

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

ARTHUR RAY BOWLING, et al. : CASE NO. C-1-91-256  
Plaintiffs, :  
v. :  
PFIZER INC, et al. : Judge S. Arthur Spiegel  
Defendants. :

**SUPPLEMENTED AGREEMENT  
OF COMPROMISE AND SETTLEMENT**

The Plaintiffs (as hereinafter defined), by and through their counsel, and the Defendants (as hereinafter defined), hereby enter into this Supplemental Agreement of Compromise and Settlement dated as of January 23, 1992 (the "Agreement" or "Settlement Agreement"), providing for settlement of the claims herein described against the Defendants pursuant to the terms and conditions set forth below, and subject to the approval of the Court. This Agreement incorporates and supersedes the original "Agreement of Compromise and Settlement" executed by the parties on January 23, 1992; the "Supplement to Agreement of Compromise and Settlement" dated May 29, 1992, supplemented June 1, 1992; the "Amended Supplement to Agreement of Compromise and Settlement" dated as of June 9, 1992; and the "Second Supplement

to Agreement of Compromise and Settlement" dated as of July , 1992.

**1 Background**

1.1 On April 19, 1991, Plaintiffs commenced the proposed class action in the United States District Court for the Southern District of Ohio, Western Division (the "Court"), styled as Arthur Ray Bowling, et al. v. Pfizer Inc, et al., C-1-91-256.

1.2 Defendant Pfizer Inc ("Pfizer") is a corporation organized under the laws of the State of Delaware, and Defendant Shiley Incorporated ("Shiley"), a corporation organized under the laws of the state of California, has been a wholly owned subsidiary of Pfizer Inc since March of 1979.

1.3 From 1978-79 to 1985-86, Shiley manufactured and marketed the Bjork-Shiley convexo-concave prosthetic heart valves ("C/C heart valve"). Plaintiffs' claims regarding the C/C heart valve are as stated in their Amended Complaint. In 1985 and 1986, Shiley voluntarily removed the C/C heart valve from the market.

1.4 Defendants have denied and continue to deny that Plaintiffs have any justiciable claim for relief and that Defendants have any liability to Plaintiffs, and have raised numerous affirmative defenses. No plaintiff alleging claims similar to those raised by Plaintiffs in their Amended Complaint has won a judgment, and no such action has reached trial to date. Defendants support the propriety of class certification in this matter solely for purposes of settlement.

1.5 Based upon extensive analysis of the facts involving the C/C heart valve and the law applicable to Plaintiff's claims, as well as the history of previous C/C heart valve litigations, counsel for the Settlement Class (as hereinafter defined) has concluded that the Settlement provided for by this Agreement (the "Settlement"), in view of the substantial benefits that the Settlement provides, is fair, reasonable and adequate and is in the best interests of the Settlement Class Members (as hereinafter defined).

1.6 The Defendants have concluded that the Settlement is desirable in order to avoid the time and expense of defending protracted litigation; to put the claims finally to rest; and also to serve as an appropriate vehicle for the Defendants to provide C/C heart valve implantees with the benefits provided for herein.

## 2 Agreement

NOW, THEREFORE, the undersigned parties agree as follows, and Plaintiffs' Class Counsel recommends, subject to the approval of the Court:

2.1 The Settlement Class and the Defendants now desire to settle the disputes existing between them, subject to the terms set forth below which are the result of arms-length negotiations of the parties.

2.2 The parties stipulate, for settlement purposes only, that a worldwide class be certified pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure, which will

consist of all living persons currently implanted with C/C heart valves, and their current spouses.

2.3 Waite, Schneider, Bayless & Chesley Co., L.P.A. represents and warrants that it has the authority to enter into this Agreement on behalf of each of the Plaintiffs.

2.4 Each Defendant has all requisite corporate power and authority to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby. The execution, delivery and performance by each Defendant of this Agreement and the consummation by it of the actions contemplated hereby have been duly authorized by all necessary corporate action on the part of such Defendant. This Agreement has been duly and validly executed and delivered by each Defendant and constitutes its legal, valid and binding obligation.

2.5 Neither this Settlement Agreement, approved or not approved, nor any exhibit, document or instrument delivered hereunder, nor any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Settlement Agreement is intended to be or shall be construed as or deemed to be evidence of an admission or concession by the Defendants of any liability or wrongdoing or of the truth of any allegations in the Amended Complaint, and none of them shall be admissible in evidence for any such purpose in this or any other proceeding.

2.6 The headings of the Sections and paragraphs of this Agreement are included for convenience only and shall not be

deemed to constitute part of this Agreement or to affect its construction.

### 3 Definitions

For the purposes of this Agreement:

3.1 "Plaintiffs" means the individuals named as plaintiffs in the Amended Complaint in this action.

3.2 "Defendants" means Pfizer Inc and Shiley Incorporated.

3.3 "Amended Complaint" means the Amended Complaint to be filed pursuant to paragraph 4.1 of this Agreement.

3.4 "Settlement Class" means the class consisting of all living persons currently implanted with C/C heart valves, and their current spouses.

3.5 "Settlement Class Members" means all persons included in the Settlement Class, except those persons who file valid and timely requests for exclusion pursuant to the notice of class action and settlement to be directed by the Court.

3.6 "Claimants" means all Settlement Class Members who timely participate in the Medical and Psychological Consultation Fund claims process. For purposes of this Agreement, a Settlement Class Member with a C/C heart valve and his or her spouse shall be treated as one Claimant.

3.7 "Fracture Claimant" means any Settlement Class Member whose C/C heart valve incurs a strut fracture after the date of this Agreement, and his or her estate, heirs, successors, legatees, and devisees.

3.8 "Outside Benefit" means health care services provided or expenses for health care services reimbursed by a Settlement Class Member's private health insurance carrier or health maintenance organization, governmental benefit or other third party payor.

3.9 "Initial Approval" means the Court's conditional certification of the Settlement Class pursuant to Fed. R. Civ. P., Rule 23(c)(1) and Rule 23(e), and entry of the Orders provided for in paragraph 4.1(b) of this Agreement.

3.10 "Final Approval" of the Settlement means when the Order and Final Judgment approving this Agreement and Settlement has been entered, all appeals have been exhausted, and no further appeal may be taken.

3.11 "Supervisory Panel" means the Panel to be selected pursuant to subsection 5.4 hereof.

#### 4 Required events; Cooperation

4.1 Promptly after execution of this Settlement Agreement,

(a) Plaintiffs shall file an Amended Complaint on consent pursuant to Fed. R. Civ. P. 15(a), in the form of Appendix A hereto, adding spouses of C/C heart valve implantees as class representatives; and

(b) the parties shall jointly move the Court for an order, in the same form as Appendix B, ordering class notice to be directed to all Settlement Class Members.

4.2 Plaintiffs, with the cooperation of the Defendants, will move to dismiss with prejudice this action and other pending actions as provided in paragraph 10.

4.3 The parties will cooperate and undertake all reasonable actions in order to accomplish the above.

#### 5 The Patient Benefit Fund

Shiley will fund and undertake activities for the benefit of C/C heart valve patients as set forth below.

5.1 Within 30 days after Final Approval of the Settlement, Shiley will establish the Patient Benefit Fund by depositing \$12.5 million with the Court. Beginning on the second anniversary of Final Approval of the Settlement, Shiley will make annual deposits into the Fund of not less than \$6.25 million. Shiley may also deposit additional amounts into the Fund at any time, and shall receive credit for such additional deposits by a reduction in the amount of any subsequent required annual deposit(s). Except for Shiley's obligation to continue reimbursement of certain expenses for valve replacement, as provided below, Shiley's obligation to contribute to the Patient Benefit Fund shall cease when a total of \$75 million has been deposited. The Patient Benefit Fund will be invested in the same manner as provided for the Consultation Fund (as defined below), and any interest earned on portions of the Fund prior to disbursement will become part of the Fund.

5.2 The Patient Benefit Fund will be used for the following activities:

5.2.1 (a) Research and development of diagnostic techniques to identify implantees who may have a significant risk of strut fracture; and

(b) Research concerning the characterization and/or reduction of the risks of valve replacement surgery, including improvement of the techniques for such surgery, as provided in paragraph 5.3.1.

5.2.2 If one or more diagnostic techniques referred to Paragraph 5.2.1 (a) is developed and is approved or accepted by the U.S. Food & Drug Administration ("FDA") as safe and effective (in terms of sensitivity, specificity and reproducibility of the diagnostic technique) for the intended use with respect to persons currently implanted with C/C heart valves, then payment of the usual and customary costs of performing these diagnostic services on Settlement Class Members with C/C heart valves, for whom the diagnostic service is medically necessary and reasonable in accordance with diagnostic guidelines adopted by the Supervisory Panel pursuant to paragraph 5.4.4.2 hereof, to the extent that such services are not covered by an Outside Benefit.

