

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

**IN RE: XARELTO (RIVAROXABAN)
PRODUCTS LIABILITY LITIGATION**

*** MDL NO. 2592
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* SECTION L
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* JUDGE ELDON E. FALLON
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* MAG. JUDGE NORTH**

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THIS DOCUMENT RELATES TO ALL CASES**

PRETRIAL ORDER NO. 15

**CONSENT ORDER REGARDING THE PRESERVATION OF DOCUMENTS AND
ELECTRONICALLY STORED INFORMATION**

The Parties having conferred, consented, stipulated and agreed to entry of the within Consent Order, and good cause appearing therefore, Paragraph 13 of Pretrial Order No. 1 relating to preservation of evidence is modified, and it is hereby **ORDERED**, as follows.

I. GENERAL

This Order governs the preservation of potentially relevant documents, data, and tangible things within the Parties’ possession, custody and/or control relevant to claims and defenses in the cases that have been consolidated before this Court, and with respect to every action that may in the future be transferred to this Court that involve claims of personal injury from use of the pharmaceutical product Xarelto® (collectively “the Litigation” or the “Action”). The preservation obligations set out herein are explicitly intended to be reasonable in scope and to be interpreted and applied in a manner consistent with the factors set forth in Rule 26.

II. DEFINITIONS

A. As used herein, “Documents, Data, and Tangible Things” shall be interpreted broadly to include electronically stored information (“ESI”) on hard drives, USB or thumb drives, databases, computers, floppy disks, CD-ROM, magnetic tape, optical disks, or other devices for digital data storage or transmittal; as well as writings, records, files, correspondence, reports, memoranda, calendars, diaries, minutes, E-mail, telephone message records, hard drives, removable computer storage media such as tapes, discs and cards, printouts, document image files, Web pages, databases, spreadsheets, books, ledgers, journals, orders, invoices, bills, vouchers, checks statements, worksheets, summaries, compilations, computations, charts, diagrams, powerpoints or other demonstrative media, graphic presentations, drawings, films, charts, digital or chemical process photographs, video, phonographic, tape or digital records and any transcripts thereof, drafts, jottings and notes, studies or drafts of studies or other similar such material. Information which serves to identify or locate such material, such as file inventories, file folders, indices, and metadata, are also included in this definition.

B. The Parties will continue to meet and confer regarding the obligation on 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.

C. In order to not unduly interfere with business needs relating to the replacement or upgrade of equipment, no Defendant is obligated to preserve hardware on which data that is required to be preserved resides, so long as such data and associated metadata has first been preserved in an accessible form on another hardware device. Plaintiff’s obligations and options as to retention of hardware are set forth in Paragraph V.

D. As used herein, and consistent with the factors set forth in Rule 26, preservation shall be reasonably interpreted to accomplish the goal of maintaining the integrity of documents, data, and tangible things relevant to claims or defenses in this action and shall include taking reasonable steps to prevent the partial or full destruction, alteration, shredding, or deletion of such materials. Electronic documents and data will be maintained and preserved in their native format, except as authorized by Paragraph V below. To the extent a party may desire to change the format of preserved materials other than format changes effected in the normal course of business or operations where the change would affect the usability or accessibility of the materials in this Litigation, such party will consult with other parties before making any change. The parties shall be under an obligation to notify the Court and the parties should it be determined that any documents, data or tangible things subject to this order have been lost, deleted, destroyed, damaged, altered, corrupted, or otherwise affected such that preservation of such evidence either at all or in its original form has been hindered.

III. As used herein the terms, “Xarelto®” means Defendants’ anticoagulant product containing rivaroxaban marketed under the trade name Xarelto® or any other trade name that is or will be used. Defendants are not obligated to preserve materials relating to any other products, except for the following: (a) materials relating to any reversal agent or antidote for Xarelto (or for any product containing rivaroxiban); (b) materials relating to any other products containing rivaroxaban, whether currently on the market or in development; (c) materials within the custody or control of Defendants relating to any product, device, method and/or assay, that is manufactured, designed, developed and/or discussed by any entity, including, but not limited to the defendants, that is used, intended and/or designed to evaluate and/or measure (quantitatively and/or qualitatively) the concentration of rivaroxaban in a rivaroxaban treated patient and/or the

anticoagulant effect(s) of rivaroxaban in a rivaroxaban treated patient; and (d) materials relating to market research, comparative or competitive research or analysis, market or scientific comparison or market surveillance (including the tracking, review and analysis of medical or scientific literature) of dabigatran (Pradaxa), apixaban (Eliquis) or any other new oral anticoagulant (commonly referred to as “NOACs”) and/or their reversal agents, warfarin (Coumadin), fondaparinux (Arix tara) or enoxaparin sodium (Lovenox) to the extent such data was created or collected in connection with Xarelto or any potential reversal agent or antidote for Xarelto.

IV. GENERAL PRESERVATION OBLIGATIONS

Consistent with the factors set forth in Rule 26, all Parties shall take reasonable steps to ensure the preservation of documents, data, and tangible things relevant to claims or defenses in this Litigation. For Defendants, this shall include the dissemination of Legal Hold Notices to Defendants’ employees and/or departments reasonably believed to possess such material. Further, Defendants shall notify any third parties or independent contractors who Defendants are aware have custody and control over relevant information of the preservation obligations or provide notice to the Plaintiffs’ Steering Committee so that appropriate subpoenas may be issued. The PSC shall first provide to Defendants a list with reasonably specific descriptions of the subject matters as to which Defendants will investigate to determine the identity of such third parties or independent contractors.

