

## **SECOND MDL PROGRAM**

### **TERM SHEET**

In February 2004 the Plaintiffs' Steering Committee and defense counsel in the suit entitled In Re: Propulsid Products Liability Litigation, United States District Court, Eastern District of Louisiana, MDL No. 1355 (hereafter "the MDL Court" or the "MDL Litigation") entered into a written agreement (hereafter "the MDL Term Sheet") whereby they established a global mediation and resolution program (hereafter the "First MDL Program"). The MDL Court thereupon entered a Consent Order on February 4, 2004 which, among other things, accepted jurisdiction over the plaintiffs and tolling agreement claimants enrolled in the First MDL Program and appointed a Special Master to exercise the rights and responsibilities set forth in the First MDL Program.

The PSC and defense counsel thereafter amended the MDL Term Sheet. The First MDL Program is now functioning pursuant to the aforesaid Consent Order and amended MDL Term Sheet.

The First MDL Program does not provide for participation by plaintiffs in state court cases where their Complaints seek damages respecting their use of Propulsid. Nor does it provide for participation by plaintiffs in cases filed in or removed to federal courts after February 1, 2004.

The PSC and SLC have received requests from counsel representing substantial numbers of plaintiffs in cases pending in state courts seeking their clients' inclusion in the First MDL Program or some version of it. The PSC and defense counsel have consulted about those inquiries. They have agreed that, in view of the extensive negotiations and effort which went into establishing the First MDL Program, it would be desirable to establish a second mediation and resolution program for the state court cases which shall be administered as an offshoot of the First MDL Program. In reaching this conclusion, they have consulted with the State Liaison Committee ("SLC") previously established by the MDL Court. This new program will be known as the "Second MDL Program." The PSC, SLC and defense counsel believe that the most effective way of resolving the claims of: (a) state court plaintiffs, (b) federal court plaintiffs who were eligible to enroll in the First MDL Program but did not do so, (c) those federal court plaintiffs (including Achord plaintiffs) whose suits were filed after February 1, 2004 and who thus were not eligible to participate in the First MDL program and (d) persons under tolling agreements who did not enroll in the First MDL Program but who may now wish to enroll, is to establish the program set forth in this Term Sheet and to bring the program and those claims under the jurisdiction of the MDL Court.

The PSC and the State Liaison Committee ("SLC") have committed to making a substantial effort to enroll in this new program the required number of state court plaintiffs and persons under tolling agreements who did not elect or were not eligible to join the First MDL Program. There are approximately 550 plaintiffs ("plaintiffs" as defined in Section 1(B) of this Term Sheet) maintaining suits in various state courts.

In addition to the plaintiffs in state court suits, there are approximately 1544 (inclusive of Achord plaintiffs) plaintiffs ("plaintiffs" as defined in section 1(B) of this Term Sheet) in federal court

actions whose suits were not pending as of February 1, 2004, thus rendering them ineligible to participate in the First MDL Program. They will be eligible to enroll in the Second Program. This Second MDL Program is an entirely voluntary one. No plaintiff or claimant is required to enter it but those who do enter it will be bound by its terms. As with the First MDL Program, entrance into the Second MDL Program will terminate any state or federal court litigation brought by those persons and will preclude those who are under tolling agreements from ever commencing any such litigation.

This document reflects the agreement which the PSC, the SLC and defense counsel have reached.

## 1. THE PROGRAM

A. The PSC, SLC and the defendants will establish a second global mediation and resolution program (hereafter the "Second MDL Program") whose purpose is to establish a system, subject to the jurisdiction of the MDL Court, whereby the claims of state court plaintiffs, certain plaintiffs in federal court suits and persons under tolling agreements will be reviewed and resolved by the panel of physicians who will be determining eligibility for payments in the "Propulsid MDL 1355 Settlement Program" (hereafter the "First MDL Program"). The Second MDL Program will be posted on the MDL Court's website.

This Program will be in lieu of any further litigation by the plaintiffs and tolling agreement claimants who enroll in this Second MDL Program respecting their acquisition or use of Propulsid.

The defendants are satisfied that the most effective and efficient way of managing the resolution of state court actions and the suits and claims of the other plaintiffs and claimants identified herein is to establish the Second MDL Program under the jurisdiction of the MDL Court which already has jurisdiction over the First MDL Program. In order for this to occur, the MDL Court will have to decide whether it chooses to exercise its jurisdiction over this matter. The PSC, SLC and the defendants will therefore jointly petition the MDL Court to accept jurisdiction on the same or similar terms found in the Consent Order of February 4, 2004. If the petition is not granted, then the agreement set forth in this Term Sheet shall terminate and become null and void.

The attorneys for the plaintiffs in the state court matters shall be given notice of the petition and shall have the right to submit their position on the same in writing and to appear before the MDL Court when the application is heard. The Second MDL Program, as noted in this Term Sheet, is entirely voluntary.

B. The Second MDL Program will not become effective unless and until (1) 90% of the plaintiffs who are maintaining wrongful death actions as of November 15, 2005 in state court cases and in federal court cases (excluding Achord cases) filed after February 1, 2004, (2) 95% of the plaintiffs who are maintaining other than wrongful death actions as of November 15, 2005 in state court cases and in federal court cases (excluding Achord cases) filed after February 1, 2004, (3) 100% of the represented Achord plaintiffs whose suits were not pending as of February

1, 2004 and (4) 5,000 of the tolling agreement claimants who did not enroll in the First MDL Program have agreed in writing by completion and service of the Enrollment Form (attached as Exhibit B) to become part of the Second MDL Court Program and to be bound by its terms. To be counted towards these enrollment minimums and to participate in this Program, plaintiffs and claimants under tolling agreements must be citizens or residents of the United States.