5.2.3 Payment of expenses for surgery to explant, due to the risk of strut fracture, a Settlement Class Member's C/C heart valve and replace it with another prosthetic valve, under the following conditions and limitations:

5.2.3.1 The surgery must be in compliance with guidelines for C/C heart valve replacement as adopted from time to time by the Supervisory Panel, with the approval of the Court, pursuant



to paragraph 5.4.4.2 hereof. For purposes of determining whether a valve replacement surgery complies with the guidelines and qualifies for valve replacement surgery benefits under this section 5, the surgery must comply only with any objective aspects of the guidelines such as those that may relate to the characteristics of the valve. Any subjective aspects of the guidelines, such as those that may relate to patient health status, are matters for consideration between the Class Member and his or her physician and will not be considered for purposes of determining qualification for valve replacement surgery benefits.

(a) The Supervisory Panel shall appoint a designee as its liaison with Settlement Class Members. The designee shall be knowledgeable concerning the Panel guidelines for valve replacement and in the risks of the valve and of valve replacement. Any class member who contemplates a valve replacement that is not a qualifying valve replacement (as defined in subsection 5.6) may communicate with the designee who shall explain the reasons behind the guidelines and why the contemplated valve replacement surgery does not qualify for benefits under this Agreement. If a Settlement Class Member contends that the contemplated surgery is within the Panel guidelines and therefore is a qualifying valve replacement, he or she may petition the Court for such determination. The designee will report annually to the Panel concerning the quantity and nature of all such communications.

(b) A Settlement Class Member whose valve replacement surgery would be within the Panel guidelines for valve replacement surgery and therefore would qualify for valve replacement surgery benefits under this Section 5 if he or she underwent such surgery, but who has not undergone the surgery and has not received any benefits in respect of a valve fracture under Section 7 of this Agreement, may elect to bring an action pursuant to paragraph 8.4 for damages for emotional distress from fear of fracture of his or her working valve. The bringing of such an action irrevocably waives the Settlement Class Member's rights to any further benefits under this Agreement, including the right to benefits for qualifying valve replacement surgery under this Section 5 and to fracture compensation under Section 7.

(c) If the Panel at any time modifies its guidelines for valve replacement surgery, then a Settlement Class Member may request that his or her previously non-qualifying valve replacement be re-evaluated under the modified guidelines. If the surgery would have been qualifying under the modified guidelines then the Settlement Class Member shall be entitled to the applicable benefits for qualifying valve replacement under subsection 5.2.3 and under subsection 5.6, if not previously waived by bringing an action for damages from the valve replacement.

(d) If following a non-qualifying valve replacement without symptoms that have been associated with a fracture it is

determined that one leg of the strut of the Settlement Class Member's valve has separated from the flange prior to the surgery, then the valve replacement shall be treated as qualifying under the Panel guidelines including for purposes of electing valve replacement surgery benefits under this agreement.

5.2.3.2 Payment will be provided only for the usual and customary costs actually incurred by the Settlement Class Members for hospital care from admission for the valve replacement surgery through discharge, medical supplies during that period, and usual and customary fees of physicians and allied health professionals during that period and for a reasonable period thereafter following discharge, for any complications directly resulting therefrom, to the extent that the costs and fees for these services are not covered by an Outside Benefit.

#### 5.2.4 Claims for payment

5.2.4.1 The Court shall appoint a designee, a major aspect of whose experience includes medical or health claims administration, as a Master to administer claims under subsections 5.2.2 and 5.2.3.

5.2.4.2 The Settlement Class Member must make all reasonable efforts to utilize or claim every applicable Outside Benefit. Upon a finding by the designee (which shall not be unreasonably withheld) that the Settlement Class Member has made reasonable efforts to secure Outside Benefits, the designee shall advise such hospital, surgeon or other health care provider as the Settlement Class Member may designate that the expenses for

valve replacement surgery covered by this Agreement will be paid on the Settlement Class Member's behalf from the Patient Benefit Fund. If in a particular case covered expenses must be advanced to health care provider in order to permit the surgery to go forward in a timely manner, the designee shall do so.

5.3 The Patient Benefit Fund will be allocated among the activities described in paragraph 5.2 as follows:

5.3.1 The Supervisory Panel may initially devote up to \$37.5 million from the Patient Benefit Fund to activities described in paragraphs 5.2.1 (a) and (b) and 5.2.2, including any related expenses of the Supervisory Panel or consultants thereto and the Master appointed pursuant to paragraph 5.2.4.1. If the entire \$37.5 million has been expended and no diagnostic technique has been developed or none has been implemented, then the Supervisory Panel, subject to the approval of the Court, may allocate additional incremental amounts to research and development described in paragraph 5.2.1 (a) and (b) until such time as a diagnostic technique is developed and is approved or accepted as provided in this Agreement.

5.3.2 The remainder of the Fund not expended pursuant to subsection 5.3.1 above will be devoted to payment of expenses for valve replacement surgery as described in subsection 5.2.3.

5.3.3 If the Patient Benefit Fund has been fully expended and one or more Settlement Class Members who qualify for payment of expenses for replacement surgery under paragraph 5.2.3 have not received such reimbursement, Shiley will provide such

reimbursement under this Agreement for as long as there are qualifying Settlement Class Members. Pfizer represents that it has and shall continue to have adequate funds to perform, if necessary, under Section 11 hereof with respect to Shiley's obligation under this paragraph 5.3.3.

5.4 The programs required to implement the purposes of the Patient Benefit Fund shall be determined, subject to the terms of this Agreement and to the overall supervision of the Court, by a Supervisory Panel as provided below. The Supervisory Panel shall approve programs and protocols, and shall designate one or more entities to manage and administer the programs and disburse money from the Fund to persons engaged to perform various activities, according to the approved protocols. Such entities shall not have a past or present affiliation with Pfizer or Shiley; provided, that this restriction shall not apply to the extent that the programs being managed or administered are pursuant to a proposal by HVRC approved under Paragraph 5.4.3.1. The Supervisory Panel shall also periodically report to the Court, as the Court shall direct, concerning expenditures from the Fund and the progress of the activities financed from the Fund. If the Panel selects the HVRC (as defined in paragraph 5.4.3.1) or other Pfizer entity for any role in management, performance of research and development, or diagnostic testing activities paid from the Fund, the Pfizer entity shall perform such role at cost, such cost to be determined by Pfizer's regular accounting practices.

5.4.1 The Supervisory Panel shall consist of 7 members, 6 of whom (including any replacement of any of these 6 members) shall be recognized scientific or medical experts (tenured professor, Board Certified or equivalent) in fields relevant to the purposes of the Patient Benefit Fund. The seventh member (including any replacement of this member) shall not be a scientist or physician. No member of the panel shall be a past or present officer or employee of defendants, or have or have had meaningful economic or professional ties to defendants, or has been a party, expert or otherwise participated in any way in any heart valve litigation (including this action).

Counsel for defendants shall agree with lead counsel for the class on the initial members; prior to such agreement lead counsel shall first consult and receive input from special counsel for implementation of the Settlement. Other counsel for class members may also provide input. If counsel for defendant and lead counsel for the class cannot agree on all members, then those on whom they have agreed shall select the remaining member(s). If at any time it is necessary to designate a replacement member of the Supervisory Panel, the parties shall agree upon the replacement. If the parties cannot agree, then such replacement will be selected by the remaining members of the Supervisory Panel. The membership of the Supervisory Panel shall be subject to the approval of the Court.

5.4.2 All fees and expenses of the Supervisory Panel shall be paid from the Patient Benefit Fund. The Supervisory

Panel may also retain any medical or scientific expert as a consultant, and may retain an auditor to monitor expenditures from the Fund, and their fees and expenses shall be paid out of the Fund.

5.4.3 Supervision of research and development

5.4.3.1 Pfizer, through a Heart Valve Research Center ("HVRC") established for this purpose, may submit a proposed program (including protocols) for, and comments and recommendations concerning, research and development contemplated by paragraph 5.2.1 hereof. HVRC shall submit its proposed program (including protocols) as promptly as practicable after Final Approval, but not later than 30 days after establishment of the Supervisory Panel. If HVRC does not, then the Panel may solicit proposals from third parties. If HVRC timely submits its proposal, the Supervisory Panel shall indicate its approval of HVRC's proposed program, or suggest modifications, and HVRC shall have a reasonable time thereafter to submit a revised proposal. The Supervisory Panel may then adopt HVRC's program, or do whatever else it deems scientifically and medically appropriate to adopt a program and protocols, including entertain submissions of other qualified persons or entities. The Panel shall then submit its adopted program as its recommendation to the Court. Depending on the Court's response, the Panel may implement its recommended program, modify that program, or do whatever else it deems scientifically and medically appropriate to prepare a further recommendation. All entities selected to do research

paid from the Patient Benefit Program shall submit progress and final reports to the Supervisory Panel.

