

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF FLORIDA  
PENSACOLA DIVISION**

IN RE: ABILIFY (ARIPIPRAZOLE)  
PRODUCTS LIABILITY  
LITIGATION

Case No. 3:16-md-2734

Chief Judge M. Casey Rodgers  
Magistrate Judge Gary Jones

This Document Relates to All Cases

**ORDER REGARDING PARTIES' DISCOVERY STIPULATIONS**

The Court enters the following Order, pursuant to the parties' stipulation (ECF No. 227).

**Scope of General Causation**

The Parties agree that the general causation will be limited to the discrete issue of whether aripiprazole can cause compulsive/impulsive behavior under the applicable legal standard. This does not take into account any elements of a failure-to-warn claim or the question of what defendants knew and when. Except as previously agreed and agreed to herein, all of these issues, as well as anything outside of this isolated question, are to be reserved to the general liability phase of the litigation.

### **Search Terms**

Plaintiffs agree to withdraw the search terms "signal" and "risk management plan." Defendants agree to use the other seven search terms previously in dispute. A comprehensive list of agreed upon search terms is attached hereto as Exhibit A.

### **Custodians**

Plaintiffs agree to withdraw, at this time, their request for additional custodians from any defendant other than OPC beyond the 25 custodians, but reserve the right to request additional custodians once Plaintiffs have had the opportunity to review the document production for the agreed upon 25 custodians. Defendants reserve the right to object to any requests for additional custodians.

Defendants agree to use best efforts to substantially produce the custodial documents by the March 20, 2017 deadline for completion of the interim document production. (See Dkt. 199). If Defendants cannot substantially produce the custodial documents by the March 20, 2017 deadline for completion of the interim document production, the parties will meet and confer on setting of interim production deadlines, and if unable to agree, will bring the issue for resolution to the Court. The Parties agree that custodial documents pre-dating January 1, 2011 and post-dating August 19, 2016 will not be produced by the March 20, 2017 deadline but will be produced as soon as practicable after that deadline.

### **Relevant Time**

Plaintiffs agree, for purposes of general causation discovery, that custodial productions will be limited to those documents created or modified during the time period January 2007 to February 28, 2017. Plaintiffs reserve the right, for purposes of general causation discovery, to request supplementary production of later created/modified documents and/or an expansion of the time period as to individually identified custodians, for good cause shown.

### **Adverse Event Database**

Plaintiffs agree to withdraw their request for the native production of the adverse event database contingent on the parties reaching agreement on the schema and tables/fields to be produced. In exchange, BMS agrees to produce information relating to the adverse events captured by the agreed upon MedDRA preferred terms as well as the narrative searches identified below in XML, or in similar output if agreed to by Plaintiffs in advance of the production. All agreed upon MedDRA and non-MedDRA search terms are listed in Exhibit B.

The Parties will work to agree upon the schema and tables/fields to be included. BMS agrees to produce as soon as practicable, to the extent available, the Oracle Argus or AWARE Safety Database Administrator's Guide (the "Guide") for the AWARE database, to assist the Parties in their negotiations over the schema and tables/fields to be included. To the extent the Guide is available, BMS agrees to

produce it in .pdf format. To the extent the Guide is not available, or the Plaintiffs and BMS are not able to reach an agreement on the schema and tables/fields to be included, they will present all issues in dispute to the Court. If necessary, this matter will be discussed at the Case Management Conference on March 24, 2017. Once the schema and tables/fields to be included have been agreed upon or ordered by the Court, BMS agrees to make good faith efforts to produce the information as quickly as practicable.

### **Narrative Searches**

BMS agrees to search the narratives of the Abilify® adverse events in the AWARE database using both the MedDRA and non-MedDRA search terms identified in Exhibit B to this Stipulation.

### **Source Files**

Upon Plaintiffs' receipt and review of the adverse event database and narrative search data, Plaintiffs will have the right to request a reasonable number of source files on a rolling basis. BMS will not unreasonably oppose these requests and will make good faith efforts to produce source files within seven business days. To the extent BMS is not able to produce the requested source files within seven business days, they will provide notice to Plaintiffs and will produce the requested documents as quickly as practicable. If necessary, these matters will be discussed at the discovery conference calls and/or case management conferences.