These four components noted in Section 1(B) shall be known as the "minimum enrollment." At the present time there are approximately 125 wrongful death actions and 1944 other than wrongful death actions pending in groups (1) and (2) above. "Pending" shall mean cases filed in any state or federal court in the United States by November 15, 2005. Plaintiffs and claimants are limited to citizens or residents of the United States. Defendants have previously supplied the PSC and SLC with relevant information about the persons in groups (1), (2), (3) and (4) and the identity of their counsel.

"Plaintiffs" in this Agreement means all persons who claim a loss as a result of the death or injury claimed to have resulted from use of Propulsid. Thus spouses qualify as one plaintiff; all persons who claim any loss as a result of the death or injury of a person qualify as one plaintiff. Thus, spouses, children and/or heirs, together with the person who sustained the claimed injury or death, constitute a single plaintiff for purposes of Section 1.

Once the minimum enrollment requirements described above and in Section 21 have been reached, the Second MDL Program enrollment shall remain open for six additional months. As the percentages of plaintiffs who enroll during this additional six-month period reach the levels beyond the enrollment percentages described in this Section, the settlement fund shall be increased in accordance with the terms of Section 3(B). The parties reserve the right to agree to extend this additional period beyond the six months.

C. The agreements described herein shall be signed by counsel for the plaintiffs or claimants who shall represent that they have full authority from their clients to enter into the agreement.

D. The Second MDL Program will be established pursuant to an order of the MDL Court. It will be administered by the Special Master appointed by the MDL Court pursuant to Federal Rule of Civil Procedure 53. The Special Master shall have the authority to engage support personnel to assist in management of the Program and shall be required to render reports to the MDL court from time to time respecting the management of the Second MDL Program, including allowance and disallowance of claims.

E. The terms, conditions and qualifications of the Second MDL Program are set forth in the First MDL Program attached hereto as Exhibit A.

F. All plaintiffs and claimants who enroll in this Second MDL Program, and their attorneys, thereby agree to submit themselves to the jurisdiction of the MDL Court over that Program for all purposes.

G. Notwithstanding any other provision of this Term Sheet, no plaintiffs or claimants shall be entitled to or allowed to enroll in this Second MDL Program if their lawsuits had not been filed by November 15, 2005 or their tolling agreements had not been signed by the defendants by November 15, 2005. Nor will any plaintiffs or claimants be entitled to or allowed to enroll in this Second MDL Program if they enrolled in the First MDL Program. No person who enrolled in the First MDL Program may enroll in the Second MDL Program. However, any person who was eligible to enroll in the First MDL Program but did not do so may enroll in the Second MDL Program.

## 2. SPECIAL MASTER AND MEDICAL PANEL

A. Eligibility for payment will be based on medical records, as is set forth in more detail in the Program.

B. The Medical Panel described herein shall have the sole and exclusive authority to determine eligibility for payment under the Second MDL Program or non-eligibility under the Second MDL Program.

C. Once the Medical Panel has made a determination that a plaintiff or claimant is eligible for payment and has determined the category in which the plaintiff or claimant falls, the Special Master shall have sole and exclusive authority to determine the sum to be awarded to that person.

D. The determinations made by the Medical Panel and the Special Master are final determinations and, other than as set forth in Louisiana Civil Code Article 1953, shall not be subject to review or appeal, whether by mandamus or otherwise, in any court by the plaintiffs, the claimants or the defendants.

## 3. SETTLEMENT AND ADMINISTRATIVE FUNDS

A. The parties agree that the defendants shall pay the sums designated below for the settlement and administrative funds and for the payment described in Section 19.

B. The settlement fund shall be funded by the defendants and shall be no less than \$14,500,000.00 and no more than \$15,000,000.00. The fund shall be \$14,500,000.00 if 90% of the state court and federal court plaintiffs described in Section 1(B) who are maintaining death cases, 95% of the state court and federal court plaintiffs described in Section 1(B) who are maintaining non-death cases, 100% of the represented Achord plaintiffs described in Section 1(B) and the 5,000 persons described in Section 1(B) agree in writing through their counsel to enter into the agreement, all as set forth in Section 1(D).

In the event more than 90% of the death case plaintiffs, as defined in Section 1, agree in writing through their counsel to enter into the agreement set forth in Section 1(D), then the settlement fund shall be increased by an additional sum as follows:

Percentage enrolling	Additional sum to be paid to settlement fund
91%	\$25,333.00

92%	\$25,333.00
93%	\$25,333.00
94%	\$34,455.00
95%	\$34,455.00
96%	\$34,455.00
97%	\$50,159.00
98%	\$50,159.00
99%	\$50,159.00
100%	\$50,159.00

Accordingly, if there is 100% enrollment of the death case plaintiffs, the additional sum to be paid to the settlement fund will total \$380,000.00.

In the event more than 95% of the non-death case plaintiffs, as defined in Section 1(B) agree in writing through their counsel to enter into the agreement set forth in Section 1D, then the settlement fund shall be increased by an additional sum as follows:

Percentage enrolling	Additional sum to be paid to settlement fund
96%	\$7,500.00
97%	\$7,500.00
98%	\$15,000.00
99%	\$30,000.00
100%	\$60,000.00

Accordingly, if there is a 100% enrollment of these non-death case plaintiffs, the additional sum to be paid to the settlement fund will total \$120,000.00.

There shall be no pro rata increased payment to the Settlement Fund if the number of plaintiffs who agree in writing through their counsel to enter into the agreement are greater than any of the above described levels. The increased payment is only due if the actual level is reached.

