

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

IN RE: : Case No. C-1-91-256
BOWLING-PFIZER LITIGATION : Judge Herman J. Weber,
: Senior Judge

TWENTY-SIXTH REPORT OF THE SPECIAL MASTERS/TRUSTEES
COVERING PERIOD FROM NOVEMBER 21, 2006 TO MAY 23, 2007

SPECIAL MASTERS/TRUSTEES

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

AGENDA

TWENTY-SIXTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 7, 2007
11:00 A.M.

Hon. Herman J. Weber, Senior Judge

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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- A. Twenty-Sixth Report of the Special Masters/Trustees
- B. Appendices to Court Report
 - 1. 2007 Guidelines
 - 2. Schedule of ongoing research projects.
 - 3. "Hit Report" regarding the Supervisory Panel's Website.
 - 4. Unaudited balance sheet as of April 30, 2007 and an unaudited statement of income and funds balance for the four months ended April 30, 2007.
 - 5. Unaudited balance sheet as of December 31, 2006 and an unaudited statement of income and funds balance for the year ended December 31, 2006.

UNITED STATES DISTRICT COURT
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IN RE: : Case No. C-1-91-256
BOWLING-PFIZER LITIGATION : Judge Herman J. Weber,
Senior Judge

TWENTY-SIXTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their twenty-sixth periodic report, covering activities from November 21, 2006 to May 23, 2007. This report is submitted fifteen days prior to the status hearing before the Court scheduled for June 7, 2007.

I. PATIENT BENEFIT FUND

A. Supervisory Panel. The Court held an evidentiary hearing on the Trustees' Motion to Approve the 2006 Amended Valve Replacement Guidelines (now called the 2007 Guidelines) on April 11, 2007. The following members of the Supervisory Panel testified at the hearing: David Miller, Dr. Tom Ivy, Dr. Ronald Brookmeyer, Dr. Arthur Weyman, Dr. Michel Ibrahim and Dr. Donald Harrison.

The initial patient studies with the ACES device at The Ohio State University have been concluded and the final report with the patient and earlier sheep study results is now being evaluated by

the Supervisory Panel. The Panel has not yet decided whether to request a proposal from ACES for additional work to further develop this potential diagnostic device.

With regard to BioQuantetics, Inc. an agreement regarding intellectual property was reached between the Trustees and BioQuantetics and certain equipment and other inventory was sold by the Trustees to BioQuantetics and to Polytec, Inc.

B. Guidelines. On April 18, 2007, the Court approved the 2007 Guidelines. Copy attached as Appendix 1. The Claims Administrator is in the process of having the 2007 Guidelines translated and distributed to Class Members and physicians.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached Appendix 2.

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, 7 implantees who may qualify for replacement surgery have been imaged.

E. Repository. The Supervisory Panel maintains 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, certain 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 address and a password.

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 2007 Guidelines, a copy of the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information. A copy of the most recent "hit report" of the Supervisory Panel's website is attached to this Report as Appendix 3.

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. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits.

The total number of qualified claims received from the beginning are: 95 (72 foreign) qualified outlet strut fracture

claims and 137 (55 foreign) qualified valve replacement surgery claims including 38 (16 foreign) qualified single leg fracture claims.

The office of the Claims Administrator has commenced to fulfill requests to calculate estimated annual fracture rates under the 2007 Guidelines. In addition, a review of the registered Class Member database was conducted and the 171 known Class Members who would potentially qualify for valve replacement surgery benefits under the 2007 Guidelines have been identified. The necessary information will be provided to Class Counsel so that after distribution of the 2007 Guidelines Class Counsel may notify those Class Members who would potentially qualify for benefits.

The office of the Claims Administrator continues to respond to other inquiries from and on behalf of Class Members.

II. FINANCIAL INFORMATION

At April 30, 2007, the total balance of cash and cash equivalents was \$23,297,712. This amount takes into account net interest earned from January 28, 1992 through April 30, 2007 in the aggregate amount of \$25,822,033.

Attached as Appendix 4 are the following: an unaudited balance sheet as of April 30, 2007 and an unaudited statement of income and funds balance for the four months ended April 30, 2007 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2007 through December 31, 2007).

