

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

MDL No. 1:13-md-2419-FDS

This Document Relates To:

All Actions

ORDER ON MEDIATION PROGRAM

This order establishes a mediation program for this matter (“the MDL”) and the associated chapter 11 bankruptcy proceeding for New England Compounding Pharmacy, Inc. (“NECC”).

I. Background

The Bankruptcy Trustee and the official committee of unsecured creditors (the “Creditors’ Committee”) appointed in the chapter 11 bankruptcy of NECC and the Plaintiffs’ Steering Committee (the “PSC”) appointed in the MDL believe it is appropriate to establish a mediation program to attempt to resolve certain claims in this proceeding. In particular, the parties seek to resolve the claims of those parties (1) who are non-debtors and who are not NECC-affiliated defendants, as defined by MDL Order No. 6; (2) who have or may have claims asserted against them as defendants by personal-injury and wrongful-death plaintiffs that arise out of or relate to NECC products; and (3) who, as a result of claims or potential claims against them, have or may have indemnification, contribution, reimbursement or other claims against the NECC estate. The parties have proposed such a program, including procedures intended to

facilitate participation in the program that are intended to avoid unnecessary and costly and protracted litigation and conserve limited resources.¹

Upon review of the proposals, the Court hereby establishes the following mediation program. The Court may refer or delegate certain of its functions under this Order to the Magistrate Judge or the Bankruptcy Judge.

II. The Mediation Program

- A. Voluntary Process.** The mediation process is entirely voluntary. No party is required to participate, nor will it be penalized for failing to participate.
- B. Good-Faith Participation.** All parties who participate in the mediation are expected to do so in good faith.
- C. Election to Participate.** Any of the following parties may choose to participate in the mediation program by filing a notice and agreement in this Court. The form of such notice and agreement is attached as Appendix A.
 - 1.** Any party named as a defendant or third-party defendant in any case presently pending in the MDL or in any other state or federal court.
 - 2.** Any other party with potential liability for claims related to or arising out of the purchase or administration of NECC products, whether or not involved in any current litigation or alternative dispute resolution (“Potentially Responsible Parties”), who, together with the defendants, comprise the “Unaffiliated Non-Debtor Claimants;” and

¹ The Bankruptcy Trustee and Creditors’ Committee and the PSC have submitted proposals in accordance with paragraph II.J of MDL Order No. 6. That order directed the parties “to confer and submit to the [MDL] Court within 30 days a proposed mediation order to be entered in [the MDL] Court and the Bankruptcy Court concerning all unaffiliated defendants and non-parties,” including certain specific requirements.

3. Any employee, officer, director, agent, partner, shareholder, guarantor, indemnitor, affiliate, or subsidiary of a defendant or Potentially Responsible Party who has potential direct or secondary liability in connection with NECC; provided that, in the alternative to filing a participation notice and agreement, such affiliated party may join in a notice filed by an Unaffiliated Non-Debtor Claimant by identifying themselves and co-executing the notice and agreement.

D. Opt-In Date. Any notice and agreement under subparagraph C shall be filed by September 23, 2013.

E. Selection of Mediator. The Bankruptcy Trustee, the Creditors' Committee, and the PSC, together with any Unaffiliated Non-Debtor Claimants who provide notice by September 23, 2013, that they wish to participate in the mediation and the mediator selection process, shall meet and confer in good faith to agree upon a mediator, subject to approval and appointment by the District Court. The Unaffiliated Non-Debtor Claimants who so elect shall then promptly meet and confer in an effort to organize themselves and appoint a self-governed liaison committee of no more than seven members for the purpose of facilitating the mediator selection process and mediation logistical issues, as well as such other agreed-upon organization, management, and liaison functions. The committee need not be appointed or approved by the Court and is solely constituted for the purposes described herein. The Unaffiliated Non-Debtor Claimants shall provide a list of the members of the committee to the Bankruptcy Trustee, the Creditors'

Committee, and the PSC no later than September 30, 2013. The parties to the mediation shall attempt to negotiate in good faith their respective responsibilities for the fees and related costs of the mediator's services and shall consider whether a cap on such fees is appropriate. The parties to the mediation shall submit a joint proposal to this Court for a mediator and a proposal for a fee-sharing structure no later than October 7, 2013. If the parties to the mediation have not agreed as to a mediator by that date, any party may submit a proposal to this Court regarding the appointment of a mediator no later than October 14, 2013. All defendants and known Potentially Responsible Parties shall thereafter be notified of the choice of mediator within ten days of the Court's order with respect to the selection of a mediator.