C. The parties have evaluated the expected costs of the administrative fund, discussed them with each other and have anticipated that the costs will not exceed \$3,000,000.00. The defendants have, nevertheless, agreed to fund the administrative fund in the amount of \$3,000,000.00. In the unlikely event it appears during the administration of the Second MDL Program that the costs of the administrative fund might exceed \$3,000,000.00, either party shall bring the matter to the attention of the MDL Court, which shall have the authority to modify the Second MDL Program to ensure that the administrative fund does not exceed \$3,000,000.00. Under no circumstances shall the defendants have any obligation to pay more than \$3,000,000.00 for the administrative fund. Any unused portion of the Administrative fund shall be returned to defendants.

D. Counsel for plaintiffs described in Section 1(B) shall not be permitted to enroll less than 100% of the plaintiffs they represent in state and federal court cases and persons they represent

under tolling agreements. Counsel for plaintiffs within the meaning of this Section are defined to be those who were counsel of record per pleadings filed before November 15, 2005.

E. The parties wish to have the settlement fund maintained in as secure a manner as possible so that those funds will be available to be paid to the plaintiffs and claimants who qualify for payment. They will consult as to the bank depository or other prudential financial institution which will be chosen to hold those funds and will also consult as to the form of prudent investment vehicles to be used for investment of the funds. The PSC and SLC shall designate the institution subject to defendants' agreement. Once a tentative decision as to the institution and the form of the investment has been made, the parties shall apply to the Court for approval of the same as having been prudent decisions. The institution so chosen shall thereupon consent to the jurisdiction of the MDL Court acknowledging that it alone has the obligation to manage the settlement fund. Periodic reports should be made to the Court of the interest earned, distributions made, and other matters involving the status of administration. Its management shall thereafter be subject to review by the MDL Court.

F. The defendants will make the initial payment into the settlement fund within 30 days of confirmation that the enrollment levels (90% of the death plaintiffs, 95% of the non-death plaintiffs, 100% of the represented Achord plaintiffs and 5000 of the remaining tolling agreement claimants as described in Section I(B)) have been reached. Thereafter, defendants will pay the additional sums set forth in 3B into the settlement fund within 30 days of confirmation for each 1% incremental increase in death and/or non-death enrollees. If, upon completion of the Second MDL Court Program, the aggregate sum of the awards of the Special Master is less than the settlement fund, the difference and interest on that difference shall be returned to the defendants.

#### 4. WAIVERS AND RELEASES

A. In consideration for the plaintiffs and claimants agreeing to enter the Second MDL Program and surrendering their rights to litigate their cases or claims, the defendants unconditionally waive all defenses in law and equity which they have or may have to those cases or claims except as otherwise described in this document.

B. In consideration for the defendants waiving the defenses they have in law and equity and agreeing to enter the Second MDL Program, the plaintiffs and claimants unconditionally release whatever rights they have or may have against the defendants, their agents, servants, employees, officers and directors and all health care professionals, health care providers, health care facilities, pharmacies and other distributors of Propulsid®, and all of these individuals' and entities' parents and subsidiaries, affiliates, agents, attorneys, servants, employees, officers and directors and those who acted in concert with them together with their respective insurers. In addition, no plaintiff shall enter the Second MDL Program until his or her counsel shall have executed a stipulation of dismissal of the entire action with prejudice and claimants shall enter the Second MDL Program with the understanding that their claims will be subject to an order of termination once the processing of their claims has been finalized. The same shall be given to counsel for the defendants who are to hold it in escrow and who are authorized to file it only upon the determination by the Medical Panel that the claim does not qualify for payment or upon

confirmation by the Special Master that the claim has been dismissed under Section 7 or, if the claim is held by the Medical Panel to qualify for payment, only upon payment of the award.

C. By entering the Second MDL Program, the plaintiffs, claimants and defendants acknowledge that decisions to be made by the Medical Panel and Special Master may be ones with which they disagree. They further acknowledge that this eventuality is part of the Second MDL Program and they accept it.

D. All releases from plaintiffs or claimants given under this Program shall be given to Janssen, L.P (formerly known as Janssen Pharmaceutica Inc.) Johnson & Johnson, Janssen Research Foundation, Janssen Pharmaceutica, N.V., Robert Wood Johnson Pharmaceutical Research Institute, and all entities and persons related to them and all health care professionals, health care providers, health care facilities, pharmacies and other distributors of Propulsid®, and all of these individuals' and entities' parents and subsidiaries, affiliates, agents, attorneys, servants, employees, officers and directors and those who may have acted in concert with them, together with their respective insurers, and serves as a waiver of California Civil Code Section 1542, if applicable, which provides that, "a general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor."

## 5. MEDICAL RECORDS SUBMISSIONS.

A. The parties shall submit with the Consent Order the Enrollment and Claim Forms attached as Exhibits B and C. The Special Master shall make those forms available to those persons who elect to join the Second MDL Program and, once completed, to the parties, and shall determine whether the completed forms adequately provide the information required under the Second MDL Program. The forms will also be available on the Court's website.

B. The attorneys representing the plaintiffs and the attorneys representing the claimants shall have the right to collect and submit the medical records called for by the Second MDL Program through their own efforts. They shall also have the right to use any common medical records collecting service which may be established for purposes of collecting the medical records and submitting them to the Medical Panel. The defendants reserve the right to submit medical records which they have gathered on plaintiffs and claimants and to examine the medical records submitted on their behalf. The attorneys representing the plaintiffs and the attorneys representing the claimants also have the right to examine the medical records submitted by the defendants. All parties have the right to argue to the Special Master whether the Medical Records Submission has been accomplished in accordance with the requirements of the Second MDL Program. All records of claimants who opt in which were at any time collected or to be collected by claimants and/or defendants shall be promptly placed in the depository. Claimants and defendants, by placing their records in the depository, consent to review of such records, including medical records, by parties' attorneys, medical experts, consultants, depository staff, the Medical Panel, the Court and the Special Master, but such records shall otherwise remain confidential in conformity with HIPAA.

