

EXHIBIT "D"
CLAIMS ADMINISTRATION PROCEDURES

1. OVERVIEW OF SETTLEMENT ADMINISTRATION

- 1.1 The procedures set forth herein are for the administration of the Settlement Agreement and for the submission, processing, approval or denial, compensation, and Challenge of Class Members' claims pursuant to the Settlement Agreement. The procedures shall be implemented by the Settlement Administrator and the Claims Adjudicators, subject to the ongoing authority and supervision of Justice Winkler.
- 1.2 The Settlement Administrator may adopt additional policies and procedures for the administration of the Settlement Agreement that are consistent with the Settlement Agreement and with any Orders of the Court or Justice Winkler, as specified herein. Any change or amendment to these Claims Administration Procedures requires approval of Justice Winkler, on reasonable notice to Class Counsel and Defendants' Counsel.
- 1.3 The Settlement Administrator shall implement the Settlement Agreement so as to provide benefits to eligible Claimants in a timely and efficient manner, designed to treat similarly situated Claimants as uniformly as possible and to minimize, to the extent reasonably practicable, the administration and other transaction costs associated with the implementation of the Settlement Agreement. The Settlement Administrator shall make every effort to minimize any delay in the processing of claims.
- 1.4 The Settlement Administrator shall provide copies of any written communications to or from the Settlement Administrator relating in any way to this settlement to Class Counsel and Defendants' Counsel. Any counsel entitled to receive copies of written communications under this provision may waive that entitlement by so advising the Settlement Administrator. The Settlement Administrator shall also provide "read-only" access to the claims administration computer system to Class Counsel and Defendants' Counsel.
- 1.5 All defined terms are as defined in the Settlement Agreement or herein. All calculations of time and deadlines pursuant to these Claims Administration Procedures shall be calculated in accordance with the Ontario *Rules of Civil Procedure* which are available at www.e-laws.gov.on.ca as Regulation 194 to the *Courts of Justice Act* R.S.O. 1990, c. C.43.

- 1.6 The Parties hereto acknowledge and agree that, where reference is made in the Settlement Agreement and the Exhibits thereto, including these Claims Administration Procedures, to the “cause” of a disease or condition for which a claim for compensation is made under the Settlement Agreement, including any determination of “cause” by a Claims Adjudicator as well as the process employed by the Claims Adjudicator in arriving at his or her determination pursuant to these Claims Administration Procedures, or where reference is made to any diagnostic criteria, such reference or determination is made only for the purposes of the administration and implementation of the settlement and is not intended to be and shall not be construed as an admission by the Defendants, the Released Parties, or any of them, that the Products are the cause of, or contribute to, any of the injuries for which Claimants may be compensated pursuant to the Settlement Agreement.

2. ROLES IN SETTLEMENT ADMINISTRATION

2.1 Role of the Settlement Administrator

- 2.1.1 Crawford Class Action Services shall be appointed by the Court as Settlement Administrator and shall be responsible for holding, investing and disbursing the Settlement Fund and, if necessary, the Additional Settlement Funds, in accordance with the terms of the Settlement Agreement.
- 2.1.2 The Settlement Administrator shall invest all funds in its possession under the Settlement Agreement pursuant to the Investment Standards and authorized investments provide for in section 27 of the *Trustee Act*, R.S.O. 1990, c.T.23 with all interest or other income on such funds being added to the monies in trust as set out in the Settlement Agreement. All fees and costs of any custodian holding and/or investing such funds shall be paid out of such funds or out of the interest and/or income of such funds and shall not be the responsibility of the Defendants.
- 2.1.3 Disbursement of any monies out of the Settlement Fund or Additional Settlement Funds shall only be made in accordance with the Settlement Agreement, these Claims Administration Procedures, or upon the direction of Justice Winkler.
- 2.1.4 The Settlement Administrator shall provide quarterly written reports to Class Counsel and Defendants’ Counsel in accordance with section 2.1.6 (iii) below, as well as reporting on such other matters as may be requested by the Court. In addition, the Parties, Class Counsel or Defendants’ Counsel may request reports or information not required by the Settlement Agreement or these Claims Administration Procedures. The Settlement

Administrator shall respond to any such request within seven (7) days. In which case any associated costs shall be borne by the requestor subject to any direction relating thereto which may be given by Justice Winkler.

2.1.5 The Settlement Administrator shall take all reasonable steps to minimize the imposition of taxes upon monies in trust, and shall have the discretion to pay any taxes imposed on such monies out of the monies in trust.

2.1.6 In addition, the Settlement Administrator shall be responsible for:

- (i) preparing and distributing Claim Packages in both French and English;
- (ii) developing, installing and implementing systems and procedures for receiving and processing Claim Packages and determining the completeness of Claim Packages;
- (iii) reporting as required by the Settlement Agreement and these Claims Administration Procedures including reporting on a quarterly basis with respect to the implementation of the settlement generally, and, without limiting the generality of the foregoing, providing information as to the number of Claim Packages received, the number of claims processed, the type of disease and benefit level of the claims processed, the total amount of money distributed, the amount of money remaining in the Settlement Fund and Additional Settlement Funds, the interest accrued, the number of Deficiency Letters delivered, the number of Determination Letters (as defined below) delivered, the number of Notices of Challenge submitted and the number of Challenge Decision Letters (as defined below) delivered;
- (iv) providing adequately trained, supervised and monitored personnel in such reasonable numbers as are required for the performance of its duties within reasonable timeframes;
- (v) receiving and responding to all inquiries and correspondence respecting claims, supplying Claim Packages upon request, delivering letters acknowledging receipt of the Claim Packages and reviewing and evaluating all Claim Packages received and delivering Deficiency and Determination Letters;
- (vi) submitting completed Claim Packages to a Claims Adjudicator for review in accordance with these Claims Administration Procedures and coordinating with the Claims Adjudicators to ensure the timely review and processing of Claim Packages;

- (vii) forwarding payment to qualified Claimants;
- (viii) communicating with Claimants, in either English or French, as the Claimant elects;
- (ix) setting up and maintaining a system for the handling of queries from Class Members and Claimants, including a bilingual toll-free telephone line and web site;
- (x) making such minor modifications to the Claim Package or Claim Forms as may be necessary for the implementation of the Settlement Agreement, however, any change or amendment to these forms requires approval of Justice Winkler, on reasonable notice to Class Counsel and Defendants' Counsel;
- (xi) co-ordinating with Class Counsel and Defendants' Counsel and holding regular administrative conference calls to advise them of the progress of the administration of the Settlement. In addition, when deemed necessary by the Settlement Administrator, calling special meetings on reasonable notice to all Parties;
- (xii) issuing a final report within ninety (90) days of the expiry of the Administration Period setting out the information as specified in (iii) above; and
- (xiii) any such other duties and responsibilities as the Court or Justice Winkler may from time to time direct.

2.2 Role of the Claims Adjudicator

- 2.2.1 As provided for pursuant to section 15 of the Settlement Agreement, the Claims Adjudicators shall be selected by the Settlement Administrator from a roster of individuals agreed upon by the Parties and appointed by the Court, and shall be responsible for the review and determination of claims pursuant to the Settlement Agreement and, where applicable, determining the Product Recipient's Age at Diagnosis, the categorization of claims pursuant to the Matrix criteria and providing the Settlement Administrator with brief typewritten reports reflecting their decisions.
- 2.2.2 The Claims Adjudicator shall act according to the terms of the Settlement Agreement, these Claims Administration Procedures, and the Medical Conditions List and Matrix that are Exhibits "E" and "F" to the Settlement Agreement.

