rochongenova.com	abilify@clg.org

# Exhibit "G"

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® CLASS ACTIONS NOTICE OF SETTLEMENT APPROVAL HEARINGS IN ONTARIO AND OUÉBEC &

# NOTICE OF CERTIFICATION OF THE ONTARIO CLASS ACTION

Please read this notice carefully. Ignoring this notice will affect your legal rights

TO: All persons in Canada, including their estates, who:

- were prescribed and ingested ABILIFY® before **February 23, 2017**;
- were prescribed and received injections of ABILIFY MAINTENA® between **February 6, 2014** and **December 16, 2016**; and
- by virtue of a personal relationship with an ABILIFY® Class Member or an ABILIFY MAINTENA® Class Member, are entitled to assert a claim pursuant to the Ontario Family Law Act as amended, the Civil Code of Québec or equivalent provincial and territorial legislation (such as spouses, children, grandchildren, parents, grandparents, brothers and sisters).

The Canadian class action lawsuits allege that the Defendants were negligent in failing to warn Class Members that ABILIFY® and ABILIFY MAINTENA® can cause, contribute to, or exacerbate Compulsive Behaviours and Impulse Control Disorders, specifically compulsive or pathological gambling, hypersexuality, binge-eating, and uncontrollable shopping.

The parties in the Ontario and Québec class action have reached a proposed settlement (the "Settlement"), subject to approval of the Ontario Superior Court of Justice and the Superior Court of Québec (the "Courts").

Neither the Ontario Court nor the Québec Court has made any determination of the merits of the claims. The Defendants have denied, and continue to deny, the allegations against them in the Class Actions and have had no role in the determination of Settlement Class Member eligibility to participate in the Settlement or the allocation of benefits available to Settlement Class Members (see Section "D" below).

The Settlement provides for the creation of a CDN \$14.75 million Settlement fund, which will be used to pay compensation for Approved Claims, \$368,750.00 in satisfaction of the claims of the Public Health Insurers, the costs of notice and administration, and Court-approved Class Counsel Legal Fees, disbursements and taxes.

This Notice explains your rights and options as a Settlement Class Member.

# A) THE ABILIFY® AND ABILIFY MAINTENA® CLASS ACTIONS

ABILIFY® (generic name aripiprazole) is a prescription medicine which is prescribed to treat certain mental health conditions, including schizophrenia, bipolar disorder and as an adjunctive treatment for major depressive disorder. During the time periods above, ABILIFY® was sold in Canada by Bristol-Myers Squibb Company Canada Co. ("BMS Canada") and Otsuka Canada Pharmaceuticals Inc ("Otsuka Canada"). ABILIFY MAINTENA® is an injectable form of aripiprazole and during the time period above was sold in Canada by Otsuka Canada and Lundbeck Canada Inc. ("Lundbeck Canada").

The Class Actions allege that ABILIFY® and ABILIFY MAINTENA® can cause, contribute or exacerbate a variety of compulsive behaviours and impulse control disorders, specifically compulsive or pathological gambling, hypersexuality, binge-eating, and uncontrollable shopping.

# B) AUTHORIZATION OF A NATIONAL CLASS ACTION BY THE SUPERIOR COURT OF QUÉBEC

On December 19, 2019, the Superior Court of Québec authorized a national class action on behalf of:

All persons residing in Canada who were prescribed and have ingested and/or used the drug ABILIFY® (aripiprazole) before February 23, 2017 and who developed one or more of the following impulse control behaviours:

- pathological gambling (also known as gambling disorder or compulsive gambling);
- compulsive eating/ binge eating;
- uncontrollable or compulsive shopping or spending; and/or
- hypersexual behaviours/ sexual addiction (the "Impulse Control Disorders").

And their successors, assigned, family members, and dependants.

Notice of Authorization of the Québec Class Action was previously published on January 6, 2020. The opt out deadline for class members who did not wish to participate in the Québec Class Action expired on November 19, 2020. If you previously opted out of the Québec Class Action and wish to participate in the Settlement, see **Part F** below.

Individuals who were prescribed and received injections of ABILIFY MAINTENA® are not part of the Québec Action, but are Settlement Class Members by virtue of being Class Members in the Ontario Class Action.

# C) CERTIFICATION OF A NATIONAL CLASS ACTION BY THE ONTARIO SUPERIOR COURT OF JUSTICE

On March 13, 2020, Justice Morgan of the Ontario Superior Court of Justice certified a national class action on behalf of:

All persons in Canada including their estates who:

- a) between July 9, 2009 and February 23, 2017 were prescribed and ingested ABILIFY® tablets;
- b) between February 6, 2014 and December 16, 2016 were prescribed and used ABILIFY MAINTENA®; and
- c) by virtue of a personal relationship with an ABILIFY Class Member or an ABILIFY MAINTENA® Class Member, are entitled to assert a claim pursuant to the Ontario *Family Law Act* as amended or equivalent provincial and territorial.

All appeals were completed on February 28, 2022.

# D) THE SETTLEMENT AGREEMENT & BENEFITS AVAILABLE TO SETTLEMENT CLASS MEMBERS

The parties to the Class Actions have reached a proposed national Settlement on behalf of Settlement Class Members. The Settlement offers monetary benefits to Settlement Class Members who experienced Compulsive Behaviours or Impulse Control Disorders and related consequences, including psychological harm, illness and hospitalization, financial loss, and loss of care, guidance, and companionship.

The Defendants will pay CDN \$14,750,000.00 (the "Settlement Amount") to settle the Class Actions on a national basis, without admitting liability. This amount is inclusive of all amounts claimed including without limitation damages, costs, interest, notice costs, administrative costs, and the claims of provincial health insurers. The Settlement Agreement, in English or French, can be obtained from the Settlement Website, through Rochon Genova LLP and Consumer Law Group Inc. or by contacting the Claims Administrator, as listed below.

MNP Ltd. – Class Actions Claims Administration 2000, 112 - 4th Avenue SW
Calgary, AB, T2P 0H3
abilifysettlement@mnp.ca
Toll-Free: 1 (855) 653-0027

Your entitlement to benefits under the Settlement will be determined by the Claims Administrator, or, in the case of a disagreement, by a referee, based on the court-approved Distribution Plan, which provides for monetary compensation based on the following categories of psychological

harm and financial harm, as well as compensation to Family Class Members. The Defendants have had no role in the development of the proposed Distribution Plan or the categories for which compensation may be available.

Claimants can qualify for compensation for both Psychological Harm and Financial Loss.

# A. Compensation for Psychological Harm

# **1.** Mild:

- a) documentary evidence of prescription<sup>1</sup> of ABILIFY or ABILIFY MAINTENA® during the class period for **at least 1-6 months**; **and**
- b) a signed attestation by or on behalf of the Class Member that they both ingested/received injections of ABILIFY®/ABILIFY MAINTENA® for 1-6 months and experienced one or more Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® and/or receiving injections of ABILIFY MAINTENA®.
- 2. Moderate: Claimants can qualify under the following scenarios:

# • Scenario #1:

- a) documentary evidence of prescription of ABILIFY®/ABILIFY MAINTENA® for **more than 6 months**; **and**
- b) a signed attestation by or on behalf of the Class Member that they both ingested/received injections of ABILIFY®/ABILIFY MAINTENA® and experienced one or more Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® and/or receiving injections of ABILIFY MAINTENA®.

# • Scenario #2:

a) documentary evidence of prescription of ABILIFY®/ABILIFY MAINTENA® for 1-6 months; and

b) medical records specifying the form of treatment or counselling sought or provided and the specific Compulsive Behaviours or Impulse Control Disorders for which treatment or counselling was sought or provided. If the treatment in question was not covered by provincial health insurance, attach receipts or confirmation of payment; and

 $<sup>^{\</sup>rm l}$  The terms "prescribed" and" "prescription" include receipts of samples of ABILIFY® from healthcare professionals.

- c) a signed attestation by or on behalf of the Class Member that they both ingested/received injections of ABILIFY®/ABILIFY MAINTENA® for 1-6 months and, while on or within 3 months of discontinuing their use of ABILIFY® and/or receiving injections of ABILIFY MAINTENA®, they experienced one or more Compulsive Behaviours or Impulse Control Disorders of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question.
- b) **Severe**: Claimants can qualify under the following scenarios, based on duration of usage:

# • Scenario #1:

- a) documentary evidence of prescription of ABILIFY®/ABILIFY MAINTENA® for a period of **more than 6 months**; <u>and</u>
- b) records demonstrating that the Class Member experienced Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA® (e.g. gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, medical records referencing the Compulsive Behaviors, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours or Impulse Control Disorders); and
- c) documentary evidence of bankruptcy, divorce, re-mortgaging of a property, and/or criminal prosecution for fraud, theft, etc. contemporaneous to or after experiencing Compulsive Behaviours and/or Impulse Control Disorders; and
- d) a signed attestation by or on behalf of the Class Member that they experienced one or more Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA® and that they experienced bankruptcy, divorce, re-mortgaging of a property, and/or criminal prosecution for fraud, theft, etc. contemporaneous to or after experiencing the Compulsive Behaviours and/or Impulse Control Disorders.

# AND/OR

# • Scenario #2:

- a) documentary evidence of both prescription of ABILIFY®/ABILIFY MAINTENA® for a period of **more than 6 months**; <u>and</u>
- b) identify and attach medical records specifying the form of treatment or counselling sought or provided and the specific Compulsive Behaviour or Impulse Control Disorders for which treatment or counselling was sought or provided. If the treatment in question was not covered by provincial health insurance, attach receipts or confirmation of payment; and
- c) records demonstrating that the Class Member experienced Compulsive Behaviours or Impulse Control Disorders (e.g. gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, medical records referencing the compulsive behaviors, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours or Impulse Control Disorders); and
- d) a signed attestation by or on behalf of the Class Member that, while on or within 3 months of discontinuing their use of ABILIFY® and/or receiving injections of ABILIFY MAINTENA®, they experienced one or more Compulsive Behaviours or Impulse Control Disorders of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question for more than 6 months.
- 4. Residual Catastrophic Injury (compensation available for catastrophic injury in addition to compensation available for Mild, Moderate and Severe Psychological Harm): documentary evidence demonstrating that the Class Member experienced catastrophic physical or psychological consequences of Compulsive Behaviours or Impulse Control Disorders alleged to have been caused by the use of ABILIFY® and/or ABILIFY MAINTENA®, including but not limited to: contracting HIV, Hepatitis, or a non-treatable STI (sexually transmitted infection) as a result of hypersexuality, suicidality and related hospitalization related to Compulsive Behaviours or Impulse Control Disorders and their consequences.

# **B.** Compensation for Financial Loss

In addition, CND \$1.5 million will be set aside from the Settlement to compensate financial harm for Claimants with provable loss of income or employment, gambling losses, or loans incurred as a result of gambling caused or exacerbated by ABILIFY® or ABILIFY MAINTENA®. Such losses will require, in addition to the documentation necessary to qualify for a claim for psychological harm, the following:

# • Compensable gambling losses:

- a) all available Gambling Records for all venues at which gambling took place. This documentation must show the gambling activities at each venue. Gambling venues include casinos, online gambling websites, and any other venue in which the at issue gambling occurred whether in person or virtually. Supportive documentation may include, but is not limited to, records of gambling counselling, ATM withdrawal at casinos, credit card or banking statements showing payments for gambling); and
- b) a signed attestation by or on behalf of the Class Member of the net amount of any gambling losses; **and**
- c) Class Members will be required to disclose if they took any other prescription medications with dopamine agonist properties while the at issue gambling occurred;

# • Compensable income loss:

- a) documentation to demonstrate that the Class Member experienced the Compulsive Behaviours (gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours); and
- b) a signed attestation that the Class Member experienced the Compulsive Behaviours or Impulse Control Disorders; and
- c) records of any income loss demonstrating that the Class Members' Compulsive Behaviours or Impulse Control Disorders resulted in their termination or loss of employment, including: the applicable employment agreement and income tax returns for the two years preceding the termination; <u>and</u>
- d) an attestation by or on behalf of the Class Member <u>and/or</u> an attestation from each of the Class Member's previous employers describing the reason for termination of the Class Members' employment;

# • Compensable loan loss:

- a) documentation to demonstrate that the Class Member experienced the Compulsive Behaviours (gambling records, such as ATM withdrawals at casinos, self-exclusion from a casino, credit card or banking statements showing payments for gambling, or medical records or counselling records documenting that treatment was sought for Compulsive Behaviours); and
- b) a signed attestation by or on behalf of the Class Member that they experienced the Compulsive Behaviours; **and**

c) all available financial records related to any loan for which compensation is sought. If the loan is from a financial institution, a current statement of account for the loan must be included. If the loan is from a private lender, friend, or family member, an attestation from the lender, under penalty of law, must be provided confirming: the balance of the loan outstanding, the loan principal, accrued interest to date, and an account of all payments toward the loan received to date.

# C. Compensation for Family Class Members (such as spouses, children, grandchildren, parents, grandparents, brothers and sisters)

Eligible Family Class Members are entitled to claim compensation. Eligible Family Class Members are spouses, children, parents, grandparents, brothers, and sisters of a Class Member by or for whom a claim is being advanced under the Settlement.

Eligible Family Members are entitled to file a claim only if the Class Member has not opted out of the class action and is submitting a claim to receive benefits under the Settlement.

Family Class Members must fill out and sign the relevant section of the Claims Package and the Claimant will file the claim on behalf of both themselves and Family Class Members, if Family Class Members wish to make claims. The following must be provided for Family Class Members to be entitled to settlement benefits:

- a) document(s) demonstrating proof of each Family Class Member's relationship to the Class Member and, where the Family Class Member is a minor, under a legal disability or deceased, document(s) demonstrating proof of the individual's authority to act on behalf of the Family Class Member; <a href="mailto:and-">and</a>
- b) the name, address, relationship to a Claimant, as well as the Family Class Member's signature.

Family Class Members who are eligible for settlement benefits will receive a fixed sum that is a percentage of the Claimant's payment for psychological harm. Spouses will receive 10%, parents and children will receive 5% each, and grandparents, brothers and sisters will receive 2.5% each. These awards are in addition to, not deducted from, the benefits conferred to the Claimant. Total compensation to Family Class Members will be capped at \$X,XXX,XXX. If the fund for Family Class claimants is oversubscribed or undersubscribed, it will be adjusted downwards or upwards on a *pro rata* basis.

# E) SETTLEMENT APPROVAL HEARINGS

For the Settlement to become effective, it must be approved by the Superior Courts of both Ontario and Québec.

A hearing to approve the Settlement will be held before the Ontario Superior Court on [insert dates and locations] and the Superior Court of Québec on [insert dates and locations] (the "Settlement Approval Hearings").

At these hearings, the Courts will determine if the Settlement is fair, reasonable and in the best interests of the Class Members.

Settlement Class Members have the right to opt out of the settlement and/or object to the Settlement, as detailed below.

If the Settlement is approved by the Courts, a further notice will be posted on the <u>Settlement Website</u> and the websites of Class Counsel at <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc.</u>

# F) IF YOU WANT TO PARTICIPATE IN THE SETTLEMENT

Settlement Class Members who wish to participate in the proposed Settlement do not need to appear at the Settlement Approval Hearings or take any other action at this time, but are encouraged to immediately begin the process of completing Claim Forms. You do not need to appear at the Settlement Approval Hearings.

Claim Forms are provisionally available now at <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc</u>. Further information regarding the process for filing claims will be made available on the <u>Settlement Website</u>, the websites of <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc</u>. or from the Claims Administrator.

# G) HOW TO OPT OUT OF THE SETTLEMENT

If you were prescribed and received injections of ABILIFY MAINTENA® and you do not wish to participate in the Settlement, you may opt out and exclude yourself from the Settlement by delivering a completed Opt Out Form to the Claims Administrator at least 14 days in advance of the Settlement Approval Hearings (the "[insert Opt-Out Deadline]").

The Opt Out Form is available on the <u>Settlement Website</u> and Class Counsel's website at <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc</u> and must be postmarked or delivered by mail, courier or facsimile to the Claims Administrator by the Opt-Out Deadline.

If you were prescribed and ingested ABILIFY® and did not previously opt out of the Québec Action, you must make a request to the Québec Court if you now wish to opt out of the Settlement. If you do not opt out and the Settlement is approved and becomes effective, you will be bound by the Settlement which includes a release of your claims.

The Claims Administrator will provide any Opt Out Forms postmarked or received by the Opt-Out Deadline to Class Counsel, who will then notify the Defendants, the Ontario Superior Court of Justice, and the Superior Court of Québec of the Opt-Outs, including any request by an ABILIFY® Class Member to opt-out late.

Settlement Class Members who have not properly opted out or have not opted out by the Opt-Out Deadline will be bound by the Proposed Settlement if it is approved by the Courts. The Settlement includes a release of any rights you may have to take further legal action against the Defendants if the settlement is approved by both the Ontario and Québec Superior Courts.

Settlement Class Members who have previously opted out of the Québec Class Action do not need to take any further action to opt out of the Settlement. If you have previously opted out of the Québec Class Action and now wish to participate in the Settlement, you must notify Class Counsel of your intention to participate in the Settlement by contacting Class Counsel at <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc.</u> before [the Opt Out Deadline].

# H) HOW TO OBJECT TO THE PROPOSED SETTLEMENT

If you are a Settlement Class Member and wish to object to the Settlement, you may deliver a written objection to the Claims Administrator. A valid objection must be postmarked or received by the Claims Administrator at the address below, at least 14 days in advance of the Settlement Approval Hearings.

A Settlement Class Member who wishes to object to the Settlement, or their counsel (if they are represented), shall provide in their objection:

- a) A caption or title that identifies it as an objection to the Settlement;
- b) The full name, current mailing address, telephone number, and email address of the person who is objecting or on whose behalf an objection is being delivered;
- c) A clear statement of the nature and reasons for the objection;
- d) A declaration that the person believes they are a Settlement Class Member and supporting documentation sufficient to establish the basis for that belief;
- e) Whether the person intends to appear at the Approval Hearings or intends to appear by counsel and if by counsel, the name, address, telephone number, and email address of counsel; and
- f) A declaration that the foregoing information is true and correct.

