

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF FLORIDA  
PENSACOLA DIVISION**

IN RE: ABILIFY (ARIPRAZOLE) PRODUCTS LIABILITY LITIGATION  This Document Relates to All Cases	Case No. 3:16-md-2734  Judge M. Casey Rodgers Magistrate Judge Gary Jones
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**DEFENDANTS' BRIEF IN SUPPORT OF  
PROPOSED ORDER REGARDING CASE REVIEW PROCESS**

The Court has witnessed in this litigation a consistent pattern of inadequate vetting of cases, dismissal of cases following initiation of discovery, and repeated failures of Plaintiffs to properly and adequately complete profile forms.

Particularly now that the parties have reached a settlement in principle, it is an appropriate procedural time for the Court to require any Plaintiffs' counsel who wish to proceed with litigation to certify their thorough and complete review of their cases.

**I. Background**

The cases in this litigation have shown consistent fundamental problems:

- *First MDL trial pool:* Of seven cases in the first MDL trial pool, Plaintiffs voluntarily dismissed three before Defendants took a single deposition. Counsel withdrew from a fourth following Plaintiff's deposition.
- *First New Jersey trial pool:* Of five cases initially selected for the first New Jersey trial pool, just two remained at the time of the summer hiatus.

- *Second MDL trial pool*: Of the six “fast-track” cases that the Court randomly selected from a discovery pool of thirty, Plaintiffs voluntarily dismissed one before any depositions, and two more during the week of mediation.
- *Plaintiff Profile Forms*: Hundreds of Plaintiffs have filed suit and then refused to fill out profile forms, and the information in the completed forms has been wildly unreliable.

Despite these weaknesses and the staggering dropout rate, the dismissals have been extremely costly and burdensome for the parties. Collecting and reviewing records alone requires a significant effort, and Defendants also have taken scores of fact witness depositions across the country in cases later dismissed. Without a case review process in place going forward, Defendants face the prospect of additional burden and expense on claims that even a cursory screening would reveal as meritless.

## **II. Case Review Process**

It is well within this Court’s authority to order Plaintiffs’ counsel to certify that they have reviewed basic medical, financial, and gambling records and that their clients are aware of the obligations for participating in civil litigation, including sitting for a deposition and potentially appearing at trial. Indeed, MDL courts frequently enter case review orders in mass torts, including in pharmaceutical litigations with similar patterns of dismissals.

For example, the Plavix MDL in the District Court for the District of New Jersey saw a comparable dropout rate. In the first round of that litigation, Plaintiffs

dismissed most of their 24 cases, and Judge Freda Wolfson granted summary judgment in the remaining six based on prescriber deposition testimony. *See, e.g., Solomon v. Bristol-Myers Squibb Co.*, 916 F. Supp. 2d 556, 570 (D.N.J. 2013); *LaBarre v. Bristol-Myers Squibb Co.*, 2013 WL 144054, at \*10 (D.N.J. Jan. 11, 2013), *aff'd*, 544 F. App'x 120 (3d Cir. 2013). In the second Plavix round, Plaintiffs dismissed or withdrew from representation in 81 of 117 discovery pool cases—or 69% of the pool. And, similar to here, Plaintiffs' theory of liability—that the defendants failed to warn of the risk of bleeding, when the product at issue was a blood thinner—did not withstand scrutiny in any individual case.

Judge Freda Wolfson then ordered counsel for the remaining Plavix plaintiffs to review their inventory and, for any cases with which they wanted to proceed, certify that they had obtained and reviewed records, that they had discussed with the plaintiff the obligations for participation in the litigation, and that they had a good faith basis for proceeding with the action. Judge Wolfson allowed the defendants to move for dismissal if a plaintiff failed to timely and completely comply with the order. *See Corrected Order Governing Supplemental Case Review Process, In re Plavix Mktg., Sales Practices & Prods. Liab. Litig. (No. II)*, MDL No. 2418 (D.N.J. June 1, 2017) (attached as Exhibit A).<sup>1</sup>

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<sup>1</sup> *See also, e.g., In re Fosamax*, 2012 WL 12892056 (S.D.N.Y. Oct. 16, 2012); *In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 2010 WL 4720335

Defendants propose a similar case review order here, with minor additions due to the differences between Plavix and this litigation. *See* Proposed Order Regarding Case Review Process (attached as Exhibit B).

