STATE OF CONNECTICUT

RETURN DATE: DECEMBER 20, 2016

STATE OF CONNECTICUT, *Plaintiff,*	:	SUPERIOR COURT
	:	JUDICIAL DISTRICT OF HARTFORD
v.	:	
	:	AT HARTFORD
BRISTOL-MYERS SQUIBB COMPANY, *Defendant.*	:	

COMPLAINT

COUNT ONE (Violation of the Connecticut Unfair Trade Practices Act)

1. This is an action under the Connecticut Unfair Trade Practices Act ("CUTPA"), Chapter 735 of the General Statutes, for injunctive relief against the defendant for alleged violations of General Statutes § 42-110b(a), which prohibits unfair or deceptive acts or practices, for restitution to consumers, for the Defendant's alleged violations of law, for civil penalties, and for other relief.

The Parties

2. The Plaintiff is the State of Connecticut, represented by George Jepsen, Attorney General, acting at the request of Jonathan A. Harris, Commissioner of Consumer Protection, pursuant to the authority of Chapter 735a of the General Statutes.

3. Defendant Bristol-Myers Squibb Company, ("Defendant" and/or "BMS"), is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, New York 10154.

Background

4. At all relevant times hereto, Defendant BMS transacted business in Connecticut and nationwide by advertising, soliciting, selling, promoting, marketing and distributing prescription drugs, including the atypical antipsychotic prescription drug Abilify, and that business is governed by CUTPA.

5. Abilify is one of several second-generation antipsychotic prescription drugs, commonly referred to as "atypical antipsychotics," that were originally used to treat schizophrenia. Most or all of these drugs have since been approved for a number of mental disorders.

6. Atypical antipsychotics can produce dangerous side effects, including cerebrovascular complications, movement disorders, diabetes, hyperglycemia, weight gain, and other severe conditions.

7. Abilify, the brand name for the prescription drug aripiprazole, was first approved by the Food and Drug Administration ("FDA") for the treatment of schizophrenia in adults in November 2002. Since then, the FDA has approved various formulations of Abilify for several indications, including: for the acute treatment of manic and mixed episodes in Bipolar I Disorder in adults and in pediatric patients aged 10-17, for the treatment of schizophrenia in adolescent patients 13 to 17 years of age, for adjunctive treatment of major depressive disorder in adults, for the treatment of irritability associated with autistic disorder in pediatric pa-

tients aged 6 to 17 years, and for the treatment of Tourette's disorder in pediatric patients aged 6 to 18 years.

Defendant's Course of Conduct

8. BMS began to market Abilify to health care professionals not only for the treatment of schizophrenia in adults in 2002, but also for a number of uses for which it was not approved by the FDA. The promotion of a drug for uses for which it is not approved by the FDA is known as off-label marketing. For example, BMS promoted Abilify off-label for use in children. BMS also promoted Abilify for use in elderly patients with symptoms consistent with dementia and Alzheimer's disease without first establishing the drug's safety and efficacy for those uses and despite the lack of FDA approval for these uses. In fact, in 2006, Abilify received a "black box" warning that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs have an increased risk of death.

9. BMS implicitly misrepresented Abilify's approved uses when BMS promoted and marketed Abilify for uses for which it was not approved.

10. BMS also made material omissions when, among other matters, it failed to disclose the fact that Abilify was not approved for the uses for which it was promoted and marketed.

11. BMS made unsubstantiated claims about Abilify by minimizing and misrepresenting risks of the drug, such as metabolic and weight gain side effects, thereby making false and/or misleading representations about Abilify's risks.

12. BMS overstated the findings of scientific studies, for example, by using results of a randomized controlled trial to demonstrate long term efficacy of Abilify for stabilization and maintenance in bipolar disorder, without disclosing in BMS's marketing messages to doctors the limitations of the study.

13. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses, misrepresented the drug's approved uses which had the capacity or tendency to deceive or mislead health care providers and patients. Pursuant to CUTPA, such misrepresentations constitute unfair or deceptive trade practices that are prohibited General Statutes § 42-110b.

14. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses, made material omissions concerning the drug's approved uses and those omissions deceived or tended to deceive consumers. Pursuant to CUTPA, such material omissions constitute unfair or deceptive trade practices that are prohibited by General Statutes § 42-110b.

15. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses, represented that Abilify had approvals, characteristics, uses, benefits, and qualities that it did not have and, pursuant to CUTPA, such misrepresentations constitute unfair or deceptive trade practices that are prohibited by General Statutes § 42-110b.

16. The Defendant, in the course of minimizing and misrepresenting risks, made false, misleading, or other representations about Abilify's side effects that had the capacity, tendency, or effect of deceiving or misleading consumers. Pursuant to CUTPA, such represen-

tations constitute unfair or deceptive trade practices that are prohibited by General Statutes § 42-110b.