The Claims Administrator will provide a copy of your objection to Class Counsel, who will in turn provide it to the Ontario and Québec Superior Courts and the Defendants. You may, but are not required to, appear at the Settlement Approval Hearing(s) in order to make submissions orally with respect to your objection. If you wish to do so, whether in person or through a lawyer, you must send a notice of intention to appear in writing served, filed and received by the Claims Administrator at least 10 days prior to the Settlement Approval Hearing.

The judge presiding over the Settlement Approval Hearing has discretion to determine whether you will be permitted to make oral submissions during the hearing.

# DO NOT send an objection directly to the Ontario or Québec Superior Courts.

An objection to the Settlement is not an Opt Out Form. If you object to the Settlement, you will remain bound by its terms if it is approved by the Ontario and Québec Superior Courts. If you wish to be excluded from the Settlement, you must opt out (see **Part G** above).

# I) WHO IS CLASS COUNSEL?

The Ontario Superior Court of Justice and the Superior Court of Québec have appointed *Rochon Genova LLP* and the *Consumer Law Group Inc.*, respectively, as Class Counsel. If you have any questions or wish to learn more about the Settlement, you may contact them at the phone number or e-mail address below.

ROCHON GENOVA LLP	CONSUMER LAW GROUP INC.
900-121 Richmond St. W. Toronto, Ontario, M5H 2K1	1030 rue Berri, Suite 102 Montreal (Québec) H2L 4C3
Joel P. Rochon Golnaz Nayerahmadi	Jeff Orenstein
Sarah J. Fiddes	Tel: 1 (888) 909-7863
	(514) 266-7863
Tel: (416) 363-1867	(613) 627-4894
1-800-462-3864	abilify@clg.org
contact@rochongenova.com	

# J) WHO IS THE CLAIMS ADMINISTRATOR?

The parties have agreed that MNP Ltd. will serve as the Claims Administrator. The Claims Administrator may be contacted at the phone number or email address below:

MNP Ltd. – Class Actions Claims Administration 2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3 abilifysettlement@mnp.ca

Toll-Free: 1 (855) 653-0027

# K) LEGAL FEES APPLICABLE TO ALL CLASS MEMBERS

At the Settlement Approval Hearings, Class Counsel will seek court approval of legal fees of \$4.425 million, plus disbursements and applicable taxes. The legal fees, disbursements, and taxes, if approved by the Ontario and Québec Courts, will be deducted from the Settlement Amount.

Class Counsel will also seek a specific amount (honorarium) for the Representative Plaintiffs in the Class Actions, up to a maximum of \$10,000, per individual, in relation to their exercise of their

duties as Representative Plaintiffs. This amount, if approved by the Court, will be deducted from the Settlement Amount.

# L) INTERPRETATION

If there is a conflict between the provisions of this Notice and the Settlement Agreement, the terms of the Settlement Agreement shall prevail. If there is a conflict between the English and the French versions of this document, the English version shall prevail. If the Settlement of the Class Actions is approved by the Ontario and Québec Superior Courts, a further notice will be published on the Settlement Website and the websites of Rochon Genova LLP and Consumer Law Group Inc. about how to participate in the Settlement. Questions regarding your right to participate in the Settlement may also be directed to the lawyers at the contact information above.

This Notice has been authorized by the Ontario Superior Court of Justice and the Superior Court of Québec. Any questions about the matters in this Notice should <u>not</u> be directed to the Courts.

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® CLASS ACTIONS NOTICE OF SETTLEMENT APPROVAL HEARINGS IN ONTARIO AND QUÉBEC & NOTICE OF CERTIFICATION OF THE ONTARIO CLASS ACTION

# PLEASE READ CAREFULLY. IGNORING THIS NOTICE WILL AFFECT YOUR LEGAL RIGHTS

### WHO IS THIS NOTICE FOR?

This Notice is directed to: All persons in Canada including their estates who:

- were prescribed and ingested ABILIFY® before February 23, 2017 ("ABILIFY® Class Members");
- were prescribed and received injections of ABILIFY MAINTENA® between February 6, 2014 and December 16, 2016 ("ABILIFY MAINTENA® Class Members"); and
- by virtue of a personal relationship with persons described above are entitled to assert a claim pursuant to the Ontario *Family Law Act* as amended, the *Civil Code of Québec* or equivalent provincial and territorial legislation ("Family Class Members").

The Canada-wide class actions (the "Class Actions") allege that the Defendants were negligent in failing to warn Class Members that ABILIFY® and ABILIFY MAINTENA® can cause, contribute to, or exacerbate Compulsive Behaviours and Impulse Control Disorders, specifically, compulsive or pathological gambling, hypersexuality, bingeeating, and compulsive shopping.

The parties have reached a proposed settlement (the "Settlement"), subject to approval of the Ontario Superior Court of Justice and the Superior Court of Québec (the "Courts").

On March 13, 2020, the Ontario Superior Court of Justice certified a national class action against Bristol-Myers Squibb, Otsuka, and Lundbeck on behalf of the Classes of person described above. All appeals were completed on February 28, 2022.

Previously, a national class action, which includes individuals in Canada who were prescribed and have ingested and/or used ABILIFY® before February 23, 2017, was authorized by the Superior Court of Québec on December 12, 2019. Notice of authorization of the Québec class action was previously provided on January 6, 2020. The opt-out deadline for ABILIFY® Class Members who did not wish to participate in the Québec Class Action expired on May 31, 2020.

# WHAT IS THE PROPOSED SETTLEMENT?

The Settlement provides for the creation of a CDN \$14.75 million Settlement fund which will be used to pay compensation for Approved Claims, \$295,000.00 in satisfaction of the claims of the Public Health Insurers, the costs of notice and administration, and Court-approved Class Counsel Legal Fees, disbursements and taxes.

Not all Class Members will be eligible for compensation. The proposed Distribution Protocol and Claim Forms, which are subject to Court-approval, are available on the Settlement Website and the websites of Class Counsel and may be requested from the Claims Administrator. The Defendants have denied, and continue to deny, the allegations against them in the Class Actions and have had no role in the determination of Settlement Class Members' eligibility to participate in the Settlement or the allocation

of benefits available to ABILIFY® and ABILIFY MAINTENA® Class Members.

# FOR MORE INFORMATION:

If you have questions about the Settlement and/or would like to obtain more information and/or copies of the Settlement Agreement and related documents, please visit the websites of Class Counsel, <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc</u>. or contact the Claims Administrator at the addresses described below:

MNP Ltd. – Class Actions Claims Administration 2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3 <u>abilifysettlement@mnp.ca</u> Toll-Free: 1 (855) 653-0027

# THE SETTLEMENT REQUIRES COURT APPROVAL

For the Settlement to become effective, Court approval is necessary. The Courts must be satisfied that the Settlement is fair, reasonable and in the best interests of Class Members. The Approval Hearings have been scheduled to be heard before the Ontario Superior Court of Justice and the Superior Court of Québec on DATE and DATE, respectively.

# RIGHT TO OPT OUT OR TO OBJECT

If you previously opted out of the Québec class action but now wish to participate in the Settlement, you may do so by contacting Class Counsel.

If you are an ABILIFY MAINTENA® Class Member, you have the right to exclude yourself from the Ontario class action and from the Settlement by delivering an **Opt Out** form before [opt-out deadline] to the Claims Administrator.

If you are an ABILIFY® Class Member, and did not previously opt out of the Québec class action, you may make a request to the Québec Court to opt out of the Settlement. If you do not opt out and the Settlement is approved and becomes effective, you will be bound by the Settlement which includes a release of your claims.

Opt Out forms are available online a twww.abilifyclassactionsettlement.com, Rochon Genova LLP and Consumer Law Group Inc.

If you wish to **object** to the proposed Settlement, you must submit a written objection to the Claims Administrator by **no later than DATE**, 2024 at the address listed in this Notice. The Claims Administrator will file copies of all objections with the Court. **Do NOT send an objection directly to the Court.** 

You may also attend the Approval Hearings on the date noted above, and if you have submitted a written objection to the Claims Administrator, you may make oral submissions to the Court.

# PARTICIPATING IN THE SETTLEMENT

If the Settlement is approved by the Courts, Claimants will have a limited Toronto, Ontario M5H 2K1 Montreal, Québec H2L 4C3 amount of time within which to submit a claim for compensation. However, downloadable versions of the Claim Form are now available online at Rochon Genova LLP and Consumer Law Group Inc. and can be processed and finalized by the Claims Administrator if the proposed Settlement is approved. Claim Forms can also be requested from the Claims Administrator. If you intend to submit a claim under the proposed LEGAL FEES Settlement, you must do so on or before the expiry of the Claim Period, which will be posted the Settlement on www.abilifyclassactionsettlement.com.

# WHO REPRESENTS ME? CLASS COUNSEL ARE:

Rochon Genova LLP Consumer Law Group Inc. Barristers • Avocats Attorneys • Avocats 900-121 Richmond St. W. 1030 rue Berri, Suite 102

Joel P. Rochon Jeff Orenstein Tel: (416) 363-1867 Tel: 1 (888) 909-7863 contact@rochongenova.com abilify@clg.org

Website: At the Approval Hearings, Class Counsel will request approval for payment of their fees, disbursements and applicable taxes. Class Counsel has pursued this lawsuit on a contingency basis and will seek approval from the Courts for such payment in accordance with the terms of their retainer agreements.

This Notice has been approved by the Ontario Superior Court of Justice and the Superior Court of Québec

## Exhibit "I"

## LIST OF PROVINCIAL HEALTH LEGISLATION

<b>Province/ Territory</b>	Ministry / Department	Legislation	Right of Recovery
Nova Scotia	Minister of Health and Wellness Department of Health and Wellness	Health Services and Insurance Act, RSNS 1989, c 197	"cost of the care, services and benefits"
New Brunswick	Minister of Health  Executive Council	Medical Services Payment Act, RSNB 1973, c M-7  Health Services Act, RSNB 2014, c 112	"entitled services"
Prince Edward Island	Minister of Health and Wellness	Health Services Payment Act, RSPEI 1988, c H-2 Hospital and Diagnostic Services Insurance Act, RSPEI 1988, c H-8	"basic health services" "insured services"
Newfoundland and Labrador	Minister of Health and Community Services	Medical Care and Hospital Insurance Act, SNL2016 cM- 5.01	"insured services"
Ontario	Minister of Health and Minister of Long-Term Care	Health Insurance Act, RSO 1990 c H 6 Home Care and Community Services Act 1994, S.O., 1994, c.26	"insured services"  "approved services"
Manitoba	Minister of Health, Seniors and Active Living	Health Services Insurance Act, CCSM, 2015 c H35	"insured services"
Saskatchewan	Minister of Health	The Health Administration Act, SS 2014, c E-13.1	"health services"
Quebec	Régie de l'assurance maladie du Québec	Health Insurance Act, 2017 CQLR c A-29	"insured services"

<b>Province/ Territory</b>	Ministry / Department	Legislation	Right of Recovery
		Hospital Insurance Act, CQLR c A-28	
Yukon	Minister of Health and Social Services	Hospital Insurance Services Act, RSY 2002, c 112 Health Care Insurance Plan Act, RSY 2002, c.107	"insured services"  "insured health services"
Northwest Territories and Nunavut	Minister of Health and Social Services	Hospital Insurance and Health and Social Services Administration Act, RSNWT 1998, c T- 3	"insured services"
		Medical Care Act, R.S.N.W.T. 1988, c.M-8	
Alberta	Minister of Health	Crown's Right of Recovery Act, SA 2009, c C-35	"the Crown's cost of health services"
British Columbia	Minister of Health	Healthcare Costs Recovery Act, SBC 2008 c. 27	"health care services"

#### Exhibit "J"

# Settlement Approved in the Canadian ABILIFY® and ABILIFY MAINTENA® Class Actions in Ontario and Québec

This notice was approved by the Ontario Superior Court of Justice and the Superior Court of Québec.

Please read it carefully as it may affect your legal rights.

**TORONTO, ON and MONTREAL, QC** — [Date of release] /Newswire/ — On [DATE] and [DATE] the Ontario Superior Court of Justice and the Superior Court of Québec (the "Courts") approved a settlement reached on behalf of all individuals and the estates and family members of individuals in Canada who were prescribed and took ABILIFY® before February 23, 2017 and/or received injections of ABILIFY MAINTENA® between February 6, 2014 and December 16, 2016 and experienced Compulsive Behaviours and Impulse Control Disorders, namely, compulsive gambling, hypersexuality, compulsive shopping/spending, and binge-eating. The Defendants are the companies responsible for the development, market approval, research, testing, manufacture, and distribution of ABILIFY® and ABILIFY MAINTENA® in Canada.

The Settlement provides for payment of CDN \$14,750,000.00, which will be used to pay compensation for Approved Claims, \$368,750.00 in satisfaction of the claims of the Public Health Insurers, the costs of notice and administration, and Court-approved Class Counsel legal fees in the amount of [XXX], disbursements and taxes. The Courts have appointed MNP Ltd. as Administrator of the Settlement.

Settlement Benefits will be distributed in accordance to the Distribution Protocol approved by the Courts. Not all Class Members will be eligible for compensation. The Defendants have no role in the determination of Settlement Class Member eligibility to participate in the Settlement or the allocation of benefits available to Settlement Class Members.

The Courts have not made any determination of the merits of the claims. The Settlement is a compromise of disputed claims and is not an admission of liability or wrongdoing of the Defendants.

Important Deadline: To be eligible for compensation, Class Members <u>must</u> submit a completed Claim Form to the Administrator <u>no later than X</u>. If you do not file a claim by this deadline, you may not be able to claim a portion of the Settlement and your claim will be extinguished. As a result, it is necessary that you act without delay.

Claim Forms are available for download on the Settlement Website at Abilifyclassactionsettlement.com.

#### **How Do I Get More Information?**

If you have questions about the Settlement, how to file a Claim Form, and/or to obtain more information and/or copies of the Settlement Agreement and related documents, please visit the

websites of Class Counsel, <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc</u>. or contact the Court Appointed Claims Administrator at the address below:

MNP Ltd. – Class Actions Claims Administration

2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3 abilifysettlement@mnp.ca

Toll-Free: 1 (855) 653-0027

The publication of this notice was authorized by the Ontario Superior Court of Justice Please Do Not Contact the Court

###

Source: Rochon Genova LLP

Media Contact(s): Joel P. Rochon, Rochon Genova LLP, 1.866.881.2292

# ONTARIO SUPERIOR COURT OF JUSTICE

BETWEEN:

**Plaintiffs** 

– and –

BRISTOL-MYERS SQUIBB, BRISTOL-MYERS SQUIBB CANADA CO./LA SOCIÉTÉ BRISTOL-MYERS SQUIBB, OTSUKA PHARMACEUTICAL CO., LTD., OTSUKA CANADA PHARMACEUTICAL INC., OTSUKA AMERICA PHARMACEUTICAL, INC., OTSUKA AMERICA, INC., OTSUKA MARYLAND MEDICINAL LABORATORIES, INC., and OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC., H. LUNDBECK A/S, and LUNDBECK CANADA INC.

Defendants

Proceeding under the Class Proceedings Act, 1992

#### **ORDER**

THIS MOTION, made by the Plaintiffs, for *inter alia*, an Order fixing the date of the Settlement Approval Hearing, approving the form, content and the manner of dissemination of the Notice of Settlement Approval Hearing and Certification of this action, appointing Dewar Communications Inc. as Administrator of the Notices, and directing that MNP Ltd. be appointed as Claims Administrator to coordinate the Notice of Settlement Approval Hearings was heard in writing this day at Osgoode Hall, 130 Queen Street West, Toronto, Ontario.

**ON READING** the materials filed, including the Settlement Agreement, dated XXXX, attached as Schedule "A" to this Order; and;

ON BEING ADVISED that the Defendants consent to this Order;

- 1. **THIS COURT ORDERS** that except as otherwise stated, the capitalized terms in this Order have the definitions set out in the Settlement Agreement;
- 2. **THIS COURT ORDERS** that the Settlement Approval Hearing shall take place on a date and time to be set by the court;
- 3. **THIS COURT ORDERS** that the form and content of the Notice of Settlement Approval Hearings substantially in the forms attached as Schedules "X" and "X" (the "Short Form Notices"), Schedules "X" and "X" (the "Long Form Notices"), and the press releases substantially in the form attached as Schedules "X" and "X" (the "Press Releases") are hereby approved;
- 4. **THIS COURT ORDERS** that the Notice of Settlement Approval Hearing and Press Releases shall be published and disseminated in accordance with the Notice Plan attached to the Settlement Agreement as Schedule X;
- 5. **THIS COURT ORDERS** that the form of the Notice of Settlement Approval Heraings and Press Releases, and the manner of their dissemination as set out in the Notice Plan, constitute sufficient notice to all persons entitled to notice and satisfies the requirements of notice under section 17 and 19 of the *CPA*;
- 6. **THIS COURT ORDERS** that Abilify Maintena Class Members may opt out of the Settlement by sending a signed Opt Out Form by mail, courier or facsimile to the Claims Administrator in the form attached to the Settlement Agreement as Exhibits X (the "Opt Out Forms") by the Opt Out Deadline;

- 7. **THIS COURT ORDERS** that any Abilify Class Member did not previously opt out of *Scheer c. Bristol-Myers Squibb Canada Co.*, 500-06-000831-160 ("Quebec action") by the opt-out deadline may not opt out of the Settlement without approval of the Superior Court of Quebec.
- 8. **THIS COURT ORDERS** that any Class Member in this action who does not opt out of this action by the Opt Out Deadline and in accordance with the Settlement Agreement may not subsequently opt out without leave of court, and will be bound by the Settlement and/or any subsequent court decision or any settlement reached by the parties and approved by the court;
- 9. **THIS COURT ORDERS** that any objector who wishes to appear before the court at the Settlement Approval Hearing must send a notice of intention to appear in writing, which should be postmarked, served, filed and be received by the Claims Administrator at least ten (10) days prior to the said Settlement Approval Hearing. Such notice of intention to appear should include the name, address, and telephone number of the Class Member and any lawyer who will appear on his or her behalf, if applicable;
- 10. **THIS COURT ORDERS** that, within 5 days of the expiration of the Opt Out Deadline and the Objection Deadline, the Claims Administrator shall provide to the Parties, through their counsel, an Opt Out and Objection Report advising as to the following information in respect of each Class Member, if any, who has opted out or objected to the Settlement:
  - i. the Class Member's full name, current address, telephone number and email address;
  - ii. the stated reasons the Class Member is seeking to opt out or object, if known; and
  - iii. a copy of all information provided by that Class Member in the opting-out or objections process, including the Opt Out Form or written objection.

