

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

**IN RE: PROPULSID** : **MDL NO. 1335**  
**PRODUCTS LIABILITY LITIGATION** :  
 : **SECTION: L**  
 :  
 : **JUDGE FALLON**  
 : **MAG. WELLS ROBY**  
**THIS DOCUMENT RELATES TO ALL CASES** :  
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**JOINT REPORT NO. 15 OF  
PLAINTIFFS' AND DEFENDANTS' LIAISON COUNSEL**

Plaintiffs' Liaison Counsel (PLC) and Defendants' Liaison Counsel (DLC) jointly submit this Report No. 15.

**I. Update of Rolling Document Production and Electronic Document Production -  
(PTO 2 - IX)**

DLC advises that as of May, 2002 approximately 6,582,211 pages of documents have been produced. The April 15, 2002 production consisted of approximately 628,483 pages of documents, the majority of which were Beerse documents.

On March 1, 2002, Defendants produced Tiff images, text files and related data (objective coding) of approximately 251,000 pages of e-mail materials and attachments to the PLC. On March 2, 2002 defendants advised PLC that the images of e-mail material and attachments produced contained privileged information and that the production had been inadvertently made. On March 20, 2002 PLC returned to defendants all of the materials. Since that time defendants have re-reviewed the production and re-produced to PLC certain CD's containing the non-privileged materials. DLC advises that the vendor retained by Defendants to process the corresponding text files and related data (objective coding) has not been able to do this and Defendants have had to engage other consultants to perform this task. Defendants have advised that they had to retain another vendor to process Propulsid-segregated e-mails from Beerse and expect to make a production at the end of June. PLC has advised DLC that it will be filing a Motion to Compel regarding all e-mails. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status Conference

PLC and Defendants met on January 22, 2002 regarding production of documents relating to databases and other electronic data. Following, on January 31, 2002, PLC sent Defendants correspondence regarding materials requested at the meeting. PLC is waiting for the materials and will be filing a Motion to Compel. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status Conference.

The parties will report to the Court with respect to the Court's decisions and instructions as to each party's Motions to Compel which were heard on March 01, 2002. PLC delivered to Defendants a proposed Protective Order regarding the confidential nature of the patient-plaintiff names. Defendants agreed to preserve confidentiality pending the issuance of a protective order. PLC is waiting for a response

from defendants to the proposed order forwarded by PLC to DLC. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status Conference.

The parties are continuing discussions regarding a nominee for Special Master as required by Section H(3) of PTO 10.

**II. State Liaison Counsel - (Minute Entry, November 16, 2000)**

PLC has actively participated in scheduling matters of depositions in the MDL and state court litigations. For at least two of the state/federal coordinated depositions counsel for the state court litigations did not appear or participate. No advance notice was provided to the MDL that the states would not participate. Further, the states did not physically appear at either of two recently scheduled foreign depositions and did not attend one foreign deposition ( France) scheduled for the week of June 3, 2002 previously coordinated between states and the MDL. The states participated in the other foreign deposition, in Belgium, via videoconference and by phone. In the deposition in Belgium, state lawyers were to lead and irrespective of that role the lead portion of the deposition lasted only two hours and placed an unexcepted discovery burden on the MDL. PLC is concerned that the state court litigations may no longer desire to coordinate with the MDL. Further, regular scheduled telephone conferences with the state court litigation attorneys to coordinate matters have recently not had state court litigation counsel participating. PLC will be prepared to discuss this at the June 12, 2002 Monthly Status Conference.

The State Liaison Counsel Committee will report to the Court regarding the efforts of the Committee at the June 12, 2002 Monthly Status Conference.

**III. Patient Profile Form and Authorization**

As of June 4, 2002, Defendants have received 1352 Patient Profile Forms (PPFs). 94 are

currently overdue, and 27 PPFs will become due within thirty (30) days. PLC and DLC continue to communicate directly with plaintiff counsel whose PPFs are overdue. DLC and PLC will work together to contact counsel for plaintiffs whose PPFs are overdue to obtain the delinquent documents. In the event such efforts are not successful, DLC will prepare a Motion to Dismiss with Prejudice as to these plaintiffs.

Defendants forwarded to PLC a draft of a Motion for Entry of Judgment under FRCP 54(b) as to all plaintiffs who have been dismissed with prejudice from MDL-1355. PLC has reviewed the draft and consulted with DLC. Defendants will present the Motion to the Court at the June 12, 2002 Monthly Status Conference.