17. The Defendant, in the course of overstating the findings of scientific studies in marketing messages, made false, misleading, or other representations about scientific studies that had the capacity or tendency to deceive or mislead health care providers and patients. Pursuant to CUTPA, such representations constitute unfair or deceptive trade practices that are prohibited by General Statutes § 42-110b.

COUNT TWO (Willfulness)

18. The allegations contained in paragraphs 1-17 are incorporated by reference as if they were set out at length herein.

19. The Defendant has engaged in the acts or practices alleged herein when it knew or should have known that its conduct was unfair or deceptive in violation of CUTPA.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays that the Court enter an Order:

1. Issuing a permanent injunction prohibiting Defendant, its agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive trade practices in the promotion and marketing of pharmaceutical products;

2. Ordering the Defendant to pay the reasonable attorneys' fees and costs of this action, as

provided by General Statutes § 42-110m(a);

3. Ordering the Defendant to pay civil penalties of up to $5,000.00 for each and every willful violation of CUTPA, as provided by General Statutes § 42-110o(b); and

4. Granting such other and further relief as the Court deems equitable and proper, as provided by General Statutes § 42-110m(a).

Dated at Hartford, Connecticut this 8th day of December, 2016.

Respectfully submitted,

PLAINTIFF
STATE OF CONNECTICUT,

GEORGE JEPSEN
ATTORNEY GENERAL

BY: _____

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STATE OF CONNECTICUT

RETURN DATE: DECEMBER 20, 2016

STATE OF CONNECTICUT, *Plaintiff,*	:	SUPERIOR COURT
	:	JUDICIAL DISTRICT OF HARTFORD
v.	:	
	:	AT HARTFORD
BRISTOL-MYERS SQUIBB COMPANY, *Defendant.*	:	

STATEMENT OF AMOUNT IN DEMAND

The Plaintiff states that the amount in demand is greater than $15,000, exclusive of interest and costs.

PLAINTIFF
STATE OF CONNECTICUT,

GEORGE JEPSEN
ATTORNEY GENERAL

BY: _____

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DOCKET NO. HHD-CV-16-6073669S

STATE OF CONNECTICUT, *Plaintiff,*	:	SUPERIOR COURT
	:	JUDICIAL DISTRICT OF HARTFORD
v.	:	
	:	AT HARTFORD
BRISTOL-MYERS SQUIBB COMPANY, *Defendant.*	:	DECEMBER 8, 2016

FINAL JUDGMENT BY STIPULATION

AND NOW, comes the Plaintiff, State of Connecticut (the "State"), by and through the Connecticut Attorney General, George Jepsen, having filed an action pursuant to Connecticut's Unfair Trade Practices Act ("CUTPA"), Chapter 735a of the General Statutes, and the parties having consented to entry of this Final Judgment by Stipulation ("Judgment").

NOW THEREFORE, upon the Judgment of the parties hereto, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:**

PARTIES

1. The State is the plaintiff in this case, acting upon the request of the Connecticut Commissioner of Consumer Protection pursuant to General Statutes Section 42-110m(a).

2. Bristol-Myers Squibb Company ("BMS") is a corporation with its principal executive office located at 345 Park Avenue, New York, New York 10154. At all times relevant hereto, BMS engaged in trade or commerce, within the meaning of General Statutes § 42-110a(4), in Connecticut.

FINDINGS

1. This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.

2. The terms of this Judgment shall be governed by the laws of Connecticut.

3. Entry of this Judgment is in the public interest and reflects a negotiated agreement among the Parties.

4. The Parties have agreed to resolve the issues resulting from the Covered Conduct involving Atypical Antipsychotics by entering into this Judgment.[1]

5. BMS is willing to enter into this Judgment regarding the Covered Conduct solely in order to resolve the State's concerns under the State Consumer Protection Laws as to the matters addressed in this Judgment and thereby avoid unnecessary expense, inconvenience, and uncertainty. Nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing (including allegations of the Complaint), all of which BMS expressly denies. BMS does not admit any violation of law, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by BMS. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. It is the intent of the Parties that this Judgment shall not be binding or admissible in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Judgment. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment.

[1] This agreement is entered into pursuant to and subject to the State Consumer Protection Laws cited in footnote 3.

6. BMS is entering into this Judgment solely for the purpose of settlement of the instant action. This Judgment does not create a waiver or limit BMS's legal rights, remedies, or defenses in any other action by the Signatory Attorney General and does not waive or limit BMS's right to defend itself from, or make argument in, any other matter, claim, or suit, including, but not limited to any investigation or litigation relating to the subject matter or terms of this Judgment. Nothing in this Judgment shall waive, release or otherwise affect any claims, defenses, or positions BMS may have in connection with any investigations, claims, or other matters the State is not releasing hereunder. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

7. In response to legitimate, verified scientific requests from qualified researchers, BMS currently shares clinical trial data from Bristol-Myers Squibb sponsored Phase I – IV interventional trials in patients in accordance with the policies and procedures described on the BMS website.