4

11. THIS COURT ORDERS THAT the Defendants shall pay Notice Expenses and Claims

Administration Expenses before approval of the Settlement, such expenses to be deducted from

the Settlement Amount payable if the Settlement is approved. In the event that the Settlement is

not approved, the Defendants shall bear the Notice Expenses as well as all Claims Administration

Expenses up until the date of termination of the Settlement, such costs being non-refundable to the

Defendants;

12. **THIS COURT ORDERS** that Dewar Communications Inc. be appointed as Administrator

of the Notices;

13. THIS COURT ORDERS that MNP Ltd. be appointed as Claims Administrator to

administer the proposed Settlement, including processing opt outs and coordinating the Notice of

Settlement Approval Hearings;

14. THIS COURT ORDERS that if the Settlement Agreement is not approved, if it is

terminated in accordance with its terms or otherwise fails to take effect for any reason, this Order,

and all Opt Out Forms delivered pursuant to this Order, shall be set aside and declared null and

void and of no force or effect, without the need for any further order of this Court.

15. THIS COURT ORDERS that there be no costs on this consent motion.

THE HONOURABLE JUSTICE MORGAN

**Plaintiffs** 

BRISTOL-MYERS SQUIBB, et al.

-and-

Defendants

Court File No.: CV-16-553833-00CP

SUPERIOR COURT OF JUSTICE ONTARIO

PROCEEDING COMMENCED IN

TORONTO

ORDER

ROCHON GENOVA LLP

Barristers • Avocats 121 Richmond Street West, Suite 900 Toronto, ON M5H 2K1

Golnaz Nayerahmadi (LSO #: 68204C) Sarah J. Fiddes (LSO #: 84897H) Joel P. Rochon (LSO #: 28222Q)

Fax: 416.363.0263 Tel: 416.363.1867

Lawyers for the Plaintiffs

#### SUPERIOR COURT

(Class Action)

CANADA
PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

N<sup>o</sup>: 500-06-000831-160

DATE: , 2024

BY: THE HONOURABLE PIERRE NOLLET, J.S.C.

Plaintiff

٧.

BRISTOL-MYERS SQUIBB CANADA CO.

and

OTSUKA CANADA PHARMACEUTICALS INC.

Defendants

# JUDGMENT (NOTICE APPROVAL)

- [1] **WHEREAS** by judgment dated December 12, 2019, the present class action was authorized on behalf of a national class;
- [2] **WHEREAS** on , 2024, the Plaintiff filed an Application for: (a) Approval of the Notice of Settlement Approval Hearings; (b) Approval of the Notice Plan; (c) Approval of the Claim Form; (d) Approval of the Opt-Out Form; and (e) Appointment of the Claims Administrator (the "Application");
- [3] **CONSIDERING** the materials filed, including the Settlement Agreement entered into by the Parties as at August , 2024;

500-06-000831-160 PAGE: 2

[4] **CONSIDERING** the submissions of counsel for the Plaintiff and counsel for the Defendants;

- [5] **CONSIDERING** that the Parties all consent to this Judgment;
- [6] **CONSIDERING** articles 580, 581, and 590 of the *Code of Civil Procedure*;

POUR CES MOTIFS, LE TRIBUNAL :	WHEREFORE, THE COURT:
[7] <b>ACCUEILLE</b> la présente Demande ;	GRANTS the present Application;
[8] <b>ORDONNE</b> que, sauf indication contraire, les termes commençant par une majuscule dans le présent Jugement ont la définition qui leur est donnée dans l'Entente de règlement;	the capitalized terms in this Judgment have the definitions set out in the Settlement
[9] <b>ORDONNE</b> que l'Audience d'approbation du règlement ait lieu à une date et à une heure fixées par le tribunal ;	ORDERS that the Settlement Approval Hearing shall take place on a date and time to be set by the Court;
[10] <b>APPROUVE</b> la forme et le contenu de l'Avis d'audiences d'approbation de règlement, essentiellement dans les formes jointes aux Annexes « X » et « X » (les « Avis abrégés »), les Annexes « X » et « X » (les « Avis détaillés »), et les communiqués de presse essentiellement dans la forme jointe aux Annexes « X » et « X » (les « Communiqués de presse ») de l'Entente de règlement ;	Notice of Settlement Approval Hearings substantially in the forms attached as Schedules "X" and "X" (the "Short Form Notices"), Schedules "X" and "X" (the "Long Form Notices"), and the press releases substantially in the form attached as Schedules "X" and "X" (the "Press
[11] <b>ORDONNE</b> que l'Avis d'audiences d'approbation de règlement et les Communiqués de presse soient publiés et diffusés conformément au Plan de notification joint à Annexe X de l'Entente de règlement ;	ORDERS that the Notice of Settlement Approval Hearings and Press Releases shall be published and disseminated in accordance with the Notice Plan attached as Schedule X to the Settlement Agreement;
[12] <b>ORDONNE</b> que la forme de l'Avis d'audiences d'approbation du règlement et des Communiqués de presse, ainsi que le mode de leur diffusion tel qu'il est indiqué dans le plan de notification, constituent un	ORDERS that the form of the Notice of Settlement Approval Hearings and Press Releases, and the manner of their dissemination as set out in the Notice Plan, constitute sufficient notice to all persons

500-06-000831-160 PAGE: 3

avis suffisant à toutes les personnes ayant entitled to notice and satisfies the droit à un avis et satisfont aux exigences de requirements of notice under sections 581 notification en vertu des articles 581 et 590 and 590 C.C.P.: C.p.c.; [13] **APPROUVE** le Formulaire d'exclusion **APPROVES** the Opt-Out Form in the form tel qu'il figure à l'Annexe X de l'Entente de attached as Schedule X to the Settlement règlement : Agreement: [14] **APPROUVE** le Formulaire de APPROVES the Claim Form in the form réclamation tel qu'il figure à l'Annexe X de attached as Schedule X to the Settlement l'Entente de règlement ; Agreement; [15] **ORDONNE** que les Membres du **ORDERS** that Abilify Maintena Class groupe Abilify Maintena puissent s'exclure Members may opt out of the Settlement by du Règlement en envoyant un Formulaire sending a signed Opt Out Form by mail, d'exclusion signé par poste, messagerie ou courier or facsimile to the Claims l'Administrateur télécopieur à des Administrator in the form attached to the réclamations dans le formulaire joint à Settlement Agreement as Exhibits X (the l'Entente de règlement comme Pièce X (les l'Opt Out Forms") by the Opt Out Deadline; « Formulaires d'exclusion ») avant la Date limite d'exclusion; [16] **ORDONNE** que tout Membre du **ORDERS** that any Abilify Class Member Groupe Abilify qui ne s'est pas exclu de la that did not previously opt out of the present présente recours québécoise avant la date Quebec proceeding by the opt-out deadline limite d'exclusion ne peut s'exclure du may not opt out of the Settlement without Règlement sans l'approbation de ce approval of this Court; Tribunal; [17] **ORDONNE** que tout Membre du **ORDERS** that any Class Member who did groupe qui ne s'est pas exclu de ce recours not opt out of this action by the Opt Out avant la Date limite d'exclusion et Deadline and in accordance with the conformément à l'Entente de règlement ou Settlement Agreement or with leave of the encore avec l'autorisation du Tribunal, est Court, will be bound by the Settlement lié par l'Entente de règlement et/ou toute and/or any subsequent court decision or ultérieure ou tout any settlement reached by the parties and décision iudiciaire et approved by the Court: règlement conclu par les parties approuvé par le Tribunal; [18] **ORDONNE** que tout objecteur qui **ORDERS** that any objector who wishes to souhaite comparaître devant le Tribunal lors appear before the court at the Settlement de l'Audience d'approbation du règlement Approval Hearing must send a notice of doit envoyer un avis d'intention de intention to appear in writing, which should 500-06-000831-160 PAGE: 4

comparaître par écrit, qui doit être timbré, be postmarked, signifié, déposé et reçu par l'Administrateur des réclamations au moins dix (10) jours least ten (10) days prior to the said avant ladite Audience d'approbation du rèalement. Cet avis d'intention comparaître doit inclure le nom, l'adresse et name, address, and telephone number of le numéro de téléphone du Membre du the Class Member and any lawyer who will groupe et de tout avocat qui comparaîtra en appear on his or her behalf, if applicable: son nom, le cas échéant;

served, filed and be received by the Claims Administrator at Settlement Approval Hearing. Such notice de of intention to appear should include the

suivant l'expiration de la Date limite expiration of the Opt Out Deadline and the d'exclusion et de la Date limite d'opposition. l'Administrateur des réclamations fournira Administrator shall provide to the Parties. aux Parties, par l'intermédiaire de leurs through their counsel, an Opt Out and Rapport d'exclusion avocats, un d'opposition contenant les informations following information in respect of each suivantes concernant chaque Membre du Class Member, if any, who has opted out or groupe, le cas échéant, qui s'est exclu ou s'est opposé à l'Entente de règlement :

- le nom complet, l'adresse actuelle, le numéro de téléphone et l'adresse électronique du Membre du groupe ;
- ii. les raisons invoquées par le Membre du groupe pour s'exclure s'opposer, si elles sont connues ; et
- une copie de toutes les informations iii. fournies par ce Membre du groupe dans le cadre de la procédure d'exclusion ou d'objection, y compris Formulaire d'exclusion ou l'objection écrite;

[19] **ORDONNE** que, dans les 5 jours **ORDERS** that, within 5 days of the Objection Deadline. the Claims et Objection Report advising as to the objected to the Settlement:

- i. the Class Member's full name. current address, telephone number and email address:
- ii. stated reasons Class the the Member is seeking to opt out or object, if known; and
- a copy of all information provided by iii. that Class Member in the opting-out or objections process, including the Opt Out Form or written objection;

[20] **ORDONNE** que les Défenderesses **ORDERS** that the Defendants shall pay doivent payer les Frais d'avis et les Frais Notice Expenses and Claims Administration d'administration des réclamations avant Expenses l'approbation du Règlement, ces frais Settlement, such expenses to be deducted devant être déduits du Montant règlement payable si le Règlement est Settlement is approved. In the event that the approuvé. Dans l'éventualité Règlement n'est pas approuvé,

before approval of the du from the Settlement Amount payable if the le Settlement is not approved, the Defendants les shall bear the Notice Expenses as well as Défenderesses devront supporter les Frais all Claims Administration Expenses up until 500-06-000831-160 PAGE: 5

d'avis ainsi tous les que d'administration des réclamations jusqu'à la such costs being non-refundable to the date de résiliation du Règlement, ces frais Defendants; remboursables n'étant pas aux Défenderesses ;

Frais the date of termination of the Settlement,

[21] ORDONNE que la date et l'heure de ORDERS that the date and time of the l'Audience d'approbation du règlement Settlement Approval Hearing shall be set soient indiquées dans l'Avis d'audiences d'approbation du règlement, mais qu'elles Hearings, puissent faire l'objet d'un ajournement par ce Tribunal sans autre publication d'un avis aux Membres du groupe que l'affichage de other than by posting any new date and time toute nouvelle date et heure de cette for that hearing on the Settlement Website audience sur le Site Web du règlement established and maintained by the Claims établi et maintenu par l'Administrateur des Administrator; réclamations ;

forth in the Notice of Settlement Approval but may be subject adjournment by this Court without further publication of any notice to Class Members

[22] ORDONNE Dewar que Communications soit Inc. Administrateur des avis :

**ORDERS** that Dewar Communications Inc. nommé be appointed as Administrator of the Notices:

Administrateur des réclamations pour administrer le Règlement proposé, compris le traitement des exclusions et la opt outs and coordinating the Notice of coordination l'Avis d'audiences de d'approbation du règlement ;

[23] **ORDONNE** que MNP Ltd. soit nommé **ORDERS** that MNP Ltd. be appointed as Claims Administrator to administer the proposed Settlement, including processing Settlement Approval Hearings;

[24] **ORDONNE** que si l'Entente de **ORDERS** that if the Settlement Agreement règlement n'est pas approuvée, si elle est is not approved, if it is terminated in résiliée conformément à ses termes ou si elle ne prend pas effet pour quelque raison to take effect for any reason, this Order, and que ce soit, le présent Jugement et tous les Formulaires d'exclusion délivrés en vertu du Order, shall be set aside and declared null présent Jugement seront annulés déclarés nuls et non avenus et sans effet. sans qu'il soit nécessaire d'obtenir une autre ordonnance de ce Tribunal;

accordance with its terms or otherwise fails all Opt Out Forms delivered pursuant to this et and void and of no force or effect, without the need for any further order of this Court;

est subordonné à une ordonnance parallèle upon a parallel order being made by the rendue par la Cour supérieure de justice de Ontario Superior Court of Justice and the l'Ontario et que les termes de ce Jugement | terms of this Judgment shall not be effective

[25] **ORDONNE** que le présent Jugement **ORDERS** that this Judgment is contingent

500-06-000831-160 PAGE: 6

ne seront pas en vigueur tant qu'une telle ordonnance n'aura pas été rendue par la Cour supérieure de justice de l'Ontario ;	unless and until such an order is made by the Ontario Superior Court of Justice;
[26] <b>LE TOUT</b> sans frais de justice.	THE WHOLE without legal costs.
	PIERRE NOLLET, J.S.C.

Me Jeff Orenstein Me Lawrence David CONSUMER LAW GROUP INC. Attorneys for the Plaintiff

Me Robert Torralbo Me Ariane Bisaillon BLAKES LLP Attorneys for Defendant Bristol-Myers Squibb Canada Co.

Me Marianne Ignacz INF LLP Attorneys for Defendant Otsuka Canada Pharmaceutical Inc.

#### Exhibit "M"

#### CANADIAN ABILIFY® AND ABILIFY MAINTENA® SETTLEMENT

#### ACKNOWLEDGMENT LETTER

**DATE** 

CLASS MEMBER'S NAME CLASS MEMBER'S ADDRESS CLASS MEMBER'S CITY, PROV, POSTAL

RE: Your file #

We are writing to you as the Court-appointed Claims Administrator of the Canadian ABILIFY® and ABILIFY MAINTENA® Class Action Settlement. Thank you for submitting your Canadian ABILIFY® and ABILIFY MAINTENA® Settlement Claim Package. Unless otherwise indicated in this letter, all capitalized terms have the meanings set out in the Settlement Agreement.

This letter confirms that we have received your Claim Package and any attached supporting documentation. Your Claim Package will now be reviewed for completeness and, if it is considered to be deficient (i.e., missing any of the required information and/or documentation), you will be notified in writing and given an opportunity to provide additional information and/or documentation.

If your Claim Package is complete at this time, we will move forward with reviewing your Claim Package for a determination of the eligibility of your Claim, after which you will be sent a Claim Determination Letter that will advise you as to: i) whether you have been approved to receive compensation for Psychological Harm, ii) the category of Psychological Harm (Mild, Moderate, Severe) under which you have qualified (compensation under which is distributed in accordance with the Distribution Grid), iii) whether you qualify for compensation for Residual Catastrophic Injury, iv) whether you are entitled to receive compensation for Financial Loss, and v) the estimate of recovery for any eligible Financial Loss.

Please note that all preliminary determinations of the amount of compensation the Class Member may receive are subject to *pro rata* reductions or increases, depending on the total number of Approved Claims. If your Claim is NOT approved, you will have the opportunity to challenge that decision. The details about how to do so will be set out in the Claim Determination Letter.

No Claims will be paid until all submitted Claims have been finally adjudicated (including the resolution of all Challenges). Within ninety (90) days after all Claims have been finally adjudicated, you will be sent a Final Claim Determination Letter which will advise you of the final determination on your Claim and, if your Claim was approved, it will set out the final amount of your compensatory payment and enclose a cheque in that amount.

If you have any questions or concerns, or if your mailing address or contact information changes, please contact the Claims Administrator's Information Line at 1 (855) 653-0027or <a href="mailto:abilifysettlement@mnp.ca">abilifysettlement@mnp.ca</a>.

Sincerely,

Claims Administrator

#### Exhibit "N"

## CANADIAN ABILIFY® AND ABILIFY MAINTENA® SETTLEMENT

#### FINAL CLAIM DETERMINATION LETTER

DATE

CLASS MEMBER'S NAME CLASS MEMBER'S ADDRESS CLASS MEMBER'S CITY, PROV, POSTAL

RE: Your file #

We are writing to you as the Court-appointed Claims Administrator of the Canadian ABILIFY® and ABILIFY MAINTENA® Class Action Settlement. Unless otherwise indicated in this letter, all capitalized terms have the meanings set out in the Settlement Agreement.

[if an appro	ved Claim and the Claims Admin decision was NOT challenged, use followin
language oi	ly] All Claims under the Canadian ABILIFY® and ABILIFY MAINTENA
Settlement h	we now been finally adjudicated. Your Claim was approved and the Compensator
Payment has	been determined in accordance with the terms of the Settlement Agreement in the
amount of \$_	A cheque in the amount of
\$	is enclosed herewith.

[If the Claim was challenged, use the following language] Your Challenge Materials (including your Claim Package and supporting documentation, the Claim Determination Form, the Claim Determination Letter, your Notice of Challenge [if submitted, add reference to written submissions here]) were submitted to the Adjudicator on [insert date].

In accordance with the written reasons of the Adjudicator, which are attached hereto, your Challenge has been [add "allowed" or "denied", as the case may be, and any resulting particulars; i.e., not eligible, eligible, same compensation payable, different compensation payable, etc. and if Challenge allowed, note the amount of the Compensatory Payment and that a cheque in that amount is enclosed]

The decision of the Adjudicator is final and binding and is not subject to any further Challenge, appeal, or revision.

