

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS**

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IN RE: YASMIN AND YAZ (DROSPIRENONE)	)	3:09-md-02100-DRH-PMF
MARKETING, SALES PRACTICES AND PRODUCTS	)	
LIABILITY LITIGATION	)	MDL No. 2100
	)	

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**This Document Relates to:**

**ALL CASES**

**ORDER # 61  
CASE MANAGEMENT  
(Preservation of Records and *Prima Facie* Evidence of Usage, Injury and Causation  
Requirements for Gallbladder Plaintiffs)**

This Order applies to all plaintiffs with personal injury claims in MDL No. 2100 alleging in either their complaint or Plaintiff Fact Sheet, a gallbladder injury either alone or in combination with another injury, unless that other injury is a venous or arterial thromboembolism (collectively, “Gallbladder Plaintiffs”). This Order requires such Gallbladder Plaintiffs to produce certain specified information regarding their gallbladder claim (“Gallbladder Case” or “Gallbladder Claim”). This Order does *not* apply to plaintiffs in MDL Docket No. 2100 who do not allege gallbladder injuries or who allege a venous or arterial thromboembolism as well as a gallbladder injury. Persons who represent themselves *pro se* in this proceeding shall comply fully with all obligations required of counsel by this Order, unless otherwise stated.

**I. PRESERVATION NOTICE REQUIREMENT**

- A. For Gallbladder Cases pending in the MDL as of the entry of this Order or filed prior to March 26, 2013, counsel for a Gallbladder Plaintiff shall, no later than July 8, 2013, notify the following individuals or entities, by registered mail (with return receipt), that the individual or entity may have records relevant to the Plaintiff’s

claim in this MDL Proceeding (“Claim”) and that any records relating to the Plaintiff must be preserved pursuant to CMO No. 11 entered by this Court on February 18, 2010 (the “Notice”), pending collection by the Plaintiff:

1. All Pharmacies that dispensed any medications to the Plaintiff for the period from three years prior to the date of the first diagnosis of the gallbladder injury to the present;
  2. All Physicians, Medical Facilities, other Healthcare Providers and/or other persons (“Other Providers”) who prescribed drospirenone-containing oral contraceptives (“DCOCs”) for the Plaintiff, or provided any samples of DCOCs to the Plaintiff;
  3. All Physicians and/or other Healthcare Providers who treated Plaintiff for the period from three years prior to the date of the first diagnosis of the gallbladder injury to the present; and
- B. For Gallbladder Cases filed on or after March 26, 2013, counsel (or if a plaintiff is proceeding *pro se*, the plaintiff) shall, within thirty (30) days of their Claim being filed in or transferred to this MDL be responsible for (1) ensuring that all records in the possession of the Plaintiff’s Pharmacies, Physicians, Medical Facilities, Healthcare Providers, and/or Other Providers as described in Paragraph A above have been preserved, collected and reviewed, and (2) sending a Notice, by registered mail (with return receipt), to the individuals or entities listed above in Paragraph A.
- C. A copy of CMO No. 11 shall be attached to the Notice sent pursuant to this Section and all copies of the Notice shall be preserved by Counsel for Plaintiff for so long as the Claim remains pending in this proceeding.
- D. Gallbladder Plaintiffs shall serve a statement listing the names and addresses of all individuals or entities to which Notices were sent, along with copies of the Notices and a signed certification that the Notices were sent as required by this Order in accordance with the following schedule:
1. Gallbladder Plaintiffs with cases pending in the MDL as of the entry of this Order or filed prior to March 26, 2013 shall serve the statement and certification required by this Paragraph D no later than July 8, 2013.
  2. Gallbladder Plaintiffs who file cases on or after March 26, 2013 shall serve the statement and certification required by this Paragraph D within forty-five (45) days of filing of their Claim in or their case being transferred to this MDL.
  3. Service of the Notice on Defendant by Plaintiffs shall be made by one of the following methods:
    - a. By email to [ServeBayer@shb.com](mailto:ServeBayer@shb.com); or

- b. By United States Mail or other carrier, post-marked on or before the Notice Deadline as set forth above, return receipt requested, to the following:

Douglas Beck  
Shook, Hardy & Bacon L.L.P.  
2555 Grand Blvd.  
Kansas City, MO 64108-2613