8. BMS is not responsible for the conduct of Otsuka America Pharmaceutical, Inc. or any of its parents, subsidiaries, or affiliates (hereinafter, "Otsuka") with respect to the marketing or promotion by Otsuka of any Atypical Antipsychotic, including Abilify, up through the Effective Date. The Parties agree that this Judgment does not operate to impute to BMS responsibility for conduct of Otsuka with respect to any Atypical Antipsychotic that is marketed or promoted by Otsuka. This Judgment shall not impose obligations on BMS with regard to functions concerning an Atypical Antipsychotic for which Otsuka, not BMS, has responsibility. Notwithstanding this paragraph, BMS is responsible for claims and representations regarding an Atypical Antipsychotic it creates or disseminates after the Effective Date of this Judgment that are disseminated by a third party or BMS.

9. This Judgment (or any portion thereof) shall in no way prohibit, limit, or restrict BMS from making representations with respect to an Atypical Antipsychotic that are permitted or authorized under Federal law, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), U.S. Food and Drug Administration ("FDA") regulations, or FDA Guidances for Industry, currently issued or as revised, except to the extent BMS agrees to certain conduct or limitations in this Judgment which are more restrictive than what is otherwise permitted or authorized under Federal law, the FDCA, FDA regulations, or FDA Guidances for Industry. Further, the Judgment shall in no way prohibit, limit, or restrict BMS from making representations with respect to an Atypical Antipsychotic that are required or authorized by or consistent with the FDA-approved Labeling or prescribing information for an Atypical Antipsychotic, or by any Investigational New Drug Application for an Atypical Antipsychotic, New Drug Application for an Atypical Antipsychotic, Supplemental New Drug Application for an Atypical Antipsychotic, or Abbreviated New Drug Application for an Atypical Antipsychotic filed with the FDA so long as the representation, taken in its entirety, is not false, misleading or deceptive.

10. Nothing in this Judgment shall require BMS to:

a. Take any action that is prohibited by the FDCA or any regulation promulgated thereunder, or by the FDA; or

b. Fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA.

DEFINITIONS

The following definitions shall be used in construing this Judgment:

1. **"Atypical Antipsychotic"** shall mean all products promoted and/or marketed by BMS that are FDA-approved drug formulations containing aripiprazole.

2. **"BMS"** shall mean Bristol-Myers Squibb Company, including all of its subsidiaries, predecessors, successors and assigns doing business in the United States.

3. **"BMS's Law Department"** shall mean personnel of the BMS Law Department or its designee providing legal advice to BMS.

4. **"BMS Marketing"** shall mean BMS personnel responsible for marketing an Atypical Antipsychotic in the U.S.

5. **"BMS Sales"** shall mean the BMS sales force responsible for U.S. Atypical Antipsychotic sales, including, but not limited to, BMS personnel whose employment responsibilities include working with public or private entities that decide whether to include an Atypical Antipsychotic on a prescription drug formulary or preferred drug list.

6. **"BMS Independent Medical Education Department"** or **"BMS IMED"** shall mean the organization within BMS responsible for oversight of medical education grants, including the acceptance, review, approval, and payment of all medical education grant requests.

7. **"BMS Scientifically Trained Personnel"** shall mean BMS personnel who are highly trained experts with specialized scientific and medical knowledge, usually with an advanced scientific degree (e.g., an MD, PhD, or PharmD), whose roles involve the provision of specialized, medical or scientific information, scientific analysis and/or scientific information to HCPs and includes Medical Science Liaisons, but excludes anyone performing sales, marketing, promotional ride alongs, or other commercial roles.

8. **"Clearly and Conspicuously"** shall mean with respect to a disclosure or information presented that such information meets the requirements of the FDCA, the

requirements of FDA regulations, and the recommended actions in FDA Guidances for Industry, including FDA's "Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion," or as revised.

9. **"Clinically Relevant Information"** shall mean information that reasonably prudent clinicians would consider relevant when making prescribing decisions regarding an Atypical Antipsychotic.

10. **"Clinical Response"** shall mean a non-Promotional, scientific communication to address Unsolicited Requests for medical information.

11. **"Covered Conduct"** shall mean BMS's Promotional and marketing practices, sampling practices, dissemination of information and remuneration to HCPs in the United States in connection with an Atypical Antipsychotic through the Effective Date.

12. **"Effective Date"** shall mean the date on which a copy of this Judgment, duly executed by BMS and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

13. **"FDA Guidances for Industry"** shall mean documents, as currently drafted or as revised, issued by the FDA pursuant to 21 U.S.C. § 371(h) that represent the FDA's current thinking on a topic related to prescription drug advertising, promotion, labeling, and/or communication of scientific information, including but not limited to "Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Use--Recommended Practices," "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescriptions Drugs and Medical Devices," and "Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion."