Sincerely,

Claims Administrator

### Exhibit "O"

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® SETTLEMENT CLAIM DETERMINATION FORM

NAME OF CLASS MEMBER:				
FILE#:				
DATE OF BIRTH:				
The Claim Package and supporting documentation related to the claim of the above-referenced Class Member in the Canadian ABILIFY® and ABILIFY MAINTENA® Class Action Settlement has been eviewed and it has been determined, in accordance with the terms of the Settlement Agreement, as follows:				
☐ The Class Member <b>did not</b> suffer a Compensable Injury; <b>OR</b>				
☐ The Class Member <b>did</b> suffer a Compensable Injury, as follows:				
Psychological Harm				
1) Mild:				
☐ The Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for <b>1-6 months</b> and experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA® (check all that apply):				
☐ Compulsive gambling ☐ Binge eating				
☐ Hypersexuality ☐ Uncontrollable shopping				
DATES DURING WHICH BEHAVIOURS OCCURRED:				

	The Class Member provided a signed attestation that received injections of ABILIFY MAINTENA® for <b>1-6</b> I or more of the above Compulsive Disorders or Impulse C within 3 months of discontinuing their use of ABILIFY ABILIFY MAINTENA®.	nonths <u>and</u> experienced one Control Disorders while on or	
2) N	Ioderate:		
	The Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for <b>more than 6 months and</b> experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders (check all that apply) while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®:		
	☐ Compulsive gambling	☐ Binge eating	
	☐ Hypersexuality	☐ Uncontrollable shopping	
	DATES DURING WHICH BEHAVIOURS OCCURRE	D:	
	The Class Member provided a signed attestation (Section and/or received injections of ABILIFY MAINTENA® experienced one or more Compulsive Behaviours or Impulsion within 3 months of discontinuing their use of ABILITABILIFY MAINTENA®.	for <b>more than 6 months <u>and</u></b> lse Control Disorders while on or	
	OR		
	The Class Member took ABILIFY® and/or received injections of ABILIFY MAINTENA® for <b>1-6 months</b> and, while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, experienced one or more of the following Compulsive Behaviours or Impulse Control Disorders of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question (check all that apply):		
	☐ Compulsive gambling	☐ Binge eating	
	☐ Hypersexuality	☐ Uncontrollable shopping	

The Class Member attached medical records specifying the following forms of treatment or counselling were sought or provided. If the treatment in question was not covered by provincial health insurance, the Class Member attached receipts or

	confirmation of payment for:	
	☐ Gambling counselling	☐ Binge eating clinic
	☐ Hypersexuality clinic	☐ Uncontrollable shopping clinic
	DATES DURING WHICH BEHAVIOURS OCC	CURRED:
	DATES DURING WHICH SPECIALIZED COUSOUGHT OR RECEIVED:	UNSELLING OR TREATMENT WAS
	The Class Member provided a signed attestation took ABILIFY® and/or received injections of months and, while on or within 3 months of discreceiving injections of ABILIFY MAINTENA®, Disorders or Impulse Control Disorders of such was sought for the Compulsive Behaviours or Impulse Control Disorders or Impulse Control Disorders of Such was sought for the Compulsive Behaviours or Impulse Control Disorders or Impulse Control Disorders of Such was sought for the Compulsive Behaviours or Impulse Control Disorders or Impulse Control Disorde	f ABILIFY MAINTENA® for 1-6 continuing their use of ABILIFY® or experienced one or more Compulsive severity that treatment or counselling
3) Se	vere:	
a)	The Class Member took ABILIFY® and/or MAINTENA® for more than 6 months and ex Compulsive Behaviours or Impulse Control Diso discontinuing their use of ABILIFY® or MAINTENA® (check all that apply), and exmortgaging of a property, and/or criminal prosections of employment, contemporaneous to experie Impulse Control Disorders	sperienced one or more of the below orders while on or within 3 months of receiving injections of ABILIFY sperienced bankruptcy, divorce, recution for fraud, theft, termination or
	☐ Compulsive gambling	☐ Binge eating
	☐ Hypersexuality	☐ Uncontrollable shopping
	The Class Member attached records demonstration Behaviours or Impulse Control Disorders (e.g. withdrawals at casinos, self-exclusion from a case showing payments for gambling, or medical documenting that treatment was sought for Comp Disorders).	g. gambling records, such as ATM ino, credit card or banking statements al records or counselling records

☐ The Class Member attached records demons mortgaging of a property, and/or criminal prosecu loss of employment, etc. contemporaneous to exp and/or Impulse Control Disorders, check all that a	tion for fraud, theft, termination or eriencing Compulsive Behaviours
☐ Declaration of Bankruptcy	☐ Re-mortgaging a property
☐ Divorce	☐ Criminal prosecution
☐ Other	
DATES DURING WHICH BEHAVIOURS OCCU	RRED:
DATES OF BANKRUPTCY, DIVORCE, RE-MORAND/OR CRIMINAL PROSECUTION FOR FRA	
☐ The Class Member provided a signed attestate ABILIFY® and/or received injections of ABILIFY months, experienced one or more Compulsive Disorders while on or within 3 months of discon receiving injections of ABILIFY MAINTENA divorce, re-mortgaging of a property, and/or crimic contemporaneous to or after experiencing Computer Control Disorders	Y MAINTENA® for more than 6 Behaviours or Impulse Control tinuing their use of ABILIFY® or ®, <u>and</u> experienced bankruptcy, nal prosecution for fraud, theft, etc.
OR/ AND (if applicable)	
b) While on or within 3 months of discontinuing the injections of ABILIFY MAINTENA®, the Class M the following Compulsive Behaviours or Impulse C months of such severity that treatment or counselli Behaviours or Impulse Control Disorders in questionall that apply):	ember experienced one or more of Control Disorders for <b>more than 6</b> ng was sought for the Compulsive
☐ Compulsive gambling	☐ Binge eating
☐ Hypersexuality	☐ Uncontrollable shopping

	The Class Member attached records demonstrating they experienced the Compulsive Behaviours or Impulse Control Disorders (e.g. gambling records, such as ATI withdrawals at casinos, self-exclusion from a casino, credit card or banking statement showing payments for gambling, or medical records or counselling record documenting that treatment was sought for Compulsive Behaviours or Impulsional Control Disorders).		
	The Class Member attached records specifying the form of treatment or counselling sought or provided. If the treatment in question was not covered by provincial health insurance, the Class Member attached receipts of same:		
	☐ Gambling counselling ☐ Binge eating clinic		
	☐ Hypersexuality clinic ☐ Uncontrollable shopping		
	DATES DURING WHICH BEHAVIOURS OCCURRED:		
	DATES DURING WHICH SPECIALIZED COUNSELLING OR TREATMENT WAS SOUGHT OR RECEIVED:		
	The Class Member provided a signed attestation (Section 7A) that they took ABILIFY® and/or received injections of ABILIFY MAINTENA® for more than 6 months and, while on or within 3 months of discontinuing their use of ABILIFY® or receiving injections of ABILIFY MAINTENA®, experienced one or more of the Compulsive Behaviours or Impulse Control Disorders of such severity that treatment or counselling was sought for the Compulsive Behaviours or Impulse Control Disorders in question for more than 6 months.		
Re	sidual Catastrophic Injury:		
	The Class Member provided documentary evidence demonstrating that, in addition to claiming under the Mild, Moderate or Severe Psychological Harm categories they:		
	i) experienced catastrophic physical or psychological consequences of Compulsive Behaviours or Impulse Control Disorders alleged to have been caused by the use of ABILIFY® and/or ABILIFY MAINTENA®, including but not limited to: contracting HIV, Hepatitis, or a non-treatable STI (sexually transmitted infection) as a result of hypersexuality, suicidality and related hospitalization related to Compulsive Behaviours or Impulse Control Disorders and their consequences. Specifically, they experienced (attach additional sheets if needed):		

4)

# Financial Harm

# 1) Compensable gambling losses

gambl	ling activity at each venue v	vailable documentation capable of showing where gambling took place. In the aggregate Member suffered a net gambling loss of: \$
	not taking any other dopan	t when the at issue gambling occurred, they nine agonist medications, including but not
	☐ Pramipexole (Mirapex)	
	☐ Ropinirole (Requip)	
	☐ Pergolide (Permax)	
	☐ Other (please fill in):	
2) Compen	sable income loss	
	ass Member provided docun ation or loss of employment.	nentation for entitlement to compensation for
3) Compens	sable loan losses	
	ass Member provided docum asable loan losses.	entation for entitlement to compensation for
	ass Member provided comp , in the following amounts:	plete Financial Records from the following
i.	Lender:	_ Loan Amount: \$
ii.	Lender:	Loan Amount: \$
iii.	Lender:	_ Loan Amount: \$
iv.	Lender:	_ Loan Amount: \$
v.	Lender:	Loan Amount: \$ .

# **Family Class Member Claims:**

•	lass Member provide entitled to settlemen	onstrating the fo	ollowin	g Family Class
i.	Relationship:	Claim	%	Entitlement
ii.	Relationship:	Claim	%	Entitlement
iii.	Relationship:	Claim	%	Entitlement
iv.	Relationship:	Claim	%	Entitlement
v.	Relationship:	Claim	%	Entitlement
DAT	_			

Unless otherwise indicated herein, all capitalized terms have the meanings set out in the Settlement Agreement.

#### Exhibit "P"

#### CANADIAN ABILIFY® AND ABILIFY MAINTENA® SETTLEMENT

#### **DEFICIENCY LETTER**

DATE

CLASS MEMBER'S NAME CLASS MEMBER'S ADDRESS CLASS MEMBER'S CITY, PROV, POSTAL

RE: Your file #

We are writing to you as the Court-appointed Claims Administrator of the Canadian ABILIFY® and ABILIFY MAINTENA® Class Action Settlement. Thank you for submitting your Canadian ABILIFY® and ABILIFY MAINTENA® Settlement Claim Package. Unless otherwise indicated in this letter, all capitalized terms have the meanings set out in the Settlement Agreement.

We have now reviewed your Claim Package for completeness pursuant to the terms of the Settlement, and have determined that the package is missing the following information and/or documentation necessary to support your Claim:

#### [particulars as to nature of deficiency/ies to be listed here]

As your Claim Package and/or supporting documentation has been deemed to be deficient, you may seek to obtain the referenced missing information and/or documentation. If you choose to do so, any such further information and/or documentation must be submitted to the Claims Administrator within sixty (60) days of receipt of this letter. You are not required to provide the requested information or further documentation. However, if you do not provide the requested information or documentation listed above, this may affect your eligibility to obtain compensation for your Claim.

Kindly submit all further documentation to the Claims Administrator at the following address:

Attention: Canadian ABILIFY® and ABILIFY MAINTENA® Class Action Settlement

MNP Ltd. – Class Actions Claims Administration 2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3
<a href="mailto:abilifysettlement@mnp.ca">abilifysettlement@mnp.ca</a>
Toll-Free: 1 (855) 653-0027

If you have any questions or concerns, please contact the Claims Administrator at the toll-free number or e-mail, set out above.

Sincerely,

Claims Administrator

## Exhibit "Q"

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® SETTLEMENT NOTICE OF CHALLENGE

NA.	ME OF CLASS
ME	MBER: FILE#:
DA	TE OF BIRTH:
I, <u> </u>	
date	
und	er the Canadian ABILIFY® and ABILIFY MAINTENA® Settlement and I wish to challenge
the	determination(s) set out therein as follows (check all that apply):
	I challenge the determination that the Class Member <b>did not</b> suffer a Compensable Injury;
	I challenge the determination as to the categorization of the Class Member' Psychological Harm (please indicate the category of Compensable Psychological Harm that you believe the Class Member suffered):
_	I challenge the determination that I am not qualified for additional compensation for Catastrophic Residual Injury
	I challenge the determination as to whether compensable Financial Harm was suffered (please indicate the Financial Harm that you believe the Class Member did suffer, along with the documentation supporting that this Financial Harm was suffered):
	I challenge the determination as to the approved estimated range of compensation for Psychological Harm or Financial Harm.
П	Other challenge (please describe):

Please state the reason(s) for challenging the determination(s):

If you wish, you may attach written submissions in support of your Challenge. Any such submissions must not exceed **five (5)** pages in length. Your Notice of Challenge and any additional submissions you wish to submit must be sent to the Claims Administrator **no later than thirty (30) days** following the date of the Claim Determination Letter.

Unless otherwise indicated herein, all capitalized terms have the meanings set out in the Settlement Agreement.

#### Exhibit "R"

# CANADIAN ABILIFY® AND ABILIFY MAINTENA® SETTLEMENT

#### FINAL CLAIM DETERMINATION LETTER

DATE

CLASS MEMBER'S NAME CLASS MEMBER'S ADDRESS CLASS MEMBER'S CITY, PROV, POSTAL

RE: Your file #

We are writing to you as the Court-appointed Claims Administrator of the Canadian ABILIFY® and ABILIFY MAINTENA® Class Action Settlement. Unless otherwise indicated in this letter, all capitalized terms have the meanings set out in the Settlement Agreement.

lif an approv	ed Claim and the Claims Admin decision was NOT challenged, use following
language onl	$[\mathbf{y}]$ All Claims under the Canadian ABILIFY ${\mathbb R}$ and ABILIFY MAINTENA ${\mathbb R}$
Settlement hav	ve now been finally adjudicated. Your Claim was approved and the Compensatory
Payment has b	been determined in accordance with the terms of the Settlement Agreement in the
amount of \$	A cheque in the amount of
\$	is enclosed herewith.

[If the Claim was challenged, use the following language] Your Challenge Materials (including your Claim Package and supporting documentation, the Claim Determination Form, the Claim Determination Letter, your Notice of Challenge [if submitted, add reference to written submissions here]) were submitted to the Adjudicator on [insert date].

In accordance with the written reasons of the Adjudicator, which are attached hereto, your Challenge has been [add "allowed" or "denied", as the case may be, and any resulting particulars; i.e., not eligible, eligible, same compensation payable, different compensation payable, etc. and if Challenge allowed, note the amount of the Compensatory Payment and that a cheque in that amount is enclosed]

The decision of the Adjudicator is final and binding and is not subject to any further Challenge, appeal, or revision.

Sincerely,

Claims Administrator

#### EXHIBIT "S": PROVINCIAL HEALTH INSURER CONSENT AND RELEASE

WHEREAS [province specific legislation] (the "Act") permits a direct or subrogated claim (a "Claim") for the recovery of the costs for [insured services or analogous term] that have been incurred in the past and that will probably be incurred in the future and as further described in the Act and its regulations (collectively ["Insured Services or Analogous Term"]);

AND WHEREAS a proceeding was commenced in Ontario and Quebec against OTSUKA PHARMACEUTICAL CO., LTD., OTSUKA CANADA PHARMACEUTICAL INC., OTSUKA AMERICA PHARMACEUTICAL, INC., OTSUKA AMERICA, INC., OTSUKA MARYLAND MEDICINAL LABORATORIES, INC., **PHARMACEUTICALS DEVELOPMENT** COMMERCIALIZATION, & BRISTOL-MYERS SQUIBB, BRISTOL-MYERS SQUIBB CANADA CO./LA SOCIÉTÉ BRISTOL-MYERS SQUIBB (collectively, the "Defendants") on behalf of a proposed class of Canadian residents who have been prescribed and/or ingested ABILIFY® ("Abilify") and ABILIFY MAINTENA® ("Maintena") (collectively the "Abilify Drugs");

**AND WHEREAS** pursuant to a Settlement Agreement dated [date] (the "Settlement Agreement") the Proceeding and all of the present and future claims of Class Members (as defined in the Settlement Agreement) for or relating in any way to the Abilify Drugs are to be fully resolved, on a national basis, without admission of liability;

**AND WHEREAS** the Provincial Health Insurer (as defined in the Settlement Agreement) hereby consents to the Settlement Agreement;

**AND WHEREAS** pursuant to the Settlement Agreement, Class Members will have an opportunity to submit individual claims for settlement benefits (the "Settling Claimants" as further defined in the Settlement Agreement);

IN CONSIDERATION OF the payment to be made from the Settlement Amount to the Provincial Health Insurer as good and valuable consideration, the receipt and sufficiency of which are hereby irrevocably acknowledged, the undersigned, [•], on behalf of the Provincial Health Insurer (hereinafter "Releasor"), releases any and all manner of claims which the Provincial Health Insurer ever had, now has or hereafter can, shall or may have pursuant to provincial or territorial legislation that permits the recovery of healthcare costs or medical expenses from third parties, whether known or unknown, past or future, direct or indirect or subrogated, relating in any way to the design, manufacture, sale, distribution, labelling, and/or use of the Abilify Drugs by Class Members during the Class Period, and including all subrogated and/or direct claims in respect of Class Members that were or could have been brought for the cost of medical care or treatment provided to Class Members, as well as medical screening or monitoring, arising from the facts alleged in the Proceeding, against the Released Parties (as defined in the Settlement Agreement).

AND THE STATUTORILY DESIGNATED OFFICIAL FOR THE PROVINCIAL

**HEALTH INSURER REPRESENTS AND CONFIRMS** that s/he has authority to bind the Releasor.

**AND THE RELEASOR ACKNOWLEDGES** and agrees that s/he has not been induced to execute this Release by reason of any representation or warranty of any nature or kind whatsoever and that there is no condition express or implied or collateral agreement affecting the said release.

**AND FOR THE SAID CONSIDERATION** the Releasor covenants and agrees not to make a claim or to commence or take proceedings against any of the Released Parties, including any person, firm, partnership, business or corporation who or which might claim contribution from, or to be indemnified by the Released Parties, in respect of those matters to which this release applies.

**AND IT IS UNDERSTOOD** that Released Parties, and each of them, do not admit any liability to the Releasor or others and that such liability is specifically and expressly denied.

IN WITNESS WHEREOF the Releasor [•] has hereunto set his/her hand and seal this day of , 2024.

Witness

Printed Name of Statutorily
Designated Official for the Provincial
Health Insurer on
behalf of [Province]

Signature of Statutorily Designated
Official for the Provincial Health Insurer
on behalf of [Province]

#### Exhibit "T"

# Proposed Settlement Reached in the Canadian ABILIFY® and ABILIFY MAINTENA® Class Actions, Settlement Approval Hearings Scheduled in Ontario and Québec for XXXX and XXX

This notice was approved by the Ontario Superior Court of Justice and the Superior Court of Québec.