- 2.2.3 The Claims Adjudicator shall be a medically trained Canadian resident with a specialization and training appropriate to the review of Matrix Claims, or certain categories of claims. The roster of Claims Adjudicators shall include both English and French-speaking members.
- 2.2.4 The Claims Adjudicators shall implement the Settlement Agreement so as to provide benefits to qualified Claimants and not to unqualified Claimants, and in a timely and efficient manner designed to treat similarly situated Claimants as uniformly as reasonably practicable and to minimize to the extent reasonably practicable the administration and other transaction costs associated with the implementation of the Settlement Agreement.

2.3 Role of Justice Winkler

- 2.3.1 As set out more fully in sections 16 and 17 of the Settlement Agreement, Justice Winkler shall consider all Challenges brought by Claimants pursuant to these Claims Administration Procedures and the Settlement Agreement.
- 2.3.2 The Challenge process shall be conducted exclusively in writing. Each Challenge shall be reviewed on the basis of supporting material submitted by the Claimant except as otherwise authorized or directed by Justice Winkler.
- 2.3.3 Where the Challenge relates to the issue of whether the Claimant has satisfied the “best efforts” requirement with respect to Supporting Medical Documentation as defined below, or where the claim has been rejected as incomplete for another reason, the documentary material which shall form the basis of the Challenge shall include all materials submitted to the Settlement Administrator with the original Claim Package and, if the Claimant so chooses, an affidavit, made in accordance with Rule 4.06 of the Ontario *Rules of Civil Procedure* (“Affidavit”) supporting the position taken by the Claimant on the Challenge. Where directed by Justice Winkler, such materials may also include materials submitted by the Defendants.
- 2.3.4 Where the Challenge relates to a claim delivered after the expiration of the Claim Period, the documentary material which shall form the basis of the Challenge shall include all materials submitted to the Settlement Administrator with the original Claim Package, together with an affidavit from the Claimant giving reasons for the timing of the filing of the Claim Package and such further and other material as may be directed by Justice Winkler.

- 2.3.5 Where the Challenge relates to a Claimant's eligibility for, or quantum of, compensation, including Progressed Claims and New Pathology Evidence Claims, the supporting documentary material which shall form the basis of the Challenge shall include all material submitted with the original Claim Package, all additional documentation submitted as part of the Progressed Claim or New Pathology Evidence Claim, where applicable, and, if the Claimant so chooses, one report from a Qualified Physician with appropriate specialization, training or expertise supporting the position taken by the Claimant on the Challenge. Where directed by Justice Winkler, such materials may also include materials submitted by the Defendants.
- 2.3.6 The standard of review to be applied on a Challenge relating to eligibility for, or quantum of, compensation shall be whether the Claims Adjudicator or the Settlement Administrator misapprehended the evidence or made an error in principle, or whether the decision of the Claims Adjudicator is unreasonable.
- 2.3.7 In addition, Justice Winkler shall hear and determine all applications for supplemental benefits pursuant to Matrix Level V(b) as set out in Exhibit "F". The determination of Justice Winkler on such applications shall be final and binding and shall not be the subject of any challenge, appeal, or revision, except in the case of a clerical or obvious error, which shall be subject to correction by Justice Winkler.

3. EVIDENCE OF FRAUD

- 3.1 If the Settlement Administrator reasonably believes that a claim has been submitted on the basis of false, misleading or fraudulent information, the Settlement Administrator shall reject the claim. If the Claims Adjudicator reasonably believes that a claim has been submitted on the basis of false, misleading or fraudulent information, the Claims Adjudicator shall immediately notify the Settlement Administrator and the Settlement Administrator shall reject the claim. If a claim is rejected on this basis, the Settlement Administrator shall immediately notify the Claimant, Class Counsel and Defendants' Counsel in writing, and shall advise of the basis on which the claim is being rejected. Upon such notification, any Party, or the Claimant, shall have the right to move for directions before Justice Winkler with respect to such claim.

4. CLAIM PACKAGE

4.1 General Provisions

- 4.1.1 A completed Claim Package shall include a completed and signed Claim Form (including the Product Identification Documentation) in the form attached as Exhibit “G” to the Settlement Agreement, and a completed and signed Medical Diagnosis Form in the form attached as Exhibit “H” to the Settlement Agreement (including the Supporting Medical Documentation as defined below).
- 4.1.2 Qualification for benefits pursuant to the Settlement Agreement requires the timely filing with the Settlement Administrator of a completed and signed Claim Form and Medical Diagnosis Form, which forms are attached as Exhibits "G" and "H" to the Settlement Agreement. The Settlement Administrator may propose modifications to such forms and may propose the use of such other forms as is deemed necessary for the implementation of the Settlement Agreement, but any change or amendment to the forms that are Exhibits to the Settlement Agreement or any proposed additional forms require approval of Justice Winkler, on reasonable notice to Class Counsel and Defendants’ Counsel.
- 4.1.3 Where a Claim Package is rejected as incomplete, the Settlement Administrator shall deliver a letter to the Claimant, indicating what deficiencies exist (a “Deficiency Letter”) and requiring that the Claimant cure the deficiency within sixty (60) days of receipt of the Deficiency Letter. The Claimant shall be entitled to re-submit the Claim Package twice in accordance with the terms and conditions set out in the Settlement Agreement and these Claims Administration Procedures. If a claim is rejected as incomplete a third time, such Claim Package shall be finally rejected by the Settlement Administrator who shall deliver a letter to the Claimant (a “Determination Letter”) advising of the rejection and advising the Claimant of the Challenge procedures more particularly set out at sections 10 and 12.1.3 herein.
- 4.1.4 Where a Claim Package is rejected because it was filed after the expiry of the Claim Period, but within the Administration Period, the Settlement Administrator shall deliver a letter to the Claimant (a “Determination Letter”) advising that Claimant of the rejection and advising the Claimant of the Challenge procedures more particularly set out at sections 10 and 12.1.3 herein.

4.2 Claim Form

- 4.2.1 The Claim Form, attached to the Settlement Agreement as Exhibit “G”, shall be completed and shall be signed by the Claimant. Failure to complete the Claim Form shall result in the claim being rejected.
- 4.2.2 The Claim Form shall attach the Product Identification Documentation, and shall include a declaration under penalty of perjury from the Claimant that, to the best of the Claimant’s knowledge, the Product Recipient ingested the Products, and that, to the best of the Claimant’s knowledge, the Product Recipient's specific condition for which the claim is made was not present prior to use of the Products.
- 4.2.3 A claim may be filed for a deceased Product Recipient. Where a claim is filed on behalf of a deceased Product Recipient, it must be filed by an executor, administrator or other person with the legal authority to administer the Product Recipient’s estate.
- 4.2.4 In respect of claims filed for Product Recipients under a legal disability, a claim may be filed by a Representative Claimant. In such circumstances, the Representative Claimant must provide proof of his or her legal authority to act on behalf of the Product Recipient.