5.4.3.2 In the event that the FDA approves or accepts one or more diagnostic techniques as referred to in Paragraph 5.2.2 hereof, then the Supervisory Panel may cease further expenditures from the Fund for research and development under paragraph 5.2.1 (a) and/or (b) so that the remainder of the Fund can be devoted to the purposes specified in paragraphs 5.2.2 and 5.2.3.

5.4.3.3 Any protocol approved by the Panel shall require that any patent or technology rights accruing as a result of research and development funded under this Agreement be dedicated to the Settlement Class; provided, that if in the Panel's judgment the best interests of the Settlement Class are served by permitting contracting entities other than Shiley or Pfizer to retain said patent or technology rights, the Panel may do so. Any protocol approved by the Panel shall also entitle the Panel to obtain any technical information concerning the progress and results of research and development funded under this agreement and to make such information available to the FDA and to any other agency or body as the Panel deems appropriate. The Panel may also in its discretion place any such information in the public repository provided under paragraph 5.4.4.3.

5.4.4 Supervision of diagnostic testing and valve replacement

5.4.4.1 If the FDA approves or accepts one or more diagnostic techniques as referred to in paragraph 5.2.2 hereof,



then the panel may direct expenditures from the Fund pursuant to paragraph 5.2.2 to provide diagnostic services to Settlement Class Members using those techniques. No such diagnostic services shall be provided to Settlement Class Members, including in clinical testing, except after approval or acceptance by the FDA.

5.4.4.2 The Supervisory Panel, subject to Court approval, shall adopt guidelines for use of diagnostic testing techniques (as referred to in paragraph 5.2.2) and for valve replacement surgery (as referred to in subsection 5.2.3). In adopting such guidelines the Supervisory Panel shall consult with the International Society of Cardiovascular Surgeons, the American College of Cardiology, and the Bjork-Shiley 60° and 70° C/C Heart Valve medical advisory panels. The Panel or the parties shall invite the U.S. Food & Drug Administration and any appropriate institute of the National Institutes of Health to consult with the Panel in a manner agreeable to the agency or institute and to the Panel, and the Panel shall consider the findings of foreign agencies with similar responsibilities. Until the Panel has issued its guidelines, availability of benefits for valve replacement surgery shall be determined by the current guidelines of the Bjork-Shiley 60° and 70° C/C Heart Valve medical advisory panels.

5.4.4.3 The Supervisory Panel will create a publicly accessible repository of information concerning the status of the research and the risks of valve fracture and of valve

replacement. The Panel shall place in such repository such data, scientific and statistical information as it deems useful to the medical community regarding heart valves, including but not limited to information useful in assessing the risk of valve fracture; the development, availability use and evaluation of diagnostic testing; and the propriety of valve replacement surgery.

5.5 ~~§~~ the Supervisory Panel at any time determines that any money remaining in the Patient Benefit Fund cannot productively be spent for the specific purposes set forth herein, including payment of benefits for valve replacement surgery, it may recommend to the Court that such remainder should therefore be devoted to some other purpose for the benefit of the Settlement Class (other than direct distribution to class members). Subject to the approval of the Court, the Panel shall then direct the disposition of the remainder of the Fund. At such time, all of Shiley's and Pfizer's obligations under this section 5 shall cease, except to make any remaining unpaid required installments (up to a maximum of \$75 million) into the Patient Benefit Fund.

5.6 Any Settlement Class Member who undergoes valve replacement surgery that qualifies for payment of certain incurred costs under subsection 5.2.3 hereof ("qualifying valve replacement") may elect to receive additional or alternative benefits as provided below.

5.6.1 A Settlement Class Member whose qualifying valve replacement does not result in death or permanent total disability may elect the benefits provided in this subsection 5.6.1 under the conditions and limitations specified. Benefits paid under this subsection 5.6.1 are not subject to subrogation.

5.6.1.1 Allowance for all miscellaneous costs and expenses relating to and following hospitalization (including travel and lodging expenses; care of family during hospitalization and recuperation; post-operative home care; miscellaneous other economic loss; etc.) in the amount of \$38,000. No category of expense covered by this paragraph 5.6.1.1 shall be a covered expense under paragraph 5.2.3.2 relating to medical expenses for valve replacement surgery.

5.6.1.2 The Settlement Class member's actual lost income due to time lost from work during hospitalization and recuperation from the qualifying valve replacement, to the extent not covered by workman's compensation, sick pay, disability insurance or Outside Benefit; up to a maximum of \$1500 per week.

(a) The Settlement Class Member shall be entitled to such lost income for up to 16 weeks following the qualifying valve replacement upon submission of evidence of such lost income satisfactory to the Court designee (appointed pursuant to paragraph 5.2.4.1). The designee shall determine the amount due.

(b) The settlement Class Member shall be entitled to such lost income for the period from 16 through a maximum of 52 weeks following the qualifying valve replacement upon submission of the

evidence contemplated by subparagraph (a) above and medical evidence satisfactory to the designee establishing disability directly resulting from the qualifying valve replacement. The Settlement Class Member may apply 8 months after the surgery for income lost since the expiration of the benefits provided under subparagraph (a), and again 12 months after the surgery for income lost during the prior 4 months.

5.6.1.3 If, one year after the valve replacement surgery, the Settlement Class Member is partially disabled as a direct result of complications of the surgery, and as a direct result of such partial disability continues to suffer economic loss in the form of diminished earning capacity and/or extraordinary medical expenses (other than those normally associated with use of a prosthetic heart valve), then he or she shall receive compensation for the future amount of such loss, to the extent that it is not covered by workmen's compensation, sick pay, disability insurance or Outside Benefit, as follows:

The Settlement Class Member shall submit to the Court designee (1) his or her income tax returns for the three years prior to the surgery, (2) evidence of his or her current earnings, (3) evidence of any replacement income from workmen's compensation, sick pay, disability insurance or Outside Benefit, and (4) a written statement by one or more treating physicians concerning his or her current and anticipated future medical condition and current and anticipated need for medical care directly resulting from the qualifying valve replacement. The

designee shall provide such information to Shiley, and shall consider any responsive information that Shiley may provide. The designee may request any additional information from the Settlement Class Member or from Shiley, and shall then determine the amount due, which shall not in any event exceed 75 % of the amount that would be payable under subsection 5.6.2 below if the qualifying valve replacement had resulted in death or permanent total disability.

5.6.2 Alternative payment for death or permanent total disability.

5.6.2.1 In the event that a Settlement Class Member suffers death or permanent total disability directly resulting from a qualifying valve replacement, then the Settlement Class Member or his or her estate may elect to receive an amount determined by (1) the formula payment that would be available under subsection 7.2 or 7.3 hereof if the death or permanent total disability had resulted from a valve fracture, or (2) an arbitration of compensatory damages under the procedure set forth in subsection 7.4.

5.6.2.2 A benefit elected under paragraph 5.6.2.1 is exclusive and is in lieu of all other benefits otherwise available under this subsection 5.6. Any amount received by the Settlement Class Member or his heirs or assigns under subsection 5.2.3 shall be deducted from any award under this subsection 5.6.2.

5.6.3 Election of a benefit under subsection 5.6.1 or 5.6.2 is irrevocable when made and constitutes a waiver of and a covenant not to sue defendants concerning any and all claims relating to the qualifying valve replacement that the Settlement Class Member might otherwise have. As a condition of receiving payment of a benefit under subsection 5.6.1 or 5.6.2, the Settlement Class Member and all other persons who may make a claim relating to the qualifying valve replacement under applicable law shall each execute and deliver to Defendants a full Release of all Claims in a form to be provided by Defendants subject to Court approval. The persons required to execute the Release shall be reasonably determined by the Defendants based upon a review of those persons, if any, who are financially dependent upon the Settlement Class Member who underwent the qualifying valve replacement and any other criteria reasonably determined by defendants to be relevant.

5.6.4 If a Settlement Class Member institutes a legal action against Defendants alleging any injury or damage with respect to a qualifying valve replacement, the Settlement Class Member shall irrevocably waive any and all right to any benefit under this subsection 5.6. Any payment received by the Settlement Class Member or his heirs or assigns pursuant to subsection 5.2.3 shall be deducted from any award resulting from such legal action.

5.6.5 This subsection 5.6 does not apply to any replacement or attempted replacement of a fractured valve; i.e.,

medical emergency surgery where the valve ceased functioning prior to surgery. Such circumstances are governed by section 7 hereof.

5.6.6 No payment to a Settlement Class Member under this subsection 5.6 shall reduce the amount available under paragraph 5.3.1 for research activities described in paragraphs 5.2.1 (a) and (b). If required benefits under section 5 exceed at any time the amount available in the Patient Benefit Fund under the payment schedule provided in paragraph 5.1, then Pfizer will accelerate its payments into the fund (as permitted by paragraph 5.1) so that benefits due under section 5 can be paid from the fund in a timely manner. Payments provided under this subsection 5.6 are covered by subsection 5.3.3 hereof.