**PDC Minutes**

Defendants will produce all PDC minutes by April 12, 2017.

**Depositions**

The Parties will meet and confer on the scope of general causation deposition discovery. To the extent the parties are unable to reach an agreement, Plaintiffs will submit their brief on the issue by March 13, 2017 and Defendants will file their brief by March 17.<sup>1</sup>

**OPC's Readiness Plan**

OPC and Plaintiffs agree to continue to meet and confer concerning OPC's Readiness Plan. If these Parties cannot reach an agreement, they will submit briefs on this issue on the schedule set for the deposition issue above.

**DONE and ORDERED** on this 9th day of March, 2017.

*M. Casey Rodgers*

---

**M. CASEY RODGERS  
CHIEF UNITED STATES DISTRICT JUDGE**

---

<sup>1</sup> These dates are based on joint request of the parties.

# **EXHIBIT A**

## EXHIBIT A

### Agreed Upon Search Terms

“[Product Terms]” as used herein shall mean the search:

(Arip\* OR Abilify OR Abilitat OR 337039 OR maintena OR “42,776” OR 42776 OR “21-436” OR 21436 OR 21-713 OR 21713 OR “21-729” OR 21729 OR “21-866” OR 21866 OR 14597 OR “OPC-31” OR Alizapride OR Apokyn OR apomorphine OR Clozaril OR "clozapine tablet" OR Dostinex OR cabergoline OR Fanapt OR iloperidone OR Fazaclo OR "clozapine orally disintegrating tablet" OR Geodon OR ziprasidone OR Haldol OR haloperidol OR Invega OR "Invega Sustenna" OR "Invega Trinza" OR paliperidone OR Latuda OR lurasidone OR Mirapex OR pramipexole OR Motilium OR domperidone OR "Neupro patch" OR rotigotine OR Norprolac OR quinagolide OR Parlodel OR bromocriptine OR Reglan OR metoclopramide OR Requip OR ropinirole OR Risperdal OR "Risperdal Consta" OR "Risperdal M-Tab" OR risperidone OR Saphris OR asenapine OR Seroquel OR "Seroquel XR" OR quetiapine OR Symbyax OR olanzapine OR fluoxetine OR Thorazine OR chlorpromazine OR Versacloz OR "clozapine suspension" OR Zyprexa OR "Zyprexa Relprevv" OR "Zyprexa Zydis" OR olanzapine)

The following searches shall be conducted:

1. (Dopamine! w/10 (Receptor OR Agoni\* OR Antagoni\* OR Pathwa\* OR Intrinsic OR Effec\* OR Affec\* OR Mechanis\* OR Affinit\* OR Mesolimbic OR hypodopaminergic OR “hypo-dopaminergic” OR hyperdopaminergic OR “hyper-dopaminergic” OR hypothes\* OR Caus\* OR Link\* OR Assoc\* OR Partial OR activit\* OR reward)) W/25 [Product Terms]
2. “DA” w/10 (Receptor OR Agoni\* OR Antagoni\* OR Pathwa\* OR Intrinsic OR Effec\* OR Affec\* OR Mechanis\* OR Affinit\* OR Mesolimbic OR hypodopaminergic OR “hypo-dopaminergic” OR hyperdopaminergic OR “hyper-dopaminergic” OR hypothes\* OR Caus\* OR Link\* OR Assoc\* OR Partial OR activit\* OR reward)) W/25 [Product Terms]