C. In the event the Medical Panel finds that a plaintiff or claimant is not entitled to payment under this Second MDL Program, a \$250 payment to defray costs paid for the medical records or assembly of same by the attorney for the plaintiff or the attorney for the claimant shall be paid from the administrative fund pursuant to Section 16B. It is understood that the only records required to be submitted to qualify for the \$250 reimbursement is a single medical or pharmacy prescription record indicating Propulsid use and a medical condition or injury which the claimant has attributed to Propulsid in Section 5A. All Orders or Minute Entries previously made or hereafter to be made by the MDL Court respecting the medical records needed to satisfy this requirement will control this Second MDL Program. This aspect of the Second MDL Program and the payment described are only for the benefit of actual Propulsid users.

## 6. PAYMENTS BY CATEGORY

A. Once the Medical Panel has determined that a person is eligible for payment and has identified the category, the Special Master shall decide what sum shall be awarded. In so deciding, the Special Master shall give consideration to those factors relevant to the payment of damages for the particular person under commonly accepted rights of recovery.

B. It is not possible to determine what payment will be made to any plaintiff or claimant until: (1) the Medical Panel has made its determinations of eligibility and, if eligible, the category of eligibility and (2) the Special Master has determined the amount to be paid. The final amount of these payments will not be determinable until the claims of all who enroll in this Program have been decided.

C. The Special Master is not to consider the amount of the settlement fund or the exhaustion of that fund as a limitation in making any award. In the event the total sums to be awarded to those persons found eligible under the Second MDL Program exceed the total sum available in the settlement fund, the awards shall be reduced and paid on a pro rata basis.

D. All relevant liens shall have been resolved before any payments are made under this Second MDL Program.

E. The parties will explore whether it is feasible to make a partial payment of a sum awarded to a plaintiff or claimant in advance of the final determination of the total sums to be awarded to all plaintiffs and claimants and the timing of release and indemnity agreement. If such a payment is made it will be recognized as a partial, not final payment, all subject to Section 6(B).

## 7. MEDICAL PANEL

A plaintiff or claimant shall have 120 days from the date of service by the PSC/SLC of notice that the Second MDL Program's minimum enrollment levels have been reached, or 120 days from the date a plaintiff or claimant serves an Enrollment Form, whichever is later, to serve a Claim Form. In extraordinary circumstances in cases where the attorney for plaintiffs or claimants has more than 100 such clients and has not submitted all the Claim Forms in a timely manner, the Special Master may grant a reasonable extension of time to complete submission of



the remaining Claim Forms. If a plaintiff or claimant fails to submit the required medical records within 60 days after he or she has completed the claim form described in Section 5(A), that person's claim shall be dismissed with prejudice. No further action is to be taken on it and no litigation may be commenced or maintained to attempt to pursue that claim. However, if a plaintiff or claimant has made a good faith effort to secure records, then the period will be extended for 60 days, upon application to the Special Master. If the Special Master has determined that a good faith effort has been made to obtain the medical records, but they are still not available, the Panel may review the records available, but the possible recovery must still meet the requirements of the guidelines. If a plaintiff or claimant fails to submit the required medical records within the 60 day extension and the Special Master has determined that the plaintiff or claimant has not made a good faith effort to secure records, that person's claim shall be dismissed with prejudice. No further action is to be taken on it and no litigation may be commenced or maintained to attempt to pursue that claim. Once the required medical records have been received in the medical records depository, they shall be given to the Medical Panel together with the claim forms so that the Panel can decide whether the claim is eligible for payment.

## 8. ADMINISTRATION

The parties intend that the administration of this Second MDL Program shall be conducted in a manner designed to expedite medical records collections, the analysis of claims and the determination whether they qualify for acceptance or rejection.

## 9. MDL ASSESSMENT

A. This Second MDL Program is MDL 1355 work product, originally developed and agreed upon through court-ordered negotiations between Janssen, L.P. and the Plaintiffs' Steering Committee in MDL 1355. The use of this Second MDL Program for settlement purposes shall constitute consent by the plaintiff or a claimant under a tolling agreement to pay 6% of the gross amount of any award issued by the Special Master. This is pursuant to the common benefit trust fund to be established by a Pretrial Order in MDL 1355. This order will be available on the court's website, <http://propulsid.laed.uscourts.gov>.

## 10. NO ADMISSION OF LIABILITY

Neither Janssen's agreement to, nor participation in, this Second MDL Program constitutes an admission of liability to any person or other entity by Janssen, L.P. or any corporate entity or person related to it, e.g., Johnson & Johnson, Janssen Research Foundation, Janssen Pharmaceutica, N.V.

## 11. CONFIDENTIALITY

The amount and fact of settlements reached under this Second MDL Program are confidential, except as may be required by statute, court order, court rule, or the settlement approval process where court approval of a settlement is required by law in the relevant jurisdiction. Agreement to, and maintenance of, confidentiality are material terms of any settlement reached. An

exemplar release will be jointly prepared by the parties. See Section 24 for additional provisions relating to confidentiality.

## 12. INFORMATION REQUIRED TO CONSUMMATE SETTLEMENT

A list of the information which must be provided to the attorneys for Janssen before a settlement check is delivered will be provided to the PSC.

## 13. PARTICIPATION

A. Death cases / cardiac arrest cases (Tiers I and II) - In these cases, the parties may provide within 60 days of the deadline for serving all required medical records confidential memoranda (simultaneously submitted at a date set by the two physician panel), explaining the party's contention as to a plaintiff's or claimant's qualification or non-qualification under the Second MDL Program and the category. Defendants shall have 60 additional days, and such further time as may be approved by the Special Master, to submit their memoranda if additional medical records must be subpoenaed after plaintiff's/claimant's deadline for submitting all medical records has expired. Memoranda are limited to five (5) pages and exhibits attached may be abstracts or full documents not to exceed thirty (30) pages. There shall be no submission by either party of expert reports or affidavits in support of or in opposition to qualification or category.

