UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN)	*	MDL 2592
PRODUCTS LIABILITY LITIGATION	*	
	*	SECTION L
THIS DOCUMENT RELATES TO	*	
ALL CASES	*	JUDGE ELDON E. FALLON
	*	
	*	MAG. JUDGE NORTH
* * * * * * * * * * * * * * * * * * * *	* *	

JOINT REPORT NO. 15 OF PLAINTIFFS' AND DEFENDANTS' LIAISON COUNSEL

Plaintiffs' Liaison Counsel ("PLC") and Defendants' Liaison Counsel ("DLC") respectfully submit this Joint Report No. 15. All Pre-Trial Orders are posted on the court's website located at www.laed.uscourts.gov/Xarelto. The Court's website also includes other postings relevant to the litigation.

1. <u>PRE-TRIAL ORDERS</u>

The Court has issued the following Pre-Trial Orders:

Pre-Trial Order No. 1 [Rec. Doc. 2] entered December 17, 2014 – Setting initial conference;

Pre-Trial Order No. 2 [Rec. Doc. 38] entered January 16, 2015 – Appointing Plaintiffs' Liaison Counsel;

Pre-Trial Order No. 3 [Rec. Doc. 39] entered January 16, 2015 – Appointing Defendants' Liaison Counsel;

Pre-Trial Order No. 4 [Rec. Doc. 61] entered January 26, 2015 – Requiring Counsel to provide contact information to Liaison Counsel, and amending PTO No. 1 regarding docketing procedure;

Pre-Trial Order No. 4A [Rec. Doc. 62] entered January 26, 2015 – Approving and attaching Counsel Contact Information Form;

Pre-Trial Order No. 5 [Rec. Doc. 63] entered January 26, 2015 – Clarifying duties of transferor court under MDL Rule 1.6;

Pre-Trial Order No. 5A [Rec. Doc. 149] entered February 3, 2015 – Amending PTO No. 5 to allow transferor court to retain original file;

Pre-Trial Order No. 6 [Rec. Doc. 150] entered February 3, 2015 – Appointing Defendants' Co-Lead Counsel;

Pre-Trial Order No. 7 [Rec. Doc. 169] entered February 9, 2015 – Appointing Plaintiffs' Steering Committee (PSC); Appointing Plaintiffs' Co-Lead Counsel; Ordering that PLC and Plaintiffs' Co-Lead Counsel shall comprise PSC Executive Committee; Appointing Chair of the State Liaison Committee, to be *ex-officio* member of PSC; and Listing responsibilities of PSC. On February 3, 2016, the Court issued a Minute Entry [Rec. Doc. 2077] reappointing the PSC members for another one year term from the date of the Minute Entry;

Pre-Trial Order No. 7A [Rec. Doc. 830] entered April 29, 2015 – Appointing Michael Weinkowitz, Daniel Gallucci, and Gibson Vance to serve on the State Liaison Committee;

Pre-Trial Order No. 8 [Rec. Doc. 183] entered February 13, 2015 – Establishing standards and procedures for counsel seeking reimbursement for common benefit fees and costs;

Pre-Trial Order No. 9 [Rec. Doc. 356] entered March 24, 2015 – Providing for the Direct Filing of Complaints in the MDL;

Pre-Trial Order No. 10 [Rec. Doc. 357] entered March 24, 2015 – Providing for the Streamlined Service on Certain Bayer Defendants;

Pre-Trial Order No. 11 [Rec. Doc. 893] entered May 4, 2015 – Providing for Bundling of Complaints, Answers and Responsive Pleadings, with attached Attorney Instructions for Filing Individual Severed Xarelto Cases [Rec. Doc. 893-1];

Pre-Trial Order No. 11A [Rec. Doc. 923] entered May 20, 2015 – Providing exemplar Joint Complaint and exemplar Short Form Complaint;

