UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ARTHUR RAY BOWLING, ET AL.,	:	
	:	No. C-1-91-256
PLAINTIFF,	:	
	:	
V.	:	JUDGE WEBER
	:	
PFIZER, INC. ET AL.,	:	
	:	
DEFENDANT.	:	
	:	

NOTICE OF FILING OF THE NINETEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING PERIOD FROM JUNE 6, 2003 TO NOVEMBER 25, 2003

NOTICE IS HEREBY GIVEN to all counsel of record that the NINETEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING PERIOD FROM JUNE 6, 2003 TO NOVEMBER 25, 2003, is hereby filed with the Court.

Respectfully submitted,

Nancy A. Lawson

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Attorney for SpecialMasters/Trustees

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this Notice of Filing of the Nineteenth Report of the Special Masters/Trustees Covering Period from June 6, 2003, to November 25, 2003, has been hand delivered to those in Cincinnati and federal express to those outside Cincinnati this 25th day of **November, 2003.**

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961183

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

IN RE:	:	Case No. C-1-91-256
BOWLING-PFIZER LITIGATION	:	(Judge Weber)

NINETEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

COVERING PERIOD FROM JUNE 6, 2003 TO NOVEMBER 25, 2003

SPECIAL MASTERS/TRUSTEES

Hon. Robert L. Black, Jr.
Peter J. Strauss, Esq.

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AGENDA

NINETEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 12, 2003
10:00 A.M.

Hon. Herman J. Weber

1. Introductory remarks by Judge Weber.
2. Report of the Special Masters/Trustees.
3. Comments from Counsel:

   Class Counsel.
   Counsel for Defendants.

4. Questions and comments from those in attendance.
5. Request for date of next report of Trustees.
6. Closing remarks of Judge Weber.

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NINETEENTH REPORT OF THE TRUSTEES

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

IN RE:	:	Case No. C-1-91-256
BOWLING-PFIZER LITIGATION	:	(Judge Weber)

NINETEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

To the Honorable Herman J. Weber, Judge, United States District Court:

Your Special Masters/Trustees respectfully present their nineteenth periodic report, covering activities from June 6, 2003 to November 25, 2003. This report is submitted seventeen days prior to the status hearing before the Court scheduled for December 12, 2003.

I. PATIENT BENEFIT FUND

A. Supervisory Panel. The Supervisory Panel met On September 15 and 16, 2003, in Cincinnati, Ohio. All members were present. Chairman Kermit Smith chaired the meeting. In the morning, the Supervisory Panel discussed what the Panel should be doing in

research to reach its goals including what research should be continued, what research should be terminated, and what new research should be initiated to benefit the class. In the afternoon, the attorneys joined the Supervisory Panel and participated in the discussion of what research should be undertaken to benefit the class. On September 16, 2003, the Supervisory Panel met, considered committee reports and took action on the proposals for research which had been submitted. The Panel discussed and considered eleven (11) research projects, either for continuing work on existing projects or for new projects. All proposals were approved.

Dr. James Thomas has resigned due to an alleged conflict of interest. He will be submitting his written resignation shortly.

On November 5 and 6, 2003, the Supervisory Panel met in London, England. All remaining members were present. Mr. Kermit Smith chaired the meeting. On November 5, 2003, Dr. Harrison summarized the research conducted to date for the benefit of all of the participants. Ten Presentations were then made by investigators regarding on going research and regarding proposals for new research by Dutch, Swiss, German and American organizations.

On Thursday, November 6, 2003, proposals for new research studies were presented by additional four organizations. In addition, there was discussion regarding the use of animal testing in the evaluation of research projects and a discussion by Professor Nicholas Bom regarding the planning, preparation,

coordination, and evaluation of biomedical engineering research projects that are beneficial to the BSCC Heart Valve patient.

In the afternoon of November 6, 2003, there was an open discussion chaired by Professor Nicholas Bom, Dr. Donald Harrison and Professor Ned Weyman regarding research. The Supervisory Panel then met to consider the five written proposals that were before the Panel. One proposal was approved pending receipt of certain data requested and four were disapproved as submitted with suggestions for submittal of revised proposals.

B. Guidelines. As the Court is aware, the 2003 Amended Guidelines have been approved by the Court. In September, an executive summary of the Guidelines and in October, a Dear Doctor letter were sent to physicians regarding the new Guidelines. A copy of the executive summary and the letter are attached as Appendix 1. A Notice of the 2003 Amended Guidelines with a copy of the Guidelines was sent to registered class members in October. A copy of that Notice is attached as Appendix 2.

C. Research. Our report on the status of the research program of the Supervisory Panel is set forth in three appendices attached hereto, in accordance with the agreed arrangement used in the Seventeenth Report. Appendix 3 covers the projects that are ongoing at this time, divided into three categories (epidemiological projects, surgical projects and imaging and acoustic projects). Appendix 4 shows those projects that have been approved and are pending the finalization of contracts. Appendix 5

sets forth those projects that remain under further consideration at this time.

For a description of the Panel's division of its research program into three categories, reference is made to Section II. C of the Seventeenth Report.

D. Imaging. Since the imaging program at Penn State resumed fifteen implantees who may qualify for replacement surgery have been imaged, and their valves were interpreted to be intact. Six more implantees are thinking about using this service.

E. Repository. The Supervisory Panel continues to maintain a publicly accessible repository of certain documents and information concerning the BSCC heart valve. The repository contains hard copy printouts of various items including, but not limited to, reports on the status and results of research sponsored by the Supervisory Panel, minutes of meetings of the Supervisory Panel, a bibliography of published literature regarding the BSCC heart valves, certain unpublished reports prepared by Dr. Brookmeyer of his statistical analysis, the Bowling Settlement Agreement, and other information. The repository is currently located at the Trustees' office.

In addition, the Trustees have made many of the documents in the repository available electronically in a database which can be accessed through the internet at www.bowling-pfizer.com/repository. Individuals are able to search for information using descriptive words. Some of the information, such as published articles, are not available for review online due to copyright and other intellectual property concerns. To access the online repository,

an individual need only contact the Trustees' office for the website location and a password. The Trustees have placed an announcement on its website providing class members and other interested individuals with information about the electronic database.

F. Website. The Supervisory Panel's website continues to be found at www.bowling-pfizer.com. It provides basic information on the parties involved (biographies, addresses, telephone numbers, email, etc.), certain orders of the Court including the 2003 Amended Guidelines, a copy of the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information.

As noted above, an announcement has been placed on the website explaining that many of the documents contained in the document repository are now available on-line. Further, a copy of the most recent "hit report" of the Supervisory Panel's website is attached to this Report as Appendix 6.

G. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator continues to receive and process claims for valve replacement surgery and outlet strut fracture. The processing of some claims had been initiated by Shiley in the interim period from the date of the Settlement Agreement until the Claims Administrator was appointed. Also, some qualified claims were settled by Shiley with the Settlement benefits during this interim period. In addition, some of the claimants have elected

other courses of action rather than to receive the Settlement benefits.

Since the date of the last Trustees' report on June 5, 2003, two outlet strut fractures and three qualified valve replacement surgeries have been confirmed. One of the outlet strut fractures occurred prior to June 5, 2003.

During the period from the last Report to the date of this Report, $102,118 was paid from the Patient Benefit Fund for the medical expense component of the benefits for a qualifying replacement surgery. Also, Pfizer Inc. paid $76,000 for other components of the benefits for two of the replacement surgery claims processed by the Claims Administrator.

The total number of qualified claims received from the beginning are now: 89 (69 foreign) qualified outlet strut fracture claims and 134 (54 foreign) qualified valve replacement surgery claims including 38 (16 foreign) qualified single leg fracture claims.

The office of the Claims Administrator is fulfilling requests to calculate estimated annual fracture rates under the 2003 Amended Guidelines. In addition, a review of the valve replacement surgery claims that did not previously qualify, as well as the Consultation Fund claims, is being conducted in order to identify those implantees who may potentially qualify for valve replacement surgery benefits under the 2003 Amended Guidelines. This review is complete with the exception of those patients whose qualification may be affected by the rework factor in the guidelines calculation

formula. For these patients certain of the valve manufacturing records need to be examined in order to verify the rework status of the valve(s). In addition, the office of the Claims Administrator continues to respond to other inquiries from and on behalf of Class Members.

II. FINANCIAL INFORMATION

At October 31, 2003, the total balance of cash and cash equivalents was $28,387,056. This amount takes into account net interest earned from January 28, 1992 through October 31, 2003 in the aggregate amount of $23,144,147.

Attached as Appendix 7. are the following: an unaudited balance sheet as of October 31, 2003 and an unaudited statement of income and funds balance for the ten months ended October 31, 2003 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2003 through December 31, 2003).

Attached as Appendix 8. is a copy of the Independent Auditors' Report for the year ended December 31, 2002.

III. COMMUNICATIONS

Communications remain open, whether with physicians, Class Members, other BSCC heart valve implantees, Class Counsel, Special Counsel, Defendant's Counsel, or Counsel for Public Citizen.

IV. APPROVALS

Your honor, the Special Masters/Trustees request that the Court:

- Approve this Report, and
- Approve, or provide guidance with respect to, each of the Appendices to this Report, and
- Provide guidance with respect to any duty of the Special Masters/Trustees, and
- Fix the date for the next Report.

Respectfully submitted,

Dated: November 25, 2003

Robert L. Black, Jr.
Hon. Robert L. Black, Jr.

Peter J. Strauss
Peter J. Strauss, Esq.

APPENDICES

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

September 2003

IN JULY 2003 THE SUPERVISORY PANEL OF THE BOWLING-PFIZER TRUST ISSUED NEW GUIDELINES FOR COMPENSATION FOR VALVE REPLACEMENT SURGERY FOR QUALIFYING PATIENTS WITH BJORK-SHILEY CONVEXO-CONCAVE (BSCC) HEART VALVES.

The monetary benefits include reimbursement of medical expenses not covered by an outside benefit, a lump sum payment of $38,000 to cover out-of-pocket expenses, and reimbursement for lost income.

- These 2003 Amended Guidelines for qualification for benefits are based on the comparison of risk of valve fracture with the risk of reoperation to replace the valve. Those whose risk of valve fracture exceeds the risk of reoperation qualify for monetary benefits under these guidelines.

- These 2003 Amended Guidelines as well as the 2000 Amended Guidelines differ from earlier versions in that they identify younger patients, primarily those less than 55 years of age, as being at greatest risk.

- Risk of fracture is associated with valve size, implant position, some manufacturing characteristics, age and gender

- Calculations used to obtain operative mortality were derived from actual experience with BSCC reoperations and from large current studies of similar types of patients undergoing elective explantation of other types of valves

- Data on the risk of fracture were based on the world wide experience of BSCC patients.

- These risks are statistical averages and are based on patients in optimal health, and thus may not be medically applicable in individual cases.

- Replacement surgery benefits are also available for surgery to explant a BSCC heart valve due to the risk of strut fracture, if the surgery complies with the 2000 Amended Guidelines.