14. **"Health Care Professional"** or **"HCP"** shall mean any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products.

15. **"Labeling"** shall mean all labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

16. **"Multistate Executive Committee"** shall mean the Attorneys General and their staffs representing Arizona, Colorado, Delaware, District of Columbia, Florida, Kentucky, Maryland, North Carolina, Ohio, and Pennsylvania.

17. **"Multistate Working Group"** shall mean the Attorneys General and their staff representing Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii,[2] Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

18. **"Off-Label"** shall mean a use (including indication, dosage, population, and/or method of administration) not consistent with the use approved by the FDA in the Labeling for an Atypical Antipsychotic at the time information regarding such use was communicated, or at the time the conduct occurred.

19. **"Parties"** shall mean BMS and the Signatory Attorney General.

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[2] Hawaii is represented in this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity purposes, the entire group will be referred to as the "Attorneys General" or individually as "Attorney General" and the designations, as they pertain to Hawaii, refer to the Executive Director of the State of Hawaii's Office of Consumer Protection.

20. **"Promotional," "Promoting,"** or **"Promote"** shall mean representations made to HCPs, patients, consumers, payors and other customers, and other practices intended to increase sales in the United States or that attempt to influence prescribing practices of HCPs in the United States, including direct-to-consumer.

21. **"Promotional Materials"** shall mean any item used to Promote an Atypical Antipsychotic.

22. **"Promotional Media"** shall mean Promotional Materials in any media format for use in speaker programs.

23. **"Promotional Speaker"** shall mean an HCP speaker engaged to Promote an Atypical Antipsychotic in the United States.

24. **"Reprints Containing Off-Label Information"** shall mean articles or reprints from a Scientific or Medical Journal, as defined in 21 C.F.R. 99.3(j), or Reference Publication, as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of an Atypical Antipsychotic.

25. **"Signatory Attorney General"** shall mean the Attorney General of Connecticut, or his authorized designee, who has agreed to this Judgment.

26. **"State Consumer Protection Laws"** shall mean the consumer protection laws under which the Attorneys General have conducted the investigation, which are cited in footnote 3.[3]

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[3] ALABAMA – *Alabama Deceptive Trade Practices Act*, Ala. Code § 8-19-1 et seq.; ARKANSAS -- Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq; ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; CONNECTICUT - *Connecticut Unfair Trade Practices Act*, Conn. Gen. Stat. §§ 42-110a *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 *et. seq.*; GEORGIA - Fair Business Practices Act, O.C.G.A. § 10-1-390 *et seq.*; HAWAII- *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. Sect. 480-2; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; INDIANA--Ind. Code §§ 24-5-0.5 *et seq.*; IOWA - *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 *et seq.*; KENTUCKY – *Kentucky Consumer Protection Act*, KRS Ch. 367.110, *et seq.*; LOUISIANA— LA R.S. 51:1407; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law § 13-101 *et seq.*; MASSACHUSETTS— Mass Gen. Laws c.93A; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MINNESOTA -

27. **"Unsolicited Request"** shall mean a request for information regarding an Atypical Antipsychotic communicated to an agent of BMS that has not been prompted by BMS.

COMPLIANCE PROVISIONS

I. Promotional Activities

A. BMS shall not make, or cause to be made, any written or oral claim that is false, misleading or deceptive regarding an Atypical Antipsychotic.

B. BMS shall not make any claim regarding safety or efficacy comparing an Atypical Antipsychotic to another product when that claim is not supported by substantial evidence, or by competent and reliable scientific evidence in the case of health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, or by the level of evidence required by an applicable, subsequently promulgated, regulatory standard.

C. When Promoting an Atypical Antipsychotic, BMS shall present risk information Clearly and Conspicuously, as that term is defined in this Judgment.

Minnesota Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43-48; *Minnesota False Advertising Act*, Minn. Stat. § 325F.67; *Minnesota Consumer Fraud Act*, Minn. Stat. §§ 325F.68-70; *Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act*, Minn. Stat. § 325F.71.; MISSOURI – *Missouri Merchandising Practices Act*, Mo. Rev. Stat. §§ 407.010 *et seq.*; MONTANA -- Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA – *Consumer Protection Act*, Neb. Rev. Stat. §§ 59-1601 *et seq.* and the *Uniform Deceptive Trade Practices Act*, Neb. Rev. Stat. §§ 87-301 *et seq.*; NEVADA – *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NEW HAMPSHIRE - *New Hampshire Consumer Protection Act*, RSA 358-A; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq*NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – *North Carolina Unfair and Deceptive Trade Practices Act*, N.C.G.S. 75-1.1, *et seq.*; NORTH DAKOTA – *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; OKLAHOMA – *Oklahoma Consumer Protection Act* 15 O.S. §§ 751 *et seq.;* OREGON – *Oregon Unlawful Trade Practices Act*, Or. Rev. Stat. § 646.605 et seq.; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq.*; RHODE ISLAND - *Rhode Island Deceptive Trade Practices Act*, Rhode Island General Laws § 6-13.1-1 *et seq.*; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE – *Tennessee Consumer Protection Act*, Tenn. Code Ann. 47-18-101 *et seq.*; TEXAS – *Texas Deceptive Trade Practices-Consumer Protection Act*, Tex. Bus. And Com. Code 17.41, *et seq.*; VERMONT – *Consumer Fraud Act*, 9 V.S.A. §§ 2451 *et seq.*; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 *et seq.*; WEST VIRGINIA- *West Virginia Consumer Credit and Protection Act*, W.Va Code § 46A-1101 *et seq.*; and WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