Attached as Appendix 5 are the following: an unaudited balance sheet as of December 31, 2006 and an unaudited statement of

income and funds balance for the year ended December 31, 2006 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 2006.)

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.

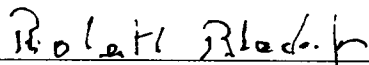
IV. APPROVALS

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

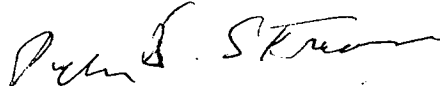
- Approve this Report, and
- Approve, or provide guidance with respect to, each of the Appendices to this Report, and
- Provide guidance with respect to any duty of the Special Masters/Trustees, and
- Fix the date for the next Report.

Respectfully submitted,

Dated: May 23, 2007



Hon. Robert L. Black, Jr.



Peter J. Strauss, Esq.

APPENDIX

1

BOWLING-PFIZER HEART VALVE SETTLEMENT

2007 AMENDED VALVE REPLACEMENT GUIDELINES

*GUIDELINES TO DETERMINE IF CLASS MEMBERS WITH
BJORK-SHILEY CONVEXO-CONCAVE (BSCC) HEART VALVES
QUALIFY FOR PAYMENT OF MONETARY BENEFITS FOR
ELECTIVE VALVE REPLACEMENT SURGERY*

Proposed by the Bowling-Pfizer Supervisory Panel and Approved by the United States District Court for the Southern District of Ohio on April 18, 2007.

PART I. SUMMARY

A. IMPORTANT INFORMATION.

- The terms of the Settlement Agreement in *Bowling, et. al. v. Pfizer Inc., et. al.* provide that benefits are available to certain qualifying *Bowling* Class Members who undergo BSCC heart valve replacement surgery *due to the risk of outlet strut fracture*.
- These 2007 Amended Valve Replacement Guidelines (2007 Guidelines) identify who is eligible to receive valve replacement surgery benefits from the *Bowling* Settlement funds.
- A summary of the valve replacement surgery benefits available for Class Members who undergo qualifying explant surgery is set forth in Appendix A: Glossary and Important Patient Information.
- The 2007 Guidelines are based on statistical estimates of the risks of fracture and the risks of reoperation.
- The 2007 Guidelines are based on a statistical analysis of group data and it should be noted that the risk for an individual patient may differ from those of the group.
- Class Members implanted with a BSCC heart valve manufactured after April 1, 1984 will *not* qualify for valve replacement surgery benefits because there have been no reported fractures of valves manufactured after that date.
- Class Members who have BSCC valve conduits will *not* qualify for valve replacement benefits because there have been no reported fractures of these valves.
- Replacement surgery benefits are age-related so qualification may be lost due to the passage of time. For example, if you potentially qualify for benefits now, you may not qualify in the future due to your change in age, because the passage of time is associated with a statistical reduction in the risk of BSCC outlet strut fracture, and an increase in operative mortality.
- If a Class Member's valve replacement surgery did not qualify for benefits in the past, it may now qualify under the 2007 Guidelines and if so, benefits will be paid.
- The 2007 Guidelines may be changed in the future.
- The 2007 Guidelines do not constitute medical advice.
- To learn whether you qualify for valve replacement surgery benefits or to make a claim for benefits, you must contact the *Bowling* Claims Administrator at:

Wayne Smith
Bowling Claims Administrator
P. O. Box 3598
Cincinnati, Ohio 45201-3598
U. S. A.
800-977-0779 (United States or Canada)
00-1-513-421-3517 (International)
513-421-7696 (Facsimile)
bowlingpfizer@fuse.net (E-mail)
www.bowling-pfizer.com (Website)