While these guidelines were developed for administrative purposes to identify patients who would qualify for monetary benefits from reoperation, they also may provide useful medical background for patients and their physicians considering elective BSCC heart valve replacement.

To determine whether an individual patient qualifies for benefits under these guidelines one should contact the claims administrator for the Bowling-Pfizer Trust at:

Bowling-Pfizer Trustees
Claims Administrator
P.O. Box 3598
Cincinnati, OH 45201-3598

Telephone: 800/977-0779 or 513/421-4415
Fax: 513/421-7696

To follow-up this summary you will be sent a copy of the 2003 Amended Guidelines.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

525 VINE STREET SUITE 2300 – CINCINNATI, OHIO 45202-3124
TELEPHONE 513/421-4415 OR 800/977-0779 FAX 513/421-7696

TRUSTEES

HON ROBERT L BLACK, JR
PETER J STRAUSS, ESQ

October 2003

IMPORTANT UPDATED INFORMATION FOR PHYSICIANS ABOUT PATIENTS WITH BJORK-SHILEY CONVEXO-CONCAVE HEART VALVES

Dear Doctor

This letter provides new information about the risk of outlet strut fracture for Bjork-Shiley Convexo-Concave (BSCC) heart valves and new recommendations from an independent expert panel regarding prophylactic valve replacement. The recommendations are described in detail in the enclosed attachment.

Under the Settlement Agreement that was entered into by a worldwide class of BSCC heart valve patients and Shiley Incorporated and approved by the U S. District Court in Cincinnati, Ohio in Bowling v. Pfizer, an independent expert medical and scientific panel consisting of cardiothoracic surgeons, cardiologists, epidemiologists and a cardiovascular radiologist was created called the Supervisory Panel (Panel). Under the terms of the Settlement Agreement, the Panel is charged with the responsibilities of conducting studies and research, and of making recommendations regarding which BSCC heart valve patients should be considered for prophylactic valve replacement. The Panel's recommendations also serve to determine which class members qualify for explantation benefits under the Settlement Agreement. The Panel's work has enabled it to develop these 2003 Amended Guidelines for valve replacement surgery.

Recommendations Regarding Prophylactic Valve Replacement

In order for a Bowling class member to receive monetary benefits from the Bowling Patient Benefit Fund for prophylactic valve replacement, the valve replacement must meet the objective standards set forth in the 2003 Amended Guidelines Qualification under these objective standards does **not** mean that replacement surgery is appropriate for a particular patient, but only that monetary benefits under the Bowling settlement are available should the surgery take place due to the risk of strut fracture

The recommendations regarding prophylactic valve replacement require the calculation of patient-specific estimated annual fracture rates. The 2003 Amended Guidelines set forth a formula based upon current information that can be used to identify BSCC heart valve patients who may have a significantly greater risk of outlet strut fracture The Panel has identified eight risk factors in addition to the constant factor to be used in calculating estimated annual fracture rates for 60 degree BSCC heart valve patients' valve size, valve

The Panel's recommendations are based upon the best data available at the present time and are not meant to be absolute recommendations for individual patients. The final decision regarding explantation in an individual patient must be made by the patient in consultation with the treating cardiologist or cardiovascular surgeon, after careful examination and explanation of the available data

The Panel will soon send letters to BSCC heart valve patients to inform them that new information regarding their BSCC heart valve is available. In the letter, we recommend that patients contact their physicians to discuss this new information. **The Panel encourages you to obtain estimated annual fracture rates for your BSCC heart valve patients and to speak with them about this new information.** Also note that in the event that you or any of your patients disagree with the decision rendered regarding qualification for valve replacement surgery, please contact the Claims Administrator for information regarding an appropriate appeal process.

The Panel and the Trustees of the Bowling-Pfizer Heart Valve Settlement Funds have created a website to provide information to the Class Members and other interested individuals. The Website can be found on the internet at www.bowling-pfizer.com and is available for anyone to review at no cost. The Website provides basic information such as: the parties involved (addresses, telephone numbers, email, biographies, etc.), certain orders of the Court, the Panel's recommendations and Amended Guidelines, a copy of the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information. The Website continues to be updated as additional relevant information becomes available

If you have any questions about this letter or want to obtain an estimated annual fracture rate for a specific patient, please contact the Claims Administrator toll free at 800-977-0779. Someone will be available to answer questions between 9:00 a.m. and 5:00 p.m. Eastern Time, Monday through Friday. You can also contact the Claims Administrator by fax at 513-421-7696, or by mail at Claims Administrator, P.O. Box 3598, Cincinnati, Ohio 45201-3598.

Sincerely,

J. Kermit Smith
Chairman
Supervisory Panel
Bowling-Pfizer Settlement

Amended Guidelines To Assess Patients With

Bjork-Shiley Convexo-Concave Heart Valves

For Elective Explantation

Proposed by the Bowling-Pfizer Supervisory Panel

and

Adopted on July 9, 2003 by the

U.S. District Court, Southern District, Western Division

Cincinnati, Ohio

I. INTRODUCTION

Under the terms of a Settlement Agreement resolving Class Member claims in the *Bowling, et al. v. Pfizer Inc., et al.* heart valve litigation, financial benefits are made available to certain patients implanted with Bjork-Shiley Convexo-Concave (BSCC) heart valves, who undergo replacement surgery due to the risk of valve strut fracture. In accordance with the Settlement Agreement, an independent Supervisory Panel was appointed in May 1994 to develop and amend guidelines to be used to determine qualification for payment of benefits for qualifying valve replacement surgery.

In 1997, The Supervisory Panel adopted *Guidelines to Assess Patients with Bjork-Shiley Convexo-Concave Heart Valves for Elective Explantation*. These *Guidelines* were adopted after the Supervisory Panel had monitored a number of clinical studies, analyzed the worldwide database for BSCC valves, studied manufacturing records and undertaken extensive studies to understand the operative risk of elective explantation as it relates to age and cardiac functional ability. Expert cardiovascular surgeons, cardiologists, biostatisticians, epidemiologists and ethicists evaluated newly available data and formulated recommendations for the Supervisory Panel's *Guidelines*. The U.S. District Court approved these *Guidelines* in August 1997.

In 1999, based upon updated data from cohort studies and other updated data in the research database, the Supervisory Panel proposed amendments to the 1997 Guidelines, including adding gender as a risk factor. On March 8, 2000 the Supervisory Panel's proposed Amended Guidelines were adopted by the U.S. District Court (the 2000 Amended Guidelines).

The Supervisory Panel's research and work has continued and as a result, the Supervisory Panel has developed these *2003 Amended Guidelines* based on the best medical judgment of the Supervisory Panel.

Although these *2003 Amended Guidelines* will be used to establish qualification for compensation for elective replacement surgery, the *2003 Amended Guidelines* are not meant to imply that surgery is appropriate for individual patients. The final decision regarding explantation for a patient must be made by the patient in consultation with the managing cardiologist or cardiovascular surgeon, after careful examination and discussion of the individual patient's situation.

These *2003 Amended Guidelines* are based on the best estimates of the risks of fracture and reoperation from all data that are currently available. Standard statistical criteria were used to identify factors associated with increased risks of fracture and reoperative mortality. Each of the factors identified in these *2003 Amended Guidelines* have met those statistical criteria. However, because outlet strut fracture is a relatively rare event, and the worldwide data about reoperative mortality and morbidity for elective surgery are limited, there remains uncertainty in the risks of fracture and reoperative mortality. The *2003 Amended Guidelines* identify the subgroup of patients for whom on *average* reoperation will result in a gain in life expectancy. However, for some individual patients there can be a significant loss of life (if death results from reoperation) and for other patients there can be a significant gain (if a strut fracture is avoided by a successful operation). For many other patients who undergo reoperation there may well be no change in life expectancy even if they survive the reoperation because they may not have had an outlet strut fracture if the valve had been left in place. Accordingly, in interpreting the *2003 Amended Guidelines*, it is important to emphasize that the recommendations are based on a biostatistical analysis of group data, and that the risk for an individual patient may differ from those of the group.

We emphasize that these *2003 Amended Guidelines* will be continuously reviewed by the Supervisory Panel as new data become available. They will be modified when appropriate in accord with the best epidemiological, clinical and other relevant information made available to the Supervisory Panel.

II. QUALIFICATION FOR VALVE REPLACEMENT SURGERY BENEFITS

Provided below are the procedures for determining the qualification for monetary benefits from the *Bowling* settlement when surgery for explantation of a BSCC heart valve takes place due to the risk of strut fracture. Qualification is dependent upon the elective replacement of a BSCC heart valve reasonably offering a meaningful extension of life expectancy, because of elimination of the risk of valve outlet strut fracture (OSF), assuming the reoperative risk of a patient in optimal health status. Qualification under these *2003 Amended Guidelines* does <u>not</u> mean that replacement surgery is appropriate for a particular patient because it assumes that the patient is in optimal health status and that the surgery would take place at a significantly experienced facility. Qualification only means that monetary benefits are available upon surgery for explantation due to the risk of strut fracture.

The determination of qualification for monetary benefits requires estimation of the risk from OSF of the individual patient's BSCC valve as well as the risk an optimal patient would experience from the reoperative surgery. In order to determine the OSF rate, the responsible physician managing the patient will need to communicate the valve serial number, along with the current age, gender and valve implant position of the patient, to the Claims Administrator. This may be accomplished by telephone to 800-977-0779 in the United States or Canada or to 00-1-513-421-3517 internationally, by fax to 513-421-7696, or by mail to Claims Administrator, P.O. Box 3598, Cincinnati, Ohio 45201-3598, U.S.A.

From this information, the patient's estimated OSF rate may be calculated along with the determination as to whether an optimal patient with such an estimated OSF rate would be predicted to have a gain in life expectancy should explantation take place at a significantly experienced facility. If there is a predicted gain, the patient would qualify for monetary valve replacement surgery benefits.

"Optimal patient" means a patient whose health history and status present the optimal estimated risks of valve replacement surgery. See discussion on page 10 below.

The Supervisory Panel emphasizes that risk of valve fracture for the large majority of BSCC heart valve patients is not high enough to warrant explantation. Furthermore, not all patients who qualify for monetary benefits are in optimal health and good candidates for reoperation. Considerations which should be addressed by the patient and physician before deciding on the advisability of replacement surgery are provided in Part IV.

The procedures to be followed for determination of qualification to receive monetary valve replacement surgery benefits when surgery for explantation of a BSCC heart valve takes place due to the risk of strut fracture for three categories of patients with BSCC heart valves are summarized below.

1. Patients with single or multiple BSCC valves with known serial number(s).

Step One: The responsible physician managing the patient will communicate to the *Bowling* Claims Administrator the patient's age, gender, valve serial number and valve implant position.

Step Two: The patient's estimated OSF rate (expressed as the per cent chance that the valve will fracture in the next year) will be calculated by the Claims Administrator using the formula and methods described in Part III. For patients with multiple valves, the patient's OSF rate will be calculated by summing the OSF rates for each valve.