Pre-Trial Order No. 11B [Rec. Doc. 1117] entered July 14, 2015 – Governing a Joined Plaintiff's responsibility for a filing fee and modifies second sentence of paragraph 1(a) of Pre-Trial Order No. 11;

Pre-Trial Order No. 11C [Rec. Doc. 1118] entered July 14, 2015 – Clarification for some issues that have arisen since the Court issued Pre-Trial Order No. 11;

Pre-Trial Order No. 11D [Rec. Doc. 2002] entered January 27, 2016 – Updated Exemplar Joint Complaint;

Pre-Trial Order No. 11E [Rec. Doc. 2850] entered March 21, 2016 – Terminating Joint Complaint filing procedure;

Pre-Trial Order No. 11F [Rec. Doc. 3065] entered April 15, 2016 – Clarification of Pre-Trial Order No. 11E;

Pre-Trial Order No. 12 [Rec. Doc. 894] entered May 4, 2015 – Stipulated Protective Order;

Pre-Trial Order No. 13 [Rec. Doc. 895] entered May 4, 2015 – Governing the Form and Schedule for Service of Plaintiff Fact Sheets and Executed Authorizations for Release of Records;

Pre-Trial Order No. 14 [Rec. Doc. 896] entered May 4, 2015 – Governing the Form and Schedule for Service of Defendant Fact Sheets;

Pre-Trial Order No. 13A & 14A [Rec. Doc. 1040] entered June 23, 2015 – Regarding Plaintiff Fact Sheets and Authorizations and Defendant Fact Sheets;

Pre-Trial Order No. 14A [Rec. Doc. 1221] entered August 17, 2015 – Regarding Defendants Fact Sheets with attached Consent Letter from IMS Health Inc. for release of information and data;

Pre-Trial Order No. 14B [Rec. Doc. 1847] entered January 6, 2016 – Regarding Defendants Fact Sheets with attached Consent Letter from IMS Health Inc. for release of information and data;

Pre-Trial Order No. 15 [Rec. Doc. 897] entered May 4, 2015 – Consent Order Regarding the Preservation of Documents and Electronically Stored Information;

Pre-Trial Order No. 15A [Rec. Doc. 1301] entered September 17, 2015 – Consent Order Regarding Preservation of Voicemail, Text Messages and Instant Messages; [vacated by Pre-Trial Order No. 15B, *infra*]

Pre-Trial Order No. 15B [Rec. Doc. 1477] entered October 21, 2015 – Consent Order Regarding Preservation of Voicemail, Text Messages, and Instant Messages;

Pre-Trial Order No. 16 [Rec. Doc. 898] entered May 4, 2015 – Filing Requests for Summons and Summons Returns;

Pre-Trial Order No. 17 [Rec. Doc. 924] entered May 20, 2015 – Electronic Service/MDL Centrality for Plaintiffs Only;

Pre-Trial Order No. 18 [Rec. Doc. 925] entered May 20, 2015 – Science Day;

Pre-Trial Order No. 19 [Rec. Doc. 951] entered June 4, 2015 – Protocol for Treatment of Privileged and Work Product Materials;

Pre-Trial Order No. 20 [Rec. Doc. 1007] entered June 15, 2015 – Regarding the Format for Production of Hardcopy Documents and Electronically Stored Information;

Pre-Trial Order No. 21 [Rec. Doc. 1302] entered September 17, 2015 – Consent Order Regarding Document Production Protocol;

Pre-Trial Order No. 22 [Rec. Doc. 1745] entered December 11, 2015 – Mailing Lists for Dear Doctor Letters;

Pre-Trial Order No. 23 [Rec. Doc. 2283] entered February 17, 2016 – Deposition Guidelines;

Pre-Trial Order No. 24 [Rec. Doc. 2879] entered March 23, 2016 – Dismissal Guidelines; and

Pre-Trial Order No. 25 [Rec. Doc. 3038] entered April 14, 2016 – Production of Materials Pursuant to Subpoenas to Third Parties.