At the last status conference defendants advised that they had drafted a Motion to Enforce Pre-Trial Order No. 9 as to plaintiffs who have submitted restricted medical authorizations and that the DLC would deliver a copy of the final draft to the PLC for review. PLC has not received the draft and the parties have agreed that before any such motion is filed, they will consult with one another.

#### **IV. Subpoena to FDA**

In April, 2002 FDA advised that additional documents had been discovered and would be produced. The FDA produced these documents to DLC at the beginning of April, in turn, Defendants delivered the documents to PLC shortly after. DLC advises that production of the FDA documents was completed on April 18, 2002. PLC is reviewing the production to confirm this. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status Conference.

#### **V. Service List of Attorneys**

The parties will present the Court with the most current Master List of all Counsel, which will contain, where available, e-mail addresses.

**VI. Ongoing Studies/Subpoena to BevGlen**

On May 3, 2002, the PSC conducted an inspection at BevGlen of the documents and data responsive to this subpoena. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status Conference.

Pursuant to the court's order, DLC delivered to PLC a spreadsheet of the compiled data by DLC of ongoing studies. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status Conference.

At the deposition of Patricia Robinson on May 17, 2002, the PSC was provided, for the first time, a copy of a CIS-NED-32 report. At that time only a portion of the report was delivered. PLC has requested a full, complete, unredacted copy of the CIS-NED-32 report, which was provided on June 6, 2002. DLC advises that pages 1 through 23 of this draft report have been submitted to the CPMP. PLC has requested any documents submitted to the CPMP. Other than the draft of the CIS-NED 32 report, DLC will not agree to provide prior drafts or revisions. The PLC has further requested copies of reports, summary reports or draft reports prepared for the CPMP, FDA or regulatory agencies relating to CIS-NED-32. DLC has refused to provide this information. The parties have discussed this request and conferred regarding the CIS-NED-32 information. PLC is considering filing a Motion to Compel and for Sanctions regarding the CIS-NED-32 information and the request. DLC wrote to the PLC on June 3 , 2002 with a summary fo their main points why such a motion would not be supported by the facts and the record of the case. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status

Conference.

**VII. Third Party Subpoena Duces Tecum Issued by PSC**

There remain 3 outstanding certifications from third-parties to whom subpoenas have been issued. Defendants have attempted to contact these entities on several occasions to secure such certifications, but have been unable. Per the Court's instruction, on March 15, 2002, Defendants forwarded to PLC the names and phone numbers of the attorneys for each of these third parties so that the PLC could contact the parties directly. PLC will be bringing a Motion to Compel against the non-responsive entities.

DLC produced to PLC 21,297 documents from Covance, Inc. responsive to the subpoena duces tecum issued by the PCS on October 17, 2001. On April 25, 2002, PLC acknowledged that the documents had been reviewed and that they related entirely to a single Janssen study conducted in 1993 and 1994 and that PLC was unable to locate any documents in the production which were created after July, 1995. PLC advised that the production was incomplete. DLC communicated further with Covance and has advised PLC that approximately 6,500 additional documents exists that were not produced by Covance. Defendants delivered these documents to PLC on June 6, 2002. The PLC is considering the filing of a Motion for Sanctions on this issue. The failure to timely receive the Covance documents has unnecessarily delayed this matter and it is PLC's position that these documents are integral to an understanding of CIS-NED-32 because the two companies involved in the data processing aspect of CIS-NED-32 included BevGlen and Covance. Further defendants redacted and withheld some of the Covance produced materials and PLC will be discussing with DLC the basis for such redaction. Further PLC will be setting the deposition of Covance regarding the documents to be produced responsive to the subpoena.

PLC will advise the court as to the status of third party subpoena duces tecums as issues arise in the course of discovering information.

**VIII. Motion on Class Certification.**

The hearing on the Motion for Class Certification took place on April 10, 2002. Additional submissions were made by PLC and DLC following the hearing.

In addition, on May 29, 2002, PLC filed with the court a Second Motion for Class Certification. The matter is set for hearing on June 19, 2002. The parties will be prepared to discuss this further at the June 12, 2002 Monthly Status Conference.