Step Three: Determinations of life expectancy take into account both the estimated OSF rates and the estimated risks of death or serious morbidity from reoperation for replacement of BSCC valves for optimal patients. If the estimated OSF rate is greater than the threshold rate listed in Part V, Table 5 or Part V, Table 6 for single or multiple valve patients, respectively, then the patient would qualify for valve replacement surgery benefits.

2. Patients with BSCC mitral valves with unknown serial numbers.

Step One: The responsible physician managing the patient will communicate to the *Bowling* Claims Administrator the patient's age, gender, and documentation that the patient has a 29, 31 or 33 mm BSCC mitral valve implanted prior to April 1984. Proof of the characteristics of the valve may be made by x-ray, fluoroscopy or transesophageal echocardiography.

Step Two: If the patient is currently under age 35 and has a 29, 31 or 33 mm mitral BSCC valve implanted prior to April 1984, the patient would qualify for valve replacement surgery benefits.

3. Patients with documented single leg separation (SLS).

Step One: The responsible physician managing the patient will communicate to the Bowling Claims Administrator clear evidence of single leg separation of the patient's BSCC valve, as documented by x-ray images definitively showing offset of one of the valve's two outlet strut legs (equivalent to a class 5 designation in previously reported imaging studies).

Step Two: If SLS is documented, the patient would qualify for valve replacement surgery benefits.

In addition to the foregoing three qualification categories, the Supervisory Panel determined that surgery to explant, due to the risk of strut fracture, a Class Member's BSCC heart valve that would comply with the 2000 Amended Guidelines would qualify the patient for the valve replacement surgery benefits. The Panel

concluded that it would be inappropriate to exclude those Class Members who may qualify under the 2000 Amended Guidelines but not under the *2003 Amended Guidelines*.

III. METHODS FOR DETERMINING QUALIFICATION FOR VALVE REPLACEMENT SURGERY BENEFITS

The Supervisory Panel developed the *2003 Amended Guidelines* from detailed reviews of the relevant clinical and epidemiologic data concerning risks of outlet strut fracture vs. risks from reoperations to replace BSCC heart valves. In all instances, the expert medical judgment of physicians, including those who are daily managing patients with complex cardiovascular conditions, was the final arbiter for these *2003 Amended Guidelines* as opposed to concerns about financial benefits provided to patients.

If the estimated risk from reoperation to replace the BSCC valve is such that a predicted gain in life expectancy in an optimal patient results, then the patient (regardless of his or her health status) qualifies for benefits when surgery for explantation takes place due to the risk of strut fracture. Methods used to determine estimated risks of valve fracture and estimated risks from reoperative surgery are described below.

A. METHODS FOR ESTIMATING OSF RISK

Information on the worldwide experience of OSF among BSCC heart valve patients was used to determine the characteristics of patients and their valves which are associated with increased rates of OSF. Data were obtained from a worldwide research database containing information on nearly 86,000 BSCC valves and from epidemiologic studies of nearly 20,000 BSCC patients in Europe and the United States specifically designed to measure rates of OSF according to valve size,

position, and other manufacturing characteristics and according to age, gender and other patient characteristics. Using the latest available worldwide data, statistical analyses were applied to determine which factors were significant predictors of increased risk of OSF and to estimate relative risk multipliers of OSF associated with each factor. The risk multipliers represent the extent to which the presence or level of the factor increases the risk of OSF.

Part V, Table 1 lists the factors, namely valve size, position, date of manufacture, welder, shoporder and rework status and patient age and sex, determined to significantly influence risk of fracture of BSCC 60 degree valves. From the information in Part V, Table 1 it is possible to calculate, for each individual with a known BSCC 60 degree valve serial number, the estimated rate (in per cent per year) of fracture for his or her valve. The Claims Administrator will use a formula, which applies the risk multipliers corresponding to the patient's valve characteristics and his or her gender and current age, to calculate the predicted probability (percent) that the valve will fracture within one year from the date of calculation. The constant factor (0.094) is the fracture rate (% per year) for a 35 year old patient all of whose factors in Part V, Table 1 are equal to 1. This constant factor (0.094) has been adjusted for underreporting of fractures.

Part V, Table 2 illustrates the calculation of an OSF rate for a hypothetical 50 year old male patient with a size 29 mm BSCC 60 degree mitral valve implanted in the mitral position, welded in 1983 by Welder Group AB, in a shop order in which 3% of the other valves have fractured, and not reworked. In order to obtain the manufacturing data necessary to apply the calculations, the serial number for the valve must be known. The implanted valve position is also needed. As noted above, once this information is communicated to the Claims Administrator, this calculation will be made and transmitted in response to the physician managing the patient.

Part V, Table 3 presents the factors utilized in calculating potential OSF rates for 70 degree BSCC valves. The constant factor (0.79) is the fracture rate (% per year) for a 35 year old patient all of whose factors in Part V, Table 3 are equal to 1. This constant factor (0.79) has been adjusted for underreporting of fractures.

B. METHODS FOR ESTIMATING REOPERATIVE RISK

Part V, Table 4 provides estimates of the risk of mortality and serious morbidity from elective explantation among patients of various ages in optimal health status with single or multiple BSCC valves. The percentages in Part V, Table 4 represent the Supervisory Panel's best medical judgment of reoperative risks after review of clinical and epidemiologic studies of hospital mortality and serious morbidity following operations to replace prosthetic heart valves. Included in the review were surveys of reoperative risks in relatively large series of prosthetic heart valve patients of NYHA class I and II without cardiac co-morbidity, i.e., optimal or close to optimal patients. The collective data suggest the estimated operative risk (mortality and serious morbidity) of an optimal patient with a single BSCC valve at a significantly experienced facility averages approximately 6% at an approximate age of 58, with lower risks at younger and higher risks at older ages. The values in Part V, Table 4 were determined by setting the reoperative risk at age 58 at 6%, with the reoperative risks at younger and older ages estimated from the risk-age relationship observed in a large series of over 2,000 prosthetic heart valve reoperations in the United States.

The risk from reoperation was considered to consist of two components: risk of death and risk of serious morbidity such as permanent neurologic deficit, renal failure or myocardial infarction. Based on the most recent data, the reoperative mortality for an optimal patient at a significantly experienced facility was estimated to be approximately 3% on the average at age 58. In addition, current data in the same patient studies indicate that serious permanent morbidity from reoperation approximately doubles the risk to an individual patient, so that the overall reoperative risk at age 58 is approximately 6%.

The Supervisory Panel noted that the observed rate of mortality only within 90 days of surgery among a group of 135 BSCC patients known to have undergone prophylactic replacement of their BSCC valves was 6.7% (with the rate varying with age from approximately 2% at ages below 50 to over 10% at ages above 70), but not all of these patients were optimal patients.

C. METHODS FOR COMPARING RISKS OF OSF AND REOPERATION: LIFE EXPECTANCY DETERMINATIONS

Qualification for receipt of valve replacement surgery monetary benefits is determined by comparison of predicted future life expectancies under scenarios where reoperation to replace the BSCC valve does or does not take place. Life expectancies can be calculated taking into account the patient's current OSF rate Part V, Tables 1-3, his or her future OSF rate (the annual OSF rate for successive years is 0.941 times the OSF rate in the preceding year), the reoperative risk for the optimal patient Part V, Table 4, and the patient's future underlying total mortality rate. Observed overall mortality rates during 1990-1997 from epidemiologic cohort studies of Dutch, British and American BSCC heart valve patients were used to predict future underlying mortality according to age, sex and valve position.

Part V, Table 5 presents threshold values of estimated current OSF rates (in per cent per year) according to age, sex and valve position for persons with a single BSCC valve. If the patient's estimated OSF rate (as calculated in Part V, Tables 1-3) exceeds the threshold value for the patient's current age, then (if the patient were in optimal health) the reoperation would be predicted to result in a gain in life expectancy and the patient would qualify for monetary benefits when surgery for explantation takes place due to the risk of strut fracture. If the estimated OSF rate is below the threshold, then the reoperation would be predicted to result in a loss in life expectancy, and the patient would not qualify for valve replacement surgery benefits.

Part V, Table 6 presents threshold values for patients with both an aortic and a mitral valve. For these patients, if the sum of the estimated OSF rates for the patient's two valves exceeds the threshold value for the patient's current age (rounded to the nearest 5 years), there would be predicted to be a gain in life expectancy from reoperation (if the patient was an optimal patient) and the double-valve patient would qualify for monetary benefits when surgery for explantation takes place due to the risk of strut fracture. These thresholds are higher than for single valve patients because of the higher reoperative risks for double-valve patients. Note that this increased mortality pertains even if only one valve is to be replaced.

IV. ADDITIONAL INFORMATION REGARDING EXPLANTATION

Even if a patient qualifies for monetary valve replacement surgery benefits from the *Bowling* Settlement, the Supervisory Panel provides the following information about other considerations to be discussed between the patient and physician before undertaking reoperation to replace the BSCC valve. Some considerations to assist in these deliberations are outlined below, but in all cases it is the patient and his or her physician who must decide on the advisability of valve explantation.

Part II of these *2003 Amended Guidelines* describes the method for identifying patients who qualify for monetary valve replacement surgery benefits under the terms of the *Bowling* settlement. The criteria for qualification for monetary benefits are based on a comparison of the risk of valve fracture vs. the risk of reoperation. For the purposes of defining operative risk, the Supervisory Panel assumed that surgery is to be performed on an "optimal" patient at a "significantly experienced" facility. Estimation of risk also assumed that the surgery is elective and the procedure only involves replacement of one or more BSCC valves. In practice one or more of these assumptions may often be violated with the result that the actual operative risk for an individual patient may exceed that used to calculate monetary benefits. In these cases surgery can result in a net <u>loss</u> of life expectancy and would not be medically indicated despite the fact that it would qualify for financial benefits.

The criteria used to establish risk based on each of these four assumptions (optimal patient, significantly experienced facility, elective surgery, and isolated explantation) and examples of situations in which these criteria may not be valid are listed below.

A. OPTIMAL PATIENT

In establishing reoperative risk the Supervisory Panel utilized the predicted risk for a patient in New York Heart association functional class I or class II, with no associated cardiovascular (coronary artery disease, depressed LV function, myopathy, significant arrythmia, or associated valvular or congenital heart disease), neurologic, pulmonary, renal, hepatic or other systemic disease likely to increase surgical mortality or morbidity. The risk for reoperation is greater for patients in non-optimal health as opposed to optimal health. While many factors need to be considered by the patient and physician in deciding whether to reoperate, the increased reoperative risk for some non-optimal patients may be such that a gain in life expectancy would be unlikely and therefore explantation not medically justified. Risk, for example, is more than double compared to the optimal patient in cases with moderate left ventricular dysfunction (NYHA Class III), chronic renal failure and important tricuspid insufficiency.

There have been no reported fractures in BSCC valve conduits. The operative risk in these patients is 4.5 times higher than an optimal patient. Thus none of these patients qualify for valve replacement surgery benefits and should not undergo explantation.