2. <u>CASE MANAGEMENT ORDER NOS. 2, 3, & 4:</u>

On September 17, 2015, the Court entered Case Management Order No. 2 [Rec. Doc. 1305], on consent of the parties, which addressed the course of the proceedings in this litigation through the first four bellwether trials. On November 30, 2015, the Court issued Amended Case Management Order No. 3, which addresses the process for selection into the bellwether discovery pool and the bellwether plaintiff cases. [Rec. Doc. 1680-1]. On December 17, 2015, the Court issued Case Management Order No. 4 [Rec. Doc. 1785], which sets forth the criteria for and selection of the bellwether discovery pool selection process and eligibility criteria.

3. <u>BELLWETHER SELECTIONS</u>

The Parties exchanged bellwether selections on January 11, 2016 and random selections from the BrownGreer MDL Centrality arrays were made on January 15, 2016. Challenges

permitted under CMO 3 were made and on January 21, 2016 the bellwether discovery pool selections were finalized. On March 7, 2016, the Court entered an Order listing the 40 discovery pool plaintiffs. [Rec. Doc. 2626]. The parties will be prepared to discuss this matter at the April 20, 2016 status conference.

4. <u>COUNSEL CONTACT INFORMATION FORM</u>

All counsel in the MDL are required to complete the Counsel Contact Information Form attached to PTO No. 4A, and forward it to the appropriate Liaison Counsel. This information must be kept current by counsel providing the information, and will be relied upon throughout the litigation.

5. <u>PLAINTIFF FACT SHEETS</u>

On May 4, 2015, the Court issued Pre-Trial Order No. 13 [Rec. Doc. 895], which governs the form and schedule for service of Plaintiff Fact Sheets ("PFSs"), as well as executed Authorizations for the release of records to be completed by plaintiffs in all individual cases. Pre-Trial Order No. 13A and 14A [Rec. Doc. 1040] provides the procedure for the online submission and service of Fact Sheets and Authorization forms through the BrownGreer MDL Centrality System.

On January 4, 2016, Defendants provided to plaintiffs' counsel a listing of plaintiffs who have either: (1) failed to submit PFSs in accordance with the deadlines set by the Court; or (2) failed to provide records demonstrating proof of use of Xarelto® as required for their PFSs to be substantially complete. *See* PTO 14 ¶1. The PSC communicated with all counsel identified on the list to encourage compliance with PTO 14 on a timely basis. On February 19, 2016, Defendants filed two Motions for Orders to Show Cause Regarding: (1) Plaintiffs Who Have Failed to Serve a

Case 2:14-md-02592-EEF-MBN Document 3071 Filed 04/18/16 Page 6 of 14

Plaintiff Fact Sheet [Rec. Doc. 2375]. The Court entered the Orders to Show Cause on February 24, 2016 [Rec. Docs. 2424 & 2425]. A hearing on the Orders to Show Cause took place after the March 16, 2016 status conference. Per the Court's decisions at the hearing, on April 6, 2016, various Orders were subsequently entered either dismissing the cases with prejudice, giving the Plaintiffs additional time to cure the deficiency, or removing cases from the Orders to Show Cause that had been subsequently resolved. The parties continue to meet and confer regarding plaintiffs who have been left *pro se* by withdrawal of counsel and will be prepared to discuss the matter further at the April 20, 2016 Conference.

Prior to filing a Motion for Extension of PFS Deadlines, plaintiff's counsel should contact Defendants' Liaison Counsel to determine whether there is any opposition. The parties will be prepared to discuss this matter further at the April 20, 2016 status conference.

The parties continue to meet and confer to further discuss the issue that arose with regard to the deadline for the submission of Defendant Fact Sheets, in cases where plaintiffs amend or supplement their original Plaintiff Fact Sheet.