B. *WHAT IS NEW TO THE 2007 AMENDED VALVE REPLACEMENT GUIDELINES.*

1. There has been an overall decrease in surgical mortality and morbidity for elective explant surgery and this decrease in risk has been incorporated into the 2007 Guidelines.
2. The outlet strut fracture threshold rates found in Appendix D, Tables 3 and 4 are now provided in yearly age increments rather than in 5 year increments.
3. Additional time to make a claim has been provided to make sure that a Class Member who is eligible to receive valve replacement surgery benefits has sufficient time in which to make the decision regarding explant surgery.
 - A Class Member who is registered with the Claims Administrator as of April 18, 2007 and who potentially qualifies for valve replacement surgery benefits under the 2007 Guidelines has until July 18, 2009 OR the length of time of eligibility determined under the 2007 Guidelines, whichever is longer, in which to make the decision and have explant surgery and still receive valve replacement surgery benefits. A Class Member who registers with the Claims Administrator after April 18, 2007 and who potentially qualifies for valve replacement surgery benefits under the 2007 Guidelines will have two years from the date of registration OR the length of time of eligibility determined under the 2007 Guidelines, whichever is longer, in which to make the decision and have explant surgery and still receive valve replacement surgery benefits.
 - A Class Member who potentially qualified for valve replacement surgery benefits under the 2003 Guidelines as of April 18, 2007 (the effective date of the 2007 Guidelines), but does not qualify under the 2007 Guidelines, has until July 18, 2009 to undergo qualified valve replacement surgery.
4. A Glossary and Important Patient Information is included in Appendix A.
5. The Warning Signs of Outlet Strut Fracture (OSF) are contained in the Glossary and Important Patient Information in Appendix A.

C. HOW QUALIFICATION FOR VALVE REPLACEMENT SURGERY BENEFITS IS DETERMINED.

Provided below are the procedures for determining the qualification for monetary benefits when valve replacement surgery of a BSCC heart valve takes place due to the risk of strut fracture.

1. Class Members with single or multiple BSCC heart valves with known serial number(s).

Step One: The Class Member, his or her physician, or other authorized representative must contact the Bowling Claims Administrator and provide the Class Member's heart valve serial number, implant position, age and gender.

Step Two: The Class Member's estimated OSF rate (expressed as the percent chance that the valve will fracture in the next year) will be calculated by the Claims Administrator. For Class Members with multiple valves, the Class Member's OSF rate will be calculated by summing the OSF rates for each valve.

Step Three: If the estimated OSF rate is greater than the estimated risk of death or serious morbidity—that is, above the established threshold—then the Class Member would qualify for valve replacement surgery benefits.

2. Class Members with BSCC mitral valves with unknown serial numbers.

Step One: The Class Member, his or her physician, or other authorized representative must contact the Claims Administrator and provide the Class Member's age and gender and documentation showing that the Class Member has a 29, 31, or 33 mm BSCC mitral valve implanted prior to April 1984. Proof of the characteristics of the valve may be shown by x-ray, fluoroscopy, transesophageal echocardiography, or a review of medical records.

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

3. Class Members with documented single leg separation (SLS).

Step One: The Class Member, his or her physician, or other authorized representative must provide to the Claims Administrator clear evidence of single leg separation of the Class Member's BSCC heart valve, documented by x-ray images or information definitively showing offset of one of the valve's two outlet strut legs.

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

D. WHERE TO FIND MORE INFORMATION.

Visit www.bowling-pfizer.com for additional information about the *Bowling* Settlement and the Guidelines.

PART II. THE FULL TEXT OF THE 2007 AMENDED VALVE REPLACEMENT GUIDELINES

A. INTRODUCTION.

Under a class action Settlement Agreement in the *Bowling, et al. v. Pfizer Inc., et al.* heart valve litigation, monetary benefits are available to certain patients implanted with BSCC heart valves who undergo valve replacement surgery because of the risk of outlet strut fracture. Under the Settlement Agreement, an independent Supervisory Panel was appointed in May 1994 to develop and amend guidelines to be used to determine qualification for monetary benefits for qualifying valve replacement surgery. The 2007 Guidelines determine eligibility for valve replacement surgery benefits if the patient, after consulting with his or her treating physician, decides to undergo valve replacement surgery. A summary of the monetary benefits that are available for eligible patients who undergo valve replacement surgery are set forth in the Glossary and Important Patient Information contained in Appendix A to the 2007 Guidelines.

The Supervisory Panel recommended its first set of Guidelines in 1997, and they were approved by the Court. The Guidelines were revised and approved by the Court in 2000 and 2003 when updated data became available.