## 6 The Medical and Psychological Consultation Fund

6.1 The Medical and Psychological Consultation Fund ("Consultation Fund") is intended to provide Claimants with funds to obtain medical and psychological consultation with respect to their C/C heart valves.

6.2 As soon as practicable after signing of this Agreement, but before notice is sent to members of the class, Shiley shall deposit with the Clerk of the Court for the Southern District of Ohio, or other Court designee, the sum of eighty million dollars (\$80,000,000) designated for the Consultation Fund. This sum shall be deposited by the Court in an interest-bearing account or invested in an interest-bearing instrument

approved by the Court. Interest earned by the Consultation Fund shall become part of the Consultation Fund.

6.3 The Court may in its discretion select a Master to administer the Consultation Fund and its disbursement, as needed.

6.4 If the total number of Claimants exceeds twenty thousand (20,000), then Shiley shall make additional payments to the Consultation Fund based on the number of additional Claimants, as follows:

- a) For each Claimant over 20,000 up to 30,000, \$2,500 per Claimant.
- b) For each Claimant over 30,000 up to 35,000, \$1,500 per Claimant.
- c) For each Claimant over 35,000 up to 40,000, \$1,200 per Claimant.
- d) For each Claimant over 40,000, \$750 per Claimant.

Shiley shall have until 18 months after the date of Final Approval of the Settlement to make any additional payments specified in this paragraph.

6.5 After providing for the fees and expenses to be paid out of the Fund, the total amount of the fund will be divided among all Claimants and all Claimants shall be paid equally.

6.6 As soon as practicable after final approval, Shiley shall deposit an additional ten million dollars (\$10 million) designated for the Consultation Fund which shall be treated in accordance with paragraph 6.2. After providing for



the fees and expenses to be paid out of the Fund, the \$10 million will be divided equally among all Claimants who are spouses of class members with C/C valves; provided, that any such spousal claimant whose spouse with a C/C valve has opted out of this settlement shall not receive such a payment and shall not be counted for purposes of calculating the amount of such payments.

## 7 Fracture Compensation Mechanism

7.1 Following Final Approval of the Settlement, all Fracture Claimants shall receive fair compensation, which shall be determined in accordance with the following provisions.

7.2 In the case of a strut fracture where the C/C valve implantee is a United States resident at the time of fracture, the Fracture Claimant may elect to receive fair compensation from Shiley determined in accordance with the formula set forth in Appendix C. All costs and expenses incurred in determining the fair compensation to be received by the Fracture Claimant pursuant to Appendix C shall be borne by Defendants.

7.3 In the case of a strut fracture where the C/C heart valve implantee is not a United States resident at the time of the fracture, the Fracture Claimant may elect to receive fair compensation from Shiley to be determined as follows:

7.3.1 As soon as practicable after Initial Approval, the parties, subject to approval of the Court, shall select a panel of appropriate legal or other experts to determine fair compensation formulae for strut fractures for countries other

than the United States. The Panel shall establish a formula for each of four groups of countries, as specified in Appendix D. The cost and expenses of the panel shall be borne by the Defendants. No member of the panel shall be a past or present officer or employee of defendants, or have or have had meaningful economic or professional ties to defendants, or has been a party, expert or otherwise participated in any way in any heart valve litigation (including this action).

7.3.2 The Panel shall develop fair compensation formulae for each group of countries. The formulae shall be based upon, and consistent with, the amounts of compensatory damages generally awarded or agreed upon in settlements, in the countries comprising the group, for comparable personal injury or wrongful death claims.

7.3.3 The Panel may move any country to a higher GNP/GDP group if it concludes that the level of comparable personal injury or wrongful death awards in such country is more typical of that higher group than it is of any other group in Appendix D. All such comparisons shall be made using the groups as originally constituted in Appendix D, without giving effect to the prior movement of any other countries pursuant to this paragraph 7.3.3. No country shall be moved to a lower GNP/GDP group.

7.3.4 Regardless of the formula for each group of countries as determined by the Panel, the compensation that a Fracture Claimant may elect under this subsection 7.3 shall be not less than two hundred thousand dollars (\$200,000) for

fracture claimants who are residents of countries in groups I or II at the time of the fracture (taking in account any movement of countries by the Panel pursuant to paragraph 7.3.3), and not less than fifty thousand dollars (\$50,000) for fracture claimants who are residents of countries in groups III or IV at the time of the fracture.

7.4 As an alternative to receiving payment in accordance with the applicable formula, the Fracture Claimant may elect binding arbitration by a three person panel, one member of such panel being selected by the Fracture Claimant, the second member being selected by the Defendants and the third member being selected by the first two members. The arbitration shall be conducted in accordance with the rules of the American Arbitration Association. The arbitration panel will determine and award an amount that constitutes fair compensation for the strut fracture in the Fracture Claimant's country of residence at the time of the fracture, based upon the historic levels of damages for personal injury and wrongful death tort claims in that country for a person in the Fracture Claimant's circumstances. The panel will be empowered to award compensatory damages only and may not award any punitive damages. The decision of the arbitrators shall be final and binding on the parties.

7.5 In order to receive a payment under the applicable formula or to elect the binding arbitration under this Section 7, the Fracture Claimant shall submit proof of occurrence of a strut

fracture and any other information relevant to determining compensation under the applicable formula. In addition, as a condition of the Fracture Claimant's receiving any payment under the applicable formula or any award pursuant to binding arbitration, the Fracture Claimant and all other persons who may make a claim relating to the fracture under applicable law shall each execute and deliver to Defendants a full Release of all Claims in a form to be provided by defendants subject to Court approval. The persons required to execute the Release shall be reasonably determined by the Defendants based upon a review of those persons, if any, who are financially dependant upon the Settlement Class Member incurring the fracture and any other criteria reasonably determined by Defendants to be relevant. Defendants specifically waive and will not raise as a defense, with respect to any payment to a Fracture Claimant under the formula or pursuant to binding arbitration under this Agreement, any statute of limitation or statute of repose which would be otherwise applicable.

7.6 Any Fracture Claimant may decline to elect either the formula payment or binding arbitration, and may bring a litigation in an appropriate forum to seek claimed damages resulting from the fracture. By this agreement, Defendants do not consent to jurisdiction or venue in this or any other Court for any such litigation. In the event of litigation regarding a fracture, all parties retain the claims and procedural and substantive defenses that they would have had if there were no

class action determination or Settlement. In this regard, Defendants will not raise any defense in such fracture litigation that arises because of a plaintiff's participation in the class action or Settlement or any alternate dispute resolution pursuant to this paragraph 7.6, and will not assert that, because of any plaintiff's participation in this class action or the Settlement, or any alternate dispute resolution pursuant to this paragraph 7.6,

(a) a statute of limitation or statute of repose became applicable (when it otherwise would not have been applicable), or

(b) plaintiff knew of any alleged facts relating to the C/C heart valve, split a cause of action, or in any respect waived or is estopped from asserting his or her fracture claim.

Defendants may assert any defense that would have been available to them had this class action not been commenced or settled.

## **8 Settled Claims, Covenant Not To Sue and Release**

8.1 All parties hereto desire and intend that this Agreement apply to and settle all claims of injury, loss or damage deriving from the implantation of or relating to any C/C heart valve, other than (a) claims for benefits provided under this Agreement, (b) claims alleging injury (except for alleged emotional distress relating to fear of fracture of a working valve), including pain and suffering, from a Settlement Class Member's surgery to replace a C/C valve without symptoms that have been associated with a fracture but due to risk of strut fracture, and (c) claims alleging injury due to an actual in vivo

malfunction of the Claimant's valve (the "Settled Claims"). All of the Settled Claims shall be and hereby are conclusively compromised and settled, and shall be dismissed with prejudice pursuant to Section 10 hereof.

8.2 Defendants and their foreign and domestic predecessors, successors, parents, subsidiaries, affiliates and insurers, as well as any of their stockholders, directors, officers, employees and agents (the "Defendant Related Parties"), are not, and in the future shall not be, subject to liability or expense of any kind to any Settlement Class Member or their respective estates, executors, heirs, successors and assigns (the "Class Member Related Parties") with respect to any of the Settled Claims. Claims under this Agreement shall be the exclusive remedy of Settlement Class Members and the Class Member Related Parties against Defendants and the Defendant Related Parties concerning the Settled Claims. Each of the Settlement Class Members and Class Member Related Parties is forever barred from asserting any of the Settled Claims against Defendants or any of the Defendant Related Parties.

8.3 When this action is dismissed pursuant to Section 10 hereof, each Settlement Class Member and Class Member Related Party shall be deemed to have covenanted and agreed (a) that it will forever refrain from instituting, maintaining, or proceeding against Defendants or any of the Defendant Related Parties on any Settled Claim, including Settled Claims known and not now known, suspected or claimed, which it ever had, now has or hereafter may

have against them; and (b) that it releases Defendants and each of the Defendant Related Parties from each and every such Settled Claim.

