

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

MDL No. 2419  
Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

**ORDER GRANTING PLAINTIFFS LEAVE  
TO SERVE SUBPOENAS AND QUALIFIED PROTECTIVE  
ORDER REGARDING PROTECTION OF HEALTH INFORMATION**

WHEREAS, the Court recognizes that protected health information may be produced in response to subpoenas issued by parties in the MDL;

WHEREAS, nothing in this order shall deprive a subpoena recipient of the opportunity to object to requests to produce such protected information;

WHEREAS, the Court desires to establish an up-front process for the production of any such protected health information in compliance with applicable federal and state law.

IT IS HEREBY ORDERED that “Personal Health Information,” and “individually identifiable health information” protected under the Health Insurance Portability and Accountability Act of 1996 (hereinafter “HIPAA”) (42 USC §1320d et seq.) and the regulations promulgated thereunder (45 CFR §§160, 164 et seq.), shall only be disclosed as follows:

1. Healthcare facilities and/or providers that have examined, tested or treated patients who have been identified as recipients of one or more of New England Compounding Pharmacy, Inc. (“NECC”) solutions, medications or compounds, shall produce protected health information pursuant to this order and a subpoena issued by Plaintiffs.

2. The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 – November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

3. All protected health information produced pursuant to this order shall be produced in electronic or hard copy format only to a third party vendor (the "Vendor") to be selected jointly by the Plaintiffs' Steering Committee, the chapter 11 trustee appointed in NECC's chapter 11 case (the "Trustee"), and the Official Committee of Unsecured Creditors appointed in NECC's chapter 11 case (the "Official Committee"), after meeting and conferring.

4. The Vendor shall hold such protected health information in the strictest confidence and shall not release such information to any other person or entity until further order of this Court.

5. In the case of electronic data, the Vendor shall maintain the obtained protected health information on a server that is housed in a data center secured and hardened against unauthorized access or download, including unauthorized access via the Internet or any wireless device. The information obtained in electronic form pursuant to the subpoenas shall be loaded to a database that is password-protected and encrypted. The Vendor shall maintain similar protections against unauthorized access to any protected information produced in hard copy format.

6. The documents, data, or other information produced pursuant to the subpoenas and this Order shall be provided for the sole purposes of (i) investigating, litigating and resolving potential claims involved in this litigation; (ii) litigating and resolving potential claims in the chapter 11 case of NECC (the "Chapter 11 Case"); and (iii) the administration of the Chapter 11 Case, and not for any other purpose. In the event Defendants wish to use documents, data or other information produced pursuant to the subpoenas and this Order, they may seek permission of the Court to do so.

7. Within thirty (30) days of entry of this Order, the Plaintiffs' Steering Committee, Defense Liaison counsel, the Trustee, and the Official Committee shall propose to the Court a protocol for sharing the protected health information housed by the Vendor with necessary parties approved by the Court, including without limitation, their experts for purposes of providing expert reports and or analysis. That proposed protocol will also seek to ensure that any such protected health information shared with other parties or experts is provided a level of security against unauthorized disclosure that is compliant with HIPPA.

8. Nothing in this Order authorizes direct communications between defendants, their counsel or other agents or representatives and the patients' healthcare providers providing disclosure pursuant to this Order, nor does it bar such communications.

9. The Vendor shall maintain the information received in connection with the subpoenas until the later of (i) one (1) year after the resolution of this matter or (ii) one (1) year after the resolution of all claims in NECC's chapter 11 case (in either case, the "Retention Period"), or as otherwise ordered by the Court. At the end of the Retention Period, or as ordered by the Court, it shall destroy any and all originals and copies of the information obtained, including electronic and hard copies.

10. Plaintiffs' Counsel are authorized to serve subpoenas issued by this Court on the entities listed in NECC's Customer list located at:

<http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf> as well as Pharmacy Support, Inc., CuraScript, Inc., and Clint Pharmaceuticals.

11. All subpoenaed entities that provide requested information shall be deemed to fall within the safe harbor of HIPAA for court-ordered production of personal health information, 45 C.F.R. § 164.512(e)(1), and shall have no liability under HIPAA or any other federal or state statute, regulation, or other requirement related to protected health information, for supplying patient or member information to the Vendor.

12. The Vendor shall not be deemed to be a guarantor of the completeness and accuracy of the data provided to it and shall have the right to rely in good faith upon the information provided by any subpoenaed entity.

13. The subpoenaed entities are to use their best effort to supply the requested information.

14. The subpoenaed entities must produce the requested information to the Vendor within 30 days of receipt of the subpoena.

15. A copy of this Order shall be appended to the subpoenas.

**SO ORDERED.**

Dated this 21<sup>st</sup> day of June, 2013.

/s/ F. Dennis Saylor  
F. Dennis Saylor, IV  
United States District Judge