*First*, the Proposed Order requires Plaintiffs' counsel to certify that they have obtained and reviewed critical medical, financial, and gambling records regarding each Plaintiff's (i) use of Abilify, (ii) alleged compulsive behavior(s) during Abilify use, (iii) prior and subsequent history of compulsive behaviors, and (iv) claimed damages. This will help avoid the filing of cases that have no proof of injury, causation, and/or damages. While the case review order in Plavix did not expressly require review of pre- and post-Plavix use records or records supporting the damages claims, those issues were far less at play in that litigation. Here, most Plaintiffs exhibited compulsive behaviors both before and after their use of Abilify, which confounds their claims that Abilify caused such behaviors. Indeed, it often appeared that Plaintiffs' counsel did not learn of these fundamental flaws in their causation theory until the Plaintiffs' own depositions and that these issues were not discovered in counsel's pre-litigation investigation. And there was no question in Plavix that, if a plaintiff did suffer a bleed, that person incurred damages associated

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(E.D. Pa. 2010); *In re Rezulin Prods. Liab. Litig.*, 2005 WL 1105067 (S.D.N.Y. 2005); *In re Baycol Prods. Liab. Litig.*, 2004 WL 626866 (D. Minn. 2004).

with medical treatment. Discovery in this litigation, by contrast, has shown damages claims to be unreliable and unsupported.<sup>2</sup>

*Second*, the Proposed Order requires Plaintiffs to reaffirm they wish to proceed with the action, knowing that it may obligate them to participate in discovery and/or trial. If Plaintiffs' counsel is unable to timely furnish such a certification, that itself raises serious doubts as to whether a Plaintiff would actively participate in the litigation if selected for further workup. Requiring counsel to discuss the obligations specific to this litigation—including providing personal psychiatric and financial records and having family members sit for deposition—only makes sense given that Plaintiffs themselves have put their mental health, personal history and financial history at issue by pursuing these claims. In deciding whether to proceed, they should be aware that they are committing to disclose this information.

*Third*, the Proposed Order requires Plaintiffs' counsel to certify they have a good faith and reasonable basis to proceed. This simply reinforces Plaintiffs' Rule 11 obligations, which require signed pleadings attesting that claims have legal support and factual allegations have evidentiary support. Unlike in *Plavix*, the Proposed Order does not provide for amendment of the attorney certification. That

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<sup>2</sup> For example, 75% of Plaintiffs who submitted Plaintiff Profile Forms gave only ballpark estimates of their damages (e.g., \$500 or \$1,000 increments), and the verified damages provided in the Supplemental Plaintiff Profile Forms accounted for a fraction of Plaintiffs' initial damages claims.

is due to the record in this litigation, where Plaintiffs have repeatedly amended or corrected information provided under oath. Counsel should not be permitted to avoid their fundamental obligation to investigate their clients' claims before filing suit. Should Plaintiffs' counsel believe there are extenuating circumstances for why they have not timely provided correct and complete certifications, they can oppose for good cause any motion by Defendants for an order to show cause.

*Fourth*, the Proposed Order provides deadlines by which Plaintiffs' counsel must submit the attorney certification. For Plaintiffs who are eligible to participate but decline to do so, that deadline is within 5 days of notification of the declination to Defendants, giving Plaintiffs' counsel ample time to prepare the certification. For Plaintiffs who filed their Complaints after the January 28, 2019 eligibility date, their counsel must file the certification within the later of 21 days after entry of this Order or 5 days of filing the Complaint. Counsel in *Plavix* had a longer time period to comply, but that was because the order there applied to thousands of already filed cases. Here, there are only a handful of cases subject to the 21-day deadline because they were filed after January 28, 2019 and, going forward, Plaintiffs will know in advance of filing a Complaint or declining to participate that they are subject to a 5-day certification deadline. They should be prepared to provide the certification promptly after filing or declining to participate.

*Finally*, the Proposed Order includes an enforcement mechanism if a Plaintiff fails to timely and completely serve the required documentation. MDL courts routinely dismiss cases with prejudice for failure to make submissions required by case review orders.<sup>3</sup> This Court itself has dismissed claims with prejudice for failure to serve Plaintiff Profile Forms. *See, e.g.*, ECF No. 1112; Order, *Inman v. Bristol-Myers Squibb Co.*, 3:17-cv-00597, ECF No. 8 (N.D. Fla. Oct. 29, 2018). The same result should obtain here if Plaintiffs are noncompliant.

In sum, the record justifies placing reasonable requirements on Plaintiffs to result in only cases that meet the required threshold for merit to be filed, prevent burden on the court, and ensure the “just, speedy, and inexpensive determination of every action and proceeding.” Fed. R. Civ. P. 1. Defendants accordingly respectfully request that the Court enter the Proposed Order.