8.4 The foregoing provisions of this Section 8 notwithstanding, a Settlement Class Member may elect to bring a claim for damages from emotional distress due to fear of fracture of a working valve under the conditions specified in Sub-paragraph 5.2.3.1(b).

#### 9 Counsel Fees and Administrative Expenses

9.1 Counsel for the Settlement Class shall receive, as compensation for all services performed, a Court award of fees and expenses based upon gross amounts of monies and benefits received by the Settlement Class from both funds.

9.2 At the time Class Counsel makes an application to the Court for compensation, the Defendants shall not oppose the application or any portion of the application, and the Defendants shall not oppose any award to Class Counsel ordered by the Court.

9.3 All expenses incurred in administering the Settlement, including the cost of all required notices to Class Members and compensation to all masters and trustees, shall be paid from the amount in the Consultation Fund as ordered by the Court; provided, however, that expenses directly related to the Patient Benefit Fund, including fees and expenses of all medical or scientific experts retained by the Supervisory Panel, and expenses incurred after the Consultation Fund is fully expended, may be taken from the Patient Benefit Fund as ordered by the

Court. Defendants shall assist and cooperate with Plaintiffs' class counsel in issuing the class notice ordered by the Court.

9.4 In no event will Defendants be required to make any further payments on account of compensation to Class Counsel or administrative or other expenses of this Settlement.

#### 10 Dismissal of Actions

10.1 Upon Initial Approval of this Settlement, Plaintiffs, with the cooperation of the Defendants, shall move the United States District Court for the Eastern District of Kentucky for a stay, and upon Final Approval shall move for a voluntary dismissal with prejudice, of the action styled as Emma C. Wright, et al. v. Pfizer Inc, et al., Civil No. 91-58.

Counsel for Plaintiffs shall cooperate with Defendants to cause the dismissal, with prejudice, of any other similar action of a Settlement Class Member, pending in state or federal court.

10.2 Upon distribution of the Consultation Fund, plaintiffs shall move for a voluntary dismissal with prejudice and the Court shall dismiss with prejudice the lawsuit settled herein. The Court shall retain jurisdiction with respect to future performance of, and any claims seeking performance of, this Agreement. The Court's retained jurisdiction shall not apply to any actions by Settlement Class Members not settled hereby, including actions alleging damages from a strut fracture as permitted in paragraph 7.6 hereof. Whether or not this action has yet been dismissed pursuant to this paragraph 8.2, Defendants' entry into this Agreement shall not constitute



consent to jurisdiction or venue in this Court for any such action.

**11 Pfizer Performance in Event of Shiley Default.**

Pfizer hereby agrees to guarantee all of Shiley's obligations under this Agreement. Notwithstanding the foregoing, in the event that Shiley fails to perform any of its material obligations hereunder, then Pfizer shall directly perform such obligations, including but not limited to all financial obligations, on behalf of Shiley. In no event shall Settlement Class counsel, or any Plaintiff, be required to proceed against Shiley or any other person before seeking to enforce Pfizer's agreements under this paragraph.

**12 Miscellaneous Provisions**

12.1 All parties hereto agree to exercise their best efforts and to take all reasonable steps necessary to effectuate the Settlement set forth in this Agreement. Defendants will make reasonable efforts to provide Class Counsel with any information in their possession that Class Counsel requests in order to facilitate giving notice to potential Settlement Class Members.

12.2 This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective estates, heirs, successors and assigns.

12.3 This Agreement, including the appendices hereto, constitutes the entire agreement among the parties with regard to the subject matter of this Agreement and supersedes any previous agreements and understandings between the parties with respect to

the subject matter hereof. This Agreement may not be modified or amended except in writing signed by all parties hereto.

12.4 This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

12.5 Except as otherwise specifically provided for in this Agreement, no party shall be liable for any costs or expenses incurred by or on behalf of any other party in connection with this Agreement and the actions contemplated hereby.

12.6 Any notice, request, instruction or other document to be given hereunder by any party hereto to any other party (other than class notification) shall be in writing and delivered personally or sent by registered or certified mail, postage prepaid, if to Defendants to:

Paul S. Miller, Esq.  
General Counsel  
Pfizer Inc  
235 East 42nd St.  
New York, N.Y. 10017

Attention: President  
Shiley Incorporated  
17600 Gillette Ave.  
Irvine, CA 92713

If to Class counsel, any Plaintiff or Class member to:

Stanley M. Chesley, Esq.  
Waite, Schneider, Bayless  
& Chesley Co., L.P.A.  
1513 Central Trust Tower  
Fourth & Vine Streets  
Cincinnati, Ohio 45202

or at such other address for a party as shall be specified by like notice. Any notice which is delivered personally in the manner provided herein shall be deemed to have been duly given to the party to whom it is directed upon actual receipt by such

party (or its agent for notices hereunder). Any notice which is addressed and mailed in the manner herein provided shall be conclusively presumed to have been duly given to the party (other than class notification) to which it is addressed at the close of business, local time of the recipient, on the third day after the day it is so placed in the mail.

12.7 This Agreement shall be construed in accordance with and governed by the laws of the State of Ohio applicable to agreements made and to be performed in such jurisdiction.

12.8 Plaintiffs shall make available to the Medic-Alert Foundation, confidentially and solely for the purpose of permitting Medic-Alert to contact implantees concerning the C/C heart valve patient registry and medical information relating to their C/C heart valve, the names and addresses of all persons responding to the Class Notice.

12.9 Waiver of valve replacement benefits under section 5 and of fracture compensation under section 7 due to the filing of a legal action for damages shall be effective 15 days after the filing of such action unless the action is previously dismissed with prejudice.

### 13 Termination of the Agreement

13.1 This Settlement Agreement shall, without notice, be automatically terminated if the Court, or any appellate court, denies the certification of the Settlement Class pursuant to paragraphs 3.3 and 4.1.

13.2 The Defendants shall have the option and discretion to terminate and withdraw from this Settlement Agreement if:

a. the Court, or any appellate court, denies leave to file the Amended Complaint, or denies or changes any portion or term of this Settlement Agreement; or

b. the Defendants, in their sole discretion, determine that the number of persons who have elected to be excluded from the Settlement Class is significant, substantial or material.

13.3 The Defendants shall exercise their right to withdraw from and terminate this Agreement, pursuant to paragraph 13.2(b) above, within 90 days after the last date for prospective Settlement Class Members to file requests for exclusion from the Settlement Class.

13.4 Should this Settlement Agreement terminate pursuant to this Section 13, the Settlement Agreement shall have no further force or effect; all moneys deposited by Shiley (and not yet expended pursuant to this Agreement), including all attorneys fees, will be returned to it with all interest earned thereon; and all parties herein shall be restored to their respective positions immediately prior to execution of this Settlement Agreement.

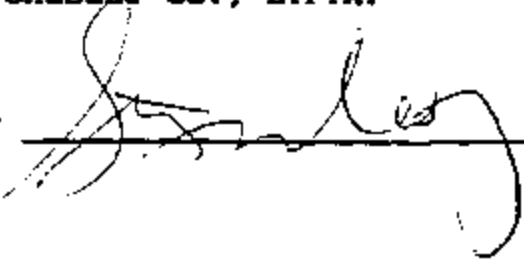
PFIZER INC

SHILEY INCORPORATED

By  \_\_\_\_\_

By  \_\_\_\_\_

WAITE, SCHNEIDER, HAYLESS &  
CHESLEY CO., L.P.A.

By  \_\_\_\_\_

APPENDIX A

Amended Complaint

Case No. 1:00-cv-00000

**APPENDIX B**

**Form of Order directing notice  
to Settlement Class Members**

**APPENDIX C**

**Fair Fracture Compensation Formula for U.S. residents**



## APPENDIX C

### Fair Fracture Compensation Formula for U.S. Residents

In the case of a strut fracture incurred by a Settlement Class Member who is a resident of the United States at the time of the fracture, if the fracture results in death or permanent total disability, the Fracture Claimant shall receive compensation equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below; provided, that in no event shall the total payment be less than \$500,000 or more than \$2,000,000.

a) \$500,000

b) \$100,000 if the Settlement Class Member incurring the fracture has a spouse at the time of fracture.

c) \$100,000 multiplied by the number of minor children, if any, that the Settlement Class Member has at the time of fracture.

d) The Settlement Class Member's lost income, calculated as the sum of (i) a percentage of the "adjusted current annual income" equal to the number of days from the fracture to the end of the year divided by 365, and (ii) the present value of future "adjusted current annual income" beginning the year following the fracture, ending the year of the Settlement Class Member's 65th birthday, and discounted to the year of the fracture at a net interest rate of 1.5% (which percentage is calculated as the

difference between 5.5% growth and a 7% discount rate).

"Adjusted current annual income" means 78.5% (which percentage is calculated to reflect fringe benefits as well as personal maintenance expenditures) of the Settlement Class Member's average actual income from wages, salary, personal services, personal business activity or other form of income from self-employment, as reported on his or her Federal Income Tax Return over the three years prior to the year of the fracture. If the Settlement Class Member has no such income or is age 65 or greater at the time of the fracture, then there is no payment under this component of the formula.