The Supervisory Panel has continued to monitor mortality (death) and morbidity (serious illness) data for elective valve replacement surgery, and, based on new data, the Supervisory Panel has developed, and the Court has approved, the 2007 Amended Valve Replacement Guidelines (2007 Guidelines). These 2007 Guidelines are based on all currently available data to derive the best statistical estimates of the risks of fracture and reoperation. Standard statistical criteria were used to identify valve and patient characteristics associated with these risks. The overall decrease in surgical mortality and morbidity for elective explant surgery has been incorporated into the risk calculations. Furthermore, a decision zone is provided to ensure that a Class Member who is potentially eligible to receive valve replacement surgery benefits has sufficient time in which to make the decision regarding elective explant surgery.

The 2007 Guidelines identify the subgroup of patients for whom, on average, BSCC heart valve replacement surgery will result in a gain in life expectancy. However, for some individual patients there can be an immediate loss of life expectancy (if death results from reoperation), while for other patients there can be a significant gain (if a strut fracture is avoided by a successful operation). For most patients who undergo replacement surgery, 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, it is important to emphasize that the 2007 Guidelines are based on a statistical analysis of group data and that the risk for an individual patient may differ from those of the group.*

The 2007 Guidelines will be reviewed by the Supervisory Panel as significant new data become available. They may be modified when appropriate, consistent with the best available epidemiologic, clinical, and other relevant information.

There are several words or terms used in or related to these 2007 Guidelines that may require explanation. A Glossary and Other Important Patient Information is included as Appendix A, which provides more information on the following:

- Advice to patients, including Outlet Strut Fracture (OSF) Warning Signs
- Elective surgery
- Group data
- Intact valve, Single Leg Separation (SLS) and OSF
- Monetary benefits
- New York Heart Association (NYHA) classification
- Optimal patient
- Rework status
- Shop order
- Significantly experienced facility
- Supervisory Panel
- Valve conduit
- Welder group

B. HOW THE GUIDELINES ARE FORMULATED.

1. RATIONALE AND ASSUMPTIONS

The Supervisory Panel developed the 2007 Guidelines from detailed reviews of the relevant clinical and epidemiologic data concerning risks of OSF versus risks from reoperations to replace BSCC heart valves. These 2007 Guidelines incorporate two critical risk factors: (1) the risk that the valve will fracture, which results in death in approximately 65% of patients who suffer a fracture, and; (2) the risk of death or serious illness as a result of having surgery to replace the valve. In considering these two factors, the 2007 Guidelines attempt to identify those circumstances in which replacement of the valve would offer a meaningful extension of life expectancy.

The 2007 Guidelines weigh the benefit of eliminating the risk of OSF through surgery against the risk of mortality and morbidity associated with the surgery. The 2007 Guidelines assess reoperative risk based on two assumptions: (1) that the patient is in optimal health, and (2) that the surgery is performed at a significantly experienced facility. Qualification under these 2007 Guidelines does not mean that replacement surgery is appropriate for a particular patient because many patients are not in optimal health and some explantation surgeries take place at facilities that do not have significant experience in heart valve replacement surgery. Thus, when either of these assumptions is not met, the risk of surgery would increase and the likelihood of benefit to the patient would decrease.

2. METHODS FOR ESTIMATING OSF RISK

To determine the characteristics of patients and their heart valves that 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. The latter studies were specifically designed to determine the effects of valve size, implant position, and other manufacturing characteristics as well as patient characteristics such as age and gender on OSF rates. 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 affects the risk of OSF.

The factors that significantly influence risk of OSF are valve size, implant position, weld date, welder group, shop order rate, rework status, patient age and gender. Using a statistical prediction formula the estimated annual rate of fracture (in per cent per year) for a patient with a valve with a known serial number is determined. The Claims Administrator will apply this formula upon request.

Appendix B provides an example of calculating an OSF rate in a 50-year-old male patient with a size 29 mm BSCC 60° 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, where the patient's valve had not been reworked. To obtain the manufacturing data necessary to apply the calculations to a specific patient, the valve's serial number and implant position are needed. As noted above, once this information is provided to the Claims Administrator, this calculation will be made and transmitted to the patient, his or her physician, or other authorized representative.