Please read it carefully as it may affect your legal rights.

TORONTO, ON and MONTREAL, QC – [Date of release] /Newswire/ – A proposed Settlement has been reached on behalf of all individuals in Canada who were prescribed and took ABILIFY® before February 23, 2017 ("ABILIFY® Class Members") and/or received injections of ABILIFY MAINTENA® between February 6, 2014 and December 16, 2016 ("ABILIFY MAINTENA® Class Members") and their family members. The Defendants are the companies responsible for the development, market approval, research, testing, manufacture, and distribution of ABILIFY® and ABILIFY MAINTENA® in Canada.

The Settlement provides for the creation of a CDN \$14,750,000.00 Settlement fund, which will be used to pay compensation for Approved Claims, \$368,750.00 in satisfaction of the claims of the Public Health Insurers, the costs of notice and administration, and Court-approved Class Counsel legal fees, disbursements and taxes. Not all Class Members will be eligible for compensation. The Defendants have no role in the determination of Settlement Class Member eligibility to participate in the Settlement or the allocation of benefits available to Settlement Class Members. To become effective, the proposed Settlement must be approved by the Ontario Superior Court of Justice and the Superior Court of Québec (the "Courts").

On March 13, 2020, the Ontario Superior Court of Justice certified a national class action on behalf of ABILIFY® and ABILIFY MAINTENA® Class Members relating to the Defendant drug manufacturers' alleged failure to warn of the risks of compulsive gambling, hypersexuality, compulsive shopping, and binge eating ("Compulsive Behaviours") associated with ABILIFY® and ABILIFY MAINTENA®.

Previously, on December 19, 2019, the Superior Court of Québec authorized a national class action on behalf of ABILIFY® Class Members. Notice of authorization of the Québec class action was provided on January 6, 2020. The opt-out deadline for ABILIFY® Class Members who did not wish to participate in the Québec Class Action expired on May 31, 2020.

The Courts have not made any determination of the merits of the claims. The Defendants have denied, and continue to deny, the allegations against them in the Class Actions.

If you are an ABILIFY® Class Member who previously opted out of the Québec class action but now wish to participate in the Settlement, you may do so by contacting Class Counsel. If you are an ABILIFY® Class Member, and did not previously opt out of the Québec class action, you may make a request to the Québec Court to opt out of the Settlement. If you do not opt out and the

Settlement is approved and becomes effective, you will be bound by the Settlement which includes a release of your claims.

ABILIFY MAINTENA® Class Members who DO NOT want to participate in the action must opt out by [DATE]. A Class Member who opts out will not be entitled to file a Claim seeking benefits under the Settlement, but will preserve their right to pursue individual actions, subject to any applicable limitation periods. To opt out, ABILIFY MAINTENA® Class Members will need to complete an opt out form and send it to Class Counsel no later than [DATE]. The Opt Out form and accompanying instructions are available online on the Settlement Website and on the websites of Class Counsel at Rochon Genova LLP and Consumer Law Group Inc. Alternatively, ABILIFY MAINTENA® Class Members can request the Opt Out form and instructions from Class Counsel. For assistance in English or French, contact:

ROCHON GENOVA LLP	CONSUMER LAW GROUP INC.
900-121 Richmond St. W.	1030 rue Berri, Suite 102
Toronto, Ontario, M5H 2K1	Montreal (Québec) H2L 4C3
Tel: 1-800-462-3864 (416) 363-1867 contact@rochongenova.com	Tel: 1 (888) 909-7863 (514) 266-7863 (613) 627-4894 abilify@clg.org

No person may opt out a minor or a mentally incapable member of the Class without permission of the court after providing notice to The Children's Lawyer and/or the Public Guardian and Trustee, as appropriate.

#### **Settlement Approval Hearing**

For the Settlement to become effective, Court approval is necessary. The Courts must be satisfied that the Settlement is fair, reasonable and in the best interests of Class Members. The Approval Hearings have been scheduled to be heard before the Ontario Superior Court of Justice and the Superior Court of Québec on [DATE] and [DATE], respectively.

#### **Class Counsel and Legal Fees**

The Class is represented by *Rochon Genova LLP* and *Consumer Law Group Inc*. Legal fees must be approved by the Ontario Superior Court and the Superior Court of Québec. At the Approval Hearings, Class Counsel will request the Courts' approval for payment of their contingency fees, in an amount not exceeding \$4.425 million, plus disbursements and applicable taxes.

#### **How Do I Get More Information?**

If you have questions about the Settlement and/or would like to obtain more information and/or copies of the Settlement Agreement and related documents, please visit the websites of Class Counsel, <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc</u>. or contact the Claims Administrator at the address below:

#### MNP Ltd. – Class Actions Claims Administration

2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3 abilifysettlement@mnp.ca

Toll-Free: 1 (855) 653-0027

The publication of this notice was authorized by the Ontario Superior Court of Justice Please Do Not Contact the Court

###

Source: Rochon Genova LLP

Media Contact(s): Joel P. Rochon, Rochon Genova LLP, 1.866.881.2292

#### Schedule "B"

# Settlement Approved in the Canadian ABILIFY® and ABILIFY MAINTENA® Class Actions in Ontario and Québec

This notice was approved by the Ontario Superior Court of Justice and the Superior Court of Québec.

Please read it carefully as it may affect your legal rights.

TORONTO, ON and MONTREAL, QC – Date of release /Newswire/ – On DATE and DATE the Ontario Superior Court of Justice and the Superior Court of Québec (the "Courts") approved a settlement reached on behalf of all individuals and the estates and family members of individuals in Canada who were prescribed and took ABILIFY® before February 23, 2017 and/or received injections of ABILIFY MAINTENA® between February 6, 2014 and December 16, 2016 and experienced Compulsive Behaviours and Impulse Control Disorders, namely, compulsive gambling, hypersexuality, compulsive shopping/spending, and binge-eating. The Defendants are the companies responsible for the development, market approval, research, testing, manufacture, and distribution of ABILIFY® and ABILIFY MAINTENA® in Canada.

The Settlement provides for payment of CDN \$14,750,000.00, which will be used to pay compensation for Approved Claims, \$368,750.00 in satisfaction of the claims of the Public Health Insurers, the costs of notice and administration, and Court-approved Class Counsel legal fees in the amount of \$5,350,697.00, disbursements and taxes. The Courts have appointed MNP Ltd. as Administrator of the Settlement.

Settlement Benefits will be distributed in accordance to the Distribution Protocol approved by the Courts. Not all Class Members will be eligible for compensation. The Defendants have no role in the determination of Settlement Class Member eligibility to participate in the Settlement or the allocation of benefits available to Settlement Class Members.

The Courts have not made any determination of the merits of the claims. The Settlement is a compromise of disputed claims and is not an admission of liability or wrongdoing of the Defendants.

Important Deadline: To be eligible for compensation, Class Members <u>must</u> submit a completed Claim Form to the Administrator <u>no later than X</u>. If you do not file a claim by this deadline, you may not be able to claim a portion of the Settlement and your claim will be extinguished. As a result, it is necessary that you act without delay.

Claim Forms are available for download on the Settlement Website at <u>Abilifyclassactionsettlement.com.</u>

#### **How Do I Get More Information?**

If you have questions about the Settlement, how to file a Claim Form, and/or to obtain more information and/or copies of the Settlement Agreement and related documents, please visit the

websites of Class Counsel, <u>Rochon Genova LLP</u> and <u>Consumer Law Group Inc</u>. or contact the Court Appointed Claims Administrator at the address below:

MNP Ltd. – Class Actions Claims Administration

2000, 112 - 4th Avenue SW Calgary, AB, T2P 0H3 abilifysettlement@mnp.ca

Toll-Free: 1 (855) 653-0027

The publication of this notice was authorized by the Ontario Superior Court of Justice Please Do Not Contact the Court

###

Source: Rochon Genova LLP

Media Contact(s): Joel P. Rochon, Rochon Genova LLP, 1.866.881.2292

Schedule "C"

# Avez-vous pris du Abilify et éprouvé un comportement de jeu compulsif?

VOUS POURRIEZ AVOIR LE DROIT À UNE INDEMNISATION

**VOUS POURRIEZ** Avez-vous pris du Abilify et éprouvé **AVOIR LE DROIT À UNE** un comportement de jeu compulsif? INDEMNISATION

Avez-vous pris du Abilify et éprouvé de la frénésie alimentaire?

**VOUS POURRIEZ AVOIR LE DROIT À UNE INDEMNISATION** 

**VOUS POURRIEZ** Avez-vous pris du Abilify et éprouvé **AVOIR LE DROIT À UNE** de la frénésie alimentaire ? INDEMNISATION

Avez-vous pris du Abilify et éprouvé de l'hypersexualité compulsive?

> VOUS POURRIEZ AVOIR LE DROIT À UNE INDEMNISATION

**VOUS POURRIEZ** Avez-vous pris du Abilify et éprouvé **AVOIR LE DROIT À UNE** de l'hypersexualité compulsive ? **INDEMNISATION** 

Avez-vous pris du Abilify et éprouvé un comportement d'achats/dépenses compulsifs?

VOUS POURRIEZ AVOIR LE DROIT À UNE INDEMNISATION Avez-vous pris du Abilify et éprouvé **VOUS POURRIEZ AVOIR LE** un comportement d'achats/dépenses DROIT À UNE compulsifs? INDEMNISATION Did you take Abilify and experience compulsive gambling?

YOU MAY BE ENTITLED TO COMPENSATION

Did you take Abilify and experience **YOU MAY BE ENTITLED TO** compulsive gambling? COMPENSATION **Did you take Abilify** and experience compulsive binge eating?

YOU MAY BE ENTITLED TO COMPENSATION

Did you take Abilify and experience **YOU MAY BE ENTITLED TO** compulsive binge eating? COMPENSATION **Did you take Abilify** and experience compulsive hypersexuality?

YOU MAY BE ENTITLED TO COMPENSATION

Did you take Abilify and experience **YOU MAY BE ENTITLED TO** compulsive hypersexuality? COMPENSATION

**Did you take Abilify** and experience compulsive shopping/spending?

YOU MAY BE ENTITLED TO COMPENSATION

Did you take Abilify and experience **YOU MAY BE ENTITLED TO** compulsive shopping/spending? COMPENSATION

# Schedule "D"

Court File No. CV-16-553833-00CP

# ONTARIO SUPERIOR COURT OF JUSTICE

BETWEEN:



**Plaintiffs** 

- and -

BRISTOL-MYERS SQUIBB, BRISTOL-MYERS SQUIBB CANADA CO./LA SOCIÉTÉ BRISTOL-MYERS SQUIBB, OTSUKA PHARMACEUTICAL CO., LTD., OTSUKA CANADA PHARMACEUTICAL INC., OTSUKA AMERICA PHARMACEUTICAL, INC., OTSUKA AMERICA, INC., OTSUKA MARYLAND MEDICINAL LABORATORIES, INC., and OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC., H. LUNDBECK A/S, and LUNDBECK CANADA INC.

**Defendants** 

Proceeding under the Class Proceedings Act, 1992

# **AMENDED STATEMENT OF CLAIM**

#### TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

**TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED** if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date:	Issued by:		
	•	I 1 D ! - 4	

Local Registrar

Address of 393 University Avenue

court office: 10<sup>th</sup> Floor

Toronto, ON M5G 1E6

TO: Bristol-Myers Squibb

345 Park Avenue, New York

N.Y. 10154 United States

Bristol Myers Squibb Canada Co./La Société Bristol Myers Squibb 2344 Alfred-Nobel Boulevard, Suite 300 Montreal, Ouebec H4S 0A4

<del>vionifeai, Quebec 1145 0/14</del>

Canada

#### **BLAKE, CASSELS & GRAYDON LLP**

Barristers & Solicitors
199 Bay Street, Suite 4000
Commerce Court West
Toronto, ON M5L 1A9

S. Gordon McKee Robin Linley

Tel: 416.863.3884 Fax: 416.863.2653

Lawyers for the Defendant, Bristol-Myers

#### Squibb Canada Co./ La Societe Bristol-Myers Squibb

#### AND TO: Otsuka Pharmaceutical Co., Ltd.

2-9, Kanda Tsukasa-machi,

Chiyoda-ku, Tokyo 101-8535, Japan

Otsuka Canada Pharmaceutical Inc.

2250 Alfred Nobel Blvd., Ste. 301

Saint Laurent, QC H4S 2C9

Canada

#### Otsuka America Pharmaceutical, Inc.

**The Corporation Trust Company** 

**Corporation Trust Center** 

Wilmington, DE 19801

**United States** 

Otsuka Maryland Medicinal Laboratories, Inc.

2440 Research Blvd.

Rockville, MD 20850

#### **Resident Agent**

The Corporation Trust Incorporated

351 West Camden Street

Baltimore, MD 21201

**United States** 

#### Otsuka America, Inc.

One Embarcadero Center, Suite 2020

San Francisco, CA 94111

#### **Agent for Service of Process**

**C T Corporation System** 

818 West Seventh St. Ste 930

Los Angeles, CA 90017

**United States** 

#### Otsuka Pharmaceutical Development & Commercialization, Inc.

1 University Square Drive, #500

Princeton, NJ 08540

#### **Agent for Service of Process**

**The Corporation Trust Company** 

820 Bear Tavern Road

West Trenton, NJ 08628

#### **Main Business Address**

508 Carnegie Center

Princeton, NJ 08540

**United States** 

#### NORTON ROSE FULBRIGHT CANADA LLP

Suite 3800, Royal Bank Plaza South Tower, 200 Bay Street P.O. Box 84 Toronto, ON M5J 2Z4

#### **Randy Sutton**

Tel: 416.216.4080 Fax: 416.216.3930

Lawyers for the Defendant, Otsuka Canada Pharmaceutical

AND TO: H. Lundbeck A/S

Ottiliavej 9, 2500 Valby, Denmark

Lundbeck Canada Inc.

**Main Business Address** 

1000 rue de la Gauchetiere Quest

Bureau 500

Montreal, Quebec

H3B 4W5

Canada

#### **Address for Service**

Fasken Martineau

Tour de la Bourse, Bur 3700 C.P. 242, 800, Place Victoria

Montreal, QC H4Z1E9

Canada

### McCARTHY TETRAULT LLP

66 Wellington Street West
Suite 5300, TD Bank Tower
Box 48
Toronto, ON M5K 1E6

# Frank J. McLaughlin Dorothy Charach

Tel: 416.362.1812 Fax: 416.868.0673

<u>Lawyers for the Defendants, H. Lundbeck A/S</u> <u>and Lundbeck Canada Inc.</u>

#### CLAIM

#### **DEFINED TERMS**

- 1. The following terms used throughout this Statement of Claim have the meanings indicated:
  - (a) "Abilify" means aripiprazole tablets designed, manufactured, marketed, distributed and sold under the trademark ABILIFY in Canada;
  - (b) "Abilify Maintena" means a prolonged release injectable suspension of aripiprazole;
  - (c) "BMS" means Bristol-Myers Squibb Company;
  - (d) "BMS Canada" means Bristol-Myers Squibb Canada Co./ La Société Bristol-Myers Squibb Canada;
  - (e) "CBCA" means the Canada Business Corporations Act, R.S.C. 1985, c. C-44;
  - (f) "CJA" means the Courts of Justice Act, R.S.O. 1990, c. C.43, as amended;
  - (g) "Classes" and "Class Members" mean the Ability Class, Ability Maintena Class,
    Ability Family Class and Ability Maintena Family Class defined as follows:

All persons in Canada, including their estates, who were prescribed and ingested Abilify between July 9, 2009 and February 23, 20176, and/or ("Abilify Class" or "Abilify Class Member");

All persons in Canada, including their estates, who were prescribed and used Abilify Maintena between February 6, 2014 and December 16, 2016 ("Abilify Maintena Class" or "Abilify Maintena Class Members");

All persons resident in Canada who, by virtue of a personal relationship with an Abilify Class Member, are entitled to assert a derivative claim for damages pursuant to *Family Law Act*, R.S.O. 1990, c. F.3, as amended or equivalent provincial and

territorial legislation ("Abilify Family Class" or "Abilify Family Class Members"); and

All persons resident in Canada who, by virtue of a personal relationship with an Abilify Maintena Class Member, are entitled to assert a derivative claim for damages pursuant to *Family Law Act*, R.S.O. 1990, c. F.3, as amended or equivalent provincial and territorial legislation ("Abilify Maintena Family Class" or "Abilify Maintena Family Class Members").