B. SIGNIFICANTLY EXPERIENCED FACILITY

Although it is not possible to rank specific surgical facilities, a significantly experienced facility was considered to be one with a national or international reputation for cardiac surgery, a large surgical volume (>1000 cases per year) and

extensive experience in prosthetic valve explantation surgery. The Supervisory Panel strongly advises patients undergoing prophylactic valve removal to consult with their physicians to obtain advice on referral to centers with greater experience and overall excellence in reoperative valve procedures since such centers can be presumed to have the lowest surgical mortality.

C. ELECTIVE SURGERY

Risk estimates in Part II are based on elective surgery under ideal circumstances. Surgery in patients with infective endocarditis, hemodynamic instability, or prosthetic valve malfunction is not elective and is associated with higher surgical risk. Decisions in these cases must be based on medical necessity.

D. SURGERY IS PERFORMED FOR THE SOLE PURPOSE OF REMOVING ONE OR MORE BSCC PROSTHETIC VALVES

The surgical risk estimates described in Part II are based on data for elective explantation and replacement of a single or multiple prosthetic valves as an isolated procedure. In patients with multiple prior cardiac surgical procedures, those in whom additional valve surgery is anticipated in addition to replacement of their BSCC valve, and those with coexisting coronary artery disease requiring concomitant by-pass surgery the reoperative risk is increased by 40 to 80%.

Based on the above assumptions, data from literature suggests an operative mortality of approximately 3% for an optimal patient at an approximate age of 58, (See Part III). However, the actual mortality rate among a group of 135 BSCC patients known to have undergone prophylactic replacement of their BSCC valves was 6.7%. This suggests that not all patients were optimal patients.

The Supervisory Panel therefore advises that the decision reached by the patient and physician on whether to actually undergo replacement surgery (irrespective of qualification for monetary benefits) take into account the patient's actual health status (since many patients with prosthetic heart valves do not meet the criteria for optimal health) and the risk associated with the type of procedure to be performed.

E. GENERAL RECOMMENDATIONS FOR ALL BSCC PATIENTS

All patients with BSCC valves should regularly consult their physicians and should have a clear understanding of the symptoms which occur at the time of OSF. These should be made known to those relatives or friends in contact with the patient. These patients should also be made aware of the nearest center with significant experience in cardiovascular surgery, since early recognition and prompt surgical intervention may be lifesaving for the small percentage of BSCC valve recipients who actually experience OSF.

V. STATISTICAL TABLES

Table 1. Factors for Calculation of Rates of OSF (% per year) of BSCC 60 Degree Valves

Factor	Subgroup	Multiplier
Constant [1]	All	0.094
Size (mm)	21 or 25	1.00
	23 or 27	2.84
	29	3.99
	31	5.51
	33	9.60
Position	Aortic	1.00
	Mitral	2.51
Weld date	<1980, 7/82-3/84	1.00
	1980	0.48
	1/81-6/82	1.64
	> 4/84	0.00
Welder Group	AB	1.00
	C	1.51
Shop Order Rate [2]	<1.0%	1.00
	1.0-5.0%	1.88
	>5.0%	2.35
Current Age	<35	1.00
	>35	$(.941)^{(Age - 35)}$
Gender	Male	1.00
	Female	0.46
Rework	No crack or rework	1.00
	Crack, rework, missing	1.57

[1] Corresponds to the OSF rate for an individual whose factors are all equal to 1

[2] The percent of other valves in the same shop order which have fractured

Table 2.

Formula for and Example of Calculation of the Estimated OSF Rate (% per Year) for a Particular Patient with a BSCC 60° Valve

Estimated OSF Rate=Constant x Size x Position x Weld date x Welder group x Shop order rate x Current age x Gender x Rework status

Example for hypothetical 50 year old male with size 29 mm mitral valve implanted in the mitral position welded in 1983 by welder group AB in a shop order where the OSF rate of other valves is 3% and the valve has not been reworked:

Estimated OSF Rate =

Constant	0.094
Size	x 3.99
Position	x 2.51
Weld date	x 1.00
Welder group	x 1.00
Shop order rate	x 1.88
Current age	x $(.941)^{50-35}$ =0.40
Gender	x 1.00
Rework	x 1.00
	= 0.70 % per year

Table 3. Factors for Calculation of Rates of OSF (% per year) **of BSCC 70 Degree Valves**

Factor	Subgroup	Risk Multiplier
Constant [1]	All	0.79
Size (mm)	21 or 25	1.00
	23 or 27	1.40
	29	2.13
	31 or 33	3.22
Position	Aortic	1.00
	Mitral	1.81
Welder Group	D	1.00
	E	2.29
Shop Order Rate [2]	<1.0%	1.00
	1.0-5.0%	2.46
	>5.0%	2.72
Current Age	<35	1.00
	>35	$(.941)^{(Age - 35)}$
Gender	Male	1.00
	Female	0.46
Rework	No Crack or Rework	1.00
	Crack, Rework or Missing	1.71

[1] Corresponds to the OSF rate for an individual whose factors are all equal to 1

[2] The percent of other valves in the same shop order which have fractured

Table 4. Estimated Risks of Death or Serious Morbidity from Reoperation for Replacement of BSCC valves for the Optimal Patient According to Age and Single and multiple valve status

	Reoperative Risk (%)	
Age	Single Valve	Multiple Valve
35	3.6	5.8
40	3.9	6.3
45	4.3	7.0
50	4.9	7.8
55	5.5	8.9
60	6.4	10.1
65	7.4	11.7
70	8.7	13.6
75	10.2	16.0
80	12.2	18.8

Table 5. Outlet strut fracture rates (per cent per year), by age, gender and valve position, above which the patient with a single BSCC valve will qualify for valve replacement surgery benefits

	Male		Female	
Age	Aortic	Mitral	Aortic	Mitral
30	0.26	0.27	0.25	0.26
35	0.37	0.39	0.36	0.38
40	0.43	0.46	0.42	0.44
45	0.51	0.54	0.49	0.52
50	0.61	0.66	0.58	0.62
55	0.75	0.81	0.71	0.76
60	0.94	1.02	0.89	0.96
65	1.20	1.31	1.12	1.22
70	1.57	1.72	1.45	1.59
75	2.08	2.30	1.92	2.11
80	2.81	3.14	2.59	2.87

Table 6. Outlet strut fracture rates (per cent per year), by age and gender, above which the patient with multiple BSCC valves will qualify for valve replacement surgery benefits

Age	Male	Female
30	0.45	0.43
35	0.65	0.62
40	0.75	0.72
45	0.89	0.85
50	1.08	1 02
55	1.33	1.25
60	1.68	1.57
65	2.15	2.00
70	2 81	2.60
75	3.75	3.44
80	5.10	4.65

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

525 VINE STREET, SUITE 2300 – CINCINNATI, OHIO 45202-3124
TELEPHONE 513/421-4115 OR 800/977-0779 FAX 513/421-7696

October 2003

IMPORTANT

NOTICE OF 2003 AMENDED GUIDELINES

Dear Bowling Class Member:

As Chairman of the court-appointed Supervisory Panel (Panel) in the BSCC heart valve class action settlement (Bowling v. Pfizer), I am writing to provide Bjork-Shiley Convexo-Concave (BSCC) heart valve implantees like you with important new information about your heart valve. The Panel has developed new findings about the risk of strut fracture and 2003 Amended Guidelines regarding the medical care of BSCC heart valve patients. These 2003 Amended Guidelines also determine when surgery to replace a BSCC heart valve will qualify for benefits under the Bowling settlement agreement.

The 2003 Amended Guidelines include manufacturing rework status as a new risk factor for calculation of estimated annual fracture rates for BSCC heart valve patients. The rework factor describes any special manufacturing operations that were carried out on the valve concerning polishing a crack or rewelding a valve. The data were provided in the BSCC worldwide database and was based on a review of baggie cards. Based upon statistical analyses, the rework factor in the proposed new guidelines classifies valve into two categories. The first category refers to those valves for which there was no indication on the baggie card of either a crack or rewelding operation. The second classification refers to all valves that had either an indication of a crack-polishing or rewelding operation. There were some valves for which the data provided in the research database was incomplete and the classification could not be determined. These valves with incomplete documentation of the manufacturing process were first considered separately in the analysis, but because it was found that the fracture rates of these valves were similar to valves in the second classification (evidence of crack or rewelding), ultimately all of these valves were grouped together.

In brief, based upon the Panel's findings, the Panel has developed more precise estimates of annual rates of outlet strut fracture. The Panel has also issued 2003 Amended Guidelines that recommend changes in the medical care of some BSCC heart valve patients. For the vast majority of patients, the 2003 Amended Guidelines will not change their medical care in any way. A copy of the 2003 Amended Guidelines is attached.

Replacement surgery benefits are also available for surgery to explant a BSCC heart valve due to the risk of strut fracture, if the surgery complies with the 2000 Amended Guidelines.

The Panel has already sent this new information to doctors. Please contact your doctor to discuss this new information, so that together you can make informed decisions about your medical care If your doctor did not receive this new information, please have your doctor contact the Claims Administrator at the number provided below.

Again, I strongly urge you to contact your doctor to discuss whether there should be any changes in your medical care.

The Panel and the Trustees of the Bowling-Pfizer Heart Valve Settlement Funds have created a website to provide information to the Class Members and other interested individuals. The Website can be found on the internet at www.bowling-pfizer.com and is available for anyone to review at no cost. The Website provides basic information such as: the parties involved (addresses, telephone numbers, email, biographies, etc), certain orders of the Court, the Panel's recommendations and Amended Guidelines, a copy of the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information The Website continues to be updated as additional relevant information becomes available.

We also want to take this opportunity to provide you additional information which appears in two additional attachments to this letter. One attachment provides simple precautions that BSCC heart valve patients may find helpful. The other attachment provides updated information regarding the work of the Panel.

If you have any questions about the information contained in this letter, you can contact the Settlement Claims Administrator toll free by telephone at 800-977-0779. Someone will be available to answer questions between 9:00 a.m. and 5:00 p.m. Eastern Time, Monday through Friday. You can also contact the Claims Administrator by fax at 513-421-7696, or by mail at Claims Administrator, P.O. Box 3598, Cincinnati, Ohio 45201-3598.

Sincerely,

J. Kermit Smith
Chairman
Supervisory Panel
Bowling-Pfizer Settlement

Amended Guidelines To Assess Patients With

Bjork-Shiley Convexo-Concave Heart Valves

For Elective Explantation

Proposed by the Bowling-Pfizer Supervisory Panel

and

Adopted on July 9, 2003 by the

U.S. District Court, Southern District, Western Division

Cincinnati, Ohio

I. INTRODUCTION

Under the terms of a Settlement Agreement resolving Class Member claims in the *Bowling, et al. v. Pfizer Inc., et al.* heart valve litigation, financial benefits are made available to certain patients implanted with Bjork-Shiley Convexo-Concave (BSCC) heart valves, who undergo replacement surgery due to the risk of valve strut fracture. In accordance with the Settlement Agreement, an independent Supervisory Panel was appointed in May 1994 to develop and amend guidelines to be used to determine qualification for payment of benefits for qualifying valve replacement surgery.