D. BMS shall not make any written or oral Promotional claim of safety or effectiveness for any Atypical Antipsychotic product in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), any regulation promulgated thereto, any voluntary agreement between BMS and the FDA, or any order, settlement, or other resolution of an FDA enforcement action with BMS related to the promotion of an Atypical Antipsychotic, including any modifications agreed to between BMS and the FDA subsequent to such resolution.

The following subsections of Section I. shall be effective for five years from the Effective Date.

E. BMS shall not Promote an Atypical Antipsychotic for any Off-Label use.

F. In Promotional Materials for an Atypical Antipsychotic, BMS shall Clearly and Conspicuously disclose the risks associated with the Atypical Antipsychotic as set forth in the product's boxed warning and shall present information about effectiveness and risk in a manner consistent with the recommendations in the FDA's "Guidance for Industry; Presenting Risk Information in Prescription Drug and Medical Device Promotion," or as revised.

G. BMS shall not compensate an HCP for merely attending a Promotional activity for an Atypical Antipsychotic.

H. BMS shall not present patient profiles/types based on selected symptoms of the FDA-approved indication(s) when Promoting an Atypical Antipsychotic, unless:

1. The Atypical Antipsychotic's specific FDA-approved indication(s) is stated Clearly and Conspicuously in the same spread (i.e., on the same page or on a facing page) in any Promotional Materials that refer to selected symptoms;

2. With respect to Promotional Media:

a. BMS states, Clearly and Conspicuously, the FDA-approved indication(s) on the same slide or page in which selected symptoms are first presented; and

b. With respect to each subsequent reference to selected symptoms, BMS states on the same slide or page that the Atypical Antipsychotic is not approved for the selected symptom referenced in the slide or page and includes on the same slide or page a shorthand reference to the FDA-approved indications (e.g., "[Atypical Antipsychotic] is not approved for X selected symptom referenced in this slide. See complete list of FDA-approved indications at p. Y").

3. Promotional Materials have a reference indicating that the full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V or current version), where applicable.

I. BMS shall require that any Promotional Speakers for any Atypical Antipsychotic engaged by or on behalf of BMS comply with BMS's obligations in paragraphs I.A- I.F, I.H, II.D, and VI.B. of this Judgment, including, but not limited to, ensuring that all Promotional Speakers' Promotional Materials and Promotional Media for any Atypical Antipsychotic comply with BMS's obligations in paragraphs I.A.-I.F, I.H, II.D and VI.B.

J. BMS's systems and controls shall:

1. Be designed to ensure that financial incentives do not motivate individuals to engage in improper promotion, sales, and marketing, including Off-Label Promotion, of any Atypical Antipsychotic;

2. Require the review, and modification, if necessary, of call plans of BMS Sales and BMS Marketing personnel who Promote an Atypical Antipsychotic to ensure that

BMS Sales and/or BMS Marketing Promote Atypical Antipsychotics only for FDA-approved uses.

II. Dissemination and Exchange of Medical Information

A. General Terms

1. BMS's communications concerning Off-Label uses of an Atypical Antipsychotic shall not be false, misleading or deceptive.

2. BMS shall not disseminate information describing any Off-Label or unapproved use of an Atypical Antipsychotic, unless such information and materials comply with the standards in applicable FDA regulations and with recommendations in FDA Guidances for Industry, including FDA's "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" and FDA's "Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices," or as revised.

The following subsections of Section II. shall be effective for five years from the Effective Date.

B. Clinical Responses

1. To the extent that BMS develops Clinical Responses regarding an Atypical Antipsychotic, BMS, through BMS Scientifically Trained Personnel, shall have ultimate responsibility for developing and approving all such Clinical Responses regarding an Atypical Antipsychotic, including any that may describe Off-Label information. Additional approvals may be provided by BMS's Law Department. BMS shall not distribute any Clinical Response regarding an Atypical Antipsychotic, unless:

a. Clinically Relevant Information is included in these materials to provide scientific balance;

b. Data in these materials are presented in an unbiased, non-Promotional manner; and

c. These materials are clearly and conspicuously distinguishable from sales aids and other Promotional Materials.