If the strut fracture does not result in death or permanent total disability, the Fracture Claimant shall receive compensation equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below; provided, that in no event shall the total payment exceed the amount that would have been payable under this Appendix C if the fracture had resulted in death or permanent total disability.

(a) \$500,000

(b) \$100,000 if the Settlement Class Member incurring the fracture has a spouse at the time of fracture.

(c) the Fracture Claimant's medical expenses directly related to the fracture, determined in the same manner as provided in paragraph 5.2.3.2 of the Settlement Agreement.

(d) the Fracture Claimant's actual lost income due to temporary and/or partial disability resulting from the fracture,

not to exceed the amount that would have been allowed under component (d) of this Appendix C for fractures resulting in death or permanent total disability.

**APPENDIX D**

**Groups of countries for determination of fair  
fracture compensation outside the United  
States**

APPENDIX D

Groups of Countries For Determination Of Fair  
Fracture Compensation Outside The United States

CATEGORY 1 (Countries with common law tort system)

Australia  
Canada  
United Kingdom  
New Zealand

CATEGORY II (Countries with per capita GDP/GNP greater than  
60% of United States level)

Andorra	Iceland
Austria	Italy
Belgium	Japan
Bermuda	Liechtenstein
Cayman Islands	Luxembourg
Denmark	Netherlands
Faroe Islands	Norway
Finland	Portugal
France	San Marino
Germany	Spain
Greece	Sweden
	Switzerland

CATEGORY III (Countries with per capita GDP/GNP 30% - 60% OF  
United States level)

Aruba	Ireland	Saint Pierre and
Bahamas	Israel	Miquelon
Bahrain	Kuwait	Singapore
British Virgin Islands	Macau	Soviet Union
Brunei	Man, Isle of	(Former
Cyprus	Monaco	constituents)
Czechoslovakia	Nauru	Taiwan
Greenland	Northern Mariana Islands	United Arab Emirates
Guam	Qatar	Virgin Islands
Hong Kong		

CATEGORY IV (Countries with per capita GDP/GNP below 30% of U.S. level)

Afghanistan	Gambia	Namibia
Albania	Gaza Strip	Nepal
Algeria	Ghana	Netherlands
American Samoa	Gibraltar	Antilles
Angola	Grenada	New Caledonia
Anguilla	Guadeloupe	Nicaragua
Antigua and Barbuda	Guatemala	Niger
Argentina	Guinea	Nigeria
Bangladesh	Guinea-Bissau	Niue
Barbados	Guyana	Oman
Belize	Haiti	Pacific Islands, Trust Territory of
Benin	Honduras	Pakistan
Bhutan	Hungary	Panama
Bolivia	India	Papua New Guinea
Botswana	Indonesia	Paraguay
Brazil	Iran	Peru
Bulgaria	Iraq	Philippines
Burkina Faso	Ivory Coast	Poland
Burma	Jamaica	Reunion
Burundi	Jordan	Romania
Cambodia	Kenya	Rwanda
Cameroon	Kiribati	Saint Kitts and Nevis
Cape Verde	Korea, North	Saint Lucia
Central African Republic	Korea, South	Saint Vincent and the Grenadines
Chad	Laos	Sao Tome and Principe
Chile	Lebanon	Saudi Arabia
China	Leshotho	Senegal
Colombia	Liberia	Seychelles
Comoros	Libya	Sierra Leone
Congo	Madagascar	Solomon Islands
Cook Islands	Malawi	Somalia
Costa Rica	Malaysia	South Africa
Cuba	Maldives	Sri Lanka
Djibouti	Mali	Sudan
Dominica	Malta	Suriname
Dominican Republic	Marshall Islands	Swaziland
Ecuador	Martinique	Syria
Egypt	Mauritania	Tanzania
El Salvador	Mauritius	Thailand
Equatorial Guinea	Mexico	Togo
Ethiopia	Micronesia, Federated States of	Tokelau
Fiji	Mongolia	
French Guiana	Montserrat	
French Polynesia	Morocco	
Gabon	Mozambique	

Tonga  
Trinidad and  
Tobago  
Tunisia  
Turkey  
Turks and Caicos  
Islands  
Tuvalu  
Uganda  
Uruguay  
Vanuatu  
Venezuela  
Vietnam  
Wallis and Futuna  
West Bank  
Western Samoa  
Yemen  
Yugoslavia  
Zaire  
Zambia  
Zimbabwe

that may relate to patient health status, are matters for consideration between the Class Member and his or her physician and will not be considered for purposes of determining qualification for valve replacement surgery benefits.

II. A new paragraph 6.6 is added to section 6 as follows:  
6.6

III. A new paragraph 7.3.4 is added to section 7 as follows:  
7.3.4        sand dollars (\$50,000) for fracture claimants who



**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing document has been served upon the following counsel of record, by regular U.S. Mail, this 3 day of August, 1992.

John T. Johnson, Esq.  
1000 Louisiana, #4500  
Houston, TX 77002-5012  
Facsimile: 713-654-8023

Gates T. Richards, Esq.  
3807 Carew Tower  
441 Vine Street  
Cincinnati, Ohio 45202  
Facsimile: 513-621-2036

Brian Wolfman, Esq.  
Public Citizen  
2000 "P" Street, N.W. #700  
Washington, D.C. 20026  
Facsimile: 202-452-8658

Brian Magana, Esq.  
1801 Avenue of the Stars, #810  
Los Angeles, CA 90067  
Facsimile: 310-785-9143

Paul Tobias, Esq.  
414 Walnut Street  
Cincinnati, Ohio 45202  
Facsimile: 513-241-7836

Lewis Saul  
7315 Wisconsin Avenue  
Suite #601, North  
Bethesda, MD 20814  
Facsimile: 301-961-9561

Charles Wolfson, Esq.  
P. O. Box A-266  
Sydney, South  
NSW, 2000 AUSTRALIA  
Facsimile: 011-61-2-261-3318

David Klingsburg, Esq.  
425 Park Avenue

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FILED  
KENNETH J. MURPHY  
CLERK


IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

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U.S. DISTRICT COURT  
SOUTHERN DIST OHIO  
WEST DIV CINCINNATI

ARTHUR RAY BOWLING, et al. : CASE NO. C-1-91-256  
Plaintiffs, :  
v. : Judge S. Arthur Spiedel  
PFIZER INC, et al. :  
Defendants. :

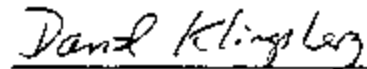
Judge	481
Mag.	
Journal	
Motion	
Issue	
Card	
H/S	
Booked	

It is agreed among the undersigned class counsel for plaintiffs, counsel for defendants and counsel for amicus Public Citizen that the provisions set forth on exhibit A hereto shall be submitted to and enforceable by the Court as part of the binding protocols for implementation by the Supervisory Panel of § 5.4.4.2 of the Supplemented Agreement of Compromise and Settlement.

  
Stanley M. Chesley, Esq.

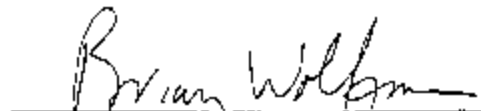
WAITE, SCHNEIDER, BAYLESS  
& CHESLEY  
Class Counsel for Plaintiff

October 26, 1992

  
David Klingsberg, Esq.

KAYE, SCHOLER, FIERMAN,  
HAYS & HANDLER  
Counsel for Defendant

October 26, 1992



Brian Wolfman, Esq.  
Public Citizen Litigation  
Group  
Counsel for Public Citizen

October 23, 1992

EXHIBIT A

In its guidelines for valve replacement surgery, the Supervisory Panel is to identify those circumstances in which prophylactic replacement of a Bjork-Shiley Convexo-Concave heart valve would reasonably offer a meaningful extension of life expectancy because of the risk of strut fracture. The Panel shall, to the extent possible, establish these guidelines premised on an implantee whose health history and status presents the optimal estimated risks for valve replacement surgery; the Panel shall also, to the extent possible, separately identify those factors of an implantee's health history or status that might increase these risks. Additionally, the Panel shall establish these guidelines on the assumption that the experience of the facility at which the surgery will be performed presents the optimal estimated risks for valve replacement surgery; the Panel may also, to the extent possible, separately identify those factors of facility experience that might increase these risks.

AMENDED FINAL REPORT OF THE FOREIGN FRACTURE PANEL

1. In the case of a strut fracture incurred by a Settlement Class Member who is, at the time of fracture:

- (a) resident in one of the countries listed in Schedule 1 hereto; and
- (b) has been resident in that country for the three years immediately preceding the date of fracture.

compensation shall be paid in accordance with Clause 7.5 of the Settlement Agreement. Such compensation shall be equal to the sum of the amount allowed for a country in the relevant Category of Schedule 1 provided that in no event shall the total payment for a Fracture Claimant (hereinafter referring to a person whose C/C heart valve incurs a strut fracture after the date of the Settlement Agreement) resident in a country in Categories 1 or 2 be less than \$200,000 US or in the case of Categories 3 or 4 be less than \$50,000 US.