In 1997, The Supervisory Panel adopted *Guidelines to Assess Patients with Bjork-Shiley Convexo-Concave Heart Valves for Elective Explantation*. These *Guidelines* were adopted after the Supervisory Panel had monitored a number of clinical studies, analyzed the worldwide database for BSCC valves, studied manufacturing records and undertaken extensive studies to understand the operative risk of elective explantation as it relates to age and cardiac functional ability. Expert cardiovascular surgeons, cardiologists, biostatisticians, epidemiologists and ethicists evaluated newly available data and formulated recommendations for the Supervisory Panel's *Guidelines*. The U.S. District Court approved these *Guidelines* in August 1997.

In 1999, based upon updated data from cohort studies and other updated data in the research database, the Supervisory Panel proposed amendments to the 1997 Guidelines, including adding gender as a risk factor. On March 8, 2000 the Supervisory Panel's proposed Amended Guidelines were adopted by the U.S. District Court (the 2000 Amended Guidelines).

The Supervisory Panel's research and work has continued and as a result, the Supervisory Panel has developed these *2003 Amended Guidelines* based on the best medical judgment of the Supervisory Panel.

Although these *2003 Amended Guidelines* will be used to establish qualification for compensation for elective replacement surgery, the *2003 Amended Guidelines* are not meant to imply that surgery is appropriate for individual patients. The final decision regarding explantation for a patient must be made by the patient in consultation with the managing cardiologist or cardiovascular surgeon, after careful examination and discussion of the individual patient's situation.

These *2003 Amended Guidelines* are based on the best estimates of the risks of fracture and reoperation from all data that are currently available. Standard statistical criteria were used to identify factors associated with increased risks of fracture and reoperative mortality. Each of the factors identified in these *2003 Amended Guidelines* have met those statistical criteria. However, because outlet strut fracture is a relatively rare event, and the worldwide data about reoperative mortality and morbidity for elective surgery are limited, there remains uncertainty in the risks of fracture and reoperative mortality. The *2003 Amended Guidelines* identify the subgroup of patients for whom on *average* reoperation will result in a gain in life expectancy. However, for some individual patients there can be a significant loss of life (if death results from reoperation) and for other patients there can be a significant gain (if a strut fracture is avoided by a successful operation). For many other patients who undergo reoperation there may well be no change in life expectancy even if they survive the reoperation because they may not have had an outlet strut fracture if the valve had been left in place. Accordingly, in interpreting the *2003 Amended Guidelines*, it is important to emphasize that the recommendations are based on a biostatistical analysis of group data, and that the risk for an individual patient may differ from those of the group.

We emphasize that these *2003 Amended Guidelines* will be continuously reviewed by the Supervisory Panel as new data become available. They will be modified when appropriate in accord with the best epidemiological, clinical and other relevant information made available to the Supervisory Panel.

II. QUALIFICATION FOR VALVE REPLACEMENT SURGERY BENEFITS

Provided below are the procedures for determining the qualification for monetary benefits from the *Bowling* settlement when surgery for explantation of a BSCC heart valve takes place due to the risk of strut fracture. Qualification is dependent upon the elective replacement of a BSCC heart valve reasonably offering a meaningful extension of life expectancy, because of elimination of the risk of valve outlet strut fracture (OSF), assuming the reoperative risk of a patient in optimal health status. Qualification under these *2003 Amended Guidelines* does not mean that replacement surgery is appropriate for a particular patient because it assumes that the patient is in optimal health status and that the surgery would take place at a significantly experienced facility. Qualification only means that monetary benefits are available upon surgery for explantation due to the risk of strut fracture.

The determination of qualification for monetary benefits requires estimation of the risk from OSF of the individual patient's BSCC valve as well as the risk an optimal patient would experience from the reoperative surgery. In order to determine the OSF rate, the responsible physician managing the patient will need to communicate the valve serial number, along with the current age, gender and valve implant position of the patient, to the Claims Administrator. This may be accomplished by telephone to 800-977-0779 in the United States or Canada or to 00-1-513-421-3517 internationally, by fax to 513-421-7696, or by mail to Claims Administrator, P.O. Box 3598, Cincinnati, Ohio 45201-3598, U.S.A.

From this information, the patient's estimated OSF rate may be calculated along with the determination as to whether an optimal patient with such an estimated OSF rate would be predicted to have a gain in life expectancy should explantation take place at a significantly experienced facility. If there is a predicted gain, the patient would qualify for monetary valve replacement surgery benefits.

"Optimal patient" means a patient whose health history and status present the optimal estimated risks of valve replacement surgery. See discussion on page 10 below.

The Supervisory Panel emphasizes that risk of valve fracture for the large majority of BSCC heart valve patients is not high enough to warrant explantation. Furthermore, not all patients who qualify for monetary benefits are in optimal health and good candidates for reoperation. Considerations which should be addressed by the patient and physician before deciding on the advisability of replacement surgery are provided in Part IV.

The procedures to be followed for determination of qualification to receive monetary valve replacement surgery benefits when surgery for explantation of a BSCC heart valve takes place due to the risk of strut fracture for three categories of patients with BSCC heart valves are summarized below.

1. Patients with single or multiple BSCC valves with known serial number(s).

Step One: The responsible physician managing the patient will communicate to the *Bowling* Claims Administrator the patient's age, gender, valve serial number and valve implant position.

Step Two: The patient's estimated OSF rate (expressed as the per cent chance that the valve will fracture in the next year) will be calculated by the Claims Administrator using the formula and methods described in Part III. For patients with multiple valves, the patient's OSF rate will be calculated by summing the OSF rates for each valve.

Step Three: Determinations of life expectancy take into account both the estimated OSF rates and the estimated risks of death or serious morbidity from reoperation for replacement of BSCC valves for optimal patients. If the estimated OSF rate is greater than the threshold rate listed in Part V, Table 5 or Part V, Table 6 for single or multiple valve patients, respectively, then the patient would qualify for valve replacement surgery benefits.

2. Patients with BSCC mitral valves with unknown serial numbers.

Step One: The responsible physician managing the patient will communicate to the *Bowling* Claims Administrator the patient's age, gender, and documentation that the patient has a 29, 31 or 33 mm BSCC mitral valve implanted prior to April 1984. Proof of the characteristics of the valve may be made by x-ray, fluoroscopy or transesophageal echocardiography.

Step Two: If the patient is currently under age 35 and has a 29, 31 or 33 mm mitral BSCC valve implanted prior to April 1984, the patient would qualify for valve replacement surgery benefits.

3. Patients with documented single leg separation (SLS).

Step One: The responsible physician managing the patient will communicate to the Bowling Claims Administrator clear evidence of single leg separation of the patient's BSCC valve, as documented by x-ray images definitively showing offset of one of the valve's two outlet strut legs (equivalent to a class 5 designation in previously reported imaging studies).

Step Two: If SLS is documented, the patient would qualify for valve replacement surgery benefits.

In addition to the foregoing three qualification categories, the Supervisory Panel determined that surgery to explant, due to the risk of strut fracture, a Class Member's BSCC heart valve that would comply with the 2000 Amended Guidelines would qualify the patient for the valve replacement surgery benefits. The Panel

concluded that it would be inappropriate to exclude those Class Members who may qualify under the 2000 Amended Guidelines but not under the *2003 Amended Guidelines*.

III. METHODS FOR DETERMINING QUALIFICATION FOR VALVE REPLACEMENT SURGERY BENEFITS

The Supervisory Panel developed the *2003 Amended Guidelines* from detailed reviews of the relevant clinical and epidemiologic data concerning risks of outlet strut fracture vs. risks from reoperations to replace BSCC heart valves. In all instances, the expert medical judgment of physicians, including those who are daily managing patients with complex cardiovascular conditions, was the final arbiter for these *2003 Amended Guidelines* as opposed to concerns about financial benefits provided to patients.

If the estimated risk from reoperation to replace the BSCC valve is such that a predicted gain in life expectancy in an optimal patient results, then the patient (regardless of his or her health status) qualifies for benefits when surgery for explantation takes place due to the risk of strut fracture. Methods used to determine estimated risks of valve fracture and estimated risks from reoperative surgery are described below.

A. METHODS FOR ESTIMATING OSF RISK

Information on the worldwide experience of OSF among BSCC heart valve patients was used to determine the characteristics of patients and their valves which are associated with increased rates of OSF. Data were obtained from a worldwide research database containing information on nearly 86,000 BSCC valves and from epidemiologic studies of nearly 20,000 BSCC patients in Europe and the United States specifically designed to measure rates of OSF according to valve size,

position, and other manufacturing characteristics and according to age, gender and other patient characteristics. Using the latest available worldwide data, statistical analyses were applied to determine which factors were significant predictors of increased risk of OSF and to estimate relative risk multipliers of OSF associated with each factor. The risk multipliers represent the extent to which the presence or level of the factor increases the risk of OSF.

Part V, Table 1 lists the factors, namely valve size, position, date of manufacture, welder, shoporder and rework status and patient age and sex, determined to significantly influence risk of fracture of BSCC 60 degree valves. From the information in Part V, Table 1 it is possible to calculate, for each individual with a known BSCC 60 degree valve serial number, the estimated rate (in per cent per year) of fracture for his or her valve. The Claims Administrator will use a formula, which applies the risk multipliers corresponding to the patient's valve characteristics and his or her gender and current age, to calculate the predicted probability (percent) that the valve will fracture within one year from the date of calculation. The constant factor (0.094) is the fracture rate (% per year) for a 35 year old patient all of whose factors in Part V, Table 1 are equal to 1. This constant factor (0.094) has been adjusted for underreporting of fractures.

Part V, Table 2 illustrates the calculation of an OSF rate for a hypothetical 50 year old male patient with a size 29 mm BSCC 60 degree mitral valve implanted in the mitral position, welded in 1983 by Welder Group AB, in a shop order in which 3% of the other valves have fractured, and not reworked. In order to obtain the manufacturing data necessary to apply the calculations, the serial number for the valve must be known. The implanted valve position is also needed. As noted above, once this information is communicated to the Claims Administrator, this calculation will be made and transmitted in response to the physician managing the patient.

Part V, Table 3 presents the factors utilized in calculating potential OSF rates for 70 degree BSCC valves. The constant factor (0.79) is the fracture rate (% per year) for a 35 year old patient all of whose factors in Part V, Table 3 are equal to 1. This constant factor (0.79) has been adjusted for underreporting of fractures.