F. Supervision by Court. The Court expects that the mediation efforts will be largely self-executing, and will not require active court supervision or intervention. This Court shall have jurisdiction over all aspects of the mediation program, except as specifically delegated by this Court. The parties to the mediation shall meet and confer no later than October 21, 2013, regarding any procedures that may be necessary and appropriate to govern any disputes that may arise in the mediation.

G. Formal Discovery. To the extent that formal discovery is reasonably necessary to preserve evidence, the involved parties by agreement or by order of the this Court may take such discovery. Any party may apply for relief on shortened notice in such situations may be made to this Court if exceptional circumstances

warrant.

H. Informal Discovery. In order to participate in the mediation program, eligible entities or individuals must provide the following informal discovery to the Bankruptcy Trustee, the Creditors' Committee, and the PSC by the deadlines and in the manner established by the mediator:

1. As to Clinic, Health Care Provider, and Hospital Participants Only:

- a.** Such information as the mediator may reasonably require concerning the number and identity of potential claimants who may have been administered methylprednisolone acetate that came, or likely came, from one of the following three lots produced by NECC: 05212012@68, 06292012@26, and 08102012@51 (the "Lots"), consistent with the physician-patient privilege and any other healthcare privacy protections.
- b.** A statement fully identifying the entity(ies) or person(s) from whom the Lots were purchased or obtained.

2. As to All Defendants and Potentially Responsible Party Participants:

- a.** Any professional liability, general liability, and comprehensive or umbrella insurance policies, issued to the clinic or healthcare provider and/or its principal officers and directors, for the policy periods including calendar years 2012 and 2013.
- b.** Any documents relating to any reservation of rights or rejection or limitation of insurance coverage relating to the claims related to or arising out of the purchase or administration of the Lots.

c. Any agreements covering calendar year 2012 whereby the participant agreed to indemnify another party (or required another party to indemnify it) in connection with the claims related to or arising out of the purchase or administration of the Lots.

d. A list of all Potentially Responsible Parties liable to tort claimants or liable to the defendants or another Potentially Responsible Party regarding injuries related to the allegedly contaminated methylprednisolone acetate and the grounds or basis of the claim.

- 3.** The mediator and/or the Court shall determine whether any additional information or documents should be provided or exchanged in order to facilitate a mediated settlement or resolution and the timing and manner of the production. The Court may in its discretion allow examinations under oath under such terms, limits, and conditions as it may prescribe and which may be conducted in deposition format pursuant to the Federal Rules of Civil Procedure or equivalent Federal Rule of bankruptcy Procedure.
- 4.** This Court's protective orders concerning HIPAA and healthcare information shall be applicable to mediation program's participants. Any party producing materials within the mediation program may designate such materials as confidential pursuant to such protective order.
- 5.** All such documents produced or exchanged in connection within the mediation shall be deemed confidential for purposes of mediation, and

shall not be admissible in any later proceeding except to the extent necessary to address the sufficiency of such production, or relating to failure to mediate in good faith. Such documents, if filed with the Court, shall be filed under seal. No parties participating in the mediation program shall disclose information obtained in the mediation program to anyone other than other participants in the mediation program (including the mediator), the Bankruptcy Court, or this Court. All documents supplied by any participant during the mediation process will be returned in the event the mediation process is not successful, with no copy of any such document being retained by any other party. The relevant parties may mutually agree, however, to retain documents that ordinarily would be produced or obtained during discovery and are encouraged to so agree to minimize costs.