6. <u>DEFENDANT FACT SHEETS</u>

On May 4, 2015, the Court issued Pre-Trial Order No. 14 [Rec. Doc. 896], which governs the form and schedule for service of Defendant Fact Sheets to be completed by defendant in all individual cases. Pre-Trial Orders No. 13A, 14A, and 14B [Rec. Docs. 1040, 1221, & 1847] provide the procedure for the online submission and service of Fact Sheets and Authorization forms through the BrownGreer MDL Centrality System, as well as for the release of information and data from IMS Health, Inc.. At the March 16, 2016 status conference, the parties will report to the Court on the status of Defendant Fact Sheets. Pursuant to paragraph 3 of PTO 14 [Rec. Doc. 896], it is the responsibility of the Plaintiffs' Liaison Counsel to send written notices of

Case 2:14-md-02592-EEF-MBN Document 3071 Filed 04/18/16 Page 7 of 14

DFS deficiencies to counsel for Defendants. However, any needed follow-up addressing such deficiencies remains the responsibility of individual counsel for plaintiff (a responsibility which the PSC is coordinating with individual plaintiffs' counsel only as to the 40 selected discovery pool plaintiffs).

7. <u>BUNDLING OF COMPLAINTS/ANSWERS/RESPONSIVE PLEADINGS</u>

On May 4, 2015, the Court issued Pre-Trial Order No. 11 [Rec. Doc. 893], which addresses Bundling of Complaints, Answers, and Responsive Pleadings and on May 20, 2015, the Court issued Pre-Trial Order 11A [Rec. Doc. 923], which provided an exemplar Joint Complaint and an exemplar Short Form Complaint; and on January 27, 2016, Pre-Trial Order 11D was entered [Rec. Doc. 2002] providing an updated exemplar Joint Complaint. On June 18, 2015, in accordance with PTO 11 [Rec. Doc. 893], Omnibus Answers with Jury Demands were filed by the following defendants: Bayer Healthcare Pharmaceuticals, Inc.; Bayer Pharma AG; and Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho, LLC (collectively, "the Janssen Defendants"), and Johnson & Johnson. On March 21, 2016, the Court issued Pre-Trial Order 11E [Rec. Doc. 2850], which announced that the filing of joint complaints will no longer be accepted by the Clerk's office as of May 20, 2016, and on April 15, 2016, the Court issued Pre-Trial Order 11F [Rec. Doc. 3065], which clarifies PTO 11E.

Under paragraph 2(c) of PTO 11 [Rec. Doc. 893], the voluntary dismissal of cases in which Omnibus Answers are operative can occur only by stipulation of the parties or a Court order following a properly-noticed motion. Due to this requirement, the Court issued an Order on July 22, 2015 [Rec. Doc. 1143] vacating prior Orders of voluntary dismissal without prejudice which had been granted *ex parte*, and further ordered that the motions to voluntarily dismiss these cases be scheduled for submission on August 6, 2015, with any opposition briefs

Case 2:14-md-02592-EEF-MBN Document 3071 Filed 04/18/16 Page 8 of 14

filed on or before July 29, 2015. On August 17, 2015, the Court entered an order [Rec. Doc. 1237] setting out the standard for without prejudice dismissals.

On March 23, 2016, the Court issued Pre-Trial Order No. 24 (Dismissal Guidelines) [Rec. Doc. 2879], which addresses dismissals of matters based upon subject matter jurisdiction. The parties also continue to meet and confer on the issue of subject matter jurisdiction in certain cases as well as whether the deferred filing fees of bundled parties (as established in PTO 11B) are implicated and will report to the Court on these issues at the April 20, 2016 status conference.