- E. Gallbladder Plaintiffs who fail to fully comply with the requirements of Paragraph D above shall be given notice of such failure by e-mail or fax from Defendants' Liaison Counsel or his designee and shall be provided ten (10) additional days to cure such deficiency ("Cure Period"). No other extensions will be granted unless agreed to by all Parties. If Plaintiff fails to cure the deficiency within the Cure Period, Defendant's Liaison Counsel or his designee may file a Motion to Show Cause why the Gallbladder Claim should not be dismissed with prejudice. Plaintiff shall thereupon have thirty (30) days to respond to the Notice to Show Cause. Any failure to respond to the Motion within the required period of time shall lead to the dismissal of the Gallbladder Claim with prejudice, except for good cause shown.
- F. A Gallbladder Plaintiff may not seek to introduce into evidence at trial any document or information asserting that a DCOC was dispensed by a pharmacy or provided to the Plaintiff as a sample, or asserting that a DCOC caused or contributed to the Plaintiff's gallbladder injury, if a Notice was not sent to the Plaintiff's Pharmacy, Physician, other Healthcare Provider and/or Other Provider as required by this Order. A Gallbladder Plaintiff who fails to comply with this Order may also be subject to other sanctions or such orders deemed appropriate by this Court.
- G. The preclusion of evidence or the imposition of any sanction pursuant to this Section shall apply only to the assertion of the claim that the DCOC caused a gallbladder injury and shall not apply to any other injury.

## **II. DISCOVERY REQUIREMENTS**

- A. All Gallbladder Plaintiffs must produce all of the documents and/or information described in this Section II:
  - 1. All pharmacy records regarding the dispensing of drugs to the Plaintiff for the period from three years prior to the date of the first diagnosis of the gallbladder injury to the present.
  - 2. A Plaintiff Fact Sheet ("PFS") and authorizations in the forms previously approved by the Court, unless Plaintiff has already served a PFS that complies with the requirements of CMO No. 12, entered by this Court on March 3, 2010.

3. All medical records relating to the Plaintiff from all healthcare providers listed in the PFS for the period from three years prior to the date of the first diagnosis of the gallbladder injury to the present.
  4. An affidavit signed by the Plaintiff or their counsel (i) attesting that records have been collected from all pharmacies that dispensed drugs to, or for, the Plaintiff; (ii) attesting that all medical records described in subparagraph (3) above have been collected; and (iii) attesting that all records collected pursuant to subparagraphs A(1) and (3) have been produced pursuant to this Order.
  5. A Rule 26(a)(2) expert report on general causation concerning the alleged gallbladder injury.
  6. A Rule 26(a)(2) case-specific expert report concerning causation of the Plaintiffs' alleged gallbladder injury.
- B. If any of the documents described in subparagraphs A(1) and (3) above do not exist, the Plaintiff or Plaintiff's counsel shall state that fact and the reason, if known, why they do not exist in this affidavit, and provide a "No Records Statement" from the pharmacy or healthcare provider.
- C. Gallbladder Plaintiffs shall produce the items set forth above in this Section II in accordance the following schedule:
1. For Gallbladder Plaintiffs with cases filed in or transferred to the MDL prior to March 26, 2013, the items set forth above shall be produced on or before July 22, 2013.
  2. For Gallbladder Cases filed in or, transferred to the MDL on or after March 26, 2013, those Gallbladder Plaintiffs shall produce the items set forth above within sixty (60) days of the filing of their Claim in this MDL or transfer of their case to this MDL.
- D. Plaintiffs shall serve the items set forth above in accordance with the service procedures of CMO No. 12.
- E. Plaintiffs who fail to fully comply with the requirements of this Order shall be given notice of such failure by e-mail or fax from Defendants' Liaison Counsel or his designee and shall be provided thirty (30) additional days to cure such deficiency ("Cure Period"). No other extensions will be granted. If Plaintiff fails to cure the deficiency within the Cure Period, Defendant's Liaison Counsel or his designee shall file a Motion to Show Cause why the Gallbladder Claim should not be dismissed with prejudice. Plaintiff shall thereupon have thirty (30) days to respond to the Notice to Show Cause. Any failure to respond to the Motion within the required period of time shall lead to the dismissal of the Gallbladder Claim with prejudice, except for good cause shown.

- F. The preclusion of evidence or the imposition of any sanction pursuant to this Section shall apply only to the assertion of the claim that the DCOC caused a gallbladder injury and shall not apply to any other injury.
- G. Nothing in this Order abrogates or replaces each Plaintiff's obligation to submit the Plaintiff Fact Sheet, authorizations, and other materials required under CMO No. 12.

**III. APPOINTMENT OF SPECIAL MASTER**

The Court, by this Order, appoints Professor Stephen Saltzburg as Special Master to hear all motions regarding compliance with this Order, including motions directed to the sufficiency of the expert reports required under subparagraphs II (A) (5) and (6) above, and to recommend to this Court a ruling on each of the motions.

**IV. PENALTIES FOR FRAUD AND DECEPTION**

Any party and/or counsel for that party who submits false or misleading information, or otherwise attempts to satisfy the documentation requirements of this Order through any form of deception, dishonesty or fraud, may be subject to appropriate sanctions (including monetary sanctions and costs) and dismissal with prejudice pursuant to Federal Rule of Civil Procedure 37.

**SO ORDERED:**

Date: March 15, 2013

 Digitally signed by  
David R. Herndon  
Date: 2013.03.15  
08:54:36 -05'00'

Honorable David R. Herndon  
Chief Judge, United States District Court