3. “D-A” w/10 (Receptor OR Agoni\* OR Antagoni\* OR Pathwa\* OR Intrinsic OR Effec\* OR Affec\* OR Mechanis\* OR Affinit\* OR Mesolimbic OR hypodopaminergic OR “hypo-dopaminergic” OR hyperdopaminergic OR “hyper-dopaminergic” OR hypothes\* OR Caus\* OR Link\* OR Assoc\* OR Partial OR activit\* OR reward)) W/25 [Product Terms]
4. “D2” w/10 (Receptor OR Agoni\* OR Antagoni\* OR Pathwa\* OR Intrinsic OR Effec\* OR Affec\* OR Mechanis\* OR Affinit\* OR Mesolimbic OR hypodopaminergic OR “hypo-dopaminergic” OR hyperdopaminergic OR “hyper-dopaminergic” OR hypothes\* OR Caus\* OR Link\* OR Assoc\* OR Partial OR activit\* OR reward)) W/25 [Product Terms]
5. “D-2” w/10 (Receptor OR Agoni\* OR Antagoni\* OR Pathwa\* OR Intrinsic OR Effec\* OR Affec\* OR Mechanis\* OR Affinit\* OR Mesolimbic OR hypodopaminergic OR “hypo-dopaminergic” OR hyperdopaminergic OR “hyper-dopaminergic” OR hypothes\* OR Caus\* OR Link\* OR Assoc\* OR Partial OR activit\* OR reward)) W/25 [Product Terms]
6. “D3” w/10 (Receptor OR Agoni\* OR Antagoni\* OR Pathwa\* OR Intrinsic OR Effec\* OR Affec\* OR Mechanis\* OR Affinit\* OR Mesolimbic OR hypodopaminergic OR “hypo-dopaminergic” OR hyperdopaminergic OR “hyper-dopaminergic” OR hypothes\* OR Caus\* OR Link\* OR Assoc\* OR Partial OR activit\* OR reward)) W/25 [Product Terms]
7. “D-3” w/10 (Receptor OR Agoni\* OR Antagoni\* OR Pathwa\* OR Intrinsic OR Effec\* OR Affec\* OR Mechanis\* OR Affinit\* OR Mesolimbic OR hypodopaminergic OR “hypo-dopaminergic” OR hyperdopaminergic OR “hyper-dopaminergic” OR hypothes\* OR Caus\* OR Link\* OR Assoc\* OR Partial OR activit\* OR reward)) W/25 [Product Terms]
8. “Nucleus accumbens”
9. “ventral striatum”
10. Dechalleng!

11.de-challeng!

12.Rechalleng!

13.re-challeng!

14.EB05

15.“Cumulative Review” AND [Product Terms]

16. “Pharmacovigilance Review”

17.“Risk Management Plan” AND [Product Terms]

18.“Full Development and Commercialization Plan”

19.“Clinical Development Plan” AND [Product Terms]

20.“Integrated Summary” AND [Product Terms]

21.Etminan

22.“Moore, T” OR \*tmoore\* OR “Tho\* Moore” OR “T Moore” OR “T. Moore” OR (Moore w/4 (journal OR article OR study OR report OR research OR piece OR JAMA))

23.Glenmullen

24.Grall-Bronnec

25.Gaboriau

26.“Smith, N” OR \*nsmith\* OR “Nei\* Smith” OR “N Smith” OR “N. Smith” OR (Smith w/4 (journal OR article OR study OR report OR research OR piece OR BJP\*))

27.“Cohen, J” OR “Julian.cohen\*” OR “Jul\* Cohen” OR “J Cohen” OR “J. Cohen” OR (Cohen w/4 (journal OR article OR study OR report OR research OR piece OR “current drug safety”))

28.Gavaudan

29.Roxanas

30.Kodama

31.Schlachetzki

32.Ceylon

33.(Abnorm\* w/2 behav\*) AND [Product Terms]

34.Addict\* AND [Product Terms]

35.(Appetite\* w/4 (excess\* OR disord\* OR increase\* OR patholog\*)) AND [Product Terms]

36.Binge\* AND [Product Terms]

37.Binging

38.\*Compuls\* AND [Product Terms]

39.Crave!

40.Craving AND [Product Terms]

41.Disinhibition AND [Product Terms]

42.Dysregulation syndrom!

43.(Eat\* w/2 (disord\* OR excess\* OR increas\* OR patholog\*)) AND [Product Terms]

44.(Exercis\* w/2 (disord\* OR excess\* OR increase\* OR patholog\*)) AND [Product Terms]

45.(Feed\* w/2 (disord\* OR excess\* OR increase\* OR patholog\*)) AND [Product Terms]

46.(Food w/2 (disord\* OR excess\* OR increase\* OR patholog\*)) AND [Product Terms]

47.Gambl!

