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

Counsel for Plaintiffs and Defendants in the New Jersey state court consolidated Abilify cases agreed that Defendants would produce the following documents as "core discovery" in that litigation by January 21, 2017:

- All agreements between Otsuka and Bristol-Myers Squibb relating to the parties' co-promotion of Abilify;
- All documents contained in the New Drug Application and Investigational New Drug Application for Abilify, except for the "Chemistry, Manufacturing and Controls" documents;
- Communications with Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and Health Canada relating to pathological gambling or impulse control disorders;
- Correspondence with FDA regarding the "dimmer switch" promotion;
- Periodic Safety Update Reports and Periodic Benefit-Risk Evaluation Reports for Abilify submitted to regulatory agencies;
- Adverse event reports regarding pathological gambling or impulse control disorders;
- Final clinical study reports and investigative brochures prepared in connection with any clinical trials assessing the safety and/or efficacy of Abilify;

- Relevant organizational charts from the safety and pharmacovigilance groups governing Abilify to the extent reasonably available from central sources;

- Standard Operating Procedures relating to adverse event reporting, signal detection and labeling to the extent available for the relevant time periods;

- All versions of the U.S. Package Insert, including full U.S. label and patient medication guides;

- All iterations of the Core Company Data Sheet;

- FDA Form 2253 files for Abilify marketing materials;

- Formal Medical Information Requests and the responses thereto relating to Abilify for pathological gambling and impulse control disorders;

- Official communications to the medical profession or public about pathological gambling and impulse control disorder in Abilify patients, including any Dear Doctor letter, if any;

- Public securities filings;

- Corporate integrity agreements regarding Abilify;

- The Abilify Marketing Plans that were approved by the Joint Commercialization Committee referenced in defendants' co-promotion agreements; and

- Safety-related correspondence referenced in Section 4.0 of the Revised Amended and Restated Pharmacovigilance Data Exchange Agreement, to the extent reasonably available from central sources.

This court similarly orders that the foregoing categories of documents be produced to plaintiffs in this MDL action, pursuant to Fed R. Civ. Proc. 34, by January 21, 2017. Any responsive documents withheld by any Defendant on the

grounds of privilege, work-product, or other protection against discovery must be described in a privilege log, produced at the same time as the core discovery.

DONE and **ORDERED** on this 16th day of November, 2016.

M. Casey Rodgers

M. CASEY RODGERS
CHIEF UNITED STATES DISTRICT JUDGE