B. Tier III - In these cases no memoranda of the type described in Section 13(A) shall be permitted and the Medical Panel shall rest its decision on the medical records submitted in accordance with Section 13(A). A one page summary may be submitted to point out the supporting documents and expedite medical review. There shall be no submission by either party of expert reports or affidavits in support of or in opposition to qualification or category.

C. In the event that the two medical panelists cannot agree on a plaintiff's or claimant's qualification or non-qualification and, if qualified, in which category, a third panel member will be selected on a rotating basis by the Special Master to cast the deciding vote. The rotation shall be a panelist appointed by the PSC, then a panelist appointed by the defense and so on in that order.

D. All decisions of the Medical Panel are final and not appealable (See Section 2(D)). All cases submitted to the Panel for decision will be decided within 45 days of submission to the Panel. In the event a third panelist is required, a decision will be forthcoming within 30 additional days. The deadlines may be extended by the Special Master upon showing of good cause. Thereafter, the Special Master may call for additional records such as birth, death, and/or marriage certificates, economic loss evidence (tax returns, pay stubs, benefits books income and support records) which must be furnished within 30 days of the request. The Special Master shall tentatively decide the level of payment to plaintiff claimant within 45 days of submission to him by the Medical Panel of its decision that a case qualifies for payment. This shall be subject to revision under Section 18(D). It shall remain confidential until a final determination is made by the Special Master. The final award by the Special Master is conclusive and non-appealable.

E. Except as is set forth in Section I(A)(B) defendants, by engaging in this Second MDL Program, waive and dismiss with prejudice all defenses of liability as to participating claimants such as statutes of limitation and repose, jurisdiction, venue, mitigation, comparative/contributory negligence, assumption of risk, independent intervening cause and products' liability, specific defenses such as state of the art, no safe alternative design; preemption, FDA and other regulatory approval, learned intermediary, etc. The defendants do not waive the defenses that the plaintiff or claimant was not exposed to Propulsid and that the claimed event was not caused or contributed to by use of Propulsid, as those requirements are necessary for any payment to be made pursuant to Tiers I, II and III in Exhibit A.

#### 14. STANDARDS TO BE USED

A finding for eligibility to enter a defined category does not require findings of medical certainty but only findings that something is more probable than not. The following standards should be used by the Medical Panel or upon inquiries by it to the Special Master:

A. "But for" tests - whether harm (death, cardiac arrest or serious tachycardia ventricular arrhythmia) would more probably have occurred or not because of the user's ingestion of Propulsid.

B. Concurrent cause and substantial factor. Cause-in-fact is usually a "but for" inquiry which tests whether the harm would not have occurred "but for" the use of Propulsid, and the substantial factor inquiry is an alternative method of analysis used when two or more combined causes may be present. Thus, where there may be concurrent causes of an injury, the proper inquiry is whether the product in question was a substantial factor in bringing about the harm or injuries. A party's act maybe a substantial 'factor in bringing about the harm or injury when the harm would not have occurred without, the product's use.

C. The package literature identifies certain medications as contraindicated for use while Propulsid is being taken and identifies the presence of certain conditions as a contraindication for the use of Propulsid. The existence of such events in any claimant's case does not of itself entitle the claimant to a recovery nor deny a claimant a recovery.

D. Any legal interpretation of these standards may be referred by the Medical Panel to the Special Master on a case by case basis. The interpretation of the Special Master will be final and unappealable and will be rendered only in writing within 3 calendar days of the request.

#### 15. MEMBERS OF MEDICAL PANELS

A. Six physicians, licensed in Louisiana and in good standing, or a lesser or greater number agreed to by the PSC, the SLC and Janssen, will be chosen 50% by Janssen and 50% by the PSC and SLC. They shall, if possible, be the physicians who already serve on the Medical Panel in the First MDL Program. The physicians must be recognized board certified cardiologists, electrophysiologists or internists who have had substantial training and substantial experience treating cardiac problems or physicians board certified in a specialty dedicated to the treatment of cardiovascular diseases or board certified physicians who have documented substantial

training and experience treating cardiac problems. They may be active, semi-retired or retired. Each side will have veto over the other side's selection of any physician not currently on the MDL Medical Panel. A member of each physician group shall sit on a panel to determine category eligibility and non-eligibility. Once the members of the Medical Panel have been chosen and no veto as to their selection has been exercised, the parties shall have no ex parte contact with those members. In the event the parties agree to any training to be done with the members of the Medical Panel, that teaching will be done jointly.

B. If either party believes that a member of the Medical Panel is consistently disregarding the Second MDL Program's provisions respecting requirements for eligibility or non-eligibility, the PSC, SLC and defense counsel shall meet and confer to address the issue and, absent a resolution, either party may bring the matter to the attention of MDL Court which shall have the authority to remove the physician from the Medical Panel. The MDL Court will interview the-challenged panelist in camera and, if necessary, remove the panelist. No counsel may be present at such hearing and the hearing and Order of the Court will be final and non-appealable and sealed in the record. That physician's replacement, if the MDL Court removes a physician, shall then be designated by the party who originally chose that physician. This provision is not intended to create an appeal system for occasional eligibility or non-eligibility decisions with which one party disagrees.