8. <u>PRESERVATION ORDER</u>

On May 4, 2015, the Court issued Pre-Trial Order No. 15 [Rec. Doc. 897], a Consent Order Regarding the Preservation of Documents and Electronically Stored Information. Pre-Trial Order No. 15 modifies paragraph 13 of Pre-Trial Order No. 1 relating to preservation of evidence. Further, the Court issued Pre-Trial Order No. 15B on October 21, 2015 [Rec. Doc. 1477] regarding the obligation of all parties to preserve voicemail, instant messages sent or received on an instant messaging system, or text messages sent or received on a cellular phone, smartphone, tablet or other mobile device. Pre-Trial Order 15B vacated previously entered Pre-Trial Order 15A. [Rec. Doc. 1301]. The parties will be prepared to discuss this matter at the April 20, 2016 status conference.

9. <u>PROPOSED ORDER GOVERNING THE PARTIES' INTERACTIONS</u> <u>WITH MDL PLAINTIFFS' PRESCRIBING AND TREATING</u> <u>PHYSICIANS</u>

On January 6, 2016, Defendants filed a Motion for Entry of Proposed Order Regarding Contact with Physicians. [Rec. Doc. 1844]. On February 1, 2016, the PSC filed its Opposition [Rec. Docs. 2044 and 2062] and on February 17, 2016 Defendants' filed their Reply [Rec. Doc. 2286]. Oral Argument was heard immediately following the status conference on February 23, 2016. On March 9, 2016, the Court issued Order & Reasons [Rec. Doc. 2676]. On April 6, 2016, the Defendants filed a Motion to Clarify, or in the Alternative, to Reconsider and Modify the Court's Order Regarding *Exparte* Contact With Physicians [Rec. Doc. 2991] and an Exparte Motion to Set Hearing Date of April 20, 2016 [Rec. Doc. 2992]. The matter was discussed with the Court and the parties on the bi-weekly discovery status conference call of April 7, 2016 and the parties continue to meet and confer to further discuss this matter.

10. **DISCOVERY**

On July 15, 2015, the Court issued an Order [Rec. Doc. 1119] setting telephone status conferences with Lead and Liaison Counsel of the parties on a bi-weekly basis. The purpose of these conferences is to report to the Court on discovery matters after the parties have met and conferred on these matters and have provided notice to the Court and to one another of the issues which remain to be addressed with the Court. The Court issued Pre-Trial Order No. 21 on September 17, 2015 [Rec. Doc. 1302]. The parties continue to participate in the Court's bi-weekly discovery telephone status conferences and the next conference is set for May 5, 2016. [Rec. Doc. 1842].

The parties continue to meet and confer regarding issues pertaining to Defendants' privilege logs and challenges made by the PSC in accordance with Pre-Trial Order No. 19 regarding the privilege logs provided by Defendants. The parties will be prepared to discuss this further at the April 20, 2016 status conference.

Depositions have proceeded to take place in the New Jersey offices of Drinker Biddle & Reath and additional depositions are scheduled to take place both domestically and overseas. The parties are continuing to meet and confer to discuss the location of some of the depositions and will report to the Court with regard to these issues. Defendants have agreed that subpoenas for

Case 2:14-md-02592-EEF-MBN Document 3071 Filed 04/18/16 Page 10 of 14

Defendant employee witnesses are not necessary and that Defendant employee witnesses will be produced voluntarily upon issuance of notices of depositions by the PSC.

On February 22, 2016, Plaintiffs filed a Motion for Leave to File Motion to Challenge Confidentiality Designations and for Relief from Pretrial Order No. 12 (Stipulated Protective Order) and to File Unredacted Version of Motion and Exhibits Under Seal [Rec. Doc. 2380]. The Court granted the Motion for Leave on March 1, 2016. [Rec. Doc. 2563]. The Redacted version of Plaintiffs' Motion to Challenge Confidentiality Designations and for Relief from Pretrial Order No. 12 (Stipulated Protective Order) was filed into the record on March 3, 2016 [Rec. Doc. 2564], while the Unredacted version was filed under seal. Defendants filed a Memorandum in Opposition to Plaintiffs' Motion to Challenge Confidentiality Designations and for Relief from Pretrial Order No. 12 (Stipulated Protective Order) on March 8, 2016 [Rec. Doc. 2642] and on March 11, 2016, the Plaintiffs filed their Reply in Support of their Motion under seal. [Rec. Doc. 2802]. Oral Argument was heard immediately following the status conference on March 16, 2016 [Rec. Doc. 2526] and an Order was entered by the Court on March 16, 2016 [Rec. Doc. 2832].