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<sup>3</sup> *See, e.g.*, *In re Avandia*, 2010 WL 4720335, at \*2 (dismissal with prejudice upon defendant’s motion); *In re Fosamax*, 2012 WL 5877418, at \*5 (dismissal with prejudice upon failure to show cause); *In re Rezulin*, 2005 WL 1105067, at \*2 (imposition of sanctions allowed, including dismissal with prejudice); *In re Baycol*, 2004 WL 626866, at \*3 (dismissal with prejudice upon submission of proposed order).

Respectfully submitted,

*s/ Larry Hill*

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**CERTIFICATE OF SERVICE**

I hereby certify this 15th day of February, 2019, a true and correct copy of the foregoing was filed electronically via the Court's CM/ECF system, which will automatically serve notice of this filing via e-mail notification to all registered counsel of record.

*/s/ Larry Hill*  
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Larry Hill

# **EXHIBIT A**

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2418 Docket No. 13-cv-2418-FLW-TJB ALL CASES
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~~PROPOSED~~ **CORRECTED ORDER GOVERNING SUPPLEMENTAL CASE REVIEW PROCESS**

WHEREAS, before any new cases are selected for a new discovery pool, Plaintiffs’ counsel shall undertake a further review of their cases;

WHEREAS, this Order replaces the Order governing supplemental case review process entered on May 2, 2017 (ECF No. 234);

NOW THEN, the Court enters the following Order setting forth a case review process:

1. Plaintiffs’ Counsel’s Review of Case Inventory. Plaintiffs’ counsel shall have until September 1, 2017 to review their inventory of cases. Within that time frame, Plaintiffs’ counsel shall dismiss with or without prejudice or withdraw as counsel from those cases which they do not wish to pursue. For such dismissals or withdrawals, the Parties will each bear their own costs.
2. Certification. For each case Plaintiffs’ counsel wishes to pursue, no later than September 1, 2017, Plaintiffs’ counsel must serve a declaration signed by each named Plaintiff and Plaintiffs’ counsel, under penalty of perjury, certifying that:
  - a. Plaintiffs’ counsel has obtained and reviewed the following medical records<sup>1</sup>:
    - (1) medical records documenting Plavix® use, (2) medical records documenting an injury alleged to be related to such Plavix® use, and (3) all available medical records documenting treatment of the patient by each key

<sup>1</sup> “Medical records” includes but is not limited to: pharmacy records, billing records, insurance records, operative reports, hospital records, admission records, discharge records, medication lists authored by medical professionals, records from specialists, primary care physician records, and photographs of prescription bottles showing the patient’s name and date of prescription.

physician who prescribed Plavix®. A “key” physician is one who instigated the prescription and/or prescribed Plavix when asserted adverse events that are the subject of the suit commenced.

- b. Plaintiffs’ counsel and Plaintiff(s) have discussed the obligations for participation in the litigation, including sitting for a deposition and potentially appearing at trial.
- c. Based on review of the medical records and other pertinent evidence, and in consultation with the Plaintiff(s), Plaintiffs’ counsel has a good faith and reasonable basis to proceed with the action; and Plaintiffs themselves are willing to proceed with the action and to undertake the obligations necessary to do so.

Plaintiffs may amend any Certification upon receipt of additional evidence. These deadlines can be extended for good cause.

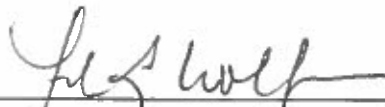
3. Supplemental Plaintiff Profile Form Questions. The Plaintiff Profile Form questions shall be amended to incorporate questions directed to the basis of the plaintiff’s claim of liability. The parties shall meet and confer in an effort to reach agreement on such questions, and within 30 days either present the Court with an agreed proposed order or letters setting forth any disagreements for the Court’s decision.
4. Proof of Representative Status. All Plaintiffs proceeding as purported representatives of decedents shall have until September 1, 2017 to supply Defendants with legally sufficient proof of representative status or similar legally sufficient document, if they have not already done so. In cases where the Plaintiff has become deceased after filing the action, Plaintiffs must likewise substitute a legally sufficient proper representative and supply Defendants with legally sufficient proof of representative status within that time frame. Alternatively, within that time frame, Plaintiffs may supply “hardship affidavits” in the previously agreed upon form.

5. Dismissal For Failure to Provide Required Documents. If any of the documents set forth above are not timely and completely supplied as to a particular Plaintiff's claims, after a meet and confer, then Defendants may move for an order of dismissal of such Plaintiff's claims. Plaintiffs may oppose such motion(s) on the basis of good cause.