#### 16. CLAIMANT ENTRANTS' BENEFITS

Any claimant electing to enter the Second MDL Program, in addition to potential entry into a category and level of payment, receives the following benefits:

- A. Waiver of defenses by the defendants to claimant's claim as provided in Section 13(E).
- B. Payment of \$250 pursuant to Section 5(C) to defray costs of obtaining the medical records described in Exhibit A, Section 2, if the Medical Panel finds, following a review of a sufficient amount of those records, that there is no entitlement to payment under the settlement fund.
- C. Establishment of a settlement process and fund.
- D. Expedited review and acceptance or rejection of claims.
- E. Evaluation of claimant's medical records and circumstances by at least (2) two qualified physicians without cost to claimant.

#### 17. ADMINISTRATIVE FUND

- A. The following are examples of administrative expenses:
  - 1. Depository costs (including storage, document or electronic retention, equipment, paralegal and other employee salaries, rent and utilities).

2. Payment of certain medical records pursuant to Section 5(C).
  3. Payment of fees to members of Medical Panels.
  4. Payment of fees to Special Master.
  5. Reimbursement of miscellaneous expenses agreed to by PSC, SLC and defendant.
  6. If the enrollments required to start the Program are reached, reimbursement of reasonable out of pocket expenses incurred by PSC and/or SLC in enrolling participants in the Program. The proposed expenses must be submitted to defense counsel in advance and agreed to within five days of their submission. If such agreement is not reached, the Special Master shall decide whether the expenses or any part of them shall be paid from The Administrative Fund.
- B. No administrative funds may be used to pay claims.
- C. Excess refunded to defendant.
- D. Defendant to supply \$3,000,000.00 after the Second MDL Program has become effective pursuant to Section 1(B).
- E. Account to be administered in New Orleans by financial institution of defendants' selection with interest accrual on balances. Periodic reports should be made to the Court of the interest earned, distributions made, and other matters involving the status of administration. Interest on those payments to be added to the administrative fund. Interest (after payment of taxes) on the \$3,000,000.00 or any portion thereof shall be added, if needed, to the Administrative Fund to meet its obligations. If not needed, the balance of any principal and/or interest shall be returned to the defendants.
- F. All category claims to be determined within 3 months of records submission.
- G. PSC and Janssen agree to establish joint medical and other records depository at the present location of the First MDL Program depository in New Orleans to be maintained and managed by the Special Master and his staff. Salary to be agreed upon and paid by the fund.

## 18. SETTLEMENT FUND

- A. The Settlement Fund will be established pursuant to Section 3(E). If there are unused funds in the MDL Settlement Fund in the First MDL Program, they shall be included as part of this Second MDL Fund and shall serve as part of the defendants' obligation under Section 3 to make settlement payments.

- B. Claims verification and payment milestones (to be detailed in documents submitted with Consent Order).
- C. Claims to be paid within an agreed time after verification compliance.
- D. Each claim to escrow a reserve and escrow paid if total claims do not exceed fund.
- E. If claims exceed amount in Settlement Fund, then the Fund will be distributed pro rata (based on claims value) after all claims have been processed.
- F. If there are excess funds left in the Settlement Fund after payment of all awards made by the Special Master, the funds, along with any interest thereon, shall be returned to the defendants.

Until such time as the Special Master shall have made an award pursuant to this Second MDL Program, the Settlement Fund remains the property of the defendants, for the benefit of Propulsid claimants, subject to distribution only pursuant to the terms of this Second MDL Program.

19. ATTORNEY FEES:

In addition to the 6% fee due to the PSC pursuant to Section 9, the PCS and SLC shall be entitled to an additional fee and the parties have agreed that the PSC/SLC may seek and recover such attorneys' fees and costs. It is agreed that the PSC's and SLC's work product and efforts to date have been responsible for developing and creating the Second MDL Program, and that the PSC's and SLC's future involvement in the administration of the Program will confer a substantial benefit on all of its participants. The parties recognize that *Sprague v. Ticonic Nat'l Bank*, 307 U.S. 161 (1939), *Mills v. Electric Auto-Lite Co.*, 396 U.S. 375, 393 (1970) and other well-established authority, permit the district court to grant such an award based upon its inherent powers of equity and that such award shall be paid separately and in addition to the assessment already authorized by the Court in PTO No. 16. Consistent with this jurisprudence, the defendants have agreed to pay and not contest any award for attorneys' fees and costs in the amount up to and including, \$4,000,000.00, but defendants will not pay any sum in excess of that amount. The PSC and SLC are required to petition for such an award and the amount and propriety of the same shall be determined by the court upon recommendation by the Special Master. The defendants will pay that award within 30 days of receipt of the Order of the MDL Court rendering that award. If a dispute arises thereafter as to division of the attorneys' fee award or challenges relating to payment of the attorneys' fees, the MDL Court, Judge Fallon, shall direct the PSC/SLC as to appropriate escrow (escrow depository to be selected by the PSC/SLC) of the fund, partial payment to entitled attorneys, and in the MDL Court's sole discretion, determine the appropriate division of fees, which decision shall be final and non-appealable. It is understood that once defendants deliver the fee check to the PSC/SLC, they have no further responsibility whatsoever for the payment of any legal fees to any firm, person or legal entity and that the MDL Court's fee order may not be reviewed pursuant to FRCP 60 or on any other basis.

## 20. SETTLEMENT WITH AN INDEPENDENT PARTY REQUIREMENT

The plaintiff or claimant must provide the amount of any settlement reached with an entity other than Janssen, the identity of the party with whom or with which the settlement has been reached and information about the pendency of any case or claim by him or her involving use of Propulsid.