4.3 Product Identification Documentation

- 4.3.1 A Claim Package must include Product Identification Documentation sufficient, as defined below, to prove that the Product Recipient was prescribed and did ingest the Products. To be deemed sufficient to establish that the Product Recipient was prescribed and did ingest the Products, "Product Identification Documentation" shall consist of a statutory declaration by the Claimant that the Products were in fact prescribed and ingested, and shall also include:
- (a) pharmacy records demonstrating that the Product Recipient’s prescription was filled; or
 - (b) medical records contemporaneous with such prescription; or
- 4.3.2 If both (a) and (b) are not available, a written statement signed by the prescribing physician stating that the Product Recipient was prescribed the Products. Such statement cannot rest upon unacceptable and insufficient proof of product identification as outlined in section 4.4 below, and it must be accompanied by an Affidavit from the Claimant stating:

- (a) the steps taken by the Claimant to obtain the Product Identification Documentation as outlined in subsection 4.3.1 above; and
- (b) the responses, if any, to those steps.

4.3.3 If unable to provide Product Identification Documentation as outlined above, the Claimant may submit to the Settlement Administrator such other objective verification of the use of the Products as may be acceptable to the Settlement Administrator. Such objective verification cannot rest upon unacceptable and insufficient proof of product identification as described in section 4.4 below. Such other objective verification must be accompanied by an Affidavit from the Claimant stating:

- (a) the steps taken by the Claimant to obtain the Product Identification Documentation as outlined above; and
- (b) the responses, if any, to those steps.

4.4 Unacceptable Product Identification Documentation

4.4.1 The following types of evidence are unacceptable Product Identification Documentation:

- (a) statements from medical personnel (including prescribing physicians) describing their typical, invariable or general practices during a given time period, or a statement from the Claimant or any other person (other than the prescribing physician as provided for in section 4.3.2 above) that seeks to verify use of the Products, dates or duration based upon recollection;
- (b) records or statements which refer to "diet drugs", "weight loss drugs" or other generic terminology which does not specifically identify the Products as the drug prescribed;
- (c) records or statements which refer to "fen-phen" or "fenfluramine", but which do not specifically identify the Products; however, reference to such terms shall not in and of itself preclude the Claimant from obtaining benefits.

4.4.2 Where the Product Identification Documentation demonstrates that the Product Recipient ingested both Pondimin and the Products, and where the Claimant was a class member in the settlement in *Knowles v. Wyeth-Ayerst Canada Inc.* (2001), 16 C.P.C. (5th) 343 (Ont. S.C.J.), the Claimant will be

entitled to 50% of any Compensable Claim amount otherwise payable, provided the Claimant meets all other criteria as set out herein.

4.5 Medical Diagnosis Form

- 4.5.1 The Medical Diagnosis Form attached as Exhibit "H" to the Settlement Agreement shall be completed and signed by the Product Recipient's treating physician, family physician, or a physician similarly situated with sufficient knowledge of the Product Recipient and/or his or her medical history to complete and sign the Medical Diagnosis Form (the "Treating Physician"), and shall be accompanied by the Supporting Medical Documentation described below.
- 4.5.2 The Treating Physician must be a resident of Canada unless the Claimant provides evidence that one or more of the following conditions are met:
- (a) the Product Recipient normally has a temporary foreign residence and therefore has regularly sought his or her primary medical care in the foreign jurisdiction, including for the condition for which a claim is made;
 - (b) the Product Recipient normally receives or received medical treatment outside of Canada, including for the condition for which a claim is made;
 - (c) the Product Recipient has received treatment in Canada which indicates that he or she has a condition such that he or she may qualify for compensation under this settlement and on the basis of that treatment or diagnosis, he or she has sought and received treatment at a tertiary care clinic outside of Canada;
 - (d) the Product Recipient sought and received treatment in relation to the condition for which a claim is made outside of Canada due to a medical emergency; or
 - (e) the Product Recipient has access to foreign health care through a foreign medical insurance plan or employee assistance plan and normally receives medical treatment outside of Canada pursuant to such plan, including for the condition for which a claim is made;

in which case completion by a foreign physician with the equivalent qualifications and credentials shall be acceptable.

- 4.5.3 Section 4.5 shall be read with modifications, as necessary, to apply to claims made on behalf of deceased Product Recipients.

4.6 Supporting Medical Documentation

- 4.6.1 "Supporting Medical Documentation" is all information and documentation described in this section, including Echocardiogram tapes, disks, and reports. To receive an FDA Positive benefit or Matrix Benefit, the Claimant must provide the Settlement Administrator with Supporting Medical Documentation of the Product Recipient's condition that forms the basis of the claim. The Claims Adjudicator appointed to consider each claim shall be responsible for determining the adequacy and sufficiency of the Supporting Medical Documentation submitted by each Claimant.
- 4.6.2 Where the Claims Adjudicator determines that the Supporting Medical Documentation is insufficient, he or she shall so advise the Settlement Administrator, who shall thereafter deliver (via regular mail) a Deficiency Letter to the Claimant advising the Claimant of the nature of the deficiency. The Claimant may submit additional Supporting Medical Documentation in response to the Deficiency Letter. Where the Claims Adjudicator determines that the Supporting Medical Documentation is still deficient he or she shall advise the Settlement Administrator who shall thereafter issue a second Deficiency Letter to the Claimant. The Claimant shall then be entitled to submit further Supporting Medical Documentation in response to the second Deficiency Letter. Where the Claims Adjudicator thereafter determines that the entirety of the Supporting Medical Documentation provided by the Claimant is insufficient, he or she shall advise the Settlement Administrator who shall thereafter issue a Determination Letter to the Claimant advising of the rejection and advising the Claimant of the Challenge procedures more particularly set out at section 10 herein.
- 4.6.3 To be eligible to receive an FDA Positive benefit, subject to section 5 herein, the necessary Supporting Medical Documentation shall consist of:
- (i) A declaration under penalty of perjury from the Treating Physician setting forth an opinion to a reasonable degree of medical certainty that:
 - (a) the Product Recipient has been diagnosed with the condition which qualifies the Claimant for an FDA Positive benefit, pursuant to the provisions of the Medical Conditions List (Exhibit "E" to the Settlement Agreement),
 - (b) to the best of the Treating Physician's knowledge, such condition which qualifies the Claimant for an FDA Positive benefit

was not present in the Product Recipient prior to the Product Recipient's first use of the Product.

- (ii) Where the only available evidence of the FDA Positive condition is an echocardiogram recording, or where the echocardiogram recording or report does not meet the requirements set out in section 3.3 of the Medical Conditions List, a certification from a physician meeting the qualifications set out in section 3.3 of the Medical Conditions List that the Product Recipient meets the criteria for having FDA Positive regurgitation;
- (iii) A true and correct copy of the complete echocardiogram recording meeting the criteria set out in section 3 of the Medical Conditions List, including the echocardiogram report interpreting the echocardiogram, which forms the basis of the claim;
- (iv) A complete list of names, office addresses and telephone numbers of the physicians, medical consultants, experts or any other health care professionals who provided medical care, assessment, diagnosis and/or treatment to the Product Recipient dating from five (5) years prior to the Product Recipient's first ingestion of the Products, including treatment obtained during hospitalization;
- (v) An executed acknowledgment that, in the event that the claim is selected for audit, the Claimant will provide, within thirty (30) days of the request, an executed authorization, permitting the Settlement Administrator to obtain medical records relevant to the injury which forms the basis of the claim from the individuals listed in (iv) above. Failure to provide an executed authorization may result in the claim being rejected; and
- (vi) Where the Product Recipient's diagnosis of FDA Positive was made more than seven (7) years following first use of the Products, the Claimant shall be required to provide all medical records relevant to the injury which forms the basis of the claim.