3. METHODS FOR ESTIMATING REOPERATIVE RISK

The Supervisory Panel has developed estimates of the risk of mortality and serious morbidity (such as stroke, infectious endocarditis, and perivalvular leaks) that could result from valve replacement surgery among patients in optimal health implanted with single or multiple BSCC heart valves. These estimates are based on the results of a long-term epidemiologic study of heart valve reoperation patients conducted at the Cleveland Clinic and a review of the Society of Thoracic Surgeons data on valve reoperation mortality rates observed in hospitals in the United States which were used to predict future underlying mortality according to age, gender, and valve position. The percentages in Appendix C are based on the reoperative risks in a relatively large subset of patients from these reviews who are in NYHA status class I and II and without cardiac co-morbidity—that is, optimal or close-to-optimal patients who

underwent valve replacement surgery. These data suggest that the estimated operative risk of death and serious complications from surgery of an optimal patient with a single BSCC heart valve at a significantly experienced facility averages from 4.4% to 5% for patients from ages 35 to 60 and thereafter increases more rapidly with age. Patients with multiple BSCC heart valves are at an increased risk compared to a patient with a single BSCC heart valve.

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

Qualification for valve replacement surgery benefits is determined by comparing predicted future life expectancies under scenarios where reoperation to replace the BSCC heart valve does or does not take place. Life expectancies are calculated taking into account the patient's current estimated annual OSF rate and the reoperative risk for an optimal patient.

The Supervisory Panel has developed threshold rates above which the expected loss of life expectancy due to valve fracture exceeds the projected loss of life associated with valve replacement surgery. A patient meeting this criterion would qualify for monetary benefits.

The Supervisory Panel has also developed threshold rates for patients with multiple BSCC valves. For these patients, if the sum of the estimated OSF rates for the patient's multiple valves exceeds the threshold rate for the patient's current age and gender, a gain in life expectancy from reoperation would be predicted and the multiple-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 multiple-valve patients. This increase in operative risk pertains even if only one valve is to be replaced.

The threshold rate tables are provided in Appendix D, Tables 3 and 4.

C. HOW QUALIFICATION FOR VALVE REPLACEMENT SURGERY BENEFITS IS DETERMINED.

Provided below are the procedures for determining the qualification for valve replacement benefits when surgery for explantation of a BSCC heart valve takes place due to the risk of strut fracture. *Qualification means only that monetary benefits are available and should not be taken as an indication that surgery is advisable in any particular case. The Supervisory Panel emphasizes that risk of valve fracture for the large majority of BSCC heart valve patients is not high enough to warrant elective explantation.*

To determine qualification for valve replacement surgery benefits, the patient, his or her physician, or other authorized representative must provide the information listed below in either of 1, 2 or 3 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, by email to bowlingpfizer@fuse.net, via the internet at www.bowling-pfizer.com, or by regular mail to Claims Administrator, P.O. Box 3598, Cincinnati, Ohio 45201-3598, U.S.A.

The requested information and the procedures for determining qualification for valve replacement surgery benefits when surgery for replacement 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. Please note that patients with a valve manufactured after April 1, 1984 do not qualify because there have been no reported outlet strut fractures of those valves. Also, there have been no reported fractures in BSCC valve conduits, and the operative risk in these patients is approximately 4 times higher than in an optimal patient. Thus, none of these patients qualify for valve replacement surgery benefits.

1. Class Members with single or multiple BSCC heart valves with known serial number(s).

Step One: The Class Member, his or her physician, or other authorized representative must contact the Bowling Claims Administrator and provide the Class Member's heart valve serial number, implant position, age and gender.

Step Two: The Class Member's estimated OSF rate (expressed as the percent chance that the valve will fracture in the next year) will be calculated by the Claims Administrator. For Class Members with multiple valves, the Class Member's OSF rate will be calculated by summing the OSF rates for each valve.

Step Three: If the estimated OSF rate is greater than the estimated risks of death or serious morbidity—that is, above the established threshold—then the Class Member would qualify for valve replacement surgery benefits.

2. Class Members with BSCC mitral valves with unknown serial numbers.

Step One: The Class Member, his or her physician, or other authorized representative must contact the Claims Administrator and provide the Class Member's age and gender and documentation showing that the Class Member has a 29, 31, or 33 mm BSCC mitral valve implanted prior to April 1984. Proof of the characteristics of the valve may be shown by x-ray, fluoroscopy, transesophageal echocardiography, or a review of medical records.