2.1 In the event that at the date of fracture the Fracture Claimant has not been resident in the country in which he is then resident for three years his claim will be determined by reference to the amount payable to a resident of the country of his habitual residence.

2.2 In the event that the habitual residence of a Fracture Claimant is a country in a higher Category than the country in which he has been resident for three years at the date of fracture, he or his personal representatives may elect, at their sole discretion, to receive compensation calculated as appropriate to the country of his habitual residence.

3.1 In the case of a Fracture Claimant resident or habitually resident (as may be appropriate to the claim) in a Category 1 or a Category 2 country if the fracture results in death or permanent total disability compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below provided that in no event shall the total payment exceed \$1 million US.

(a) \$160,000 US.

(b) \$60,000 US if the Fracture Claimant incurring the fracture has a "spouse" at the date of fracture.

(c) \$40,000 US multiplied by the number of children, if any, that the Fracture Claimant has at the time of fracture who fall into one or more of the following categories namely:

(i) Minors.

- (ii) Those who are undergoing full time education or training for a trade or profession and are under the age of 26 years.
  - (iii) Those who provide evidence in writing to satisfy the Defendants in accordance with Clause 7.5 of the Settlement Agreement that they are under a physical or mental disability which has reasonably required the Fracture Claimant to maintain and support them.
- (d) The Fracture Claimant's lost income, calculated as the sum of (1) a percentage of the adjusted current annual income equal to the number of days from the date of fracture to the end of the year divided by 365, and (2) the present value of future adjusted current annual income beginning with the first day of the calendar year following the fracture, ending the year of the Fracture Claimant's 65th birthday and discounted to the year of the fracture at a net interest rate of 1.5% (which percentage is calculated as the difference between 5.5% growth and a 7% discount rate).
- 3.2 "Adjusted current annual income" means 78.5% (which percentage is calculated to reflect fringe benefits as well as personal maintenance expenditures) of the Fracture Claimant's average actual income from wages, salary, personal services, personal business activities or other form of income from self employment as reported to relevant tax authorities in the three years immediately preceding the date of fracture or as evidenced by such other public records reasonably to be regarded as satisfactory proof of income over the three years prior to the year of the fracture. If the Fracture Claimant has not such income or if aged 65 or greater at the time of the fracture, then there is no payment under this component of the formula.
- 3.3 If the strut fracture does not result in death or permanent total disability, the compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below; provided, that in no event shall the total payment exceed \$1.5 million US.
- (a) \$160,000 US.
  - (b) \$60,000 US if the Fracture Claimant incurring the fracture has a spouse at the time of fracture.
  - (c) The Fracture Claimant's medical expenses directly related to the fracture, determined in the same manner as provided in Clause 5.2.3.2 of the Settlement Agreement.

(d) The Fracture Claimant's actual lost income due to temporary and/or partial disability resulting from the fracture, not to exceed the amount that would have been allowed under component (d) of the formula for fractures resulting in death or permanent disability.

4.1 In the case of a Fracture Claimant resident or habitually resident (as appropriate to the claim) in a Category 3 country if the fracture results in death or permanent total disability compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below provided that in no event shall the total payment exceed \$500,000 US.

(a) \$80,000 US.

(b) \$30,000 US if the Fracture Claimant incurring the fracture has a "spouse" at the date of fracture.

(c) \$20,000 US multiplied by the number of children, if any, that the Fracture Claimant has at the time of fracture who fall into one or more of the following categories namely:

(i) Minors.

(ii) Those who are undergoing full time education or training for a trade or profession and are under the age of 26 years.

(iii) Those who provide evidence in writing to satisfy the Defendants in accordance with Clause 7.5 of the Settlement Agreement that they are under a physical or mental disability which has reasonably required the Fracture Claimant to maintain and support them.

(d) The Fracture Claimant's lost income, calculated as the sum of (1) a percentage of the adjusted current annual income equal to the number of days from the date of fracture to the end of the year divided by 365, and (2) the present value of future adjusted current annual income beginning with the first day of the calendar year following the fracture, ending the year of the Fracture Claimant's 65th birthday and discounted to the year of the fracture at a net interest rate of 1.5% (which percentage is calculated as the difference between 5.5% growth and a 7% discount rate).

4.2 "Adjusted current annual income" means 78.5% (which percentage is calculated to reflect fringe benefits as well as personal maintenance expenditures) of the Fracture Claimant's average actual income from wages, salary, personal services, personal

business activities or other form of income from self employment as reported to relevant tax authorities in the three years immediately preceding the date of fracture or as evidenced by such other public records reasonably to be regarded as satisfactory proof of income over the three years prior to the year of the fracture. If the Fracture Claimant has not such income or if aged 65 or greater at the time of the fracture, then there is no payment under this component of the formula.

4.3 If the strut fracture does not result in death or permanent total disability, the compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below; provided that in no event shall the total payment exceed \$750,000 US.

(a) \$80,000 US

(b) \$30,000 US if the Fracture Claimant incurring the fracture has a spouse at the time of fracture.

(c) The Fracture Claimant's medical expenses directly related to the fracture, determined in the same manner as provided in Clause 5.2.3.2 of the Settlement Agreement.

(d) The Fracture Claimant's actual lost income due to temporary and/or partial disability resulting from the fracture, not to exceed the amount that would have been allowed under component (d) of the formula for fractures resulting in death or permanent disability.

5.1 In the case of a Fracture Claimant resident or habitually resident (as appropriate to the claim) in a Category 4 country if the fracture results in death or permanent total disability compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below provided that in no event shall the total payment exceed \$500,000 US.

(a) \$40,000 US

(b) \$15,000 US if the Fracture Claimant incurring the fracture has a "spouse" at the time of fracture.

(c) \$10,000 US multiplied by the number of children, if any, that the Fracture Claimant has at the time of fracture who fall into one or more of the following categories namely:

(i) Minors.

- (ii) Those who are undergoing full time education or training for a trade or profession and are under the age of 26 years.
  - (iii) Those who provide evidence in writing to satisfy the Defendants in accordance with Clause 7.5 of the Settlement Agreement that they are under a physical or mental disability which has reasonably required the Fracture Claimant to maintain and support them.
- (d) The Fracture Claimant's lost income, calculated as the sum of (1) a percentage of the adjusted current annual income equal to the number of days from the date of fracture to the end of the year divided by 365, and (2) the present value of future adjusted current annual income beginning with the first day of the calendar year following the fracture, ending the year of the Fracture Claimant's 65th birthday and discounted to the year of the fracture at a net interest rate of 1.5% (which percentage is calculated as the difference between 5.5% growth and a 7% discount rate).
- 5.2 "Adjusted current annual income" means 78.5% (which percentage is calculated to reflect fringe benefits as well as personal maintenance expenditures) of the Fracture Claimant's average actual income from wages, salary, personal services, personal business activities or other form of income from self employment as reported to relevant tax authorities in the three years immediately preceding the date of fracture or as evidenced by such other public records reasonably to be regarded as satisfactory proof of income over the three years prior to the year of the fracture. If the Fracture Claimant has not such income or if aged 65 or greater at the time of the fracture, then there is no payment under this component of the formula.
- 5.3 If the strut fracture does not result in death or permanent total disability, the compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below; provided that in no event shall the total payment exceed \$750,000 US.
- (a) \$40,000 US
  - (b) \$15,000 US if the Fracture Claimant incurring the fracture has a spouse at the time of fracture.
  - (c) The Fracture Claimant's medical expenses directly related to the fracture, determined in the same manner as provided in Clause 5.2.3.2 of the Settlement Agreement.



- (d) The Fracture Claimant's actual lost income due to temporary and/or partial disability resulting from the fracture, not to exceed the amount that would have been allowed under component (d) of the formula for fractures resulting in death or permanent disability.
- 6.1 Pursuant to Clause 7.5 of the Settlement Agreement, the Defendants may require a Fracture Claimant (here defined in accordance with Clause 3.7 of the Settlement Agreement) to provide or cause to be provided to them either:
- (a) a release of all claims by such Social Security Department, or any other legally obligated provider, appropriate to the claim; or
  - (b) satisfactory evidence that such Social Security Department, or any other legally obligated provider has no right to make any claim against the Defendants.
- 6.2 Pending receipt of a release or satisfactory evidence in accordance with Clause 6.1 hereof, the Defendants shall be entitled to withhold payment to the Fracture Claimant only of such sum as may reasonably be expected to be claimed by the Social Security department or other legally obligated provider as may be appropriate to the claim.