- (h) "Class Period" means, for the purposes of the Abilify Class and Abilify Family Class, the period between July 9, 2009 and February 23, 2017, and for the purposes of the Abilify Maintena Class and the Abilify Maintena Family Class, the period between February 6, 2014 and December 16, 2016;
- (i) "Competition Act" means Competition Act, R.S.C. 1985, c. C-34;
- (j) "Compulsive Behaviours" means any one or more Impulse-Control Disorders and/or compulsive behaviours associated with the use of Abilify and Abilify Maintena, including but not limited to, namely, compulsive gambling, hypersexuality, binge-eating and compulsive shopping and/or spending;
- (k) "CPA" means the Class Proceedings Act, 1992, S.O. 1992, c. 6;
- (1)

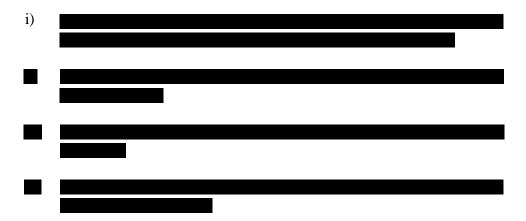
(m)

- (n) "Family Class Members" means Abilify Family Class Members and Abilify Maintena Family Class Members. means all persons resident in Canada who, by virtue of a personal relationship with a Class Member, are entitled to assert a derivative claim for damages pursuant to Family Law Act, R.S.O. 1990, c. F.3, as amended or equivalent provincial and territorial legislation;
- (o) "FDA" means the United States' Food and Drug Administration;

(p)	"FLA" means the Family Law Act, R.S.O. 1990, c. F.3, as amended, and equivalent
	legislation in other provinces and territories;
(q)	
(r)	
(s)	"Impulse-Control Behaviours" and "Impulse-Control Disorders" mean, inter
(8)	alia, an uncontrollable impulse to gamble, shop, eat; and hypersexuality; unusual
	sexual thoughts, fantasies, desires or behaviours; or any other uncontrollable
	behaviour that the individual finds distressing;
(t)	"Limitations Act, 2002" means the Limitations Act, 2002, S.O. 2002, ch. 24;
(u)	"Lundbeck" means Lundbeck Canada Inc.;
(v)	
(w)	
(x)	"OAI" means Otsuka America, Inc.;
(y)	"OMML" means Otsuka Maryland Medicinal Laboratories, Inc.;
(z)	"OPDC" means Otsuka Pharmaceutical Development & Commercialization, Inc.;
(aa)	"Otsuka" means all of the Otsuka Defendants;
(bb)	"OAPI" means Otsuka America Pharmaceutical Inc.;
(cc)	"Otsuka Canada" means Otsuka Canada Pharmaceutical Inc.;
(dd)	"Otsuka Pharma" means Otsuka Pharmaceutical Co. Ltd;
(ee)	
. ,	
(ff)	

#### **RELIEF CLAIMED**

- 2. The Plaintiffs claim on their own behalf and on behalf of others similarly situated in Canada:
  - a) an order certifying this action as a class proceeding, and appointing Matthew as the Representative Plaintiff for the Class and Gayle as the Representative Plaintiff for the Family Class the following individuals as Representative Plaintiffs, pursuant to the CPA:



- b) a declaration that the Defendants owed a duty of care to the Class Members to ensure
  that Abilify and Abilify Maintena were fit for their intended or reasonably foreseeable
  use;
- e) a declaration that the Defendants were negligent in the development, design, testing, manufacturing, distribution, marketing and sale of Abilify and Abilify Maintena and are liable to the Classes for resulting damages;

- d) a declaration that the Defendants breached their duty of care by failing to ensure that Abilify and Abilify Maintena were designed and manufactured to be reasonably safe for use by the Class Members;
- e) a declaration that the Defendants owed a duty of care to the Plaintiffs and the Class

  Members to conduct reasonable pre- and post-market testing and research on the

  increased risk of Compulsive Behaviours associated with the use of Abilify and Abilify

  Maintena, and are liable to the Classes for resulting damages;
- f) a declaration that the Defendants breached their duty of care by failing to conduct any or any adequate pre- and/or post-market testing on the increased risk of developing Compulsive Behaviours associated with the use of Abilify and Abilify Maintena;
- g) a declaration that the Defendants owed a duty of care to provide timely and adequate

  warnings to the Plaintiffs and the Class Members about the increased risk of

  Compulsive Behaviours associated with the use of Ability Maintena, and

  are liable to the Classes for resulting damages;
- a declaration that the Defendants breached their duty of care by failing to warn the Class Members of the increased risk of developing Compulsive Behaviours associated with the use of Abilify and Abilify Maintena as prescribed and indicated in the product monographs;
- i) a declaration that the Defendants conspired and agreed together to conceal the risk of Compulsive Behaviours associated with the use of Abilify and Abilify Maintena, and

- to misrepresent the safety of these drugs to the Class Members, contrary to sections 36 and 52 of the *Competition Act*;
- j) damages in the amount of \$250,000,000 or in such other amount as this Honourable
   Court deems just;
- k) pecuniary and special damages including, but not limited to, gambling losses and loss of income;
- l) damages pursuant to section 61 of the *FLA*, and equivalent legislation in other provinces and territories, in the amount of \$25,000,000 or in such other amount as this Honourable Court deems just;
- m) aggravated and punitive damages in the amount of \$100,000,000 or in such other amount as this Honourable Court deems just;
- n) an order directing a reference or giving such other directions as may be necessary to determine issues not determined at the trial of the common issues;
- o) prejudgment and post judgment interest pursuant to sections 128 and 129 of the CJA;
- p) the costs of this action on a substantial indemnity basis, together with all applicable taxes thereon;
- q) the costs of notice and of administering the plan of distribution of the recovery in this action, plus applicable taxes; and
- r) such further and other relief as this Honourable Court deems just.

#### NATURE OF THE ACTION

- 3. This action relates to the pain, suffering and losses suffered by
  and other Class Members and Family Class Members as a
  result of the Defendants' negligent development, research, design, manufacturing, testing,
  marketing, promotion, distribution and sale of aripiprazole under the brand names Abilify and
  Abilify Maintena in Canada.
- 4. Abilify is an atypical antipsychotic medication approved by Health Canada on July 3, 2009. Abilify was discovered by and is a registered trademark of Otsuka Pharma. The trademark for Abilify is currently used under licence by BMS Canada. Abilify is indicated for the following uses in Canada:
  - a) **Schizophrenia:** Abilify is indicated for the treatment of Schizophrenia and related psychotic disorders in adults and adolescents of 15 to 17 years of age;
  - b) Bipolar I Disorder: Abilify is indicated for the treatment of manic or mixed episodes in Bipolar I Disorder in adults. It may be used as acute monotherapy or co-therapy with lithium or divalproex sodium when there is an insufficient acute response to these agents alone. Abilify is also indicated as monotherapy for the acute treatment of manic or mixed episodes in Bipolar I Disorder in adolescents of 13 to 17 years of age; and
  - c) Adjunctive Treatment of Major Depressive Disorder (MDD): Abilify is indicated for use as an adjunct to antidepressants for the treatment of MDD in adult patients who have had an inadequate response to prior antidepressant treatments during the current episode;

- 5. Abilify is available in six <u>dosages strengths</u>, containing respectively 2 mg, 5 mg, 10 mg, 20 mg, and 30 mg of aripiprazole. The recommended beginning and target dosage for Abilify is 10 or 15 mg per day for adults with Schizophrenia, and 15 mg per day for adults with Bipolar I Disorder. The recommended target dosage for adolescents with Schizophrenia and Bipolar I Disorder is 10 mg per day. The recommended starting dosage for Abilify as adjunctive treatment for MDD for patients already taking an antidepressant is 2 mg to 5 mg per day, and Abilify was found to be effective in this capacity at dosage levels of up to 15 mg per day.
- 6. Abilify Maintena is a prolonged release injectable suspension of aripiprazole indicated for the treatment of Schizophrenia in adults, and as maintenance therapy for Bipolar I Disorder. It was approved by Health Canada on February 6, 2014. It is administered monthly by intra-muscular injection and is available in four strengths: a 300 mg vial, a 400 mg vial, a 300 mg dual chamber syringe, and a 400 mg dual chamber syringe.
- 7. Hundreds of thousands of individuals have been prescribed Abilify and Abilify Maintena in Canada since the approval of these drugs by Health Canada in July 2009 and February 2014, respectively.
- 8. At all times during the Class Period, it was well established in the scientific literature that dopamine agonists with similar effects on brain chemistry as Abilify and Abilify Maintena have a tendency to cause, contribute to the development of, or exacerbate Impulse-Control Behaviours and/or Compulsive Behaviours.
- 9. Further, at all times during the Class Period the Canadian product monograph for Abilify contained no warnings or precautions, or contained inadequate warnings and precautions, relating

to the increased risk of Compulsive Behaviours in patients who use this drug for indicated purposes.

- 10. When Abilify Maintena was approved for use in Canada in early 2014, the product monograph listed hypersexuality as a psychiatric disorder under the "Less Common Clinical Trial Adverse Drug Reactions <2%". However, it provided no warning regarding the risk of developing hypersexuality or other Compulsive Behaviours associated with the use of Abilify Maintena. Further, the product monograph for Abilify continued to make no mention at all of the increased risk of developing Compulsive Behaviours, including hypersexuality, despite the inclusion of that disorder in the product monograph for Abilify Maintena.
- 11. On November 2, 2015, Health Canada issued a Summary Safety Review (the "Safety Review"), concluding that there is a link between the use of Abilify and Abilify Maintena and an increased risk of certain Impulse-Control Behaviours, namely pathological gambling and hypersexuality. The Safety Review was conducted in response to product labelling revisions in Europe, which indicated that there is a clear connection between the use of aripiprazole and an increased risk of developing pathological gambling and hypersexuality.
- 12. Health Canada's review of scientific and medical literature also confirmed that in the majority of reported cases of pathological gambling and hypersexuality, the compulsive behaviour resolved completely or improved when the treatment was stopped or the dosage was reduced.
- 13. As a result of these findings, the Canadian product monographs for Abilify and Abilify Maintena were revised to include <u>certain</u> warnings about the increased risk of pathological

gambling and, in the case of Abilify, the increased risk of hypersexuality, associated with the use of the drugs.

- 14. On May 3, 2016, six months following the Health Canada information update, the FDA issued a comprehensive warning confirming the association between the use of Abilify and Abilify Maintena and the increased risk of developing Compulsive Behaviours. The FDA warning advised that the use of Abilify and Abilify Maintena is associated with a myriad of compulsive behaviours, including but not limited to pathological gambling, compulsive eating, shopping, and sexual activity, which can affect anyone who is taking the drug. These Compulsive Behaviours were reported to have stopped when the drugs were discontinued or the prescribed dosages were reduced.
- 15. On December 13, 2016 the Canadian Abilify Maintena product monograph was updated to provide more detailed warnings of the propensity of aripiprazole to cause Compulsive Behaviours, such as pathological gambling and hypersexuality. Approximately two months later on February 23, 2017 the Canadian Abilify product monograph was also updated to contain parallel warnings.
- 16. The revised product monographs for Abilify and Abilify Maintena further caution that patients with a prior history of gambling disorder may be at an increased risk of gambling while on these drugs, and should be monitored carefully.
- 17. The Plaintiffs allege, on their own behalf and on behalf of the Class Members, that Abilify and Abilify Maintena are inherently dangerous in that they cause or materially increase the risk of developing Compulsive Behaviours. The Plaintiffs allege that the Defendants were negligent in the development, research, design, testing, manufacturing, promotion, marketing, distribution and

sale of Abilify and Abilify Maintena in Canada, in that they failed to conduct adequate pre- and post-marketing research and testing relating to the association between aripiprazole and Impulse Control Disorders and Compulsive Behaviours.

- 18. The Plaintiffs further allege that the Defendants knew or ought to have known that, when used as indicated, Abilify and Abilify Maintena can cause serious and dangerous side effects, including but not limited to serious Compulsive Behaviours, which can and have resulted in significant harm and losses to the Class Members. However, despite their significant collective resources, and their knowledge of the specific risks and dangers associated with the use of Abilify and Abilify Maintena, the Defendants failed to provide any or any adequate warnings to Mathew the Plaintiffs and other Class Members.
- 19. At all times during the Class Period, the product monographs for Abilify and Abilify Maintena contained insufficient warnings and precautions, as they failed to warn, or adequately warn, the Class Members of the increased risk of developing Compulsive Behaviours associated with the use of the drugs.
- 20. Even after warnings about compulsive gambling and hypersexuality were added to the product monographs for Abilify and Abilify Maintena, in June and September 2015, respectively, these warnings remained inadequate and incomplete, as they were underinclusive and failed to warn the Plaintiff and other Class Members of the risk factors and the full breadth of Compulsive Behaviours and harms associated with the use of Abilify and Abilify Maintena.
- 21. Further, the Plaintiffs allege that the Defendants wrongfully, unlawfully, maliciously and lacking *bona fides*, conspired and agreed together, one with the other, to conceal the risk of

Compulsive Behaviours associated with the use of Abilify and Abilify Maintena from the <u>Plaintiffs</u> and <u>Matthew and</u> other Class Members.

22. As a result of the Defendants' unlawful conduct as described herein, the Plaintiffs and other members of the Classes have suffered, and will continue to suffer, significant harm and losses, including financial, emotional, psychological and other damages, for which the Defendants are liable.

# THE PARTIES

i)	The Plaintiffs				

## b) The Defendants

- 83. BMS is a corporation incorporated in the state of Delaware, with its head office located in New York City. BMS is listed on the New York Stock Exchange under the BMY symbol (NYSE:BMY). BMS operates with six facilities in the state of New Jersey.
- 84. BMS is engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of pharmaceuticals. It uses a global research, development and supply chain organization responsible for the development and delivery of products to the market. Its products are distributed and sold through regional organizations that serve the United States, Europe, Latin America, Middle East, Africa, Japan, Asia Pacific and Canada. BMS has also collaborated with Otsuka to develop and commercialize Abilify.
- 85. BMS Canada is a corporation incorporated under the *CBCA*, with its registered head office in Halifax, Nova Scotia. BMS Canada is an indirect wholly owned subsidiary of BMS and maintains a principal place of business in Toronto, Ontario. BMS Canada holds the patent for Abilify for purposes of the Patented Medicine Prices Review Board (PMPRB) in North America, including Canada.

- 86. Otsuka Pharma is a Japanese corporation, with its head office located in Tokyo, Japan. Otsuka Pharma is the owner of the trademark Abilify. Canadian Patents No. 2,458,929 and 2,445,276 pertaining to Abilify were issued to Otsuka Pharma and BMS on September 8, 2009 and October 13, 2009, respectively.
- 87. On September 21, 1999, Otsuka Pharma entered into a worldwide commercialization and collaboration agreement (the "Agreement") with BMS to co-develop and co-promote Abilify. Under the Agreement, Otsuka Pharma retained the right to commercialize Abilify in the U.S. and other "co-promotion countries" in the EU, as well as in Japan, China, North Korea, South Korea, Philippines, Thailand, Indonesia, Pakistan and Egypt, and granted BMS an exclusive license to commercialize Abilify in the rest of the world, including Canada.
- 88. Pursuant to the terms of the Agreement, BMS is the principal for third-party product sales in several countries, including Canada, where it is the exclusive distributor for or has an exclusive right to sell Abilify. BMS recognizes 100 percent of the net sales of Abilify in Canada.
- 89. At all times during the Class Period, the Agreement was in full force and effect in Canada.
- 90. OAI is a U.S. holding company that is wholly owned by Otsuka Pharma. OAPI, OPDC, and OMML are subsidiaries of OAI.
- 91. OAPI is a corporation incorporated in Delaware. Its corporate headquarters are located in Rockville, Maryland. OAPI is part of the Otsuka Group, which oversees all pharmaceutical and medical device related commercial activities in North America, including Canada.

- 92. OPDC is a corporation with headquarters located in Princeton, New Jersey. OPDC is part of the Otsuka Group responsible for the research and clinical development of healthcare products. As a global development centre for the pharmaceutical products of Otsuka, including Abilify in Canada, OPDC conducts clinical development covering a broad range of disorders in areas including the central nervous system, cardiovascular system, oncology, ophthalmology and infectious diseases.
- 93. OMML is a corporation with headquarters located in Rockville, Maryland. OMML is a research centre that conducts basic and applied research to support global clinical studies. OMML engages in drug discovery, including the discovery of Abilify, in conjunction with Otsuka Pharma.
- 94. Otsuka Pharma and OAI and its subsidiaries, OAPI, OPDC, and OMML, were responsible for the development and testing of Abilify. The July 2009 Health Canada approval for Abilify was based largely on the testing conducted by Otsuka Pharma, OAI and its subsidiaries.
- 95. Otsuka Canada is a corporation incorporated under the *CBCA*, with its head office located in Montreal, Quebec. Otsuka Canada specializes in commercializing Otsuka medical products in Canada. Otsuka Canada imports and markets Abilify and Abilify Maintena throughout Canada. Otsuka Canada also books all sales of Abilify Maintena in Canada.
- 96. At all material times, Otsuka Pharma, OAI, OAPI, OPDC, OMML, and Otsuka Canada have operated in concert, as part of a single operation known as the Otsuka Group, with regard to the development, research, distribution, manufacturing, and/or marketing of Abilify and Abilify Maintena in Canada. The Otsuka Group includes over 160 companies worldwide. Operations in North America account for nearly 40 percent of the Otsuka Group's consolidated sales.

- 97. H. Lundbeck A/S is a Danish corporation with its headquarters located in Copenhagen. H. Lundbeck A/S is a pharmaceutical company that specializes in the research and development, marketing, production and sale of drugs treating disorders of the central nervous system.
- 98. Lundbeck is a corporation incorporated under the *CBCA*, with its head office located in Montreal, Quebec. Lundbeck is a wholly owned subsidiary of H. Lundbeck A/S.
- 99. Lundbeck has operated in concert with Otsuka Canada and the other Defendants to market and promote Abilify Maintena in Canada. In November 2011, H. Lundbeck A/S entered into a development and commercialization agreement with Otsuka Pharma, which granted Lundbeck codevelopment and co-commercialisation rights for Abilify Maintena. Pursuant to this agreement, Lundbeck and Otsuka Pharma each obtain 50 percent of the net sales of Abilify Maintena in Canada, and sales efforts and costs are shared between the two companies in the same ratio.
- 100. The Defendants develop, manufacture, market, and distribute Abilify and Abilify Maintena in Canada and the United States.

#### MATERIAL FACTS

## a) The Drug

#### i) Pharmacology

101. Abilify is indicated for the treatment of Schizophrenia, Bipolar I Disorder, and MDD. Abilify Maintena is indicated for the treatment of Schizophrenia and, since November 1, 2017, as maintenance therapy for Bipolar I Disorder. Both Abilify and Abilify Maintena are trade names for aripiprazole, an atypical antipsychotic agent.

- 102. Aripiprazole's exact mechanism of action is unknown. Aripiprazole attaches to several different receptors on the surface of neurons in the brain and disrupts the transmission of neurochemical signals between brain cells, thereby disrupting the ability of neurons to communicate with each other.
- 103. Aripiprazole's design was based on the dopamine hypothesis. One of the neurochemical signals Abilify affects is dopamine. Dopamine is a neurotransmitter that helps control the brain's reward and pleasure centres. The dopamine hypothesis predicts that an excess of dopamine in the reward pathways of the brain causes delusions, hallucinations and disorganized thoughts. The reward pathways are brain regions involved in cognitive control, motivation and emotional response. Dopamine inactivity in the reward pathways and the prefrontal cortex, an area implicated in planning complex cognitive behaviour and moderating social behaviour, can cause or contribute to impairment in linguistic ability, an inability to experience pleasure, and autism.
- 104. The imbalance of dopamine activity in relation to Compulsive Behaviours has been thoroughly investigated in the scientific literature, with strong evidence supporting its contribution to long-term Impulse-Control Disorders.