- I. No Admission of Liability.** By agreeing to participate in the mediation program, a party does not admit in any way that it has actual or potential liability to any other party, and the use of the term “potential liability” in this Order shall not be construed as an admission by any party.
- J. Participation Notice and Agreement.** A participation notice and agreement must be executed and mailed to the Bankruptcy Trustee, counsel for the Creditor’s Committee, and lead counsel for the PSC at the following addresses:

1. To the Bankruptcy Trustee:

Paul D. Moore, Esq.
Duane Morris, LLP
Suite 2400
100 High Street
Boston, MA 02110
pdmoores@duanemorris.com

2. To counsel for the Creditors' Committee:

William R. Baldiga Esq.
Brown Rudnick LLP
One Financial Center
Boston MA 02111
E-mail: Wbaldiga@brownrudnick.com

3. To lead counsel for the PSC:

Thomas M. Sobol Esq.
Hagens Berman Sobol Shapiro LLP
55 Cambridge Parkway, Suite 301
Cambridge MA 02142
E-mail: tom@hbsslaw.com

K. Submission to Jurisdiction. A participation notice and agreement shall be effective on and as of the date it is executed. By executing a participation notice and agreement, a party shall be deemed to submit to the jurisdiction of this Court for all matters relating to the interpretation and enforcement of this Order.

L. Other Requirements of Mediation. Upon the effective date of a participation notice and agreement, and based upon the voluntary consent provisions contained in the participation notice and agreement:

- 1. Bankruptcy Court Proof of Claim.** Any Unaffiliated Non-Debtor Claimant or its affiliate executing a participation notice and agreement shall, if it has not already done so, file a proof of claim with the

Bankruptcy Court within ten days of the effective date of the participation notice and agreement.

- 2. MDL Discovery Stay.** Any person, organization, or entity executing a participation notice and agreement shall not be subject to discovery in the MDL except as provided in this Order, or as otherwise directed by the Court. All discovery in the MDL is stayed as to such enrolled participants until further order of this Court. Nothing in this paragraph shall prohibit the parties from voluntarily providing documents responsive to subpoenas previously served by the PSC (and as modified by agreement or by this Court).
- 3. Tolling of Limitations Periods.** Any person, organization, or entity executing a participation notice and agreement, together with their respective heirs, successors, assigns, personal representatives, or bankruptcy trustees, general partners, and joint-venture partners, are deemed to agree and warrant that, with respect to civil liability that are based upon, arising out of, or relating to persons or estate of any deceased person claiming they (or a person upon which they are derivatively claiming) were administered allegedly defective or contaminated NECC products, the running of time under any statute of limitations or repose or by way of estoppel, laches, or any other time-related defense shall be tolled and suspended from the effective date of their participation notice and agreement until further order of this Court. Each person,

organization, or entity executing a participation notice and agreement agrees and warrants that, should time-related defenses apply under state law, the time elapsed during the tolling period shall not be used in the calculation of any time-related defense, including but not limited to, any statute of limitations or repose, laches, or estoppel or state law suit requirements which would otherwise arise during such tolling period. By filing a participation notice and agreement or by deferring filing any suit in reliance on this tolling order, no party is waiving any claims or time-related defenses that may have accrued up to the effective date of the participation notice and agreement. This Order shall not be construed as a tolling or waiver of any claim or time-related defense that has arisen as of the effective date or which may arise after the date of termination of tolling period, excluding the period during which this provision has operated to toll any time-related defense.

4. **Stay and Extension of State-Law Suit Requirements.** Any person, organization, or entity executing a participation notice and agreement, together with their respective heirs, successors, assigns, personal representatives, or bankruptcy trustees, general partners, and joint-venture partners, agrees and warrants that, with respect to civil liability claims against healthcare providers filing a participation notice and agreement, any state-law suit requirements in any lawsuit, case or claim, whether filed or not, asserting, or based upon unaffiliated non-debtor liability claims are

voluntarily waived, stayed, or extended, as the case may require, until further order of this Court. Each person, organization, or entity executing a participation notice and agreement agrees and warrants that time elapsed during the period the stay/extension is in force shall not be used in the calculation of due or action dates prescribed in any state law suit requirements, including but not limited to the time to file, serve, obtain or present any pre-suit notice, any affidavit or certification of merit, or any request for panel review or arbitration requirement.

5. Lists of Potentially Responsible Parties. As to any claims arising under Tennessee, Ohio, or Nevada law that are governed by a one-year statute of limitations, all lists provided pursuant to this order relating to Potentially Responsible Parties and allegations asserted by the participating party shall not be expanded should the mediation not be successful in achieving a settlement or resolution with the party submitting it as to all claims related to or arising out of the purchase or administration of recalled NECC products.

