

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

**IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY
LITIGATION**

**MDL No. 2924
20-MD-2924**

**JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART**

_____ /

THIS DOCUMENT RELATES TO: ALL CASES

**PRETRIAL ORDER # 68
HIPAA QUALIFIED PROTECTIVE ORDER AND ORDER TO DISCLOSE
PROTECTED HEALTH INFORMATION**

The Court issues this stipulated HIPAA Qualified Protective Order in accordance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the regulations promulgated thereunder, including specifically 45 C.F.R. §§ 164.512(e)(1)(ii)(B) and 164.512(e)(1)(v), to enable the production and limit the use or disclosure of Protected Health Information in this Litigation. This order supplements the Confidentiality Order in Pretrial Order # 26, *see* Dkt. 780, and the Order on Production of Records for Initial Census for Deceased and Incapacitated Claimants in Pretrial Order # 18, *see* Dkt. 587. Both of those orders remain in full force and effect.

A. DEFINITIONS

As used herein, the following terms shall have the following meanings:

1. “Litigation” means MDL No. 2924, any actions remanded therefrom, and any appeals thereof.
2. “Covered entity” shall have the same definition as set forth in 45 C.F.R. § 160.103.
3. “Protected Health Information” (“PHI”) shall have the same definition as set forth in 45 C.F.R. § 160.103.

B. AUTHORIZATIONS, PROHIBITIONS, AND REQUIREMENTS RELATING TO PHI

1. The parties are hereby authorized through discovery to receive, subpoena, and transmit PHI, to the extent that such information is otherwise discoverable and not objectionable, subject to all conditions outlined herein. Pursuant to this Order, all parties are:

- a. prohibited from using or disclosing PHI for any purpose other than the prosecution and defense of this Litigation; and
- b. required to securely destroy all copies of PHI or to return them to the disclosing entity within forty-five (45) days of the conclusion of this Litigation.

2. **Subpoenas.** Based upon this HIPAA Qualified Protective Order and commencing immediately from the date of this Order, covered entities shall COMPLY with, and are hereby AUTHORIZED and ORDERED to use or disclose PHI in response to, any and all subpoenas for records without deposition pursuant to Federal Rule of Civil Procedure 45 to which no objection has been timely filed as well as any other subpoenas served upon them at any future time in the course of this Litigation.

3. **Interrogatories, Requests for Production, Requests for Copies, and Expert Communications.** In addition to the foregoing, pursuant to 45 C.F.R. § 164.512(e)(1)(i) and for purposes of HIPAA compliance, without waiver of any right to prepayment of costs or any other appropriate objection or privilege that may be timely asserted, the attorneys, employees, agents, and designees of each party in this Litigation are expressly and specifically AUTHORIZED and ORDERED to:

- a. respond to valid Requests for Production or Interrogatories served pursuant to the Federal Rules of Civil Procedure in the Litigation seeking PHI;

- b. respond to valid and timely Requests for Copies served pursuant to the Federal Rules of Civil Procedure in the Litigation for production of documents and things without deposition concerning PHI; and
- c. respond to each one of a party's own expert(s) who requests, either orally or in writing, PHI for purposes of reviewing the above-styled Litigation in whole or in part, whether the expert is a consulting or trial expert, and whether the expert is considered retained for compensation or non-retained, by disclosing and providing such requested PHI.

4. **Depositions.** In addition to the foregoing, pursuant to 45 C.F.R. § 164.512(e)(1)(i) and for purposes of HIPAA compliance, without waiver of any right to the prepayment of costs or any other appropriate objection or privilege that may be timely asserted, each deponent duly noticed for deposition in the Litigation, including but not limited to a party, a fact witness, a records custodian, an expert, or a healthcare provider of any type, is expressly and specifically AUTHORIZED and ORDERED to use or to disclose to the attorneys, agents, employees, and designees of each party or each party's legal counsel in this Litigation the PHI of a party that is responsive to deposition questions or a valid subpoena duces tecum at such duly-noticed deposition in the Litigation.

5. **Judicial Proceedings.** In addition to the foregoing, pursuant to 45 C.F.R. § 164.512(e)(1)(i) and for purposes of compliance with HIPAA, without waiver of any right to the prepayment of costs or any other appropriate objection or privilege that may be timely asserted, all witnesses duly appearing at, or subpoenaed for, any judicial proceeding related to this Litigation, including but not limited to trial, are specifically and expressly AUTHORIZED and ORDERED to use and disclose the PHI of a party in any form at such judicial proceeding. If a

party wishes to file PHI with the Court, it must be submitted with a motion for filing under seal. However, any party may file a pleading or document with the Court that describes, summarizes, quotes, or contains PHI, as long as that party omits or redacts the identifying information of the person to whom the PHI pertains. Any party may use documents containing PHI at trial or an evidentiary hearing, including but not limited to introducing them into evidence and asking a witness about their contents. If a party moves a document containing PHI into evidence and wants it to be a part of the record, the Court shall appropriately instruct the Clerk on how to handle such documents.

6. The parties and their attorneys shall be permitted to use PHI in any manner reasonably connected with the Litigation, including, but not limited to, disclosure to the parties and their attorneys, insurers, claims managers, experts, and consultants, the court, necessary court personnel, court reporters, copy services, trial consultants, jurors, any appellate court, and other persons and entities involved in the Litigation process. Any experts retained by a party to this Litigation to whom sharing or disclosure of PHI is made must sign the Acknowledgment attached hereto as Exhibit A unless such permission for such disclosure has been granted by the Court. Counsel providing access to PHI shall retain copies of the executed Acknowledgment(s) and provide them to another party as requested.

7. Nothing in the Order shall permit the counsel for any party, other than the party representing the patient, to engage in ex parte communications with the healthcare provider, except for those communications necessary for compliance with any subpoena or subpoena duces tecum.

8. Nothing in this Order authorizes counsel to obtain medical records or information through means other than formal discovery requests, subpoenas, depositions, patient authorizations, or other lawful processes.

9. The provisions of this Order shall not terminate at the conclusion of this Litigation. This Order shall remain in full force and effect and each person subject to this Order shall continue to be subject to the jurisdiction of the United States District Court for the Southern District of Florida, for the purposes of enforcement of the terms of this Order.

10. A copy of this Order shall be valid as an original.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 1st day of September, 2021.

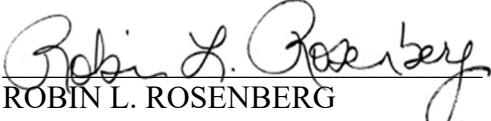

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

EXHIBIT A

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

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**ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY HIPAA QUALIFIED
PROTECTIVE ORDER**

I, _____, hereby attest to my understanding that information or documents containing Protected Health Information (“PHI”) are provided to me subject to the HIPAA Qualified Protective Order (“Order”) dated September 1, 2021, entered by the Court in the above-captioned litigation (“Litigation”); that I have been given a copy of and have read the Order; and that I agree to be bound by its terms. I also understand that my execution of this Acknowledgment to the Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any PHI disclosed pursuant to the Order.

I further agree that I shall not disclose to others, except in accord with the Order, any PHI, in any form whatsoever, and that such PHI may be used only for the purposes authorized by the Order.

I further agree to return all copies of any documents or information containing PHI I have received to counsel who provided them to me upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation. I further agree and attest to my understanding that my obligation to honor the confidentiality of such PHI will continue even after

this Litigation concludes. I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Southern District of Florida, for the purposes of any proceedings relating to enforcement of the Order, even if such enforcement proceedings occur after termination of this action. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Acknowledgment.

Date: _____

Printed Name: _____

Signature: _____