#### PROPOSED ARBITRATION CLAUSE

- 1.1 Once an election to accept compensation under the formulae for fair fracture compensation for U.S. non-residents has been made by a Fracture Claimant, any dispute or difference between a Fracture Claimant and the Defendants arising from these formulae shall be referred to and determined by a sole arbitrator ("the arbitrator"), such arbitration to be held in Cincinnati, Ohio, or such other place as the arbitrator may, in his sole discretion, determine.
- 1.2 The reference shall be reduced to writing and signed by the parties thereto.
- 1.3 The arbitrator shall be appointed by agreement between the Fracture Claimant and the Defendants or in default of that agreement by the Special Masters/trustees of the Settlement Fund. The arbitrator shall not be a current or former agent or employee of either Defendant nor a relative, current or former agent or employee of the Fracture Claimant.
- 1.4 The procedure to be followed and liability for the costs of the arbitration shall be agreed between the Fracture Claimant and the Defendants or, in default of agreement, determined by the arbitrator.
- 1.5 The award shall be in writing and shall be delivered after due payment to the parties to the reference and the Special Masters/Trustees.
- 1.6 In the event of default by either party in respect of any procedural Order made by the arbitrator, the arbitrator shall have power to proceed with the arbitration in the absence of that party and to deliver his award.
- 1.7 Any arbitration shall be governed by and conducted in accordance with the laws of the State of Ohio applicable to agreements made and to be performed in such jurisdiction.

APPENDIX D

Groups of Countries For Determination of Fair  
Fracture Compensation Outside the United States

Group 1

Countries having a Common law tort system

Australia

Canada

New Zealand

Including

Tokelau

United Kingdom

Including

Guernsey,  
Isle of Man,  
Jersey

Group 2

Countries with GDP or GNP per capita greater than 60% of that of  
the United States, and all members of the European Union

Andorra

Austria

Bahamas

Belgium

Bermuda

Cayman Islands

Denmark

Including

Faroe Islands,  
Greenland

Finland

France

Including

French Guiana,  
French Polynesia,  
Guadeloupe,  
Martinique,  
New Calendonia,  
Reunion,  
Saint Pierre and Miquelon,  
Wallis and Futana

Germany

Gibraltar

Greece

Hong Kong

Iceland

Ireland

Italy

Japan

Kuwait

Liechtenstein

Luxembourg  
Monaco  
Netherlands  
    Including           Aruba  
                          Netherlands Antilles  
Norway  
Portugal  
    Including           Macau  
Qatar  
San Marino  
Singapore  
Spain  
Sweden  
Switzerland  
United Arab Emirates

Group 3

Countries with GDP or GNP per capita or more than 30% but less than 60% of that of the United States

Bahrain  
Barbados  
Brunei  
British Virgin Islands  
Cyprus  
Czech Republic  
Guam  
Israel  
Malaysia  
Mauritius  
Mexico  
Nauru  
Northern Mariana Islands (U.S.A.)  
Oman  
Saudi Arabia  
Slovakia  
Slovenia  
South Korea  
Taiwan  
Trinidad  
Venezuela  
Virgin Islands (U.S.A.)

Group 4

Countries with GDP or GNP per capita less than 30% of that of the United States

Afghanistan  
Albania  
Algeria

American Samoa  
Angola  
Anguilla  
Antigua and Barbuda  
Argentina  
Armenia  
Azerbaijan  
Bangladesh  
Bailers  
Belie  
Begin  
Bhutan  
Bolivia  
Bosnia and Herzegovina  
Botswana  
Brazil  
Bulgaria  
Burkina  
Burma  
Burundi  
Cambodia  
Cameroon  
Cape Verde  
Central African Rep.  
Chad  
Chile  
China  
Colombia  
Comoros  
Congo  
Cook Islands  
Costa Rica  
Croatia  
Cuba  
Djibouti  
Dominica  
Dominican Republic  
Ecuador  
Egypt  
El Salvador  
Equatorial Guinea  
Eritrea  
Estonia  
Ethiopia  
Federated States of Micronesia  
Fiji  
Former Yugoslav Republic of Macedonia  
Gabon  
Gambia  
Gaza  
Georgia  
Ghana

Grenada  
Guatemala  
Guinea  
Guinea-Bissau  
Guyana  
Haiti  
Honduras  
Hungry  
India  
Indonesia  
Iran  
Iraq  
Ivory Cost  
Jamaica  
Jordan  
Kazakhstan  
Kenya  
Kiribati  
Kyrgystan  
Laos  
Latvia  
Lebanon  
Lesotho  
Liberia  
Libya  
Lithuania  
Madagascar  
Malawi  
Maldives  
Mali  
Malta  
Marshall Islands  
Mauritania  
Moldova  
Montserrat  
Morocco  
Mozambique  
Namibia  
Nepal  
Nicaragua  
Niger  
Nigeria  
Niue  
North Korea  
Pakistan  
Panama  
Paupa New Guinea  
paraguay  
Peru  
Philippines  
Poland  
Romania

Russia  
Rwanda  
Saint Kitts & Nevis  
Saint Lucia  
Saint Vincent & Grenadines  
Sao Thome & Principe  
Senegal  
Serbia and Montenegro  
Seychelles  
Sierra Leone  
Solomon Islands  
Somalia  
South Africa  
Sri Lanka  
Sudan  
Suriname  
Swaziland  
Syria  
Tajikistan  
Tanzania  
Thailand  
Togo  
Tonga  
Trust Terr. of Pacific Isl. (Paulau) (U.S.A.)  
Tunisia  
Turkey  
Turkmenistan  
Turks and Caicos Islands  
Tuvalu  
Uganda  
Ukraine  
Uruguay  
Uzbekistan  
Vanuatu  
Vietnam  
Western Samoa  
West Bank  
Yemen  
Zaire  
Zambia  
Zimbabwe

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

FILED  
MURPHY  
MAY 20 1995  
CIVIL ACTION NO. C-1-91-256

ARTHUR RAY BOWLING, et al.

Civil Action No. C-1-91-256

Plaintiffs,

v.

PFIZER, INC., et al.

Defendants.

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Vicki

**ORDER APPROVING AMENDED FINAL REPORT OF THE  
FOREIGN FRACTURE PANEL WITH CERTAIN MODIFICATIONS**

Subject to the modifications below, the Court hereby approves the Amended Final Report of the Foreign Fracture Panel (the "Report"), Appendix 1 to the First Report of the Special Masters/Trustees Covering Period From January 28, 1992 to February 28, 1995, as presented to the Court on March 3, 1995.

The Amended Final Report of the Foreign Fracture Panel, as approved, shall be deemed modified as follows:

1. With regard to paragraphs 3.1, 3.3, 4.1, 4.3, 5.1 and 5.3 of the Report, for all country groups the maximum total payment under the formulae shall be \$2,000,000 US, rather than the amounts specified in those paragraphs.

2. The following clarifying sentence is added to paragraph 2.1 of the Report: "In such a case, a fracture claimant's country of habitual residence shall be determined by the Claims Administrator, taking into account appropriate evidence concerning the fracture claimant's current residence, and may be a country where the fracture claimant has resided for less than three years."



3. With regard to paragraphs 3.1(b), 3.3(b), 4.3(b), 5.1(b) and 5.3(b), whether the fracture claimant has an eligible spouse shall be determined under the law of the country in which the fracture claimant is deemed resident for purposes of determining the applicable formula amounts. Only one spousal amount shall be paid even if there are two or more eligible spouses.

4. Paragraphs 6.1 and 6.2 of the Report are deleted and the following new Paragraphs 6.1 and 6.2 are substituted as follows:

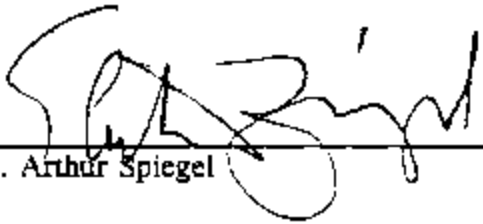
6.1 In cases where a Social Security Department or any other legally obligated provider may have claims against Defendants, Defendants under Paragraph 7.5 of the Settlement Agreement may withhold payment to the Fracture Claimant on account of such claims only of such sum as may reasonably be expected to be claimed by such Social Security Department or other legally obligated provider. Determination of such sum (if any) in each case is subject to approval of the Special Masters/Trustees.

6.2 If the fracture claimant provides

- (a) a release of all claims by the Social Security Department, or any other legally obligated provider, appropriate to the claim, or
- (b) satisfactory evidence that such Social Security Department, or any other legally obligated provider, has no right to make any claim against the Defendants, then the Special Masters/Trustees may determine that the fracture claimant has complied with Paragraph 7.5 of the Settlement Agreement with respect to such claims and upon such determination Defendants shall pay to the Fracture Claimant the sum withheld on account of such claims.

5. With regard to the proposed arbitration clause appended to the Report, the Special Masters/Trustees shall determine whether or not to implement such an arbitration for any particular claim in light of the circumstances thereof.

Dated: March 23, 1995

  
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S. Arthur Spiegel

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