On March 23, 2016, the PSC and Defendants each provided letter briefs to the Court regarding materials reviewed in advance of a deposition and Defendants' counsel's objection to questioning based upon attorney "work product" grounds. The Court construed Defendants' letter brief as a Motion for Entry of a Protective Order Regarding Attorney Work Product and entered an Order & Reasons [Rec. Doc. 3022] on April 6, 2016. The parties continue to meet and confer regarding the procedure and timing of disclosures contemplated by the Court.

Case 2:14-md-02592-EEF-MBN Document 3071 Filed 04/18/16 Page 11 of 14

The parties continue to meet and confer regarding the Defendants' preservation of biological samples for current Xarelto related studies and will report further to the Court at the April 20, 2016 status conference.

On April 1, 2016, the PSC filed a Motion to Compel Discovery of Defendants' German Employees and Their Personnel files [Rec. Doc. 2951]. The matter is to be discussed further at the discovery bi-weekly status conference of May 5, 2016.

In connection with the discovery matter regarding the personnel file of Paul Herman, Defendants raised issues concerning questions of salary information at deposition. On April 14, 2016, the Court issued an Order [Rec. Doc. 3055] directing the parties to add a discussion of this issue to the agenda for the April 20, 2016 status conference. The parties will be prepared to discuss this matter at the April 20, 2016 status conference.

11. <u>DEPOSITION GUIDELINES</u>

On January 25, 2016, the Court issued Order & Reasons [Rec. Doc. 1970] regarding the Motion for Two Cameras at Depositions [Rec. Doc. 1923]. On January 26, 2016, the Court issued Order & Reasons [Rec. Doc. 1987] regarding deponent personnel files. On February 17, 2016, the Court issued Pre-Trial Order No. 23 (Deposition Guidelines) [Rec. Doc. 2283]. The parties continue to meet and confer on the application of the deposition guidelines with respect to other state court proceedings and the parties will be prepared to discuss this matter further at the April 20, 2016 status conference. On April 18, 2016, the Defendants filed a Consent Motion for Entry of Pretrial Order Regarding Bellwether Deposition Protocol [Rec. Doc. 3066]. The parties will be prepared to discuss this matter further at the April 20, 2016 status conference.

12. <u>DISCOVERY ISSUED TO THIRD PARTIES</u>

On April 22, 2015, the Plaintiffs' Steering Committee ("PSC") issued a subpoena duces tecum to the United States Food and Drug Administration ("FDA"). The parties have met and

Case 2:14-md-02592-EEF-MBN Document 3071 Filed 04/18/16 Page 12 of 14

conferred with representatives of the FDA and the FDA has begun producing documents responsive to the subpoena. On September 2, 2015, the parties had a follow up discussion with representatives of the agency during which counsel for plaintiffs explained that plaintiffs do not desire to receive duplicative FDA materials that have already been produced by Janssen and/or Bayer. On September 4, 2015, the FDA produced indices of its IND and NDA files of the FDA. The PSC intends on receiving additional materials from the FDA.

On June 4, 2015, the Plaintiffs' Steering Committee ("PSC") issued a Subpoena to Testify at Deposition to Duke Clinical Research Institute ("DCRI"). Representatives of the PSC and Defense Counsel met with representatives of DCRI on September 24, 2015. DCRI produced documents on November 10, 2015. The PSC has provided Defendants with copies of all documents produced by DCRI. The PSC will be prepared to discuss this matter at the April 20, 2016 status conference.