4.6.4 To be eligible to receive a Matrix Benefit, subject to section 5 herein, such documentation shall consist of:

- (i) Clinical, medical and/or hospital records of any kind from all institutions, physicians, consultants, experts or other health care professionals who provided medical care, assessment, diagnosis and/or treatment to the Product Recipient, dating from at least five (5) years prior to the Product Recipient's first ingestion of the Products, including ECG and other cardiac testing, sleep studies,

laboratory and serological testing, radiological, ultrasound and other imaging study reports and films, Echocardiogram reports and tapes and/or disks;

- (ii) Medical records indicating a diagnosis of an FDA Positive or greater valvular heart disease condition or a diagnosis of Pulmonary Arterial Hypertension, as defined in the Medical Conditions List (Exhibit “E” to the Settlement Agreement”), made on a date no more than seven (7) years following the Product Recipient’s first ingestion of the Products, subject to the provisions of section 3 of the Medical Conditions List;
- (iii) A true and correct copy of the complete echocardiogram recording of any and all echocardiogram results, relating to the Product Recipient dating from five (5) years prior to the first ingestion of the Products;
- (iv) A declaration under penalty of perjury from the Treating Physician setting forth an opinion to a reasonable degree of medical certainty that:
 - (a) the Product Recipient has been diagnosed with the condition which qualifies the Claimant for a Matrix Benefit, pursuant to the provisions of the Medical Conditions List;
 - (b) in respect of a claim for a Matrix level VHD benefit, to the best of the Treating Physician’s knowledge, the Additional Medical Factors for Consideration for VHD set forth in section 6 of the Medical Conditions List either are or are not present and if present, there is still a possibility that the Product Recipient’s condition was caused by ingestion of the Products;
 - (c) in respect of a claim for a PPH benefit, to the best of the Treating Physician’s knowledge, the factors set forth in section 5.2.2 of the Medical Conditions List either are or are not present; and
 - (d) to the best of the Treating Physician’s knowledge, the specific condition, as defined in either section 4 or 5 of the Medical Conditions List, for which the Matrix Benefit is sought, was not present in the Product Recipient prior to his or her first use of the Product;

- (v) Where applicable, a declaration under penalty of perjury from a Certified Cardiologist, Certified Cardiac Surgeon, Certified Neurologist or Certified Neurosurgeon with regard to the functional outcome which the Product Recipient has had six (6) months after a stroke;

4.6.5 Costs incurred by a Claimant in obtaining and copying the records, reports and forms, (collectively “the Records”), that are required to be filed as part of the Claim Package shall be dealt with in the following manner:

- (a) The Claimant shall bear all such costs in relation to unsuccessful claims;

- (b) In respect of successful claims, the Claimant shall be entitled to claim for reimbursement for monies paid or payable to the doctors, hospitals or other similar custodians to obtain copies of the Records, where the monies paid or payable exceed \$500.00. The Claimant shall not receive any reimbursement if the amounts expended are less than \$500.00. If the amounts expended by the Claimant are greater than \$500.00 but less than \$2,500.00, the Claimant shall be entitled to receive reimbursement for all amounts expended in excess of \$500.00 upon approval of the claim and presentation of documentation evidencing the expenditures;

- (c) Where the expenditure required to obtain copies of the Records is \$2,500.00 or greater, the Claimant shall be entitled to reimbursement in accordance with (b) above with respect to the amounts less than \$2,500.00, and, in addition, for expenditures of \$2,500.00 or greater, if the Settlement Administrator determines that such excess expenditure was reasonably necessary in order for the Claimant to advance his or her claim;

- (d) Any reimbursements paid by the Settlement Administrator to Claimants pursuant to this provision shall be considered part of the costs of administration of the settlement and shall not be drawn from the Settlement Fund or Additional Settlement Funds.

5. BEST EFFORTS

5.1 In the event that any of the Product Recipient’s medical records, including the echocardiogram recording or report, is unavailable for reasons beyond the Claimant’s control and despite the Claimant’s best efforts to obtain the necessary records, such claims may nonetheless be considered for compensation where sufficient evidence is presented to allow adjudication of the claim. A Claimant shall not be precluded from obtaining benefits for failure to produce complete medical records so long as sufficient and

material medical evidence of the injury forming the basis of the claim (including an echocardiogram for VHD claims or catheterization report or echocardiogram for Primary Pulmonary Hypertension (“PPH”) claims) and sufficient evidence of compliance with the criteria set out in the Medical Conditions List is submitted and provided that the Claimant has submitted an Affidavit stating what steps he or she has taken to obtain the records in question, and the responses to those steps.

- 5.2 For any medical records which the Claimant is unable to obtain despite best efforts, the Claimant shall also include in the Claim Package a list of those records which the Claimant was unable to obtain despite best efforts, including records from treating physicians, medical consultants, specialists or other health care professionals who provided medical treatment, assessment or diagnosis to the Product Recipient dating from five (5) years prior to first use of the Products, along with an executed authorization permitting the Settlement Administrator to attempt to obtain any missing medical records. The costs of doing so shall be treated in the manner set out in section 4.6.5 above.
- 5.3 Where the Settlement Administrator has determined that this “best efforts” requirement has been satisfied by the Claimant, the Claim Package shall be submitted to a Claims Adjudicator in accordance with the procedures and timelines outlined herein and the claim shall be adjudicated by the Claims Adjudicator having regard to sections 5.1 and 5.2 herein.
- 5.4 Where the Settlement Administrator has determined that this “best efforts” requirement has not been satisfied, a Deficiency Letter shall be delivered to the Claimant within thirty (30) days of issuance of an Acknowledgment Letter. The Claimant shall have the opportunity to cure the deficiency in accordance with the procedures and timelines outlined herein at sections 4.1.3 and 4.6.2.
- 5.5 If the Settlement Administrator determines that the Claimant has not cured the deficiencies in accordance with the procedures and timelines set out herein, a Determination Letter shall be delivered to the Claimant within seven (7) days of receipt of the material submitted by the Claimant in an effort to cure the deficiencies, or the expiry of the period for submitting such material. The Claimant shall then have the right to Challenge that Determination, in accordance with the Challenge procedures outlined herein at section 10.

6. SETTLEMENT ADMINISTRATOR'S PROCESSING OF CLAIM PACKAGE

6.1 General Provisions

- 6.1.1 Upon receipt of a Claim Package (including Claim Packages for Progressed Claims and New Pathology Evidence Claims), the Settlement Administrator shall deliver a letter to the Claimant within seven (7) days, acknowledging receipt of the Claim Package (the "Acknowledgement Letter") and shall assign an individual claim number to the Claim Package and post the contents of the Claim Package on the Settlement Administrator's claims administration system. Read-only access via a secure website to the claims administration system shall be granted to all Parties hereto. The Parties shall also be entitled to obtain hard copies of the Claim Package, or any part thereof (including a copy of any Echocardiogram), upon request to the Settlement Administrator.
- 6.1.2 The Settlement Administrator shall, after delivering the Acknowledgment Letter, review the Claim Package to ensure that:
- (a) It includes a completed and signed Claim Form;
 - (b) It includes the necessary Product Identification Documentation;
 - (c) It includes a completed and signed Medical Diagnosis Form, including the Echocardiogram Report Form where applicable;
 - (d) It includes the requisite Supporting Medical Documentation;
 - (e) It indicates where in the Claim Package the initial diagnosis of FDA Positive and/or of a Matrix-level Condition can be located and, in the case of a Progressed Claim, where in the Claim Package the further diagnosis of a higher Matrix-level Condition is located;
 - (f) It is received by the Settlement Administrator within the Claim Period (subject to the Challenge process set out in sections 12.1.3 and 12.1.4 herein); and
 - (g) If the Claimant has previously submitted a Claim Package which has been rejected, the Claimant has provided an explanation of what additional material or information is included in the resubmitted Claim Package; and

- (h) If the Claim Package relates to either a Progressed Claim or a New Pathology Evidence Claim, the Claimant has included the appropriate supporting medical documentation required by section 8 below.