2. BMS Sales and BMS Marketing personnel shall not develop Clinical Responses regarding an Atypical Antipsychotic.

3. To the extent that BMS personnel disseminate Clinical Responses regarding an Atypical Antipsychotic, such Clinical Responses regarding an Atypical Antipsychotic may be disseminated only by BMS Scientifically Trained Personnel to HCPs, and BMS's Sales and Marketing shall not disseminate these materials to HCPs except in circumstances implicating public health and safety issues. In such circumstances, BMS's Sales and Marketing may disseminate a Clinical Response directly to HCPs when expressly authorized by the Head of Compliance & Ethics, the Vice President of Medical/Scientific Affairs responsible for the Atypical Antipsychotic(s) included in the Clinical Response(s), and Senior Counsel from the BMS Law Department.

4. BMS shall not knowingly disseminate any Clinical Response involving an Atypical Antipsychotic, including one that describes any Off-Label use of an Atypical Antipsychotic, that makes any false, misleading or deceptive representation regarding an Atypical Antipsychotic or any false, misleading or deceptive statement concerning a competing product.

C. Responses to Unsolicited Requests for Off-Label Information

1. If BMS elects to respond to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic, BMS Scientifically Trained Personnel shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall be a Clinical Response prepared in accordance with Section II.B and shall not Promote an Atypical Antipsychotic for any Off-Label use(s).

2. In responding to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic, including any request for a specific article related to any Off-Label use, BMS shall:

a. advise the requestor that the request concerns an Off-Label use:

b. and inform the requestor of the drug's FDA-approved indication(s) and dosage, and other relevant Labeling information.

3. Any written response to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic that BMS provides shall include:

a. A copy of the FDA-required Labeling, if any, for the product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient labeling);

b. A prominent statement notifying the recipient that the FDA has not approved or cleared the product as safe and effective for the use addressed in the accompanying materials; and

c. A complete list of references for all of the information disseminated in the response (e.g., a bibliography of publications in peer-reviewed medical journals or in medical or scientific texts; citations for data on file, for summary documents, or for abstracts).

4. To the extent that BMS responds in writing to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic, only BMS Scientifically Trained Personnel may respond in writing to such an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic.

5. Information that BMS distributes in response to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic shall be:

a. Provided only to the individual making the request as a private, one-on-one communication;

b. Tailored to answer only the specific question(s) asked;

c. Scientific in nature; and

d. Unaccompanied by other material or information that is Promotional in nature or tone.

6. BMS Sales and BMS Marketing personnel may respond orally to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic only by offering to refer the request to BMS's medical or scientific department or by offering to put the requester in touch with the scientific exchange call center. BMS Non-Scientifically Trained Personnel shall not characterize, describe, identify, name, or offer any opinions about or summarize any such Off-Label information.

7. To the extent that BMS responds to Unsolicited Requests for Off-Label information regarding an Atypical Antipsychotic, BMS shall create and subsequently maintain the following records concerning such Unsolicited Requests for Off-Label information regarding an Atypical Antipsychotic:

a. The nature of the request for information, including the names, addresses, and affiliations of the requestors;

b. Records regarding the information provided to the requestor; and

c. Any follow-up inquiries or questions from the requestor.

D. Reprints

1. To the extent that BMS disseminates Reprints Containing Off-Label Information regarding an Atypical Antipsychotic, BMS Scientifically Trained Personnel shall be responsible for approving the Reprints Containing Off-Label Information regarding an Atypical Antipsychotic. Neither BMS Sales nor BMS Marketing personnel shall disseminate these materials, except in a manner consistent with the recommendations in the FDA's "Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices," or as revised.

2. Any request by BMS to proactively disseminate a Reprint Containing Off-Label Information regarding an Atypical Antipsychotic shall be submitted to the Promotional Review Committee, which includes representatives from Medical Information, Promotion Integrity, and the BMS Law Department to examine the facts and justification for the request to distribute a Reprint Containing Off-Label Information on a case-by-case basis.

3. Reprints Containing Off-Label Information regarding an Atypical Antipsychotic that BMS disseminates:

a. shall be accompanied by the FDA-approved Labeling for the product, or a prominently displayed and clearly described hyperlink that will provide the reader with such information;

b. shall contain a disclosure that is prominently displayed, which would include the first page or as a cover page where practicable, indicating that the article may discuss Off-Label information; and

c. shall not be referred to or used in a Promotional manner.

4. Nothing in this Judgment shall preclude BMS from disseminating reprints which have only an incidental reference to Off-Label information. If reprints have an incidental reference to Off-Label information, any such reprints that BMS disseminates shall contain the disclosures required by Section II.D.3.a. and II.D.3.b in a prominent location, as defined above, and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Section II.D.3.c.

III. Grants

The following subsections of Section III. shall be effective for five years from the Effective Date.

