UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

IN RE: ABILIFY (ARIPIPRAZOLE) PRODUCTS LIABILITY LITIGATION	Case No. 3:16-md-2734
This Document Relates to All Cases	Chief Judge M. Casey Rodgers Magistrate Judge Gary Jones

ORDER REGARDING SCOPE OF GENERAL CAUSATION DISCOVERY

WHEREAS, pursuant to Case Management Order #1, ECF 67, the Court directed the parties to meet and confer regarding the scope of discovery necessary to evaluate issues of general causation under *Daubert* (i.e., whether the scientific evidence can show a relationship between Abilify and compulsive disorders).

WHEREAS, counsel for plaintiffs and defendants have met and conferred and reached the following agreement:

1. Plaintiffs may serve formal document requests under Rules 26 and 34 of the Federal Rules of Civil Procedure seeking the documents identified in Exhibit A attached hereto.

2. Defendants agree to provide formal responses in accordance with the Federal Rules of Civil Procedure regardless of whether defendants believe the requests are premature or irrelevant to discovery on "general causation." Defendants, however, reserve the right to object to the requests on any

other grounds permitted in the Federal Rules of Civil Procedure, including that the scope of a particular request is overly burdensome or disproportional to the needs of the case.

3. The Discovery Committee will address the scope of defendants' production obligations, including the timing of that production, search terms, the number of custodians to be searched, and whether a 30(b)(6) deposition of defendants is necessary to identify those custodians and the location of relevant documents.

4. Subject to Paragraphs 2 and 3 above, defendants agree that their responses to plaintiffs' document requests described in Paragraph 1 above will include production of documents from internal custodial files, including emails and other communications.

5. Defendants do not waive and expressly reserve their right to argue that any discovery produced in this phase is not relevant, reliable or admissible to any substantive analysis of general causation, in the context of *Daubert* or otherwise.

6. Plaintiffs agree not to serve additional document requests on general causation beyond those identified in Paragraph 1 above, except by order of the Court for good cause shown.

7. The parties agree to continue to negotiate the number and scope of company witness depositions including 30(b)(6) depositions on documents and

substantive issues of general causation. Defendants will not take the position that no company witness depositions will be required for general causation discovery but reserve the right to object to company witness depositions on documents.

DONE and **ORDERED** on this 30th day of November, 2016.

M. Casey Rodgers

M. CASEY RODGERS
CHIEF UNITED STATES DISTRICT JUDGE

EXHIBIT A

1. Safety and surveillance documents, communications and information including but not limited to correspondence files, the protocols for monitoring, collecting, coding and maintaining such information.

2. All documents and communications that concern the information defendants consider to determine if there is a safety signal.

3. Pre-clinical and clinical trial data, including information, documentation and communications underlying such trials (e.g., informed consent documents provided to study participants, and all study protocols along with all amendments and/or changes related to each protocol). Underlying data to clinic trials, and those mechanism studies in which Otsuka or BMS was involved or sponsored.

4. All animal behavior study data about Abilify, and communications about that data.

5. All documents, information and communications related to any and all mechanism of action by which Abilify is either causing and/or associated with an increased risk of certain compulsive behaviors that the defendants considered, evaluated, examined, researched, etc.

6. Pre-clinical and clinical trial data not part of NDA.

7. Publication Plans, documents and communications regarding ghost writing of articles about Abilify.

8. All documents and communications regarding any transfer of documents or information concerning Abilify and compulsive behaviors among defendants or to third parties and/or any entity affiliated with the defendants.

9. All documents and communications, not already produced, with FDA or foreign regulators concerning Abilify and compulsive behaviors.

10. Adverse event source files for reports of Abilify and compulsive behaviors.

11. Documents related to and/or referencing all communications, both verbal (e.g., call recordings, notes from verbal communication) and written communication, including all e-mails and "texts," to or by any employee or officer of any defendant regarding Abilify and compulsivity.

12. All documents and communications between defendants regarding Abilify and its possible association with compulsivity.

13. All documents and communications reflecting all communication to or from any healthcare provider regarding causation or alternative causes in any individual case and the increased risk and/or potential increased risk that Abilify users might experience certain compulsive behaviors.

14. All documents or communications regarding challenge, dechallenge and/or rechallenge information regarding Abilify and certain compulsive behaviors, or those methodologies generally.

15. All documents, communications and data from current ongoing studies concerning Abilify and compulsive behavior.

16. All documents and communications relating to the "cumulative review" of compulsivity cases conducted in response to or by the European regulators.

17. Preclinical, clinical and product development data provided to BMS (4.5.1 of Development and Commercialization Collaboration Agreement).

18. All documents or communications concerning analyses or studies, published or unpublished, of any possible association between Abilify and compulsivity or any safety signal regarding compulsivity including database studies, post-marketing studies and trend analysis.

19. All documents or communications concerning effect of Abilify on dopamine in animals or humans.

20. All documents and communications that mention any outsourcing of any pharmacovigilance activity, including post-marketing surveillance of Abilify.

21. All documents or communications that concern or refer to the "Sponsor's submission" described on page 16 of the March 10, 2016 FDA Pharmacovigilance Review," including all documents or communications that concern or refer to the document titled "Clinical Overview – CBE-0 Jan 2016 – Pathological Gambling."