**IX. Plaintiffs' and Defendants' Respective Requests for Production of Documents**

Plaintiffs served on Defendants Interrogatories and Request for Production of Documents, Set No. 5, on February 14, 2002. PLC continues to wait for a response.

On March 15, 2002, PLC requested additional information that was revealed at the deposition of Mr. Rouleau concerning the CPMP issuance of a final assessment regarding Cisapride. PLC requested a copy and is waiting to receive the findings or conclusions. Defendants submit that questions being presented suggest there is an incomplete understanding of the authority and work product of the European agency known as the Committee for Proprietary Medicinal Products (CPMP). Defendants further submit that body lacks authority of the type held by the FDA in the matter under review. Defendants further submit, instead, authority in these areas rests with an agency known as European Agency for the Evaluation of Medicinal Products (EMA) which, to the best of Defendants' knowledge has not issued any potentially binding discussion respecting the marketing of cisapride in certain countries in Europe. When and if such decision is rendered, Defendants will supply it to the PLC. Meanwhile, Defendants have provided CPMP

website information to the PLC. PLC is considering filing a Motion to Compel regarding this information, but before filing such a motion will confer with DLC. The parties will be prepared to discuss this at the June 12, 2002 Monthly Status Conference.

PLC has also requested information regarding insurance as to Defendants. The parties are discussing a stipulation as to several issues and will discuss this matter with the Court at the status conference.

**X. Motions for Suggestion of Remand**

Motions for Suggestion of Remand filed by J.C. Jackson and Dickie Helberg were set for hearing on April 3, 2002. The matter is pending, under advisement, with the court.

**NEW ITEMS**

**XI. Deposition Procedure**

On April 4, 2002, PLC contacted DLC regarding the procedure for attaching exhibits at depositions. PLC requested that all exhibits be provided to the court reporter and attached to the original deposition. The parties will be prepared to discuss this at the June 12, 2002, Monthly Status Conference.

**XII. Shell/Morganroth Study**

Plaintiffs have previously been ordered by this Court to produce the readings/reports, if any, performed by Dr. Morganroth and Dr. Vincent on the ECG's which are a part of this study pursuant to the Order of March 7, 2002. PLC has advised that this information has been sought from the experts and whatever information exists has been delivered to DLC.

**XIII. 30(b)(6) Deposition of Defendants Regarding Studies**



On May 9, 2002, PLC forwarded to DLC a draft deposition notice for the 30(b)(6) designee concerning studies. The Defendants have advised the PSC that they are putting into place a system to respond to a reasonable 30(b)(6) deposition notice. The Defendants do not have any one person who is familiar with the status of the approximately 800 clinical studies identified by them in the computer document development pursuant to this Court's Order of March 7, 2002 and which has previously been turned over to the PSC. Many of those clinical studies were conducted over more than a decade. Some were completed; some were discontinued; some became part of the clinical studies.

Accordingly, the Defendants have assigned a physician presently employed by Janssen and who has experience with clinical studies, who will have supporting staff, to prepare a computer data base which will contain agreed upon information about the clinical studies needed to satisfy the requirements of FRCP 30(b)(6). The Defendants submit that there should be an early meet and confer conference between the PSC and the Defendants to see if there can be agreement on what that database should contain and, failing agreement, to bring the matter before the Court for resolution. PLC believes that the matter has thoroughly been discussed with defendants and the court (who suggested that a 30(b)(6) notice be sent in draft by PLC to DLC) and will be filing a Motion to Compel.

#### **XIV. Trust Account**

The parties have met with representatives of the Whitney Bank regarding the establishment of a trust account.

#### **XV. Motion to Dismiss filed by Forshag's Pharmacy**

Plaintiffs have filed an opposition to Forshag Pharmacy's Motion to Dismiss. The matter is under advisement with the Court.

#### **XVI. Declassified documents**

The PSC requested relief from PTO-5 relating to the confidentiality of all documents filed and utilized in connection with the plaintiff's Motion for Class Certification. The parties have conferred on the request and are preparing a Joint Order to declassify the documents. This order will provide for the declassification of class certification related documents. However the parties are still discussing the declassification of approximately 12 of the documents.

**XVII. Motion to Withdraw as Counsel of Record - Anthony Scott, #01-1394**

Plaintiff's counsel has filed a Motion to Withdraw as Counsel of Record in this matter. The parties will be prepared to discuss this further at the June 12, 2002 Monthly Status Conference.