6.2 FDA Positive Benefit Claims

6.2.1 Within thirty (30) days of the issuance of the Acknowledgment Letter the Settlement Administrator shall:

- (a) Where the Claim Package is determined to be complete and the Settlement Administrator determines that the claim is eligible for an FDA Positive Benefit, the Settlement Administrator shall so advise the Claimant in a Determination Letter approving the claim; or
- (b) Where the Claim Package is determined to be complete, but the Settlement Administrator determines that the claim is not eligible for an FDA Positive Benefit, the Settlement Administrator shall so advise the Claimant in a Determination Letter rejecting the claim. Where a Claimant receives such a Determination Letter, the Challenge procedures set out in section 10 shall apply; or
- (c) Where the Claim Package is rejected as incomplete because it does not meet the criteria set out in section 6.1.2, the Settlement Administrator shall so advise the Claimant in a Deficiency Letter. Where a Claimant receives a Deficiency Letter, the remedial procedures set out in section 4.1.3 shall apply; or
- (d) Where a Claim Package is complete and the claim is to be selected for audit, the Settlement Administrator shall make such selection, shall so notify the Claimant and shall forward the Claim Package to a Claims Adjudicator; or
- (e) Where the Claim Package is complete and where the diagnosis of the Product Recipient's FDA Positive condition was made more than seven (7) years following the Product Recipient's first use of the Products, the Settlement Administrator shall forward the Claim Package to a Claims Adjudicator.; or
- (f) Where the Claim Package is rejected because it was submitted after the expiry of the Claim Period but within the Administration Period, the Settlement Administrator shall so advise the Claimant in a Determination Letter rejecting the claim. Where the Claimant receives such a Determination Letter, the challenge procedures set out in sections 10 and 12.1.3 shall apply.

6.2.2 Where the Claim Package is rejected as incomplete for a third and final time, the Settlement Administrator shall, within seven (7) days of such final rejection, so advise the Claimant in a Determination Letter rejecting the claim. Where a Claimant receives such a Determination Letter, the challenge procedures set out in section 10 shall apply. The Settlement Administrator's decision as to whether a Claim Package shall be finally rejected shall be made by the Settlement Administrator within the earlier of thirty (30) days after:

- (i) the Claimant has advised the Settlement Administrator that his or her submissions are complete; or
- (ii) the time has expired for the Claimant to make further submissions in response to a Deficiency Letter.

6.3 Matrix Benefit Claims

6.3.1 Within thirty (30) days of the issuance of the Acknowledgment Letter the Settlement Administrator shall determine whether the Claim Package meets the criteria set out above, and shall

- (a) Where the Claim Package is determined to be complete, forward the Claim Package to a Claims Adjudicator.
- (b) Where the Claim Package is rejected as incomplete because it does not meet the criteria set out in section 6.1.2, the Settlement Administrator shall so advise the Claimant in a Deficiency Letter. Where a Claimant receives a Deficiency Letter, the remedial procedures set out in section 4.1.3 shall apply.
- (c) Where the Claim Package is rejected because it was submitted after the expiry of the Claim Period but within the Administration Period, the Settlement Administrator shall so advise the Claimant in a Determination Letter rejecting the claim. Where the Claimant receives such a Determination Letter, the challenge procedures set out in sections 10 and 12.1.3 shall apply.

6.3.2 Where the Claim Package is rejected as incomplete for a third and final time, the Settlement Administrator shall, within seven (7) days of such final rejection, so advise the Claimant in a Determination Letter rejecting the claim. Where a Claimant receives such a Determination Letter, the challenge procedures set out in section 10 shall apply. The Settlement Administrator's decision as to whether a Claim Package shall be finally rejected shall be made by the Settlement Administrator within the earlier of thirty (30) days after:

- (i) the Claimant has advised the Settlement Administrator that his or her submissions are complete; or
- (ii) the time has expired for the Claimant to make further submissions in response to a Deficiency Letter.

6.4 Progressed Claims and New Pathology Evidence Claims

6.4.1 Within thirty (30) days of the issuance of the Acknowledgment Letter the Settlement Administrator shall determine whether the Claim Package meets the criteria set out above, and shall

- (a) Where the Claim Package is determined to be complete, forward the Claim Package to a Claims Adjudicator.
- (b) Where the Claim Package is rejected as incomplete because it does not meet the criteria set out in section 6.1.2, the Settlement Administrator shall so advise the Claimant in a Deficiency Letter. Where a Claimant receives a Deficiency Letter, the remedial procedures set out in section 4.1.3 shall apply.

6.4.2 Where the Claim Package is rejected as incomplete for a third and final time, the Settlement Administrator shall, within seven (7) days of such final rejection, so advise the Claimant in a Determination Letter rejecting the claim. Where a Claimant receives such a Determination Letter, the challenge procedures set out in section 10 shall apply. The Settlement Administrator's decision as to whether a Claim Package shall be finally rejected shall be made by the Settlement Administrator within the earlier of thirty (30) days after:

- (i) the Claimant has advised the Settlement Administrator that his or her submissions are complete; or
- (ii) the time has expired for the Claimant to make further submissions in response to a Deficiency Letter.

6.5 Matrix Level V(b) Claims

Where a claim for a Matrix-level VHD benefit has been approved at Level V of Exhibit "F", and the Claimant is seeking the supplementary benefits provided for at Level V(b) of Exhibit "F", the Settlement Administrator shall, within seven (7) days of receiving the approved claim from the Claims Adjudicator, forward the Claim Package, along with the Claims Adjudicator's written report to Justice Winkler for determination on the application for such supplementary benefits.

6.6 Supplementary Benefits for Approved PPH Claimants

- 6.6.1** Claimants who qualify for supplementary benefits for PPH pursuant to Exhibit “F” shall provide, on an annual basis, an affidavit in a form provided by the Settlement Administrator as evidence of entitlement to the supplementary benefit.
- 6.6.2** The Settlement Administrator shall send the form of the affidavit referred to in section 6.6.1 to all qualified Claimants pursuant to this provision at least 60 days prior to the date on which the Claimant becomes eligible for the supplementary benefit, and annually thereafter, as required.

7. CLAIMS ADJUDICATION GUIDELINES

7.1 General Provisions

- 7.1.1** Within ninety (90) days after receiving a Claim Package from the Settlement Administrator, the Claims Adjudicator shall review the Claim Package and submit his or her decision to the Settlement Administrator, along with a brief typewritten report reflecting his or her reasons therefore. If this deadline cannot be met, the Claims Adjudicator shall notify the Settlement Administrator, who shall seek directions from Justice Winkler with respect to an extension of this deadline on notice to all Parties.
- 7.1.2** The Settlement Administrator and Claims Adjudicators shall process all claims in a cost-effective and timely manner.