B. METHODS FOR ESTIMATING REOPERATIVE RISK

Part V, Table 4 provides estimates of the risk of mortality and serious morbidity from elective explantation among patients of various ages in optimal health status with single or multiple BSCC valves. The percentages in Part V, Table 4 represent the Supervisory Panel's best medical judgment of reoperative risks after review of clinical and epidemiologic studies of hospital mortality and serious morbidity following operations to replace prosthetic heart valves. Included in the review were surveys of reoperative risks in relatively large series of prosthetic heart valve patients of NYHA class I and II without cardiac co-morbidity, i.e., optimal or close to optimal patients. The collective data suggest the estimated operative risk (mortality and serious morbidity) of an optimal patient with a single BSCC valve at a significantly experienced facility averages approximately 6% at an approximate age of 58, with lower risks at younger and higher risks at older ages. The values in Part V, Table 4 were determined by setting the reoperative risk at age 58 at 6%, with the reoperative risks at younger and older ages estimated from the risk-age relationship observed in a large series of over 2,000 prosthetic heart valve reoperations in the United States.

The risk from reoperation was considered to consist of two components: risk of death and risk of serious morbidity such as permanent neurologic deficit, renal failure or myocardial infarction. Based on the most recent data, the reoperative mortality for an optimal patient at a significantly experienced facility was estimated to be approximately 3% on the average at age 58. In addition, current data in the same patient studies indicate that serious permanent morbidity from reoperation approximately doubles the risk to an individual patient, so that the overall reoperative risk at age 58 is approximately 6%.

The Supervisory Panel noted that the observed rate of mortality only within 90 days of surgery among a group of 135 BSCC patients known to have undergone prophylactic replacement of their BSCC valves was 6.7% (with the rate varying with age from approximately 2% at ages below 50 to over 10% at ages above 70), but not all of these patients were optimal patients.

C. METHODS FOR COMPARING RISKS OF OSF AND REOPERATION: LIFE EXPECTANCY DETERMINATIONS

Qualification for receipt of valve replacement surgery monetary benefits is determined by comparison of predicted future life expectancies under scenarios where reoperation to replace the BSCC valve does or does not take place. Life expectancies can be calculated taking into account the patient's current OSF rate Part V, Tables 1-3, his or her future OSF rate (the annual OSF rate for successive years is 0.941 times the OSF rate in the preceding year), the reoperative risk for the optimal patient Part V, Table 4, and the patient's future underlying total mortality rate. Observed overall mortality rates during 1990-1997 from epidemiologic cohort studies of Dutch, British and American BSCC heart valve patients were used to predict future underlying mortality according to age, sex and valve position.

Part V, Table 5 presents threshold values of estimated current OSF rates (in per cent per year) according to age, sex and valve position for persons with a single BSCC valve. If the patient's estimated OSF rate (as calculated in Part V, Tables 1-3) exceeds the threshold value for the patient's current age, then (if the patient were in optimal health) the reoperation would be predicted to result in a gain in life expectancy and the patient would qualify for monetary benefits when surgery for explantation takes place due to the risk of strut fracture. If the estimated OSF rate is below the threshold, then the reoperation would be predicted to result in a loss in life expectancy, and the patient would not qualify for valve replacement surgery benefits.

Part V, Table 6 presents threshold values for patients with both an aortic and a mitral valve. For these patients, if the sum of the estimated OSF rates for the patient's two valves exceeds the threshold value for the patient's current age (rounded to the nearest 5 years), there would be predicted to be a gain in life expectancy from reoperation (if the patient was an optimal patient) and the double-valve patient would qualify for monetary benefits when surgery for explantation takes place due to the risk of strut fracture. These thresholds are higher than for single valve patients because of the higher reoperative risks for double-valve patients. Note that this increased mortality pertains even if only one valve is to be replaced.

IV. ADDITIONAL INFORMATION REGARDING EXPLANTATION

Even if a patient qualifies for monetary valve replacement surgery benefits from the *Bowling* Settlement, the Supervisory Panel provides the following information about other considerations to be discussed between the patient and physician before undertaking reoperation to replace the BSCC valve. Some considerations to assist in these deliberations are outlined below, but in all cases it is the patient and his or her physician who must decide on the advisability of valve explantation.

Part II of these *2003 Amended Guidelines* describes the method for identifying patients who qualify for monetary valve replacement surgery benefits under the terms of the *Bowling* settlement. The criteria for qualification for monetary benefits are based on a comparison of the risk of valve fracture vs. the risk of reoperation. For the purposes of defining operative risk, the Supervisory Panel assumed that surgery is to be performed on an "optimal" patient at a "significantly experienced" facility. Estimation of risk also assumed that the surgery is elective and the procedure only involves replacement of one or more BSCC valves. In practice one or more of these assumptions may often be violated with the result that the actual operative risk for an individual patient may exceed that used to calculate monetary benefits. In these cases surgery can result in a net *loss* of life expectancy and would not be medically indicated despite the fact that it would qualify for financial benefits.

The criteria used to establish risk based on each of these four assumptions (optimal patient, significantly experienced facility, elective surgery, and isolated explantation) and examples of situations in which these criteria may not be valid are listed below.

A. OPTIMAL PATIENT

In establishing reoperative risk the Supervisory Panel utilized the predicted risk for a patient in New York Heart association functional class I or class II, with no associated cardiovascular (coronary artery disease, depressed LV function, myopathy, significant arrythmia, or associated valvular or congenital heart disease), neurologic, pulmonary, renal, hepatic or other systemic disease likely to increase surgical mortality or morbidity. The risk for reoperation is greater for patients in non-optimal health as opposed to optimal health. While many factors need to be considered by the patient and physician in deciding whether to reoperate, the increased reoperative risk for some non-optimal patients may be such that a gain in life expectancy would be unlikely and therefore explantation not medically justified. Risk, for example, is more than double compared to the optimal patient in cases with moderate left ventricular dysfunction (NYHA Class III), chronic renal failure and important tricuspid insufficiency.

There have been no reported fractures in BSCC valve conduits. The operative risk in these patients is 4.5 times higher than an optimal patient. Thus none of these patients qualify for valve replacement surgery benefits and should not undergo explantation.

B. SIGNIFICANTLY EXPERIENCED FACILITY

Although it is not possible to rank specific surgical facilities, a significantly experienced facility was considered to be one with a national or international reputation for cardiac surgery, a large surgical volume (>1000 cases per year) and

extensive experience in prosthetic valve explantation surgery. The Supervisory Panel strongly advises patients undergoing prophylactic valve removal to consult with their physicians to obtain advice on referral to centers with greater experience and overall excellence in reoperative valve procedures since such centers can be presumed to have the lowest surgical mortality.

C. ELECTIVE SURGERY

Risk estimates in Part II are based on elective surgery under ideal circumstances. Surgery in patients with infective endocarditis, hemodynamic instability, or prosthetic valve malfunction is not elective and is associated with higher surgical risk. Decisions in these cases must be based on medical necessity.

D. SURGERY IS PERFORMED FOR THE SOLE PURPOSE OF REMOVING ONE OR MORE BSCC PROSTHETIC VALVES

The surgical risk estimates described in Part II are based on data for elective explantation and replacement of a single or multiple prosthetic valves as an isolated procedure. In patients with multiple prior cardiac surgical procedures, those in whom additional valve surgery is anticipated in addition to replacement of their BSCC valve, and those with coexisting coronary artery disease requiring concomitant by-pass surgery the reoperative risk is increased by 40 to 80%.

Based on the above assumptions, data from literature suggests an operative mortality of approximately 3% for an optimal patient at an approximate age of 58, (See Part III). However, the actual mortality rate among a group of 135 BSCC patients known to have undergone prophylactic replacement of their BSCC valves was 6.7%. This suggests that not all patients were optimal patients.

The Supervisory Panel therefore advises that the decision reached by the patient and physician on whether to actually undergo replacement surgery (irrespective of qualification for monetary benefits) take into account the patient's actual health status (since many patients with prosthetic heart valves do not meet the criteria for optimal health) and the risk associated with the type of procedure to be performed.

E. GENERAL RECOMMENDATIONS FOR ALL BSCC PATIENTS

All patients with BSCC valves should regularly consult their physicians and should have a clear understanding of the symptoms which occur at the time of OSF. These should be made known to those relatives or friends in contact with the patient. These patients should also be made aware of the nearest center with significant experience in cardiovascular surgery, since early recognition and prompt surgical intervention may be lifesaving for the small percentage of BSCC valve recipients who actually experience OSF.

V. STATISTICAL TABLES

Table 1. Factors for Calculation of Rates of OSF (% per year) of BSCC 60 Degree Valves

Factor	Subgroup	Multiplier
Constant [1]	All	0.094
Size (mm)	21 or 25	1.00
	23 or 27	2.84
	29	3.99
	31	5.51
	33	9.60
Position	Aortic	1.00
	Mitral	2.51
Weld date	<1980, 7/82-3/84	1.00
	1980	0.48
	1/81-6/82	1.64
	> 4/84	0.00
Welder Group	AB	1.00
	C	1.51
Shop Order Rate [2]	<1.0%	1.00
	1.0-5.0%	1.88
	>5.0%	2.35
Current Age	<35	1.00
	>35	$(.941)^{(Age - 35)}$
Gender	Male	1.00
	Female	0.46
Rework	No crack or rework	1.00
	Crack, rework, missing	1.57

[1] Corresponds to the OSF rate for an individual whose factors are all equal to 1

[2] The percent of other valves in the same shop order which have fractured

Table 2.

Formula for and Example of Calculation of the Estimated OSF Rate (% per Year) for a Particular Patient with a BSCC 60° Valve

Estimated OSF Rate=Constant x Size x Position x Weld date x Welder group x Shop order rate x Current age x Gender x Rework status

Example for hypothetical 50 year old male with size 29 mm mitral valve implanted in the mitral position welded in 1983 by welder group AB in a shop order where the OSF rate of other valves is 3% and the valve has not been reworked:

Estimated OSF Rate =

Constant		0.094
Size	x	3.99
Position	x	2.51
Weld date	x	1.00
Welder group	x	1.00
Shop order rate	x	1.88
Current age	x	$(.941)^{50-35}=0.40$
Gender	x	1.00
Rework	x	1.00
	=	0.70 % per year

Table 3. Factors for Calculation of Rates of OSF (% per year) of **BSCC 70 Degree** Valves

Factor	Subgroup	Risk Multiplier
Constant [1]	All	0.79
Size (mm)	21 or 25	1.00
	23 or 27	1.40
	29	2.13
	31 or 33	3.22
Position	Aortic	1.00
	Mitral	1.81
Welder Group	D	1.00
	E	2.29
Shop Order Rate [2]	<1.0%	1.00
	1.0-5.0%	2.46
	>5.0%	2.72
Current Age	<35	1.00
	>35	$(.941)^{(Age - 35)}$
Gender	Male	1.00
	Female	0.46
Rework	No Crack or Rework	1.00
	Crack, Rework or Missing	1.71

[1] Corresponds to the OSF rate for an individual whose factors are all **equal to 1**

[2] The percent of other valves in the same shop order which have **fractured**

Table 4. **Estimated Risks of Death or Serious Morbidity from Reoperation for Replacement of BSCC valves for the Optimal Patient According to Age and Single and multiple valve status**