On December 16, 2015, the PSC issued a Subpoena to Testify at Deposition to Bernard "Bud" W. Chalecki, as well as filed a Notice of Subpoena [Rec. Doc. 1767]. Service was not successful and the matter is being addressed further by the PSC.

The parties will be prepared to discuss both of these matters further with the Court at the April 20, 2016 status conference.

13. <u>STATE/FEDERAL COORDINATION</u>

In accordance with Pre-Trial Orders No. 7 and 7A, as well as Case Management Order No. 1, PLC and DLC have had, and will continue to have, communications regarding the State Liaison Committee, as well as the status of coordination of MDL and state court actions. The parties will report to the Court on recent developments in state court cases brought in California and Delaware.

Case 2:14-md-02592-EEF-MBN Document 3071 Filed 04/18/16 Page 13 of 14

PLC and DLC will report to the Court on this matter at the April 20, 2016 Status Conference.

14. MATTERS SET FOR HEARING FOLLOWING STATUS CONFERENCE

None.

15. <u>NEXT STATUS CONFERENCE</u>

The Court has announced that the next status conference will be on May 24, 2016 at 8:30

a.m.

Dated: April 18, 2016

Respectfully Submitted,

/s/ Leonard A. Davis Leonard A. Davis (Bar No. 14190) Idavis@hhklawfirm.com *HERMAN, HERMAN & KATZ, LLC* 820 O'Keefe Avenue New Orleans, LA 70113 PH: (504) 581-4892 FAX: (504) 561-6024

Co-Plaintiffs' Liaison Counsel

<u>/s/ Gerald E. Meunier</u>
Gerald E. Meunier (Bar No. 9471)
<u>gmeunier@gainsben.com</u> *GAINSBURGH BENJAMIN DAVID MEUNIER & WARSHAUER, LLC*2800 Energy Centre, 1100 Poydras Street
New Orleans, LA 70163-2800
PH: (504) 522-2304
FAX: (504) 528-9973
Co-Plaintiffs' Liaison Counsel

<u>/s/ James B. Irwin</u> James B. Irwin (Bar No. 7172) <u>jirwin@irwinllc.com</u> *IRWIN FRITCHIE URQUHART & MOORE LLC* 400 Poydras Street, Suite 2700 New Orleans, LA 70130 PH: (504) 310-2100 FAX: (504) 310-2120 Defendants' Liaison Counsel

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 18, 2016, the foregoing pleading was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to Liaison Counsel for Plaintiffs and Defendants by operation of the court's electronic filing system and served on all other plaintiff counsel via MDL Centrality, which will send notice of electronic filing in accordance with the procedures established in MDL 2592 pursuant to Pre-Trial Order No. 17.

/s/Leonard A. Davis Leonard A. Davis

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN)	*	MDL 2592
PRODUCTS LIABILITY LITIGATION	*	
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ALL CASES	*	JUDGE ELDON E. FALLON
	*	
	*	MAG. JUDGE NORTH
* * * * * * * * * * * * * * * * * * * *	* *	

PROPOSED AGENDA FOR APRIL 20, 2016 STATUS CONFERENCE

- 1. Pre-Trial Orders
- 2. Case Management Order Nos. 2, 3, & 4
- 3. Bellwether Selections
- 4. Counsel Contact Information Form
- 5. Plaintiff Fact Sheets
- 6. Defendant Fact Sheets
- 7. Bundling of Complaints/Answers/Responsive Pleadings
- 8. Preservation Order
- 9. Proposed Order Governing the Parties' Interactions with MDL Plaintiffs' Prescribing and Treating Physicians
- 10. Discovery
- 11. Deposition Guidelines
- 12. Discovery Issued to Third Parties
- 13. State/Federal Coordination
- 14. Matters Set for Hearing Following the Status Conference
- 15. Next Status Conference