7.2 FDA Positive Benefit Claims

- 7.2.1** Subject to section 7.2.2 below, the Settlement Administrator shall determine if the Claimant has qualified for an FDA Positive Benefit except in respect of claims submitted where the diagnosis of the Product Recipient’s FDA Positive condition was made more than seven (7) years following the Product Recipient’s first use of the Products, in which case, the claim shall be submitted to a Claims Adjudicator for adjudication in accordance with the procedures set forth herein and the criteria set forth in section 3 of the Medical Conditions List, attached as Exhibit “E” to the Settlement Agreement.
- 7.2.2** The Settlement Administrator will randomly choose, on an on-going basis, up to 15% (fifteen per cent) of complete claims for FDA Positive Benefits, to be submitted to a Claims Adjudicator for an audit of the claim. The audit shall be completed as soon as reasonably practicable and, in any event, no later than three (3) months following the conclusion of the Claim Period.

Such audit shall include a review of the Claim Package. The Claims Adjudicator shall determine whether he or she disagrees with the assessment, severity or diagnosis of the FDA Positive condition made by the Treating Physician in the Medical Diagnosis Form. In making his or her determination, the Claims Adjudicator shall consider whether the Echocardiogram recording being relied upon to support the claim meets the criteria for Echocardiograms set out in the Medical Conditions List attached as Exhibit "E" to the Settlement Agreement.

- 7.2.3 The Claims Adjudicator will be entitled to compensation of a maximum of \$300.00 per hour, to a maximum per-claim amount of \$600.00 for the audit of claims for an FDA Positive Benefit, inclusive of taxes.

7.3 Matrix Benefit Claims

- 7.3.1 The Claims Adjudicator shall review the Claim Package and, subject to the provisions of sections 4.6.1, 4.6.2 and 4.6.4 herein, make his or her own determination of whether the Claimant has qualified for a Matrix Benefit and if so, at what Matrix Benefit the claim should be categorized. This determination shall include a review of the Supporting Medical Documentation to determine whether or not any of the Additional Medical Factors or exclusionary criteria for consideration for Matrix Level VHD claims are present, in accordance with section 6 of the Medical Conditions List.
- 7.3.2 In reviewing each claim, the Claims Adjudicator shall determine the Product Recipient's "Age at Diagnosis" for the purpose of determining the placement of a claim on the Matrix, where applicable. This determination shall be the age at which the Product Recipient is diagnosed as suffering from the level of disease severity for which a claim is being made. With respect to Progressed Claims as set out in section 8 below, the Age at Diagnosis shall be the age at which the level of disease severity for which the Progressed Claim is made was first diagnosed.
- 7.3.3 If the Claims Adjudicator agrees with the assessment, severity or diagnosis of the Matrix-level Condition made by the Treating Physician in the Medical Diagnosis Form, the Claims Adjudicator shall return the Claim Package to the Settlement Administrator with a brief typewritten report setting out the reasons for his or her decision and, where applicable, the Product Recipient's Age at Diagnosis.
- 7.3.4 If the Claims Adjudicator disagrees with the assessment, severity or diagnosis of the Matrix-level Condition made by the Treating Physician in the Medical Diagnosis Form or determines that the conclusions of the written report accompanying an Echocardiogram are not supported by the

recording, the Claims Adjudicator shall make his or her own determination with respect to the assessment, severity or diagnosis of the Matrix-level Condition and shall return the Claim Package to the Settlement Administrator with a brief typewritten report setting out the reasons for his or her decision including, where applicable, the Product Recipient's Age at Diagnosis.

- 7.3.5 The Claims Adjudicator must ensure, subject to the provisions of section 3 of the Medical Conditions List, that for all VHD Claimants, a diagnosis of at least FDA Positive (as defined in section 4.3.1 of the Medical Conditions List) was initially made within seven (7) years following the Product Recipient's first use of the Products, and that for PPH Claimants, a diagnosis of PAH (as defined in section 5.2.1 of the Medical Conditions List) was made within seven (7) years following the Product Recipient's first use of the Products.
- 7.3.6 Each Echocardiogram relied upon by a Claimant as the basis for a Matrix Claim for VHD must be reviewed by the Claims Adjudicator to determine the level of mitral and/or aortic valvular regurgitation, if any, as of the date of the Echocardiogram for the purpose of determining whether the Claimant qualifies for benefits under the Settlement Agreement.
- 7.3.7 The Claims Adjudicator shall ensure that the criteria for Echocardiograms set out in section 3 of the Medical Conditions List are met for any Echocardiogram recording which serves as the basis of the Claim.
- 7.3.8 The Claims Adjudicator will be entitled to compensation of a maximum of \$300.00 per hour, to a maximum per-claim amount of \$1,200.00, inclusive of taxes. In exceptional cases, where the volume of records provided requires further time for proper review, the Claims Adjudicator shall so advise the Settlement Administrator as soon as is reasonably practicable. The Settlement Administrator shall then determine whether further fees should be approved for payment. Notice of all requests for such further fees shall be provided by the Settlement Administrator to counsel for all Parties.

8. PROGRESSED AND NEW PATHOLOGY EVIDENCE CLAIMS

8.1 General Provisions

- 8.1.1 With respect to the adjudication of Progressed and New Pathology Evidence Claims, the Claims Adjudicator will be entitled to compensation of a maximum of \$300.00, inclusive of taxes, per Progressed or New Pathology Evidence Claim, except where the Progressed Claim relates to an initial claim for FDA Positive which has progressed to a Matrix Claim in

which case the Claims Adjudicator shall be entitled to a maximum per-claim amount of \$1,200.00, inclusive of taxes, for the review and adjudication of Progressed and New Pathology Evidence Claims. In exceptional cases, where the volume of records provided requires further time for proper review, the Claims Adjudicator shall so advise the Settlement Administrator as soon as is reasonably practicable. The Settlement Administrator shall then determine whether such further fees should be approved for payment. Notice of all requests for such further fees shall be provided by the Settlement Administrator to counsel for all Parties.

8.2 Progressed Claims (VHD)

- 8.2.1 Where a Product Recipient's level of disease severity progresses to a higher level of disease severity during the Administration Period and where the Claimant has qualified for an FDA Positive Benefit or Matrix Benefit during the Claim Period, a further claim may be advanced to recover additional benefits where the increased disease severity results in a Matrix-level Condition (in the case of an FDA Positive Claim) or a higher Matrix-level Condition (in the case of a Matrix-level Claim). Where the Claimant's initial claim was for an FDA Positive benefit, and if the Claimant has not already done so, the Claimant shall be required to submit all Supporting Medical Documentation required above for the processing of a Matrix Claim. Where the initial claim was for a Matrix Benefit, the Claimant shall be required to submit all medical records dating forward from those provided as part of the initial claim.
- 8.2.2 Where the Product Recipient is found to qualify for a higher level Matrix Benefit as a result of an increase in their disease severity level, the Claimant shall be entitled to the difference between the benefit amount previously awarded and the benefit amount which corresponds on the Matrix to the new disease severity level, subject to section 11 below with respect to the possible *pro rata* distribution of the Settlement Fund and/or Additional Settlement Funds.
- 8.2.3 In the event that a Progressed Claim is rejected by the Settlement Administrator or denied by the Claims Adjudicator, the Claimant shall have all the Challenge rights associated with a claim of first instance. The materials to be used on and the standard of review for such Challenges shall be the same as with a claim of first instance.