#### ii) Development, Testing, and Approval of Abilify

105. Abilify was discovered by Otsuka Pharma in 1988 and developed by Otsuka Pharma until November 2002, when it was approved in the U.S. for the treatment of Schizophrenia. Abilify was subsequently approved in Japan in January 2006 as a treatment for Schizophrenia.

- 106. In June 2003, OPDC (known at the time as Otsuka Maryland Research Institute) submitted a Supplemental New Drug Application to the FDA for the approval of Abilify as a treatment for Bipolar I Disorder. This application was approved on September 29, 2004.
- 107. On November 16, 2007, Abilify was approved by the FDA as an adjunctive treatment for MDD, to be prescribed in conjunction with an antidepressant.
- 108. On February 22, 2008, BMS Canada submitted a New Drug Submission to Health Canada, seeking authorization to distribute, market and sell Abilify in Canada. On July 9, 2009, Health Canada granted a Notice of Compliance to BMS Canada, approving Abilify as a treatment for Schizophrenia and Bipolar I Disorder.
- 109. Abilify was approved in Canada largely on the basis of the information included in the NDA submitted for the purpose of obtaining U.S. FDA approval. No new studies were conducted in order to obtain the Canadian Notice of Compliance.
- 110. Abilify was first marketed in Canada in September 2009.
- 111. In June 2013, Health Canada approved the use of Abilify as an adjunctive therapy, alongside an antidepressant, in treating MDD.
- 112. In contrast, in Europe, Abilify is not indicated for the treatment of depression. The European Medicines Agency denied the indication of Abilify as an adjunctive treatment for MDD due to concerns regarding the effectiveness of the drug in treating depression.

113. In February 2014, Health Canada approved the sale of Abilify Maintena. Abilify Maintena was first marketed in Canada in May 2014, and is indicated only for the treatment of Schizophrenia.

## iii) Marketing of Abilify and Abilify Maintena

- Abilify Maintena to users and prescribers in Canada despite their knowledge of the risk of Compulsive Behaviours associated with the use of dopamine agonists and, in particular, Abilify and Abilify Maintena. The Defendants have heavily promoted Abilify as a desirable option for the treatment of Schizophrenia, Bipolar I Disorder, and MDD, stating that it is more effective and safer than other alternatives available in Canada for the treatment of these disorders.
- 115. To promote widespread use of Abilify, the Defendants engaged in intensive marketing in Canada and the United States. This marketing campaign sought to, and did in fact create the impression and belief in the Plaintiffs and other Class Members that Abilify was safe for use and had fewer side effects and adverse reactions than other medications used to treat Schizophrenia, Bipolar I Disorder, and MDD.
- 116. According to the November 2, 2015 Safety Review by Health Canada, the total annual number of prescriptions of Abilify in Canada is estimated to have increased from 3000 in 2010 to over 1 million in 2013.
- 117. In 2013 Abilify was the 5th best-selling drug in the world. BMS marketed and promoted Abilify as its "2013 largest-selling product" in the U.S., reporting worldwide revenue of USD\$2.02 billion from the sale of Abilify.

- 118. In 2014, global sales of Abilify totalled over USD\$6.4 billion.
- 119. In 2015, H. Lundbeck A/S saw global revenue of approximately CAD\$669 million from the sale of Abilify Maintena.
- 120. The product warnings in effect in Canada at all times during the Class Period, including the consumer information and the prescribing information provided to physicians and pharmacists, were wholly inadequate to alert the Class Members of the serious adverse effects associated with the use of Abilify and Abilify Maintena, including the risk of Compulsive Behaviours.
- 121. In particular, the Defendants failed to provide any or any adequate warnings about the severity, frequency and nature of these adverse side effects, and failed to ensure that adequate testing and studies were conducted to assess the potential link between the use of Abilify and Abilify Maintena and the onset or exacerbation of Compulsive Behaviours.
- 122. Even after the Canadian product monographs for Abilify and Abilify Maintena were revised on June 22, 2015 and September 15, 2015, respectively, the revised warnings remained incomplete and inadequate as they advised only of an increased risk of pathological gambling and hypersexuality in the case of Abilify, and an increased risk of an urge to gamble in the case of Abilify Maintena. Both product monographs continue to omit any reference to the risk of other compulsive behaviours, including binge-eating and compulsive shopping.

## b) The Defendants' Knowledge of the Risks Associated with Abilify

- 123. The use of dopamine agonists has long been associated with <u>Impulse-Control Disorders</u>
  <a href="mailto:and-control">and-control Disorders</a>
  and Compulsive Behaviours. Prescribed usage of Abilify and Abilify Maintena, can result in harmful Impulse-Control and/or Compulsive Behaviours, including but not limited to:
  - a) uncontrollable compulsive gambling, which can occur even in patients with no prior history of gambling;
  - b) hypersexuality, even in patients who had little to no sex drive prior to using Abilify;
  - c) compulsive shopping and/or spending; and
  - d) compulsive binge-eating.
- 124. Discontinuation of Abilify often leads to near-immediate cessation of the compulsive behaviour.
- 125. Since as early as the year 2000, scientists have observed Compulsive Behaviours and Impulse-Control Behaviours associated with the use of dopamine agonists. In 2007, several studies were published linking the use of dopamine agonists, generally, and Abilify, specifically, to obsessive or Compulsive Behaviours.
- 126. For instance, Mirapex, known generically as pramipexole dihydrochloride, is also a dopamine agonist prescribed for the treatment of Parkinson's disease. A 2008 study presented at the International Congress of Parkinson's Disease and Movement Disorders conference in Chicago revealed that more than 13 percent of the 3,090 Parkinson's patients studied experienced compulsive behaviour, including compulsive gambling, shopping, hypersexuality or binge-eating.

The study found that patients who were taking Mirapex were two to three times more likely to develop one of these impulse-control disorders.

- 127. Since 2007, a rapidly growing body of scientific evidence has also demonstrated a causal link between the use of Abilify and Compulsive Behaviours.
- 128. A 2010 case study by Gavaudan and Magalon reported "a causal association" between the use of aripiprazole and pathological gambling in schizophrenic patients who had previously been treated with other antipsychotic drugs. The study revealed that the patients developed pathological gambling "a short time after starting aripiprazole" and that pathological gambling "rapidly resolved" shortly after discontinuation of aripiprazole.
- 129. In September 2011, Otsuka Pharma submitted its 6-Month Periodic Safety Update Report (the "Report") to the European Medicines Agency. The Report acknowledged seven serious cases of pathological gambling, three of which were subjects of scientific studies published in medical literature, and another sixteen cases of pathological gambling reported in the BMS safety database. The Report concluded that "a causal role of aripiprazole could not be excluded", and that "aripiprazole was suggested by the temporal relationship."
- shortly after first began to use Abilify in December 2011. However, no warning was communicated to them him-or to other members of the Classes regarding the risk of developing Compulsive Behaviours.
- 131. On October 19, 2012, the European Medicines Agency required that Otsuka warn patients and the medical community in Europe that the use of Abilify is associated with an increased risk

of pathological gambling. Specifically, the European Medicines Agency required that the Summary of Product Characteristics for Abilify contain the following warning under "Special Warnings and Precautions For Use":

Pathological gambling

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

132. The European Summary of Product Characteristics for Abilify contained additional information regarding other reported adverse reactions to the drug. The section entitled "Undesirable effects" listed the following possible side effects:

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

- 133. Despite these warnings and advisories in Europe for the same drug which was placed in the Canadian stream of commerce and which was marketed and sold to Canadians, the Canadian product monograph for Abilify made no mention of, let alone provide warnings about, the risk of developing Compulsive Behaviours. Further, the Canadian product monograph made no mention at all of the words "gambling", "compulsive", "obsessive", or "impulse control".
- 134. On June 22, 2015 and September 15, 2015, respectively, the Canadian product monographs for Abilify and Abilify Maintena were finally modified to advise of the following compulsive behaviours associated with the use of the drugs:

#### Pathological Gambling

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

#### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

. . .

The following other side effects may also happen in some people who take ABILIFY:

. . .

- hypersexuality (uncontrollable and/or inappropriate sexual behaviour of severity or duration that causes distress).
- an urge to gamble.
- 135. These warnings, however, were incomplete, inadequate, untimely and inconsistent with the state of science at all relevant times and failed to meet the applicable standard of care.
- 136. On November 2, 2015, Health Canada issued an advisory alert entitled "Safety information for antipsychotic drug Abilify and risk of certain impulse-control behaviours," notifying the public of the recent Canadian product monograph revisions. The alert states:

Labels for the prescription antipsychotic drugs Abilify and Abilify Maintena (aripiprazole) have been updated to advise of an increased risk of impulsive behaviours of pathological gambling and hypersexuality.

Abilify, a tablet taken by mouth, is authorized to treat a certain type of bipolar disorder (bipolar 1, a serious manic-depressive illness involving extreme manic or mixed episodes) in adults and adolescents aged 13 years and older. It is also authorized to treat Schizophrenia and related severe psychotic disorders in patients aged 15 years and older, and Major Depressive Disorder in adults when used in combination with other drugs. Abilify Maintena is an injectable drug administered by health professionals and is used to treat Schizophrenia in adults.

The Canadian Product Monograph revisions are the result of a Health Canada safety review that found an increased risk of two types of impulsive behaviours with the use of these drugs: pathological (uncontrollable) gambling, and

hypersexuality (uncontrollable and/or inappropriate sexual thoughts, urges or behaviours that are so severe or last so long that they cause distress).

The review identified 18 international cases of pathological gambling and six international cases of hypersexuality in the published scientific literature In most cases, the behaviours ceased or improved when treatment was stopped or when the dose was reduced, suggesting a direct link between the drug and the side effect. The reports involved male and female patients ranging from 19 to 64 years old. Health Canada also received five Canadian reports of pathological gambling and/or hypersexuality, but these contained limited information and therefore no conclusions could be made regarding what role, if any, the drugs may have played.

137. On February 23, 2017 and December 13, 2016 the warnings section of the Abilify and Abilify Maintena product monographs were updated again to provide more detailed information on Compulsive Behaviours associated with the drug:

#### Pathological Gambling and Other Impulse-Control Disorders

Post-marketing reports of pathological gambling have been reported in patients treated with aripiprazole. These reports suggest that patients can experience increased urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. With regards to pathological gambling, patients with a prior history of gambling disorder may be at increased risk and should be monitored carefully. Other urges, reported very rarely, include: increased sexual urges, compulsive spending, binge or compulsive eating, and other impulsive and compulsive behaviors. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, compulsive spending, binge or compulsive eating, or other urges while being treated with aripiprazole. It should be noted that impulse-control symptoms can be associated with the underlying disorder; however, in some cases, although not all, urges were reported to have stopped when the dose was reduced or the medication was discontinued. Although impulse-control disorders have been reported very rarely, impulse-control disorders may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole.

138. At all material times, the Defendants knew or ought to have known that Abilify and Abilify Maintena increases the risk of pathological gambling and other Compulsive Behaviours. They

nonetheless failed to warn, advise, educate, or otherwise inform Canadian Abilify and Abilify users or prescribers of such risks.

## c) The Defendants Operated as a Single Group Enterprise in Relation to Abilify

- 139. At all material times, Otsuka and BMS, including BMS Canada, shared the common purpose of developing, manufacturing, distributing, marketing and selling Abilify for profit in Canada and worldwide. In this respect, they operated as a single group enterprise in that they:
  - a) entered into the Agreement to co-develop and co-promote Abilify;
  - b) actively participated in joint executive governance and operating committees with respect to Abilify;
  - mutually provided funding and services including, *inter alia*, manufacturing,
     customer management, distribution and pharmacovigilance, for the benefit of their alliance;
  - d) collaborated to complete the clinical studies of Abilify for Schizophrenia;
  - e) copied each other with correspondence in relation to Abilify's regulatory approval, marketing and sale, and both met and conferred frequently to discuss and advance the promotion and sale of Abilify;
  - f) were aware of the harm being done to Class Members by Abilify, and participated in, acquiesced in and approved the decision to continue promoting, marketing and selling Abilify despite their knowledge of the risk of Compulsive Behaviours associated with the use of drug;

- g) collectively decided not to warn the Plaintiffs Matthew and other Class

  Members of the increased risk of Compulsive Behaviours associated with the

  use of Abilify; and
- h) owed a duty to each other and to each Class Member and Family Class Member.
- 140. Further, in relation to Abilify Maintena, at all material times, Otsuka and Lundbeck shared the common purpose of developing, manufacturing, distributing, marketing and selling Abilify Maintena for profit in Canada and worldwide. In this respect, they operated as a single group enterprise in that they:
  - a) entered into an agreement to develop and commercialize Abilify Maintena;
  - b) equally shared in the net sales of Abilify Maintena in Canada;
  - c) mutually provided funding and services for the benefit of their strategic alliance;
  - d) shared sales efforts and costs in relation to Abilify Maintena;
  - e) copied each other with correspondence in relation to Abilify Maintena's regulatory approval, marketing and sale, and both met and conferred frequently to discuss and advance the promotion and sale of Abilify Maintena;
  - f) were aware of the harm being done to Class Members by Abilify Maintena, and they participated in, acquiesced in and approved the decision to continue promoting, marketing and selling Abilify Maintena despite their knowledge of the risk of Compulsive Behaviours, including compulsive gambling, associated with the use of the drug;

- g) collectively decided not to warn the Class Members of the increased risk of Compulsive Behaviours associated with the use of Abilify Maintena; and
- h) owed a duty to each other and to each Class Member and Family Class Member.
- 141. As described herein, the Defendants' operations were so intertwined that they operated as a single group enterprise or economic unit with respect to the development, manufacturing, marketing and sale of Abilify and Abilify Maintena, respectively.

#### **CAUSES OF ACTION**

## a) Negligence

- 142. At all material times, the Defendants owed a duty of care to the Plaintiffs and Class Members to design, manufacture, market and distribute a safe product and to provide timely and adequate warnings of any health or safety risks associated with the use of these drugs.
- 143. At all material times, the Defendants knew or ought to have known that the use of dopamine agonists, generally, and Abilify and Abilify Maintena, specifically, carries an increased risk of developing Compulsive Behaviours.
- 144. Yet, despite their significant collective resources and the existence of a large body of scientific evidence highlighting the tendency of dopamine agonists generally, and aripiprazole specifically, to cause or materially increase the risk of developing Compulsive Behaviours, the Defendants failed to conduct any or any adequate pre- and/or post-market testing and research to confirm the safety of Abilify and Abilify Maintena. Instead, they continued to actively market these drugs as safe and effective treatments for Schizophrenia and, in the case of Abilify, for Bipolar I Disorder, and MDD in Canada.

- 145. Further, despite their knowledge that Abilify can cause or materially increase the risk of developing Compulsive Behaviours, the Defendants failed to provide any or any adequate warning to the Plaintiffs and other Class Members about the risk, breadth, and severity of the Impulse-Control and/or Compulsive Behaviours to which they could be exposed while using Abilify and Abilify Maintena.
- The Abilify and Abilify Maintena product monographs in use at all relevant times did not provide the Plaintiffs and Class Members with any or any adequate warnings about the increased risk of developing Compulsive Behaviours. The information contained in the product monographs was and remains insufficient for many reasons, including but not limited to the following:
  - a) The product monograph for Abilify failed to warn of the increased risk of Impulse-Control and/or Compulsive Behaviours, including compulsive gambling, hypersexuality, binge-eating, and compulsive shopping;
  - b) The product monograph for Abilify Maintena failed to warn of the increased risk of Impulse-Control and/or Compulsive Behaviours other than hypersexuality, such as compulsive gambling, binge-eating, and compulsive shopping;
  - c) The revised product monographs for Abilify and Abilify Maintena failed to reference the full range of Impulse-Control and/or Compulsive Behaviours associated with the use of Abilify; and
  - d) The product monographs for Abilify and Abilify Maintena, including the revised product monographs, failed to disclose the severity of such adverse effects.

- 147. In manufacturing, marketing and distributing Abilify in Canada as described herein, the Defendants breached their duty of care to the Plaintiffs and other members of the Class. Specifically, the Defendants:
  - a) failed to ensure that Abilify and Abilify Maintena were safe for use by Class
     Members, fit for their intended purpose and of merchantable quality;
  - failed to adequately test Abilify and Abilify Maintena in a manner that would fully disclose the various side effects and the magnitude of the risks associated with their use;
  - c) failed to conduct any or any adequate follow-up studies on the efficacy and safety of Abilify and Abilify Maintena;
  - d) failed to provide the Plaintiffs other Class Members and prescribing physicians with any or any adequate warning, in the product monographs or elsewhere, of the serious risks of developing Compulsive Behaviours while using Abilify and Abilify Maintena;
  - e) failed to investigate, research and warn the Plaintiffs, other Class Members, and physicians, pharmacists and others of the propensity of Abilify and Abilify Maintena to cause or materially increase the risk of developing Compulsive Behaviours, when they knew or ought to have known from existing scientific evidence relating to dopamine receptors and dopamine agonists that these drugs may cause or contribute to Compulsive Behaviours;

- f) failed to provide any or any adequate updated and current information to the Plaintiffs, other Class Members and their physicians respecting the risks and efficacy of Abilify as such information became available;
- g) failed to warn the Plaintiffs, other Class Members and their physicians about the need for regular monitoring to ensure that any Compulsive Behaviours were detected and addressed as early as possible;
- failed to establish any adequate procedures to educate sales representatives and prescribing physicians about the correct usage of Abilify and Abilify Maintena and their associated risks;
- i) falsely stated and/or implied that Abilify and Abilify Maintena were safe and fit for their intended purpose(s) when they knew or ought to have known that these representations were false;
- j) misstated the state of research, opinion and medical literature pertaining to the purported benefits of Abilify and Abilify Maintena and their associated risks;
- k) failed to cease the manufacture and distribution of Abilify and Abilify Maintena
   when they knew or ought to have known that these drugs have caused or could
   cause significant harm;
- disregarded reports of symptoms of Compulsive Behaviours among patients who used Abilify and Abilify Maintena;
- m) failed to monitor and to initiate a timely review, evaluation and investigation of reports of Compulsive Behaviours, associated with the use of Abilify and Abilify Maintena in Canada and around the world;

- n) after receiving actual or constructive notice of the side effects experienced from the use of Abilify and Abilify Maintena, failed to accurately and promptly disclose this information to Health Canada, cause adequate warnings to be issued, appropriately modify the product monographs, withdraw or recall the drugs, publicize the problems and otherwise act properly and in a timely manner to alert the Plaintiffs and other Class Members of all the known risks associated with the use of Abilify and Abilify Maintena, even after such warnings were issued in Europe;
- aggressively marketed Abilify and Abilify Maintena as safe and effective when they knew or ought to have known of the increased risk of developing Compulsive Behaviours; and
- p) encouraged their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the increased risk of developing Compulsive Behaviours associated with the use of Abilify and Abilify Maintena.
- 148. The Defendants' negligence involved both lawful and unlawful means with the predominant purpose of causing Class Members to acquire and use Abilify and Abilify Maintena when they knew or should have known that such use would cause harm to the Class Members and the Family Class Members.
- 149. The Defendants' negligence and failure to warn were particularly egregious as Abilify and Abilify Maintena are not addictive drugs and those who experience Compulsive Behaviours as a result of using these drugs are able to discontinue their use with little difficulty. Yet, motivated by

financial gain, including, *inter alia*, increased sales and profits, the Defendants acted in concert to conceal the risk of Compulsive Behaviours associated with the use of Abilify and Abilify Maintena.