M. Notice of this Order. A copy of this order and the form of participation notice and agreement shall also be posted on the Bankruptcy Trustee's website for NECC. To the extent any of the following (or their counsel) do not otherwise receive them electronically from this Court or the Bankruptcy Court, the Bankruptcy Trustee shall promptly provide written notice of this order and the form of participation notice and agreement to (1) those customers of NECC who

received products from the Lots; (2) all known defendants (other than affiliated defendants) in actions related to or arising out of the purchase or administration of the Lots; and (3) any party (or its representative) who the Bankruptcy Trustee learns may qualify for participation in mediation, including parties identified as Potentially Responsible Parties during the proof of claim process in the Bankruptcy Court.

- N. List of Unaffiliated Non-Debtor Claimants.** The Creditors' Committee and the PSC shall be responsible for maintaining a list all Unaffiliated Non-Debtor Claimants with an active submitted participation notice and agreement, and for providing it to the Bankruptcy Trustee on a current basis. If, for any reason, the Bankruptcy Trustee, the Creditors' Committee, or the PSC deem it necessary to file the list of Unaffiliated Non-Debtor Claimants to the Bankruptcy Court or this Court, or to identify any of the participants, they shall do so under seal.
- O. Termination by Mediator or Court.** The active mediation process shall continue until (1) the mediator declares an impasse as to a participant, in which case the mediation and discovery stay shall end either as to that participant only, or as to the mediation program as a whole (in which latter case the mediation program and the discovery stay shall end as to all parties); or (2) ordered terminated in whole or part by this Court *sua sponte* or upon application of any party showing good cause for the termination.
- P. Voluntary Termination by Party.** Any person or entity may withdraw on notice to the mediator, upon which the terms of this mediation program shall cease to

apply to that person or entity, including without limitation the stay of discovery against any such person or entity.

- Q. Schedule of Mediation.** The schedule, location and time of each mediation session shall be either (1) established by the mediator, subject to the advice and consent of the parties to the mediation or (2) should there be any conflict as to any of the foregoing not amenable to resolution by the mediator, subject to the order of this Court.
- R. Position Papers.** The mediator may require, in anticipation of any mediation session, production of such position papers or briefs as s/he may reasonably require.
- S. *Ex Parte* Communications.** *Ex parte* communication with the mediator is permitted subject to such further disclosure as the mediator and the communicating party may agree.
- T. Modification by Court.** This Court may modify the terms of the mediation program as necessary or appropriate to facilitate the mediation process contemplated hereby.

So Ordered.

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

Dated: August 15, 2013

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION**

MDL No. 1:13-md-2419-FDS

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**NECC MEDIATION PROGRAM
PARTICIPATION NOTICE AND AGREEMENT**

The undersigned hereby give(s) notice that he, she, or it is agreeing to participate in the NECC mediation program as set forth by the Court's Order on Mediation Program of August 15, 2013, entered in *In re New England Compounding Pharmacy, Inc., Products Liability Litigation*, MDL No. 1:13-md-2419-FDS ("the MDL").

By executing and filing this Participation Notice and Agreement in the MDL, the undersigned hereby stipulates, agrees, and covenants to the terms of, and agrees to be bound by, the provisions of the Court's Order on Mediation Program.

IN WITNESS WHEREOF, and intending to be legally bound hereby, the undersigned execute this Participation Notice and Agreement as their voluntary act.

Signature

Name:

Title of person signing, if on behalf of an organization:

Contact information:

Address:

Email:

Phone Number:

Names of facilities operated or associated with, if applicable:

Name, firm name, address, phone number, and email address of attorney representing participant in mediation:

(Attach additional pages if necessary)

Unaffiliated Non-Debtor Claimant Affiliate Joinder

Signature

Name:

Title of person signing, if on behalf of an organization:

Contact information:

Address:

Email:

Phone Number:

Names of facilities operated or associated with, if applicable:

Name, firm name, address, phone number, and email address of attorney representing participant in mediation:

(Attach additional pages if necessary)