8.3 New Pathology Evidence Claims (VHD)

- 8.3.1 Notwithstanding any other provision contained herein, Claimants who have filed a claim within the Claim Period which was rejected shall be entitled to resubmit a Claim within the Administration Period, based on new evidence of valve pathology which was not available at the time of the initial claim and which satisfies the criteria set out in section 6.3 of the Medical Conditions List.
- 8.3.2 Where the claim qualifies for a Matrix Benefit, the Claimant shall be entitled to benefits in accordance with the applicable Matrix level for the condition of the Product Recipient, subject to section 11 below with respect to the possible *pro rata* distribution of the Settlement Fund and/or Additional Settlement Funds.
- 8.3.3 In the event that a New Pathology Evidence Claim is rejected by the Settlement Administrator or denied by the Claims Adjudicator, the Claimant shall have all the Challenge rights associated with an initial claim. The materials to be used on and the standard of review for such Challenges shall be the same as with an initial claim.

9. NOTIFICATION OF DISPOSITION OF CLAIM

- 9.1 Within seven (7) days of receiving the decision of the Claims Adjudicator, or within seven (7) days of making a determination with respect to an FDA Positive Claim, or within seven days of finally rejecting a claim, or within seven (7) days of receiving a Challenge Decision from Justice Winkler, the Settlement Administrator shall send via regular mail to the Claimant, Class Counsel and Counsel for the Defendants, a Determination Letter which shall include, where applicable, a copy of the typewritten report of the Claims Adjudicator, or the written reasons of Justice Winkler.
- 9.2 The Determination Letter shall include, where the claim has been approved, the benefit amount to which the Claimant is entitled, the categorization of the claim as being FDA Positive or Matrix level, and, where applicable, the placement of the claim on the Matrix or, where applicable, the basis for denial of the claim. Delivery of the Determination Letter, shall be effected by regular mail Any such delivery shall be deemed to have been received seven (7) days after the date of postmark.
- 9.3 If the Claimant rejects the decision of the Claims Adjudicator or the Settlement Administrator, he or she shall be entitled to deliver a Notice of Challenge as provided for in section 10 below, otherwise the Settlement

Administrator shall issue payment in accordance with the payment schedule set out herein.

10. CHALLENGE OF CLAIMS ADJUDICATOR'S OR SETTLEMENT ADMINISTRATOR'S DECISION

10.1 Referral to Justice Winkler

10.1.1 Following receipt of the Determination Letter, the Claimant shall have the right to deliver a Notice of Challenge in respect of the decision of the Claims Adjudicator or the Settlement Administrator. The Notice of Challenge must be delivered to the Settlement Administrator within forty-five (45) days of the receipt of the Determination Letter. Failure to deliver a Notice of Challenge to the Settlement Administrator within forty-five (45) days of receipt of the Determination Letter shall be deemed acceptance of the Determination Letter.

10.1.2 The Defendants shall not participate in the Challenge process unless directed to do so by Justice Winkler.

10.1.3 Upon receipt of a Notice of Challenge, the Settlement Administrator shall forward a copy to Defendants' Counsel and Class Counsel, and shall, within thirty (30) days, forward the Claim Package, Notice of Challenge and, if the Claimant so chooses and provides same to the Settlement Administrator, an Affidavit and/or the report of one Qualified Physician as set out in section 2.3.5 above, to Justice Winkler, for review.

10.1.4 Within sixty (60) days of receiving the Challenge materials from the Settlement Administrator, the Challenge Decision shall be submitted to the Settlement Administrator by Justice Winkler with written reasons. Within seven (7) days of receiving the Challenge Decision of Justice Winkler, the Settlement Administrator shall send to the Claimant, Class Counsel and Counsel for the Defendants, a Determination Letter which shall include a copy of Justice Winkler's written reasons.

10.2 Legal Costs of the Challenge Process

10.2.1 In the event of a successful Challenge, the fees and costs of a Claimant's legal counsel and of any experts or advisors retained to assist with the Challenge process shall be fixed by Justice Winkler and shall be paid from the Settlement Fund or the Additional Settlement Funds, where applicable.

10.2.2 In the event of an unsuccessful Challenge, the Claimant shall bear his or her own costs of legal counsel and of any experts or advisors retained to assist with the Challenge process.

10.2.3 If the Defendants are directed by Justice Winkler to participate in a Challenge, which Justice Winkler subsequently determines to be frivolous or vexatious, he shall have the discretion to award costs to be payable by the Claimant to the Defendants. In no event shall such costs be payable from the Settlement Fund or the Additional Settlement Funds.

10.3 Final Decision

10.3.1 The decision of Justice Winkler respecting any Challenge of the Claims Adjudicator's decision is final and binding and shall not be the subject of any further Challenge, appeal, or revision, except in the case of a clerical or obvious error which shall be subject to correction by Justice Winkler.

11. PAYMENT SCHEDULE FOR APPROVED CLAIMS

11.1 Payments for FDA Positive Claims

11.1.1 At the conclusion of the Claim Period, on notice to all Parties, the Settlement Administrator shall seek directions from Justice Winkler with respect to the distribution of funds from the FDA Positive Fund. The Settlement Administrator and Justice Winkler shall consider, among other things, the necessity for a "holdback" of a portion of the FDA Positive Fund pending the conclusion of the Administration Period in the event that there may be further FDA Positive Benefits payable as a result of Matrix Claims reclassified by Claims Adjudicators (or by Justice Winkler as a result of a Challenge) as FDA Positive Claims, or as a result of approved late claims.

11.2 Payment for Matrix Claims

11.2.1 The benefit levels provided in the Matrix represent the maximum benefits available and may be subject to *pro rata* reductions, in the event that the total value of claims submitted under this settlement exceeds the total value of the Settlement Fund and the Additional Settlement Funds.

11.2.2 Within thirty (30) days of receiving a Claimant's acceptance or deemed acceptance of the Determination Letter which approves the claim, the Settlement Administrator shall forward to the Claimant an advance payment of 20% of their approved Matrix Benefit.

11.2.3 Class Counsel may, no earlier than three months following the Approval Notice Date, move before Justice Winkler, on notice to all Parties, for directions with respect to whether and in what amounts additional advance payments may be made to Claimants whose claims have been approved for Matrix Benefits. In determining whether such additional advance payments may be made, Justice Winkler shall consider, among other things, the

potential for Progressed Claims, New Pathology Evidence Claims, the number and nature of claims submitted to that date, outstanding and potential Challenges and information with respect to known claims that have not yet been submitted to the Settlement Administrator.