	Reoperative Risk (%)	
Age	Single Valve	Multiple Valve
35	3.6	5.8
40	3.9	6.3
45	4.3	7.0
50	4.9	7.8
55	5 5	8.9
60	6.4	10.1
65	7.4	11.7
70	8.7	13.6
75	10.2	16.0
80	12.2	18.8

Table 5. Outlet strut fracture rates (per cent per year), by age, gender and valve position, above which the patient with a single BSCC valve will qualify for valve replacement surgery benefits

	Male		Female	
Age	Aortic	Mitral	Aortic	Mitral
30	0.26	0.27	0.25	0.26
35	0.37	0.39	0.36	0.38
40	0.43	0.46	0.42	0.44
45	0.51	0.54	0.49	0 52
50	0.61	0.66	0.58	0.62
55	0.75	0.81	0.71	0.76
60	0.94	1.02	0.89	0.96
65	1.20	1.31	1.12	1.22
70	1.57	1.72	1.45	1.59
75	2.08	2.30	1.92	2.11
80	2.81	3.14	2.59	2.87

Table 6. Outlet strut fracture rates (per cent per year), by age and gender, above which the patient with multiple BSCC valves will qualify for valve replacement surgery benefits

Age	Male	Female
30	0.45	0.43
35	0.65	0.62
40	0.75	0.72
45	0.89	0.85
50	1.08	1.02
55	1.33	1.25
60	1.68	1.57
65	2.15	2.00
70	2.81	2.60
75	3.75	3.44
80	5.10	4.65

#76855

ONGOING RESEARCH PROJECTS (as of November 25, 2003)

A. Epidemiological Projects

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1. UK Cohort	12/6/01	12/31/03	Patient Follow-up to Improve Estimation of Risk of Strut Fracture	5/28/03*	£36,938	£19,105
2. Devtrack-Australia & New Zealand Heart Valve Registry	6/13/03	12/13/03	Australia & New Zealand Cohort	♣	$17,000 (AUD)	$00 (AUD)
3 International Epidemiology Institute, Ltd	11/13/03	11/13/04	Updating BSCC Patient Quality of Life Survey	♣	$116,900	$00

B. Surgical Projects

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1. UAB	7/18/02	7/18/04	Evaluate Combined Therapy Approach to Improve Risk of Re-Operation	7/03/03*	$146,073	$17,390
2. Duke	5/7/02	11/14/03	Compare Minimally Invasive and Invasive Surgical Techniques for Valve Re-Operation	11/13/03*	$83,930	$83,930

C. Imaging & Acoustic Projects

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1 University of Sheffield	12/21/01	6/21/03	Prediction of Closure Forces on BSCC Valves	9/24/03*	£177,544	£103,993
2. Information Systems Laboratories (ISL)	3/16/98	2/10/04	Noninvasive Assessment and Arterial Heart Valves	10/27/03*	$3,046,087	$2,481,766

*Date of latest Status Report which has been sent to Class Counsel
♦Final Status Report which has been sent to Class Counsel

ONGOING RESEARCH PROJECTS (as of November 25, 2003) - Cont'd.

	Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
3	Edison Welding Institute	5/24/99	2/06/03	Analysis and Assessment of Valve Failure	11/04/02*	$888,200	$807,030
4	Michigan State University	10/23/01	12/31/04	Catheter Based and EMAT Detection of SLS	11/14/03*	$1,589,392	$1,033,339
5	Eindhoven University - Tijhuis	4/18/03	4/18/04	Develop Catheter-Based Antenna for Detecting Flaws in BSCC Heart Valves	♣	$106,800	$00
6	Erasmus University – De Jong Lancee	4/1/03	1/1/04	Ultrasound to Detect SLS (Initial Phase)	♣	$45,000	$00
7	Hershey Imaging	10/6/03	10/6/04	Radiographic Imaging to Detect SLS	10/28/03*	$1,750/Session Plus overhead	$58,828
9	Penn State University	5/14/03	---	Create Database of Manufacturing Data (Feasibility Phase Approved)	♣	$346,858	$00
10	BioQuantetics	5/17/00	4/6/04	Ultrasound Detection of Single Leg Separation	2/27/03*	$2,727,475	$1,699,205
11.	Miromico, Inc	7/25/03	3/25/04	Telemonitoring System for valve related Cardiac Emergencies (Phase I)	10/27/03*	$197,778	$36,553
12	WESTAT	8/20/03	4/20/04	Survey of Physicians and Class Members	■	$199,517	$00
13	Eindhoven University	11/13/03	11/13/04	Evaluate Effect of Modeling Assumptions and Boundary Conditions on BSCC Valve Loading	♣	$194,000	$00
14	ACES	11/12/03	5/12/04	Acoustic Detection of Outlet Strut Resonance in BSCC Heart Valves	♣	$192,750	$00
15	ACES	11/12/03	8/12/04	Transmission of Acoustic Waves from a Vibrating Outlet Strut in BSCC Heart Valves	♣	$185,950	$00
16	UMC Utrecht	10/14/03	4/14/05	Development of High Frequency, Miniaturized, Electromagnetic Dip Meter (Phase I)	♣	$183,295	$00

*Date of latest Status Report which has been sent to Class Counsel
♣No Status Report Available
■On hold pending distribution of 2003 Guidelines

APPROVED RESEARCH PROJECTS PENDING CONTRACT (as of November 25, 2003)

A. Epidemiological Projects

	Name of Institution	Description of Project	Status	Cost
1	University Utrecht	Continuation of Follow-Up Study in Dutch BSCC Cohort	Awaiting Dutch Signature	77.019 Euro

B. Imaging & Acoustic Projects

	Name of Institution	Description of Project	Status	Cost
1	Cleveland Clinic	Three Dimensional Motion of Prosthetic Heart Valves by Computed Tomography and Echocardiography	Awaiting Cleveland Signature	$199,988
2	UMC Utrecht	Value of 3D Rotational Angiography in the Assessment of Fractured Bjork-Shiley Convexo-Concave Heart Valves (Feasibility)	Awaiting Budget	$100,000

C. Other

	Name of Institution	Description of Project	Status	Cost
1	EAR Medical Communications	User-Friendly Patient Brochure Regarding Guidelines	Negotiations Continue	$62,439
2	ACES	BSCC Heart Valve Performance Modeling Using Element Free Techniques	Disapproved by Class Counsel	$99,400
3	ACES	Modeling of BSCC Heart Valves—Effect of Compliant Support Conditions	Disapproved by Class Counsel	$77,800

PROPOSED BUT DEFERRED RESEARCH PROJECTS

A. Imaging & Acoustic Projects

	Name of Institution	Description of Project	Status	Proposed Cost
1	IMA Services GmbH	Security at Heart through Telemonitoring of BSCC Valve Carriers (Feasibility Study)	☼	$187,000

B. Other

	Name of Institution	Description of Project	Status	Proposed Cost
1.	Eindhoven University—de Hart	Computational and In-Vitro Analysis to Evaluate Performance and Condition of BSCC Heart Valves	☼	$163,000

☼ Deferred by Supervisory Panel for stated reasons, or made subject to clarification or a demonstration of feasibility.

	July 2003	August 2003	September 2003	October 2003
Total Visits	2917	844	1132	1162
Average Daily Visits	94	27	37	37
Average Visit Length	10:52	9 52	11:41	8:37
Median Visit Length	6:00	3 22	4 09	2 12
International Visits	12%	15%	12%	11%
US Visits	75%	70%	80%	16%
Unknown Origin Visits	13%	15%	8%	73%
Unique Visitors	1045	497	589	618
One-Time Visitors	684	401	413	423
Multiple-Time Visitors	381	96	176	195
Top Downloads	Report 18 - 244 times	Settlement - 25 times	Pamphlet - 30 times	Eighteenth Report - 200 times
	Settlement - 238 times	Precautions - 22 times	Settlement - 29 times	Settlement - 79 times
	Pamphlet - 227 times	Report 18 - 19 times	Precautions - 26 times	Guidelines_Sup - 74 times
	Guidelines 3 - 171 times	Pamphlet - 18 times	Guideline Sup - 20 times	Guidelines3 - 73 times
	Precautions - 162 times	Guideline Sup - 17 times	Eighteenth Report - 18 times	Pamphlet - 66 times
	guidelines_sup - 153 times	Guidelines3 - 15 times	Guidelines3 - 17 times	Precautions - 52 times
	Haynes - 89 times	Haynes - 14 times	Haynes - 14 times	French Translation - 47 times
Total Downloads	1916	162	549	777
Top Visitors Locations	Reston, VA	Reston, VA	Reston, VA	Reston, VA
	Sunnyvale, CA	Sunnyvale, CA	San Francisco, CA	Sunnyvale, CA
	Miami, FL	San Francisco, CA	Sunnyvale, CA	San Francisco, CA
	Palo Alto, CA	Stamford, CT	Stamford, CT	Stamford, CT
	Denver, CO	Hoffman Estates, IL	Palo Alto, CA	Denver, CO
Countries viewing the site	United States	United States	United States	United States
	Canada	Canada	Canada	Canada
	United Kingdom	Japan	United Kingdom	Germany
	Hong Kong	Netherlands	Netherlands	Spain
	Netherlands	France	Poland	France
	Japan	Saudi Arabia	Japan	Belgium
	Poland	United Kingdom	Australia	Belize
	Germany	Sweden	France	United Kingdom

	July 2003	August 2003	September 2003	October 2003
States/Provinces viewing site	Virginia	Virginia	Virginia	Virginia
	California	California	California	California
	Florida	Connecticut	Connecticut	Connecticut
	Connecticut	Ontario	Ontario	Colorado
	Colorado	Ohio	New York	North Dakota
	Ontario	Pennsylvania	Pennsylvania	Massachusetts
	Tennessee	Illinois	Ohio	Missouri
	Ohio	New York	Arkansas	Pennsylvania
	Pennsylvania	Tennessee	Washington	Ohio
Search Engine & Reference -	AOL	AOL	AOL	AOL
	Google	Google	inktomisearch.com	inktomisearch.com
	webmastersolutions com	av.com	Google	Google
	mc.videotron ca	looksmart.com	looksmart.com	av.com
	pacbell net	12 148 209 198	av com	looksmart com
	av.com	inktomisearch.com	mc.videotron.ca	alexa.com
	miami com	aatbi com	dinslaw com	fastsearch net
Top Domain Types	Commercial (com) - 1973	Commercial (com) - 495	Commercial (com) - 813	Commercial (com) - 709
	Network (.net) - 314	Network (.net) - 101	Network (net) - 105	Network (.net) - 124
	Education (edu) - 13	Education (edu) - 14	Education (edu) - 13	Education (edu) - 20
	Organization (.org) - 4	Organization (.org) - 3	Organization (org) - 3	Organization (.org) - 2
	Others - 2	Military (mil) - 2	Government (gov) - 2	Government (gov) - 2

** - NOTE - Site went active on

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF OCTOBER 31, 2003

UNAUDITED

ASSETS

CASH	$ 123,086
U.S. TREASURY BILLS	28,263,970
OTHER ASSETS	15,807
	$ 28,402,863

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	$ 603,951(1)
FUNDS BALANCE	27,798,912
	$ 28,402,863

(1) - Does not include any provision for fees and expenses for Class Counsel and Special Counsel and Public Citizen, Inc. for the period since October 2002.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME AND FUNDS BALANCE

FOR THE TEN MONTHS ENDED OCTOBER 31, 2003

UNAUDITED

INVESTMENT INTEREST INCOME	$ 233,654	
VALVE REPLACEMENT SURGERY BENEFITS	119,735	
RESEARCH PROGRAMS - COSTS	2,104,384	
LITIGATION ATTORNEYS - FEES & EXPENSES	748,849	
EXPENSES:		
Supervisory Panel	958,986	(1)
Trustees' fees and expenses	74,395	
Professional fees	165,453	
Administrative office	401,314	(1)
Notification expense	107,778	
Total	1,707,926	
CONTRIBUTION BY PFIZER INC.	6,250,000	
NET CHANGE IN FUNDS BALANCE	1,802,760	(2)
FUNDS BALANCE, DECEMBER 31, 2002	25,996,152	
FUNDS BALANCE, OCTOBER 31, 2003	$ 27,798,912	

(1) - See Schedule 1 herewith.
(2) - See note (1) on Balance Sheet herewith.