**IT IS SO ORDERED.**

Dated: \_\_\_\_\_

June 1, 2017

  
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**Honorable Freda L. Wolfson**

# **EXHIBIT B**

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

IN RE: ABILIFY (ARIPIPRAZOLE) PRODUCTS LIABILITY LITIGATION  This Document Relates to All Cases	Case No. 3:16-md-2734  Judge M. Casey Rodgers Magistrate Judge Gary Jones
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**[PROPOSED] ORDER REGARDING CASE REVIEW PROCESS**

For good cause shown, including the high rate of voluntary dismissals of cases in the discovery and trial pools, and the need for the just, speedy, and inexpensive determination of actions in accordance with Fed. R. Civ. Pro. 1, the Court hereby Orders the following:

1. Plaintiffs' Counsel's Review of the Cases. This Order applies to any cases that are filed in this MDL by any Plaintiffs who are either ineligible to participate in the Confidential Master Settlement Agreement ("the Agreement") because they filed their Complaint after January 28, 2019, or are eligible to participate in the Agreement but decline to do so. Plaintiffs' counsel in those cases must certify that:



- a. He or she has obtained and reviewed the following records: (1) medical records<sup>1</sup> documenting Plaintiff's Abilify use; (2) medical, financial,<sup>2</sup> gambling,<sup>3</sup> or other records during the period of Plaintiff's Abilify use documenting an injury (compulsive behavior) alleged to be related to such Abilify use; (3) medical, financial and gambling records before and after Plaintiff's Abilify use, consistent with the time periods imposed by the Plaintiff Fact Sheet, Plaintiff Profile Form and Supplemental Profile Form approved in this litigation, reflecting whether or not Plaintiff had a prior or subsequent compulsive behavior; (4) medical, financial, gambling, or other records sufficient to support Plaintiff's claimed damages; and (5) all

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<sup>1</sup> "Medical records" include but are not limited to: physician records, psychiatrist records, medication management records, therapy records, counseling records, pharmacy records, billing records, insurance records, hospital records, admission records, discharge records, medication lists authored by medical professionals, records from specialists, records from primary care physicians, records from treatment facilities, and photographs of prescription bottles showing the patient's name and date of prescription.

<sup>2</sup> "Financial records" include but are not limited to: bank statements, credit card statements, credit reports, statements of interest-earning accounts, bankruptcy records, loan records, tax returns, worker's compensation and/or unemployment records, records of settlement payment(s) received in connection with any other lawsuit, and any other record held by a financial institution pertaining to Plaintiff's relationship with the financial institution.

<sup>3</sup> "Gambling records" include but are not limited to: records from casinos or other facilities that house or accommodate gambling activities, lottery and scratchoff tickets, Form W-2 records, records from online gambling websites or applications, communications between Plaintiff and gambling entities, and gambling receipts.

available medical records documenting Plaintiff's treatment by each key physician who prescribed Abilify to Plaintiff. A "key" physician is one who started a Plaintiff on Abilify, or who prescribed Abilify when the compulsive behavior(s) that is/are the subject of Plaintiff's lawsuit began;

- b. Plaintiffs' counsel and Plaintiff have discussed the obligations for participation in the litigation, including providing personal medical, psychiatric, and financial records (e.g., bank statements and credit reports); completing a Plaintiff Profile Form and Supplemental Plaintiff Profile Form and attaching the required documentation; sitting for a deposition; having depositions of Plaintiff's spouse, family members, and treating physicians taken; and potentially appearing at trial and being subject to cross-examination; and
- c. Based on review of the records and other pertinent evidence, and in consultation with Plaintiff, Plaintiffs' counsel has a good faith and reasonable basis to proceed with the action, and Plaintiff is willing to proceed with the action and to undertake the obligations necessary to do so.

2. Deadline for Certification. The deadline for submitting the certification described above is as follows:

- a. For ineligible cases, within 21 days of this Order or within 5 days of filing a Complaint, whichever is later; and
  - b. For eligible cases, within 5 days of notification to Defendants that Plaintiff has rejected participation in the Agreement.
3. Dismissal for Failure to Provide Required Certification. If Plaintiffs' counsel fails to provide the certification required by this Order within the applicable deadlines for a particular Plaintiff then, after a meet and confer, Defendants may seek an order to show cause why such Plaintiff's claims should not be dismissed with prejudice for failure to comply with this Order. Plaintiffs may oppose such a motion on the basis of good cause.

**DONE** and **ORDERED** on this \_\_\_ day of \_\_\_\_\_, 2019.

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