- 11.2.4 Any advance payments shall be deducted from the total benefit found to be payable to a Claimant pursuant to the Settlement Agreement. In the event that the income accumulated in the Settlement Fund through investment pursuant to section 2.1.2 herein is not required to satisfy the payment of approved benefits, such unpaid accumulated income shall be distributed *pro rata* to Claimants with approved claims and to parties entitled to an interest in the Remainder of the Settlement Fund, if any. With respect to the portion of such investment income to be distributed to Claimants, each Claimant shall be entitled to receive a share based on a calculation which takes into account the total amount of his or her deferred benefit and the period of time for which his or her benefit was deferred. No Claimant shall be entitled to a share of the investment income in respect of any benefit paid within 120 days after the Claimant's acceptance or deemed acceptance of the Determination Letter which approved the claim. The Settlement Administrator shall distribute the investment income in accordance with this provision within sixty (60) days after the termination of the Administration Period or as directed by Justice Winkler
- 11.2.5 In the event that any advance payments are made pursuant to section 11.2.1 or ordered pursuant to section 11.2.2 above and such advance payments result in a lower payment to any Claimant than such Claimant would have otherwise been entitled to under this settlement, there shall be no recourse for any additional contribution, payment or benefit as against the Released Parties or their counsel.
- 11.2.6 Within thirty (30) days after the expiry of the Claim Period, Class Counsel shall move, on notice to all Parties, before Justice Winkler for directions relating to the payment of any remaining entitlements in respect of approved claims, based upon a consideration of, among other things, the potential for Progressed Claims, New Pathology Evidence Claims, the number and nature of claims submitted, including those not resolved to that date, outstanding and potential Challenges and information with respect to late claims, if any.

11.3 Payments for Derivative Claims

- 11.3.1 At the conclusion of the Claim Period, on notice to all Parties, the Settlement Administrator shall seek directions from Justice Winkler with respect to the distribution of funds to Eligible Derivative Claimants from the Derivative Claims Fund. The Settlement Administrator and Justice

Winkler shall consider, among other things, the necessity for a “holdback” of a portion of the Derivative Claims Fund, pending the conclusion of the Administration Period.

11.4 Final Settlement Fund Payments to Claimants

11.4.1 As soon as reasonably practicable after the expiration of the Administration Period, the processing of all Claim Packages and the deadline for Challenge of all claims, the balance of the Settlement Fund and, if applicable pursuant to the Settlement Agreement, any necessary portion of the Additional Settlement Funds, shall be distributed to all qualified Claimants, up to the maximum entitlement amount pursuant to the Matrix.

11.4.2 If the Settlement Fund and the Additional Settlement Funds are sufficient to pay out to each qualified Claimant the maximum payment pursuant to the Matrices, each qualified Claimant shall receive the remaining entitlement in respect of approved claims. If the Settlement Fund and the Additional Settlement Funds are together insufficient to provide the maximum payment to each qualified Claimant provided by the Matrix, the Settlement Fund and the Additional Settlement Funds shall be distributed *pro rata* among all qualified Claimants.

11.5 Additional Claim Guidelines

11.5.1 If a Claimant qualifies for FDA Positive Benefits or Matrix Benefits due to more than one condition of the Product Recipient, the Claimant shall be entitled to receive only the higher of such payments, but not both such payments (except with respect to Progressed Claims as described herein).

12. MISCELLANEOUS

12.1 Timeliness of Submissions

12.1.1 All Claim Packages shall be submitted to the Settlement Administrator via regular mail or courier, or by any other means agreed to by the Parties and the Settlement Administrator. All submissions by mail shall be conclusively deemed to have been submitted to the Settlement Administrator on the postmark date of such mail. All Claim Packages delivered to the Settlement Administrator by courier shall be conclusively deemed to have been submitted to the Settlement Administrator on the date of the receipt by the Settlement Administrator of such submissions. Where the Settlement Administrator and the Parties agree to an alternative means of submission, the date of receipt by the Settlement Administrator shall be conclusively deemed to be the date of submission.

- 12.1.2 In order to qualify for compensation, Claimants must submit their Claim Packages in accordance with this section prior to the expiration of the Claim Period.
- 12.1.3 In the event that the Settlement Administrator receives a Claim Package after the expiration of the Claim Period but during the Administration period, such Claim Package shall be rejected by the Settlement Administrator. The Claimant shall be entitled to Challenge the rejection in accordance with the procedures set out herein. The Settlement Administrator shall submit all such Challenges to Justice Winkler, who shall determine whether the claim is eligible for consideration under the Settlement Agreement.
- 12.1.4 Where a late claim is deemed eligible for consideration under the Settlement Agreement by Justice Winkler, the Claim Package will be forwarded to the Settlement Administrator, who shall thereafter process the Claim Package in accordance with the procedures and timelines outlined herein.
- 12.1.5 Any Claim Package submitted after the expiration of the Administration Period shall be rejected by the Settlement Administrator, with no opportunity to Challenge such rejection. In no event shall such a Claim Package be submitted for Adjudication.

12.2 Extension of Deadlines

- 12.2.1 In the event that any of the deadlines prescribed herein relating to the administration and processing of claims cannot be met, a motion may be made to Justice Winkler for directions which may allow for the extension of such deadlines in circumstances where such extensions are demonstrably justifiable. Any such motion must be made on notice to all Parties.
- 12.2.2 In the event that any deadline for the administration or adjudication of claims is not met by either the Settlement Administrator, the Claims Adjudicators or Justice Winkler, such an event shall not give rise to a right of Challenge by a Claimant and shall not affect any Claimant's entitlement to benefits pursuant to the Settlement Agreement.

12.3 Call Centre

- 12.3.1 The Settlement Administrator shall establish a bilingual toll-free call centre for the assistance of Class Members and to provide Claimants with information on the status of their claims.

12.4 Website

12.4.1 The Settlement Administrator shall establish a bilingual website for the assistance of Class Members.

12.5 Correspondence with Class Members

12.5.1 Save and except for Deficiency and Determination Letters, which shall be sent by regular mail, all written communications from the Settlement Administrator to a Class Member shall be delivered by such means as the Settlement Administrator deems to be most appropriate. The Settlement Administrator shall direct such written communications to the Class Member's legal counsel if the Class Member is represented by counsel. Otherwise such written communications shall be directed to the last known address provided by the Class Member to the Settlement Administrator. The Class Member (or legal counsel to a represented Class Member) shall be responsible for apprising the Settlement Administrator of the Claimant's and counsel's correct and current mailing address.

12.6 Legal Counsel to Claimants

12.6.1 A Claimant shall be considered to be represented by legal counsel in connection with a claim or a Challenge only if the Settlement Administrator has received written notice signed by the Claimant of the identity of the Claimant's counsel. If a Claimant discontinues such representation at any time the Claimant shall provide written notice of same to the Settlement Administrator and their former counsel. No liens or claims for counsel fees or costs may be asserted against the Settlement Administrator or the funds held by the Settlement Administrator at any time, however where the Settlement Administrator is given notice of a dispute over a claim for counsel fees or costs, the disputed amount shall be paid by the Settlement Administrator into Court. Notice in respect of such a dispute shall only be effective when it is received by the Settlement Administrator. Any such notice shall be sent by courier or registered mail.

12.7 Preservation and Disposition of Claim Packages

12.7.1 The Settlement Administrator shall preserve, in hard copy or electronic form, as the Settlement Administrator deems appropriate, the Claim Packages, until a date one (1) year following the completion of all payments out of the Settlement Fund or, where appropriate, the Additional Settlement Funds, and at such time shall dispose of the Claim Packages by shredding or such other means as will render the materials permanently illegible.

12.8 Privacy of Communications

12.8.1 Any information provided by or regarding any Class Member or Claimant, or such information otherwise obtained pursuant to this settlement shall be kept confidential and shall not be disclosed except to appropriate persons to the extent necessary to process claims or provide benefits pursuant to this settlement or as otherwise expressly provided in the Settlement Agreement and the Exhibits thereto. All Class Members shall be deemed to have consented to the disclosure of this information for these purposes.