**XVIII. Agenda**

A proposed Agenda for the June 12, 2002 Monthly Status Conference is attached.

Respectfully submitted,

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**RUSS M. HERMAN, T.A. (La. Bar #6819)**  
LEONARD A. DAVIS, #14190  
JAMES C. KLICK, #7451  
HERMAN, MATHIS, CASEY, KITCHENS & GEREL, LLP  
820 O'Keefe Avenue  
New Orleans, Louisiana 70113  
Phone: (504) 581-4892  
Fax: (504) 561-6024  
**LIAISON COUNSEL FOR PLAINTIFFS**

DANIEL E. BECNEL, JR.  
106 W. Seventh Street  
Reserve, LA 70084-0508  
Phone: (504) 536-1186  
Fax: (504) 536-6445

JAMES DUGAN  
3600 North Hullen Street  
Metairie, LA 70002  
Phone: (504) 456-8600  
Fax: (504) 456-8624

CHRISTOPHER A. SEEGER  
One William Street  
New York, NY 10004  
Phone: (212) 584-0700  
Fax: (212) 584-0799

ARNOLD LEVIN  
510 Walnut Street, Suite 500  
Philadelphia, PA 19106-3875  
Phone: (215) 592-1500  
Fax: (215) 592-4663

BOB F. WRIGHT  
556 Jefferson Street, Suite 500  
Lafayette, LA 70502-3668  
Phone: (337) 233-3033  
Fax: (337) 232-8213

STEPHEN B. MURRAY  
909 Poydras Street, Suite 2550  
New Orleans, LA 70112  
Phone: (504) 525-8100  
Fax: (504) 584-5249

CHARLES S. ZIMMERMAN  
651 Nicollet Mall  
Suite 501  
Minneapolis, MN 55402  
Phone: (612) 341-0400  
Fax: (612) 341-0844

J. MICHAEL PAPANTONIO  
316 S. Baylen Street, Suite 600  
P.O. Box 12308  
Pensacola, FL 32581  
Phone: (850) 435-7000  
Fax: (850) 435-7020

**PLAINTIFFS' STEERING  
COMMITTEE**

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**JAMES B. IRWIN, T.A. (La. Bar No. 7172)**  
QUENTIN F. URQUHART, JR. (La. Bar No. 14475)  
KIM E. MOORE (La. Bar No. 18653)  
IRWIN FRITCHIE URQUHART & MOORE, LLC  
400 Poydras Street, Suite 2700  
New Orleans, Louisiana 70130  
Phone: (504) 310-2100  
Fax: (504) 310-2101

**LIAISON COUNSEL FOR Defendants,  
JANSSEN PHARMACEUTICA INC. AND JOHNSON & JOHNSON**

DRINKER, BIDDLE & SHANLEY LLP  
THOMAS F. CAMPION  
SUSAN M. SHARKO  
500 Campus Drive  
Florham Park, NJ 07932-1047  
Phone: (973) 549-7300  
Fax: (973) 360-9831

**-and-**

DRINKER, BIDDLE & REATH, LLP  
CHARLES F. PREUSS  
DONALD F. ZIMMER, JR.  
225 Bush Street, 15th Floor  
San Francisco, CA 94104-4207  
Phone: (415) 397-1730  
Fax: (415) 397-1735  
**CO-LEAD COUNSEL FOR Defendants,  
JANSSEN PHARMACEUTICA INC. AND  
JOHNSON & JOHNSON**

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing Joint Report No. 15 of Plaintiffs' and Defendants' Liaison Counsel was served on Plaintiffs' Liaison Counsel by hand and e-mail and by e-service to all parties by uploading same to Verilaw, on this \_\_\_\_ day of June, 2002.

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5. Service List of Attorneys
6. Ongoing Studies/Subpoena to BevGlen
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13. Shell/Morganroth Study
14. Trust Account
15. Motion to Dismiss filed by Forshag's Pharmacy
16. Declassified Documents
17. Motion to Withdraw as Counsel of Record - Scott
18. Setting for trial the individual actions filed in the Eastern District of Louisiana and setting class certification hearings for those class actions filed in the Eastern District of Louisiana;
19. The appointment of a mediator to assist in settlement negotiations.