48.Hoard! AND [Product Terms]

49.(Hunger w/2 (disord\* OR excess\* OR increase\* OR patholog\*)) AND [Product Terms]

50.Hyperphagia AND [Product Terms]

51.Hypersexuality

52.Impuls! AND [Product Terms]

53.Klepto!

54.(Libido\* w/2 (disord\* OR excess\* OR increase\* OR patholog\* OR decreas\*)) AND [Product Terms]

55.Masturbat! AND [Product Terms]

56.Obsess! AND [Product Terms]

57.OCD AND [Product Terms]

58.Promiscuity

59.Prostitut!

60.(Satiety w/2 (disord\* OR excess\* OR increase\* OR patholog\*)) AND  
[Product Terms]

61.Sexu! w/2 (disord\* OR excess\* OR increase\* OR patholog\* OR decreas\*))  
AND [Product Terms]

62.(Shop\* w/2 (disord\* OR excess\* OR increase\* OR patholog\*)) AND  
[Product Terms]

63.Skin pick!

64.Steal! AND [Product Terms]

65.Stereotypy

66.Theft AND [Product Terms]

67.Trichotilloman! AND [Product Terms]

68.(Weight w/2 (disord\* OR excess OR patholog\*)) AND [Product Terms]

69.“Publication plan” AND [Product Terms]

70.“Ghost writ!”

71.(Ghost w/4 writ!)

72.Ghostwrit!

## **EXHIBIT B**

## **EXHIBIT B**

### **Agreed Upon MedDRA and Non-MedDRA Search Terms**

#### **I. Agreed Upon MedDRA Search Terms**

1. Binge Eating
2. Compulsions
3. Compulsive hoarding
4. Compulsive shopping
5. Dopamine dysregulation syndrome
6. Excessive exercise
7. Excessive masturbation
8. Excessive sexual fantasies
9. Gambling
10. Hyperphagia
11. Hypersexuality
12. Impulse-control disorder
13. Libido increased
14. Obsessive-compulsive disorder
15. Obsessive-compulsive personality disorder
16. Gambling disorder
17. Promiscuity
18. Sexual activity increased
19. Stereotypy
20. Abnormal Behaviour
21. Impulsive Behaviour
22. Disinhibition
23. Food craving
24. Clinomania
25. Compulsive cheek biting
26. Compulsive handwashing
27. Compulsive lip biting
28. Dermatillomania
29. Exhibitionism
30. Kleptomania
31. Nail picking
32. Necromania

33. Obsessive need for symmetry
34. Obsessive thoughts
35. Onychophagia
36. Poriomania
37. Pyromania
38. Trichotemnomania
39. Trichotillomania
40. Voyeurism

## **II. Agreed Upon Non-MedDRA Search Terms**

1. Abnorm! w/4 behav!
2. Addict!
3. Appetite! w/4 (disord! Or excess! Or increas! Or pathol!)
4. Binge!
5. Binging
6. \*Compuls\*
7. Crave!
8. Craving
9. Disinhibition
10. Dysregulation syndrom!
11. Eat! w/4 (disord! Or excess! Or increas! Or pathol!)
12. Exercis! w/4 (disord! Or excess! Or increas! Or pathol!)
13. Feed! w/4 (disord! Or excess! Or increas! Or pathol!)
14. Food w/4 (disord! Or excess! Or increas! Or pathol!)
15. Gamb!!
16. Hoard!
17. Hunger w/4 (disord! Or excess! Or increas! Or pathol!)
18. Hyperphagia
19. Hypersexuality
20. Impuls!
21. Klepto!
22. Libido! w/4 (disord! Or excess! Or increas! Or pathol!)
23. Masturbat!
24. Obsess!
25. OCD
26. Promiscuity

27. Prostitut!
28. Satiety w/4 (disord! Or excess! Or increas! Or pathol!)
29. Sexu! w/4 (disord! Or excess! Or increas! Or pathol!)
30. Shop! w/4 (disord! Or excess! Or increas! Or pathol!)
31. Skin pick!
32. Steal!
33. Stereotypy
34. Theft
35. Tricho!
36. Trichotillomania
37. Weight w/4 (disord! Or excess! Or pathol!)