## 21. IMPLEMENTATION OF THE PROGRAM

The PSC, SLC and the defendants will submit to the MDL Court within 30 days of the execution of this document a proposed Consent Order and other mutually satisfactory documents establishing the Second MDL Program and seeking approval of the MDL Court to have it administered by the Special Master and otherwise be subject to the jurisdiction of the MDL Court. The Court Order will incorporate the terms of this document and such additional matters as the Court may direct or the parties agree are necessary to the implementation and management of the Second MDL Program. The parties do not presently foresee that matters not addressed in this document but which are necessary for inclusion in a Consent Order cannot be resolved between them. The PSC/SLC shall have 180 days from the date of that Consent Order to secure the required number of written consents from counsel for plaintiffs and persons under tolling agreements, as set forth in Section 1, and to present them to counsel for the defendants. If the requirements set forth in Section 1 have not been satisfied within the 180 day minimum enrollment period, this agreement shall terminate and the Second MDL Program will not be implemented unless otherwise agreed by the parties.

To the Consent Order should be attached the Enrollment Form attached as Exhibit B to be signed by counsel for plaintiffs and counsel for tolling agreement claimants and the claim form to be signed by plaintiffs and tolling agreement claimants when they submit their medical records. In particular, language in the Consent Order will have to make clear that all plaintiffs and the tolling agreement claimants, i.e., persons not presently subject to the jurisdiction of the MDL Court, and the defendants accept the jurisdiction of the MDL Court and that the MDL Court is, by their consent: a) empowered to enter an order terminating plaintiffs' and claimants' rights to sue the defendants if they fail to submit the medical records within the time set forth in the term sheet or if the Medical Panel does not decide that they are entitled to compensation and, b) empowered to enter an order authorizing the Special Master to pay from the settlement fund any award that he makes in favor of such a plaintiff or claimant consistent with this agreement.

## 22. ADMINISTRATION OF THE PROGRAM

The parties will include in the Consent Order appropriate provisions for the management of the Second MDL Program including duties to be performed by the Special Master, proposed fee arrangement, for members of the Medical Panel, as well as how they should fulfill their duties, reports to the PSC, SLC and the defendants about claims submissions under the Second MDL Program and all other administrative matters designed to accomplish the purposes set forth in Section 8. All plaintiffs or claimants who participate in the Second MDL Program stipulate and

agree that the Second MDL Program is and will remain subject to the jurisdiction of the MDL Court until all proceedings under the Second MDL Program have been concluded.

23. MEDICAL PANEL REVIEW PROCEDURES.

The parties shall prepare a joint written protocol for the members of the Medical Panel to follow in the performance of their responsibilities. The protocol shall cover the administrative issues respecting the work of the Medical Panel, e.g., time limits for case reviews, adherence to the Settlement Requirements set forth in Exhibit A, etc.

24. PUBLIC STATEMENTS ABOUT THIS SETTLEMENT

The PSC, SLC and the defendants shall prepare a joint statement describing this settlement and the Second MDL Program established herein and shall agree upon the manner and timing of distribution. This shall be the only statement to be distributed except as the PSC, SLC and defendants may further agree. The plaintiffs and claimants and their counsel agree that they shall make no public statement. These conditions are material conditions to this agreement. This will not constitute a restriction on plaintiffs' or claimants' attorneys' communication with their clients about this matter except to the extent there is use of the media or any other public forum for that purpose. The contents of this term sheet shall not be made public by any party until the consent order described in Section 21 has been entered. See Section 11 for additional confidentiality requirements.

Executed in triplicate original on this the 15<sup>th</sup> day of December, 2005.

  
**RUSS M. HERMAN, T.A. (La. Bar #6819)**

**LEONARD A. DAVIS, #14190**

**JAMES C. KLICK, #7451**

**HERMAN, MATHIS, CASEY, KITCHENS & GERBEL, LLP**

**820 O'Keefe Avenue**

**New Orleans, Louisiana 70113**

**Phone: (504) 581-4892; Fax: (504) 561-6024**

**MDL LIAISON COUNSEL FOR PLAINTIFFS**

**MDL STATE LIAISON COMMITTEE**

  
**RICHARD J. ARSENAULT**

**Louisiana Bar Roll #38041**


**Neblett, Beard & Arsenault**

**P.O. Box 1190**

**Alexandria, LA 71309-1190**

**Telephone: 318-487-9874**

**Facsimile: 318-561-2591**

  
*David Bernier*  
*with permission*





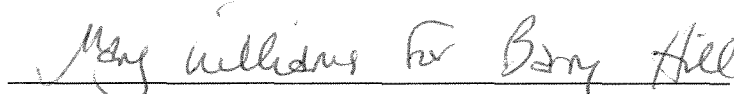
**DAWN M. BARRIOS (La. Bar No. 2821)**

Barrios, Kingsdorf & Casteix  
701 Poydras Street, Suite 3650  
New Orleans, La. 70139  
Phone: 504.524.3300  
Fax: 504.524.3313  
barrios@bkc-law.com

 *with permission*

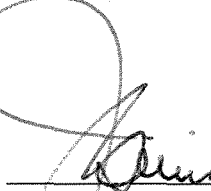
**JAMES T. CAPRETZ**

Capretz & Associates  
5000 Birch Street  
Suite 2500  
Newport Beach, CA 92660  
Telephone: 949-724-3000  
Facsimile: 949-757-2635



**BARRY M. HILL**

Hill, Toriseva & Williams, PLLC  
89 12<sup>th</sup> Street  
Wheeling, WV 26003  
Telephone: 304-233-4966  
Facsimile: 304-233-4969



**JAMES B. IRWIN, T.A. (La. Bar#7172)**

QUENTIN F. URQUHART, JR. (La. Bar #14475)

KIM E. MOORE (La. Bar #8653)

MONIQUE M. GARSAUD (La. Bar #25393)

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, L.P. AND JOHNSON & JOHNSON**

DRINKER BIDDLE & REATH 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.  
50 Fremont Street, 20<sup>th</sup> Floor  
San Francisco, CA 94105-2235  
Phone: (415) 591-7500  
Fax: (415) 591-7510  
**CO-LEAD COUNSEL FOR DEFENDANTS,  
JANSSEN, L.P. AND JOHNSON & JOHNSON**

## EXHIBIT A

### SETTLEMENT REQUIREMENTS APPLICABLE TO ALL CASES

1. **FACTUAL REQUIREMENTS.** There must be credible evidence from the medical records that each of the following is more likely than not:

A. **EVENT** - The plaintiff or the plaintiffs decedent (hereinafter referred to jointly as the "person"), must have had an event. An event is defined as death, cardiac arrest or primary tachycardic ventricular arrhythmia. Primary tachycardic ventricular arrhythmia is limited, to primary, sustained ventricular tachycardia, ventricular fibrillation or torsades de pointes.