Schedule 1

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

SCHEDULE OF EXPENSES
UNAUDITED

	BUDGET 1/1/03-12/31/03	ACTUAL 1/1/03-10/31/03
SUPERVISORY PANEL:		
Panel members' compensation		$ 678,999
Consultants' compensation		69,792
Travel and incidental expenses		194,645
Miscellaneous		15,550
Total		$ 958,986
ADMINISTRATIVE OFFICE:		
Rents	$ 72,000	$ 60,678
Office payroll	383,000	283,416
Payroll taxes	23,000	17,699
Employee benefits	30,000	29,851
Outside services	18,000	2,583
Printing and postage	9,000	2,579
General insurance	3,000	2,326
Telephone	9,000	5,493
Office supplies and expense	9,000	2,980
Travel	6,000	
Depreciation	6,000	2,021
Miscellaneous	6,000	499
Administrative services income	(12,000)	(8,811)
Total	$ 562,000	$ 401,314

Bowling-Pfizer Heart Valve Litigation Settlement Fund

Statements of Assets, Liabilities and Fund Balance—Modified Cash Basis as of December 31, 2002 and 2001 and Statements of Income, Expenses and Benefit Payments and Change in Fund Balance—Modified Cash Basis for the Years Ended December 31, 2002 and 2001 and Independent Auditors' Report

Deloitte
& Touche

INDEPENDENT AUDITORS' REPORT

Bowling-Pfizer Heart Valve Litigation Settlement Fund.

We have audited the accompanying statements of assets, liabilities and fund balance—modified cash basis of the Bowling-Pfizer Heart Valve Litigation Settlement Fund (the "Fund") as of December 31, 2002 and 2001, and the related statements of income, expenses and benefit payments and change in fund balance—modified cash basis for the years then ended These financial statements are the responsibility of the Fund's management. Our responsibility is to express an opinion on these financial statements based on our audits

We conducted our audits in accordance with auditing standards generally accepted in the United States of America Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As described in Note 2 to the financial statements, these financial statements were prepared on the modified cash basis of accounting, which is a comprehensive basis of accounting other than accounting principles generally accepted in the United States of America

In our opinion, such financial statements present fairly, in all material respects, the assets, liabilities and fund balance of the Fund at December 31, 2002 and 2001, and its income, expenses and benefit payments and change in fund balance for the years then ended, on the basis of accounting described in Note 2.

Deloitte & Touche LLP

October 27, 2003

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF ASSETS, LIABILITIES AND FUND BALANCE—MODIFIED CASH BASIS AS OF DECEMBER 31, 2002 AND 2001

	2002	2001
ASSETS:		
CASH	$ 50,072	$ 359,669
INVESTMENTS	26,605,098	25,143,077
OTHER ASSETS	19,604	21,641
TOTAL ASSETS	$26,674,774	$25,524,387
LIABILITIES AND FUND BALANCE:		
ACCOUNTS PAYABLE AND ACCRUED EXPENSES	$ 678,622	$ 607,416
FUND BALANCE	25,996,152	24,916,971
TOTAL LIABILITIES AND FUND BALANCE	$26,674,774	$25,524,387

See notes to modified cash basis financial statements

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF INCOME, EXPENSES AND BENEFIT PAYMENTS AND CHANGE IN FUND BALANCE—MODIFIED CASH BASIS YEARS ENDED DECEMBER 31, 2002 AND 2001

	2002	2001
INCOME.		
Settlement payments by Pfizer/Shiley	$ 6,250,000	$ 6,250,000
Net investment income	466,347	929,067
Total income	6,716,347	7,179,067
EXPENSES AND BENEFIT PAYMENTS.		
Benefit payments—valve replacement surgery	6,397	168,142
Research programs	3,127,174	1,593,329
Litigation attorneys—fees and expenses	630,531	491,308
Supervisory panel expenses	1,067,518	1,059,573
Trustees' fees and expenses	120,187	164,127
Notification expense		18,388
Professional fees	207,179	153,563
Other administrative expenses	478,180	476,357
Total expenses and benefit payments	5,637,166	4,124,787
RETURN OF UNNEGOTIATED CONSULTATION FUND CHECKS TO THE SETTLEMENT FUND		584,806
INCREASE IN FUND BALANCE	1,079,181	3,639,086
FUND BALANCE—BEGINNING OF YEAR	24,916,971	21,277,885
FUND BALANCE—END OF YEAR	$25,996,152	$24,916,971

See notes to modified cash basis financial statements

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

NOTES TO MODIFIED CASH BASIS FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2002 AND 2001

1. ORGANIZATION AND GENERAL INFORMATION

The Bowling-Pfizer Heart Valve Litigation Settlement Fund ("Fund") is the result of a settlement between Pfizer Inc. ("Pfizer") and its wholly-owned subsidiary Shiley Incorporated ("Shiley") and a class of plaintiffs ("Plaintiffs") consisting of all persons who were alive on January 23, 1992 with a Bjork-Shiley Convexo-Concave ("BSCC") heart valve still implanted, and their spouses on that date, except those persons who filed valid and timely requests for exclusion from the class.

The Settlement requires that Pfizer/Shiley pay a minimum of $165 million to the Fund to settle the claims of the Plaintiffs. Certain provisions exist whereby Pfizer may be required to pay additional amounts to the Fund based on certain criteria as defined in the Settlement. The minimum Settlement is allocated between the "Patient Benefit Fund" ($75 million) and the "Consultation Fund" ($90 million).

The Patient Benefit Fund is to be used for: research and development of diagnostic techniques to identify implantees who may have a significant risk of strut fracture and to make such diagnostic techniques available to Plaintiff implantees; research concerning the characterization and/or reduction of the risks of valve replacement surgery, and payment of covered medical expenses for qualifying surgery to explant, due to the risk of strut fracture, a Plaintiff implantee's BSCC heart valve and replace it with another prosthetic heart valve.

The research activities of the Patient Benefit Fund are supervised by a Supervisory Panel ("Panel") The Panel, subject to Court approval, shall adopt and amend guidelines for valve replacement surgery. Also, the 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 is made up of six members who are recognized scientific or medical experts and one member who is not a scientist or physician.

The Consultation Fund, initially $80,000,000 for Plaintiff implantees, is intended to provide Plaintiff implantees with funds to obtain medical and psychological consultation as they deem best. It is to be divided equally among qualified Plaintiff implantees after paying or providing for fees and expenses to be paid out of the implantee portion of the Fund. In addition, $10,000,000 was paid into the Fund which was paid, after fees and expenses, equally to all qualified Plaintiff spouses At December 31, 2001, the Consultation Fund had distributed $91,718,314 to claimants. Of the distributions to claimants, there were checks aggregating $584,806 that had not been negotiated and were outstanding at December 31, 2001. The Court Order filed December 13, 2001 authorized the transfer of the funds for these unnegotiated Consultation Fund claimant checks to the Patient Benefit Fund to be used for the administration of the Settlement

The terms of the Settlement required Pfizer/Shiley to initially deposit $12,500,000 into the Patient Benefit Fund. Additionally, beginning on the second anniversary of the final approval of the Settlement, Pfizer/Shiley is required to make annual deposits into the Patient Benefit Fund of not less than $6,250,000 until a total of $75,000,000 has been paid

Pfizer/Shiley paid $80,000,000 to the Consultation Fund in 1992. In 1994 Pfizer/Shiley paid $10,000,000 to the Consultation Fund and $12,500,000 to the Patient Benefit Fund. Pfizer/Shiley also paid $6,250,000 annually in 1996 through 2002 to the Patient Benefit Fund.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting—The Fund prepares its financial statements on the modified cash basis of accounting. Therefore, it records interest receivable for interest earned not yet received, taxes receivable (payable) (see Note 5) and accounts payable for expenses when incurred rather than when paid (modified cash basis). Under this basis all Settlement payments by Pfizer/Shiley are recognized when received and all benefit payments and Plaintiffs' counsel fees and expenses are recognized when paid rather than when incurred.

Use of Estimates—The preparation of financial statements on the modified cash basis of accounting requires management to make estimates and assumptions that affect the reported amounts and disclosures in the financial statements. Actual results could differ from those estimates.

Settlement Payments—All Consultation Fund claims submitted by each claimant were reviewed for qualification by the Fund and payments of qualified claims were approved by the Court.

Litigation Attorneys—Fees and Expenses—Represents Court approved payments to Plaintiffs' counsel and to Public Citizen, Inc.

Other Assets—Other assets represents prepaid expenses, office furniture and computer equipment used by the Fund.

3. INVESTMENTS

Investments at December 31, 2002 and 2001 consist of U.S. Treasury Bills and are carried at cost plus accrued interest. The market value of such investments was approximately $26,616,000 and $25,159,000, at December 31, 2002 and 2001, respectively.

4. OPERATING LEASES

The Fund leases its office facilities under an agreement classified as an operating lease from an unrelated party. Total future minimum lease payments due are as follows:

2003	$ 67,260
2004	16,815
Total	$ 84,075

5. TAX STATUS

For Federal income tax purposes, the Fund is treated as a taxable designated settlement fund under Section 468(B) of the Internal Revenue Code. The Fund is required to pay taxes on the excess of interest income earned over expenses incurred for the administration of the Fund. The Settlement payments by Pfizer/Shiley, benefit payments and payment of Plaintiffs' counsel fees and expenses are not taxable transactions.

In March 1996, the Fund requested a ruling from the Internal Revenue Service regarding the taxability of the Fund and the deductibility of certain disbursements from the Fund In January 1997, the Fund received a favorable ruling regarding these issues and, consequently, recorded no tax provision for 2002 or 2001.

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