## b) Civil Conspiracy

- 150. At all relevant times, Otsuka and BMS, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking *bona fides*, conspired and agreed together, the one with the other, to, among other things, conceal the risk of Compulsive Behaviours associated with the use of Abilify, and to mislead the Plaintiffs and other Class Members about the health and safety risks associated with the use of the drug.
- 151. Further, at all relevant times, Otsuka and Lundbeck, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking *bona fides*, conspired and agreed together, the one with the other, to, among other things, conceal the risk of Compulsive Behaviours associated with the use of Abilify Maintena and to mislead the Plaintiffs and other Class Members about the health and safety risks associated with the use of the drug.
- 152. The Defendants' conduct as described herein was unlawful and constituted material and misleading information in breach of sections 36 and 52 of the *Competition Act*.
- 153. The Defendants' conduct as described was also unlawful in that the Defendants failed\_to provide adequate and timely warnings for side effects that they knew, or ought to have known, were associated with the intended use of Abilify and Abilify Maintena.

- 154. In conspiring to conceal the risk of Compulsive Behaviours from the Class Members, each of the Defendants was motivated predominantly by the following concerns and motivations:
  - a) to increase or maintain sales volumes of Abilify and Abilify Maintena;
  - b) to increase or maintain revenue;
  - c) to increase or maintain profit;
  - d) to increase or maintain market share;
  - e) to avoid negative publicity and preserve public goodwill;
  - f) to avoid the costs associated with conducting adequate, effective and targeted testing to study the link between the use of Abilify and Abilify Maintena and the risk of developing Compulsive Behaviours; and
  - g) to place corporate revenue and profit above the safety of the Class Members.
- 155. In furtherance of the conspiracy, the Defendants and their employees, servants, and agents, engaged in, *inter alia*, the following acts:
  - a) they set out not to conduct any adequate pre-market testing to confirm the
    existence of a causal relationship between the use of Abilify and Abilify
    Maintena and the onset of Compulsive Behaviours;
  - they set out not to conduct any or any adequate post-market testing to confirm
    the existence of a causal relationship between the use of Abilify and Abilify
    Maintena and the onset of Compulsive Behaviours;

- c) they concealed the results of any pre- and post-marketing <u>testing actually</u> <u>conducted from the public, regulatory authorities, prescribing physicians, and</u> the Class Members;
- d) they disregarded or downplayed the existing body of scientific evidence on the risk of Compulsive Behaviours associated with the use of Abilify and Abilify Maintena;
- e) they knowingly or recklessly represented to the Plaintiffs and other Class Members that Abilify and Abilify Maintena were safe for use when they knew or ought to have known that the use of Abilify is associated with an increased risk of developing Compulsive Behaviours;
- f) they pursued an aggressive campaign in written form through, inter alia, product monographs, and via media communications, including television and internet advertising, to promote the use of Abilify and Abilify Maintena despite their knowledge that the use of these drugs increases the risk of developing Compulsive Behaviours; and
- g) they continued to place and distribute Abilify and Abilify Maintena in the stream of Canadian commerce without issuing any or any adequate warnings or revisions to the product monographs for these drugs.
- 156. The conspiracy was unlawful because the Defendants knowingly or recklessly, directly and indirectly, and in pursuit of their mutual business interests, made representations to the Plaintiffs, other Class Members and the public which were false or misleading in a material respect and which deceived them as to the health and safety risks associated with the use of Abilify and

Abilify Maintena. In making the misrepresentations as described herein, the Defendants breached sections 36 and 52 of the *Competition Act*.

- 157. The conspiracy was also unlawful because the Defendants knowingly or recklessly placed Abilify and Abilify Maintena into the stream of commerce with inadequate warnings about their potential to cause Compulsive Behaviours.
- 158. In the circumstances, the Defendants knew that the conspiracy would, and did, cause the Plaintiffs and other Class Members to suffer losses as described herein.

## **DISCOVERABILITY**

- The Plaintiffs did not, and could not have known, about the material facts giving rise to causes of action in negligent research and testing and civil conspiracy until November 2, 2015.

  The Plaintiffs plead and rely upon the doctrine of discoverability, s. 5(1) of the *Limitations Act* 2002, and equivalent provisions of other provincial and territorial legislation.
- 160. As early as the late 1990s, the manufacturer of Abilify had the duty and the opportunity to conduct appropriate and adequate pre-market research and testing with respect to the increased risk of Compulsive Behaviours associated with the use of partial dopamine agonists.
- 161. The Defendants failed to conduct such testing and research, conducted inadequate premarket testing and research or, in the alternative, concealed the results of their pre-market testing and research from the public and healthcare providers, such that the Plaintiffs did not, and could not have known, about the causal relationship between Abilify / Abilify Maintena and Compulsive Behaviours until the issuance of the Safety Review on November 2, 2015.

- Abilify was approved for marketing in the United States in 2002 and in Canada in July 2009. At all times prior to, and after, the approval of Abilify in Canada, the Defendants failed to conduct adequate post-marketing research and testing into the propensity of Abilify to cause, increase the risk of, or exacerbate Compulsive Behaviours. In the alternative, the Defendants concealed the results of their post-marketing research and testing from the Plaintiffs and the Class Members, such that these facts were not, and could not reasonably have been, known to the Plaintiffs and the Class Members before November 2, 2015.
- 163. As early as the early 2000s, the Defendants knew, or ought to have known, about the large number of spontaneous reports of compulsive gambling and other Compulsive Behaviours by clinicians and individuals taking Abilify and Abilify Maintena, but failed to conduct any or any adequate testing and research, or in the alternative, concealed the results of their testing and research, such that the facts giving rise to claims for negligence and conspiracy were not, and could not reasonably have been, known to the Plaintiffs and the Class Members prior to November 2, 2015.

#### FRAUDULENT CONCEALMENT

- 164. The Plaintiffs plead and rely upon the doctrine of fraudulent concealment with respect to the claims for negligent pre- and post-marketing testing and research and civil conspiracy.
- 165. The Defendants fraudulently concealed from the Plaintiffs and the Class Members that the use of Abilify and Abilify Maintena could cause, materially increase the risk of developing, or exacerbate pre-existing Compulsive Behaviours.

- 166. As manufacturers and distributers of Abilify and Abilify Maintena, the Defendants had a special relationship with the Class Members to provide adequate and timely warnings of the harmful side effects of these medications. Due to their depression, schizophrenia and/or Bipolar I Disorder, the Plaintiffs were particularly vulnerable and relied on the Defendants to provide timely and adequate warnings relating the harmful side effects of Abilify and Abilify Maintena.
- 167. The Defendants' conduct in conspiring to conceal the increased risk of Compulsive Behaviours associated with the use of Abilify and Abilify Maintena, as pleaded herein, was unconscionable as it exposed the Plaintiffs and the Class Members to further psychiatric, emotional, and financial harm.
- 168. By failing to provide adequate and timely warnings to the Class Members with respect to the causal association between Ability/Ability Maintena and Compulsive Behaviours, as pleaded herein, the Defendants concealed material facts pertinent to the Plaintiffs' and the Class Members' rights of action. The Plaintiffs could not have known of the Defendants' wrongful conduct and concealment as pleaded herein until the issuance of the November 2, 2015 Safety Review.
- 169. The doctrine of fraudulent concealment applies to limitation periods governed by the Limitations Act, 2002.

#### **DAMAGES**

170. As a result of the acts and omissions of the Defendants as alleged herein, the Plaintiffs and other Class Members have suffered, and will continue to suffer serious personal injuries, pain and suffering, including but not limited to: damage to or loss of reputation; emotional and psychological harm; expenses relating to medical treatment and other care and treatment for their

Compulsive Behaviours; extensive financial losses and out-of-pocket expenses, including loss of income as a result of their Compulsive Behaviours; and various other loss, injuries, and damages, the amounts and values of which will be particularized prior to trial.

- 171. As a further result of the acts and omissions of the Defendants, Gayle and other Family Class Members have suffered damages and loss, and will continue to suffer damages and loss, including but not limited to: actual expenses reasonably incurred for the benefit and/or due to the behaviour of the Class Members; a reasonable allowance for loss of income or the value of services provided to the Class Members; an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the Class Members; and emotional, mental and psychological damages as a result of the damages, injuries and losses sustained by the Class Members.
- 172. The Plaintiffs' injuries would not have occurred but for the acts and omissions of the Defendants, as described herein.
- 173. The undisclosed risks of Compulsive Behaviours associated with the use of Abilify and Abilify Maintena were in the exclusive knowledge and control of the Defendants and could not have been known to the Plaintiffs and other Class Members.
- 174. The Plaintiffs and other members of the Classes are also entitled to recover as damages or costs, in accordance with the *CPA*, the costs of administering the plan to distribute the recovery of damages recovered in this action.

#### AGGRAVATED AND PUNITIVE DAMAGES

- 175. The Plaintiffs claim punitive and aggravated damages for the reckless and unlawful conduct of the Defendants.
- 176. The Defendants' conduct as described herein was high-handed, reckless, and deliberate, represented a wanton disregard for the lives, health and safety of the Plaintiffs, other Class Members and the Family Class Members, and was motivated by economic incentives, thus warranting an award of punitive and aggravated damages.
- 177. The Defendants' conduct in concealing the risk of Compulsive Behaviours associated with the use of Abilify and Abilify Maintena and their failure to provide adequate, complete and timely warnings to the Plaintiffs and other Class Members exacerbated their injuries and damages, thus entitling them to aggravated damage. The Plaintiffs and other Class Members would not have used, or continued to use, Abilify and Abilify Maintena had they been properly and adequately warned about the increased risk of Compulsive Behaviours associated with the use of the drug.
- 178. Further, the Defendants' failure to provide adequate, complete and timely warning to and other Class Members was high-handed and motivated by malice, thus warranting an award of punitive damages. In particular, the Defendants continued to promote, market, and distribute Abilify and Abilify Maintena in the stream of Canadian commerce despite their knowledge of the serious risk of Compulsive Behaviours associated with the use of dopamine agonists generally, and Abilify and Abilify Maintena, specifically, which, as described herein, was recognized by the scientific community years prior to the latest revisions to the Canadian product monographs.

- The Defendants have further engaged in the unlawful destruction of documents in the face of pending litigation. One of the Otsuka Defendants, OAPI, has destroyed safety related documents created in the years 2002-2006, inclusive. During this time period, Dr. Robert McQuade, Dr. Suresh Mallikaarjun and RA Forbes were engaged in research on aripiprazole. Large amounts of their safety related correspondence, in the form of emails, were destroyed by OAPI. These documents would contain important information regarding the early post-marketing experience with Abilify in the United States which would shed light on the state of knowledge possessed by the Defendants in relation to aripiprazole and Compulsive Behaviours.
- This destruction of emails is contrary to regulatory requirements in place at the time in the United States, as well as reporting and document retention policies in Canada under *Food and Drug Regulations* C.010.020. Notably, the timing of the Defendants' unlawful destruction of documents coincides with litigation in the United States relating to the association between dopamine agonists and compulsive gambling, and the settlement of an American Department of Justice investigation into the Otsuka and BMS Defendants. It also coincides with revisions to the product monographs for dopamine agonists to include warning regarding the increased risk of pathological gambling and other Compulsive Behaviours.
- 181. The Defendants' reckless and wanton disregard for the health and safety of Canadian users of Abilify and Abilify Maintena is not an isolated incident. It forms part of a pattern of withholding critical information from, and providing inadequate warnings to, prescribing physicians and patients relating to the association between partial dopamine agonist antipsychotics and an increased risk of Impulse Control Disorders and Compulsive Behaviours.

- 182. For example, the Otsuka and Lundbeck Defendants have developed another antipsychotic drug with dopamine agonist properties, brexpiprazole sold under the tradename Rexulti, with a similar mechanism of action as Abilify and Abilify Maintena.
- 183. Rexulti received FDA approval on July 10, 2015 for the treatment of schizophrenia and as an adjunctive treatment for MDD.
- 184. Approximately two years later, on February 16, 2017 Health Canada issued a Notice of Compliance for Rexulti, which is currently indicated for the treatment of schizophrenia in Canada and also leads to Compulsive Behaviours in some individuals.
- 185. The initial 2015 American product monograph included no warning related to Compulsive Behaviours. However, in February 2018 the Warnings and Precautions section of the American product monograph was updated to provide a warning regarding Compulsive Behaviours, and specifically acknowledges a causal relationship between Rexulti and Compulsive Behaviours:

#### 5.7 Pathological Gambling and Other Compulsive Behaviors

Post-marketing case reports suggest that patients can experience intense urges, particularly for gambling, and the inability to control these urges while taking REXULTI. Other compulsive urges, reported less frequently, include: sexual urges, shopping, eating or binge eating, and other impulsive or compulsive behaviors. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or intense gambling urges, compulsive sexual urges, compulsive shopping, binge or compulsive eating, or other urges while being treated with REXULTI. In some cases, although not all, urges were reported to have stopped when the dose was reduced or the medication was discontinued. Compulsive behaviors may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urges.

186. The Defendants have not updated the Canadian product monograph warning section, despite having expanded the warning in the U.S. product monograph. The current Canadian

product monograph for Rexulti provides the following inadequate warning in the Health Professional Information section:

### **Impulsive behaviours**

Post-marketing reports of impulse-control disorders including pathological gambling and hypersexuality have been reported in patients treated with another antipsychotic with partial agonist activity at dopamine receptors. Patients with a prior history of impulse-control disorder may be at increased risk and should be monitored carefully.

187. The Patient Information section merely includes, among a 29 item list, the following:

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REXULTI. Talk about any health conditions or problems you may have, including if you:

. . .

have problems with impulse control (i.e. gambling or sex addition).

- 188. This insufficient warning is similar to the initial warning provided with Abilify Maintena when it was approved for use by Health Canada on February 6, 2014.
- 189. The Defendants are aware that Rexulti is essentially identical to Abilify. The development of Rexulti was motivated by commercial gain, not improvements in patient care. A 2017 article authored by two individuals, including Keming Gao, a member of the Otsuka advisory board notes that the development of Rexulti was predominantly a business decision related to the expiry of aripiprazole patent protection.
- 190. The Defendants' failure to provide adequate warnings, particularly to patients suffering from serious mental illnesses, is emblematic of a course of conduct which puts the Defendants' commercial interests over the health and safety of their Canadian consumers. The Defendants have

acted, and continue to act, with a deliberate, wilful, wanton, callous and reckless disregard for the well-being and safety of the Plaintiffs, entitling them to punitive, exemplary and aggravated damages.

#### **LEGISLATION**

191. The Plaintiffs plead and rely upon, *inter alia*, the following statutes and the regulations made thereunder, and their provincial and territorial equivalents (all as amended):

CPA;

Competition Act;

Consumer Protection Act 2002, S.O. 2002, c. 30, Schedule A; FLA;

Food and Drug Act, R.S.C. 1985, c. F-27;

Health Insurance Act, R.S.O. 1990, c. 11. 6;

Limitations Act, 2002, s. 5;

Negligence Act, R.S.O. 1990, c. N.1; and

Sale of Goods Act, R.S.O. 1990, c. S.1.:

#### REAL AND SUBSTANTIAL CONNECTION

- 192. There is a real and substantial connection between the subject matter of this action and the Province of Ontario for the following reasons:
  - a) several of the Defendants carry on business in Ontario;
  - b) the Defendants manufacture, distribute and sell Abilify and Abilify Maintena in Ontario and derive substantial income in Ontario from such sales;

- 58 -

c) Abilify and Abilify Maintena are approved for sale and are widely prescribed

in Ontario; and

d) the Plaintiffs' damages, and those of other Class Members resident in Ontario,

were sustained in Ontario.

**SERVICE EX JURIS** 

193. This statement of claim may be served without court order outside Ontario because the

claim is:

a) in respect of a tort committed in Ontario (rule 17.02(g));

b) in respect of damages sustained in Ontario arising from a tort or breach of

contract however committed (rule 17.02 (h));

c) against a person outside Ontario who is a necessary and proper party to this

proceeding properly brought against another person served in Ontario (rule

17.02(o)); and

d) against a person carrying on business in Ontario (rule 17.02(p)).

PLACE OF TRIAL

194. The Plaintiffs propose that this action be tried in Toronto.

Date: May 30, 2016

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Court File No.: CV-16-553833-00CP

# ONTARIO SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED IN TORONTO

## **AMENDED STATEMENT OF CLAIM**

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# ONTARIO SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED IN TORONTO

## ORDER (Motion for Approval of Settlement and Class Counsel Fees)

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