The Parties’ preservation obligations extend not just to evidence generated on or after this date but evidence in existence on this date no matter when created. Furthermore, the Parties shall disable any auto-delete features in use as to any system or device to the extent reasonably known and necessary to preserve materials subject to this Order and, with respect to Defendants,

shall terminate or indefinitely suspend deletion policies and schedules for all employees and/or departments likely to possess information relating to Xarelto defenses and the claims at issue in this Action to the extent necessary to preserve materials subject to this Order.

V. OBLIGATIONS FOR INDIVIDUAL PERSONAL INJURY PLAINTIFFS

The preservation activities set forth in this section shall fully satisfy the preservation obligations of the individual personal injury Plaintiffs in the Litigation:

- A. Preserve all potentially relevant documents, data, and tangible things in their possession or control concerning Xarelto, including all Xarelto labels, bottles, product packaging, and containers, of any kind.
- B. Preserve any documents, data, and tangible things relating to their use of Xarelto or their alleged injuries at issue in this litigation that are stored on the hard drive of a computer owned or controlled by the Plaintiff. This obligation does not require a plaintiff to copy or create a duplicate image of the hard drive. Plaintiff's obligation is fulfilled if the relevant ESI and documents are retained on the hard drive, however, if the computer is replaced the Plaintiff will, at Plaintiff's sole option, retain the old computer hard drive, create an accessible electronic copy of the hard drive, or create and maintain complete hard copies of any such documents that were saved to the hard drive, in order to satisfy Plaintiff's preservation obligation. If a Plaintiff chooses to create hard copies rather than maintain the hard drive, the Plaintiff will contemporaneously prepare a statement that all ESI relating to her use of Xarelto was printed to paper, that the ESI was not altered prior to printing, a description of the general nature of the documents/data that were printed, and the date(s) on which this was performed. Plaintiff will provide the statement to her counsel.
- C. Preserve any documents relating to Plaintiff's use of Xarelto or their alleged injuries at issue in this litigation that are stored on any removable media owned or controlled by the Plaintiff. This obligation does not require a Plaintiff to copy or create a duplicate image of the media. Plaintiff's obligation is fulfilled if the relevant documents are retained on the media or Plaintiff creates and maintains complete hard copies of any documents on the media. If a Plaintiff chooses to create hard copies rather than maintain the hard drive, the Plaintiff will contemporaneously prepare a statement that all ESI relating to her use of Xarelto was printed to paper, that the ESI was not altered prior to printing, a description of the general nature of the documents/data that were printed, and the date(s) on which this was performed. Plaintiff will provide the statement to her counsel.
- D. Preserve all medical and pharmacy records in their possession or control and records of medical expenses allegedly incurred in connection with use of Xarelto.

VI. ACCEPTABLE METHODS OF PRESERVATION

The preservation activities set forth in this section shall fully satisfy the preservation obligations of the Defendants, and with respect to any other corporation or organization that may become a party to this Litigation in the future. Individual personal injury plaintiffs' obligations are governed by Paragraph V, above, and this section is not applicable to such plaintiffs. A Defendant may select any of the alternative methods set forth under each subsection A through C as the means to preserve documents or data and the decision as to which method to use is at the sole judgment of the Defendant.

A. E-mail

Defendants shall preserve e-mail communications, including all associated metadata and associated attachments relevant to claims or defenses in this action (1) by maintaining such email files on a server or within an electronic archive that is not subject to a deletion schedule, or (2) by creating an electronic snapshot of implicated email on servers, or (3) by maintaining one set of backup tapes for implicated email servers.

B. Databases

Defendants shall preserve data relevant to claims or defenses and held in databases (1) by maintaining such data in accessible electronic systems that are not subject to a deletion schedule, or (2) by creating an electronic snapshot of relevant database servers or an export of relevant data on database servers, or (3) by maintaining one set of backup tapes for relevant database servers.

C. Electronic documents contained in Shared or Home Directories

Where electronic documents relevant to claims or defenses in this action and located in shared or home directories (e.g., word processing documents, spreadsheets, and PowerPoint presentations) are subject to a deletion schedule, the parties shall preserve such documents by (1) maintaining such directories and files contained therein in accessible electronic systems that are not subject to a deletion schedule, or (2) by creating an electronic snapshot of relevant shared drive or home directory servers, or (3) by maintaining one set of backup tapes for relevant servers.

VII. RESERVATION OF RIGHTS

The Parties do not concede that any of the information subject to this Consent Order is discoverable, relevant, or admissible, and the Parties expressly reserve the right to challenge any specific discovery request concerning any such information. The Parties also reserve the right to challenge the competency, relevance, materiality, privilege, and/or admissibility into evidence of such documents, information, or material in these or any subsequent proceedings or at the trial of these or any other actions, in this or any other jurisdiction.

IT IS SO ORDERED.

New Orleans, Louisiana this 4th day of May, 2015.

A handwritten signature in black ink that reads "Eldon E. Fallon". The signature is written in a cursive style with a horizontal line underneath it.

Honorable Eldon E. Fallon
United States District Court