Primary is further defined as a symptomatic ventricular arrhythmia (ventricular tachycardia or ventricular fibrillation) that occurs in the absence of a concurrently documented causative factor that precipitated the arrhythmia, including, but not limited to, acute myocardial infarction, active myocardial ischemia and decompensated congestive heart failure. Conditions such as hypokalemia or hypomagnesaemia documented at the time of the arrhythmia may be considered by the Medical Panel to be causative factors.

Sustained is further defined as continuous ventricular tachycardia 1) of at least 10 seconds duration, or 2) requiring termination through therapeutic intervention by precordial thump, electrical cardioversion or medication, or 3) with associated symptoms of hemodynamic deterioration such as syncope, presyncope (distinct feeling of impending loss of consciousness which does not eventuate) or shock. Neither dizziness nor lightheadedness is considered an associated symptom, nor is chest pain which precedes the arrhythmic event.

B. **INGESTION**- The person must have ingested Propulsid within 72 hours of the event or, in the case of death, within 72 hours of the arrhythmia that directly resulted in the subsequent death.

### 2. **MEDICAL RECORD REQUIREMENTS**

A. **For a person who was age 12 or older at the time of the event.** The person's relevant medical records as defined in subpart D below, immediately preceding the date of the event must be provided to the Medical Panel.

B. **For a person who was under age 12 at the time of the event.** The person's relevant medical records from birth through the date of the event must be provided to the Medical Panel.

C. **For all people.** The person's relevant medical records from the time of the event until death, or until 60 days before the time the case is submitted under The Program, whichever is applicable. These records are of particular importance in the evaluation process.

D. **Relevant records.** For the purposes of this Program, the following are a person's relevant medical records. Time periods are deemed appropriately modified where the person

was less than twelve years of age at the time of the event. The PSC and J&J may agree to order supplemental records at the expense of the administrative expense fund:

- (1) **The one-year period before the event.** Full records for any kind of medical care in the one year preceding the event (doctor, hospital, pharmacy, ambulance, therapy, etc.).
- (2) **The three-year period before the event.**
  - (a) Full hospital records for hospitalizations.
  - (b) All electrocardiogram, holter monitor, and other cardiac monitoring or testing records for the three years before the event.
  - (c) Physician records from the person's primary care physician or physicians (if any), cardiologist or cardiologists (if any), gastroenterologists and/or pediatrician or pediatricians (if any).
  - (d) Prescription records for all prescribed medications.
- (3) **The ten-year period before the event.**
  - (a) Full hospital records where cardiac concerns are implicated.
  - (b) Full hospital records where GI concerns are implicated.
  - (c) Full EKG's.

## **2. SETTLEMENT CATEGORIES**

### **TIER I: DEATH CASES**

1. The medical records and other factual information are more consistent with a primary tachycardic ventricular arrhythmia being the cause of death than any other reasonable cause, and
2. Death would not have occurred but for decedent's use of Propulsid, or in those cases where there was more than one contributory cause to the death, Propulsid was a substantial factor as defined in Section 14(B), and
3. The autopsy findings, if any, are more consistent with a primary tachycardic ventricular arrhythmia being the cause of death than any other reasonable cause.

**TIER II: NONFATAL CARDIAC ARREST  
LEVEL A**

1. No documented evidence of previous cardiac arrest, myocardial ischemia or myocardial infarction and no documentation that patient was at high risk for cardiac arrest before taking Propulsid, and
2. The arrest is more consistent with a primary tachycardic ventricular arrhythmia being the cause than any other reasonable cause, and
3. The arrest would not have occurred but for the patient's use of Propulsid, or in those cases where there was more than one contributory cause to the arrest, Propulsid was a substantial factor as defined in Section 14(B), and
4. The arrest was witnessed by a health care provider or required therapy such as CPR or defibrillation or was documented on an EKG or monitor.

**LEVEL B**

1. Some risk factors for cardiac arrest present, but no prior history of cardiac arrest and
2. The arrest is more consistent with a primary serious tachycardic ventricular arrhythmia being the cause than any other reasonable cause, and
3. The arrest would not have occurred but for the patient's use of Propulsid, or in those cases where there was more than one contributory cause to the arrest, Propulsid was a substantial factor as defined in Section 14(B), and
4. Medical Treatment was obtained following the arrest.

**TIER III: PRIMARY TACHYCARDIC VENTRICULAR ARRHYTHMIA**

1. The primary tachycardic ventricular arrhythmia must be documented in a rhythm strip, or there is documentation in the patient's medical records that the rhythm strip demonstrated the same, and
2. The primary tachycardic ventricular arrhythmia (including Torsades de Pointe) is more consistent with the patient's use of Propulsid than any other reasonable cause, and
3. The primary tachycardic, ventricular arrhythmia would not have occurred but for the patient's use, of Propulsid, or in those cases where there was more than one contributory cause to the primary tachycardic ventricular arrhythmia, Propulsid was a substantial factor as defined in Section 14 (B), and
4. Required medical attention in, the form of a hospital evaluation or ER visit for treatment of the arrhythmia.