A. BMS shall disclose information about medical education grants, including continuing medical education ("CME") grants, regarding an Atypical Antipsychotic consistent with the current disclosures of the BMS Independent Medical Education Department at http://www.bms.com/responsibility/grantsandgiving/what_we_support/Pages/default.aspx (hereinafter, "BMS IMED website") and as required by applicable law.

B. Once posted, BMS shall maintain this information on the BMS IMED website for at least two years, or longer if applicable law so requires, and shall maintain the information in a readily accessible format for review by a Signatory Attorney General upon written request for a period of five years.

C. BMS IMED shall manage all requests to BMS for funding related to medical education grants relating to an Atypical Antipsychotic. Approval decisions shall be made by BMS IMED and BMS Medical, and shall be kept separate from the BMS Sales and BMS Marketing organizations.

D. BMS shall not use medical education grants or any other type of grant to Promote an Atypical Antipsychotic. This provision includes, but is not limited to, the following prohibitions with respect to any program related to an Atypical Antipsychotic:

1. BMS Sales and BMS Marketing personnel shall not initiate, coordinate or implement a grant application on behalf of any customer or HCP;

2. BMS Sales and BMS Marketing personnel shall not be involved in selecting any grantee or medical education speaker; and

3. BMS shall not measure or attempt to track in any way the impact of grants or speaking fees on participating HCPs' subsequent prescribing habits, practices or patterns.

E. BMS shall not condition funding of a medical education program grant request relating to an Atypical Antipsychotic upon the requestor's selection or rejection of any particular speaker.

F. BMS shall not suggest, control, or attempt to influence the specific topic, title, content, speakers or audience for any CME relating to an Atypical Antipsychotic, consistent with Accreditation Council for Continuing Medical Education ("ACCME") guidelines.

G. BMS Sales and BMS Marketing personnel shall not approve any grant request regarding a proposal concerning an Atypical Antipsychotic, nor attempt to influence the awarding of any grant to any customer or HCP for his/her prescribing habits, practices or patterns.

H. BMS shall contractually require each medical education provider to clearly and conspicuously disclose to attendees of a medical education program regarding Atypical Antipsychotic(s) BMS's financial support of the medical education program and any financial relationship with any faculty or speaker at such medical education program.

I. After initial delivery of a CME program regarding an Atypical Antipsychotic, BMS shall not knowingly fund the same program, nor shall it provide additional funding for re-distribution of the same program, if the program's speakers are Promoting an Atypical Antipsychotic for Off-Label use in that program.

IV. Payments to Consultants and Speakers

Until 5 years from the Effective Date, BMS shall be required to file reports concerning any Atypical Antipsychotic consistent with the requirements of Section 6002 of the federal Patient Protection and Affordable Care Act of 2010, or, if amended, the amended version, and final regulations promulgated pursuant to the Act or, if amended, the amended version. BMS shall, on its website, in proximity to information regarding transparency and its position on the Physician Payments Sunshine Act, list the names of the entities under which BMS is making disclosures under the Physician Payments Sunshine Act.

V. Product Samples

The following subsections of Section V. shall be effective for five years from the Effective Date.

A. BMS shall provide samples of an Atypical Antipsychotic only to those HCPs whose clinical practice is such that they treat patients for which treatment with an Atypical Antipsychotic has been approved by the FDA.

B. If an HCP whose clinical practice is inconsistent with an Atypical Antipsychotic's FDA-approved Labeling requests samples of an Atypical Antipsychotic, BMS personnel shall refer the HCP to BMS Medical where the practitioner can speak directly with a BMS Medical representative who will provide answers to the HCP's questions about the Atypical Antipsychotic and may provide him/her with samples only if appropriate (*i.e.*, if the HCP requests the samples for an on-label use).

VI. Clinical Research Results

A. BMS shall report clinical research regarding an Atypical Antipsychotic in an accurate, objective and balanced manner, and as required by applicable law. For all BMS-sponsored clinical trials regarding an Atypical Antipsychotic and to the extent permitted by the National Library of Medicine, BMS shall register clinical trials and submit clinical trial results to the federal clinical trial registry and results data bank on the publicly accessible NIH website (www.clinicaltrials.gov) as required by the FDA Amendments Act of 2007, Public Law No. 110-85, 121 Stat 823, and any accompanying regulations that may be promulgated pursuant to that Act.

B. When presenting information about a clinical study regarding an Atypical Antipsychotic in any Promotional Materials, BMS shall not do any of the following:

1. Present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions, in a manner that causes the Promotional Materials to be false, misleading, or deceptive;

2. Use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of

variations around the cited average results, in a manner that causes the Promotional Materials to be false, misleading, or deceptive;

3. Use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from the study the design or protocol of which is not amenable to formal statistical evaluations, in a manner that causes the Promotional Materials to be false, misleading, or deceptive;

4. Present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does; or

5. Use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case. If any results derived from pooling data are presented, BMS shall disclose the method of pooling.