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

3. Class Members with documented single leg separation (SLS).

Step One: The Class Member, his or her physician, or other authorized representative must provide to the Claims Administrator clear evidence of single leg separation of the Class Member's BSCC heart valve, documented by x-ray images or information definitively showing offset of one of the valve's two outlet strut legs.

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

The qualification for valve replacement surgery benefits may change with time.

Some Class Members who potentially qualify for valve replacement surgery benefits under the 2007 Guidelines may lose eligibility with time. This can occur for two reasons. According to available data, as a person ages, the risk of suffering an outlet strut fracture diminishes and the operative mortality and morbidity rates increase. Thus, over time there would no longer be an assurance of any meaningful extension of life if valve replacement surgery occurs. Second, the 2007 Guidelines may be changed in the future.

A decision zone is provided to ensure that there is sufficient time to make a decision regarding valve replacement surgery. A Class Member who is registered with the Claims Administrator as of April 18, 2007 and who potentially qualifies for valve replacement surgery benefits under the 2007 Guidelines has until July 18, 2009 OR the length of time of eligibility determined under the 2007 Guidelines, whichever is longer, in which to make the decision and have explant surgery and still receive valve replacement surgery benefits. A Class Member who registers with the Claims Administrator after April 18, 2007 and who potentially qualifies for valve replacement surgery benefits under the 2007 Guidelines will have two years from the date of registration OR the length of time of eligibility determined under the 2007 Guidelines, whichever is longer, in which to make the decision and have explant surgery and still receive valve replacement surgery benefits.

The decision zone also applies to a Class Member who still potentially qualified for valve replacement surgery benefits under the 2003 Guidelines on April 18, 2007 (the effective date of the 2007 Guidelines), but does not qualify under the 2007 Guidelines, has until July 18, 2009 to undergo qualified valve replacement surgery and still be eligible for valve replacement surgery benefits.

D. ADDITIONAL INFORMATION.

Notes about potential eligibility for valve replacement surgery benefits according to certain terms of the Settlement Agreement

Section 5.2.3 of the Settlement Agreement provides, under certain conditions and limitations, for the payment of expenses for surgery to explant, due to the risk of strut fracture, a Settlement Class Member's BSCC heart valve and replace it with another prosthetic valve.

Section 5.2.3.1(c) of the Settlement Agreement states: "If the Panel at any time modifies its guidelines for valve replacement surgery, then a Settlement Class Member may request that his or her previously non-qualifying valve replacement be re-evaluated under the modified guidelines. If the surgery would have been qualifying under the modified guidelines, then the Settlement Class Member shall be entitled to the applicable benefits for qualifying valve replacement under subsection 5.2.3 and under subsection 5.6, if not previously waived by bringing an action for damages from the valve replacement."

Section 5.2.3.1(d) further states: "If following a non-qualifying valve replacement without symptoms that have been associated with a fracture it is determined that one leg of the strut of the Settlement Class Member's valve has separated from the flange prior to the surgery, then the valve replacement shall be treated as qualifying under the Panel guidelines including for purposes of electing valve replacement surgery benefits under this agreement".

General considerations for all BSCC patients

All patients with BSCC heart valves should regularly consult their physicians and should have a clear understanding of the symptoms that accompany OSF. Please refer to the Glossary and Important Patient Information at Appendix A for a description of the symptoms. These should be made known to the patient's relatives and friends. Patients also should be aware of the nearest hospital with the capacity to conduct cardiovascular surgery, because early recognition and prompt surgical intervention have been shown to save lives for the small percentage of BSCC heart valve recipients who experience OSF.

APPENDIX A: GLOSSARY AND IMPORTANT PATIENT INFORMATION

Advice to patients, including Outlet Strut Fracture Warning Signs

General valve-related advice BSCC heart valve patients should take the time to institute the following simple precautions. These are suggestions to protect your health and well-being should you suspect a strut fracture of your BSCC heart valve, or a heart problem, or become seriously ill.