VII. Terms Relating to Payment

No later than 30 days after the Effective Date, BMS shall pay $ 19.5 million to be divided and paid by BMS directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

VIII. Release

A. By its execution of this Judgment, the State releases Bristol-Myers Squibb Company and all of its past and present subsidiaries, predecessors, successors, and assigns and

each and all of their current and former officers, directors, shareholders, employees, agents, contractors, and attorneys (collectively, the "Released Parties") from the following: all civil claims, *parens patriae* claims, causes of action, damages, restitution, fines, costs, attorneys' fees, and penalties that the State has asserted or could have asserted against the Released Parties under CUTPA or any amendment thereto, or common law claims concerning unfair, deceptive, or fraudulent trade practices, other than those asserted or that could be asserted under VIII.B below, resulting from the Covered Conduct up to and including the Effective Date (collectively, the "Released Claims").

B. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

1. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Connecticut;

2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Connecticut not expressly covered by the release in Section VIII.A above, including, but not limited to, any and all of the following claims:

a. State or federal antitrust violations;

b. Claims involving "best price," "average wholesale price," or "wholesale acquisition cost," or any practices related to the reporting of prices;

c. Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse (whether common law, statutory, or otherwise), and/or kickback violations related to any State's Medicaid program; and

d. State false claims violations.

3. Actions on behalf of state program payors of the State arising from the purchase of any Atypical Antipsychotic or any other BMS drug, except for the release of civil penalties under CUTPA.

4. Any claims individual consumers have or may have under CUTPA, and any common law claims individual consumers may have concerning unfair, fraudulent or deceptive trade practices, against any person and/or entity, including Released Parties.

5. Any claims against Otsuka America Pharmaceutical, Inc., its subsidiaries, predecessors, successors and/or any other party not bound by the terms of this Judgment.

6. Claims resulting from any unfair, false, misleading or deceptive representation related to the risk of impulse-control problems, such as pathological gambling, hypersexuality, compulsive spending or shopping, and compulsive or binge eating. The parties acknowledge that this exclusion should not be construed as either an admission by BMS that Abilify causes or can cause any of the above-referenced conditions or an admission by BMS that the Abilify package insert was in any way deficient at any time. The parties further acknowledge that BMS maintains that the potential risks associated with Abilify have at all times been appropriately disclosed, and appropriately updated in accordance with applicable regulations, standards, and laws.

IX. Dispute Resolution

A. For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that BMS has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date, then such Attorney General shall notify BMS in writing of the specific objection,

identify with particularity the provision of this Judgment that the practice appears to violate, and give BMS thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action. Upon receipt of written notice, BMS shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why BMS believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how BMS intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the state's Civil Investigative Demand ("CID") or investigative subpoena authority and BMS reserves all of its rights with respect to a CID or investigative subpoena issued pursuant to such authority.

B. Upon giving BMS thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of BMS that relate to BMS's compliance with each provision of this Judgment pursuant to that State's CID or investigative subpoena authority. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to BMS.

C. The State may assert any claim that BMS has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing BMS an opportunity to respond to the notification described in Paragraph IX.A. above; provided, however, that a Signatory Attorney General may take any

action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

X. General Provisions

A. BMS shall not cause nor knowingly permit third parties acting on its behalf to engage in practices from which BMS is prohibited by this Judgment.

B. This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, neither prior versions of this Judgment nor prior versions of any of its terms that were not entered by the Court in this Judgment may be introduced for any purpose whatsoever.

C. This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

D. This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

E. The Parties agree that neither of them shall be deemed the drafter of this Judgment and that, in construing this Judgment, no provision hereof shall be construed in favor of one party on the ground that such provision was drafted by the other.

F. All Notices under this Order shall be provided to the following address via Overnight Mail:

For BMS:

Office of General Counsel
Bristol-Myers Squibb Company
345 Park Avenue
New York, New York 10154

Mitchell J. Lazris
Hogan Lovells US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004

and

For Attorney General:

Jeremy Pearlman
Assistant Attorney General
Office of the Connecticut Attorney General
110 Sherman Street
Hartford, Connecticut 06105

G. To the extent that any provision of this Judgment obligates BMS to change any policy(ies) or procedure(s) and to the extent not already accomplished, BMS shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 90 days after the Effective Date.

CONSENTED AND AGREED TO BY:

By: _____
Sandra Leung
Executive Vice President and General Counsel
Bristol-Myers Squibb Company

By: _____
Alan G. Schwartz, Juris No. 304771
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and

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555 Thirteenth Street, N.W.
Washington, D.C. 20004

and

For Attorney General:

Jeremy Pearlman
Assistant Attorney General
Office of the Connecticut Attorney General
110 Sherman Street
Hartford, Connecticut 06105

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Executive Vice President and General Counsel
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jeremy.pearlman@ct.gov

Attorney for State of Connecticut

So Ordered.

Dated: _____

_____
Judge of the Superior Court