1. Make sure you have the correct name, address, and emergency room telephone number of your hospital and your treating physician readily available and located on your person at all times. It is also an excellent idea to have an extra copy of this same information by your telephone at home and at work, and perhaps also in a highly visible and easily located place at home. Make sure your family members and close friends know where you have placed this information.
2. If you suspect you are having a cardiac emergency, it is extremely important that you be transported to a hospital that has the capability of performing emergency cardiac surgery and that can replace your BSCC heart valve if necessary. Not all hospitals have the ability to do this, so you must select your hospital carefully. Discuss this with your cardiologist or cardiac surgeon. Your selected hospital should have on staff at all times a cardiac surgeon with an appropriate heart surgery team and medical equipment, including a replacement heart valve prosthesis. Make sure your family members and close friends know this information as well.
3. You should have written instructions on your person at all times advising any Emergency Rescue Personnel or Ambulance Personnel to transport you to your selected hospital and to alert the hospital staff that you are in transit. The hospital emergency room personnel should be further advised that you are implanted with a BSCC heart valve and that a proper series of chest x-rays from the correct views should be made immediately upon your arrival at the hospital to determine whether or not your BSCC heart valve is intact. If your valve is not intact or it is not functioning properly, then open-heart surgery can be performed without delay.
4. If you are going to travel to a location some distance away from your designated hospital, you should determine prior to traveling the correct name, address, and telephone number of a hospital in the area where you will be traveling that can perform emergency cardiac surgery and can replace your BSCC heart valve if necessary.
5. Take the time to ask your treating physician what additional precautions he or she would recommend.

Outlet Strut Fracture Warning Signs There are several known warning signs that may indicate that a BSCC heart valve is not functioning properly and may be fracturing. You and your family members should be familiar with these. Also, talk with your physician about this subject.

1. Sudden, severe shortness of breath during normal activity.
2. Sudden loss of consciousness, even if it is regained shortly thereafter.
3. A sudden sharp chest pain or tight pressure in your chest that does not go away after a few minutes.
4. Sudden irregular or rapid heart beat.
5. A classic sign of an outlet strut fracture is that the mechanical heart valve will stop "clicking." You will not be able to hear the normal sound of the metallic clicking of the disc as it opens and closes. You might want to have someone listen to the normal metallic clicking sound of your BSCC heart valve for a few minutes on more than one occasion so he or she will be able to recognize the normal clicking sound. If there is an outlet strut fracture of a BSCC heart valve, there will be a noticeable absence of this normal clicking sound.

If you would experience any of the above warning signs, we recommend that you immediately contact your physician.

Elective surgery Elective surgery is surgery performed for the purpose of removing and replacing single or multiple BSCC heart valves as an isolated procedure 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.

Group data The risk of an outlet strut fracture occurring or the risk of death resulting from surgery to replace a heart valve indicates the probability of such events happening to a group of individuals with a common characteristic—for example, a group of patients 40 to 50 years old. A 10% probability means that 10 out of 100 patients 40 to 50 years old would experience the event. This also means that 90% of those patients would not experience the event. The individual's experience varies, because one may be in the group of 10 patients who experience the event or among the group of 90 patients who do not.

Intact valve, Single leg separation (SLS) and Outlet Strut Fracture (OSF) The BSCC heart valve consists of a metal ring, an inlet strut which is formed from the same metal as the ring, and a disc which moves freely between the inlet strut and the outlet strut. The outlet strut is welded to the ring and is the component of the valve which has failed at times. In an intact valve, all components are in working condition and the valve operates normally. A single leg separation is when one leg of the outlet strut breaks, usually near the site where it is welded to the ring. The valve with SLS may continue to operate for a period of time. An outlet strut fracture

occurs when both legs of the strut break. This allows the disc to escape into the bloodstream. (See “Advice to patients, including Outlet Strut Fracture Warning Signs”, earlier in the Glossary.)

Monetary benefits For qualified Bowling Class Members benefits include payment of covered medical expenses not paid for by insurance or by government benefits; a lump sum payment of \$38,000 to pay for non-medical expenses related to the surgery; reimbursement for actual lost income not paid by other benefits (with limitations) and extended disability or death compensation.

New York Heart Association (NYHA) classification In order to determine the best course of therapy, physicians often assess the stage of heart failure according to the NYHA functional classification system. This system relates symptoms to everyday activities and the patient's quality of life.

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

The NYHA definition was taken from the website of the Heart Failure Society of America.

Optimal patient In establishing reoperative risk the Supervisory Panel used the predicted risk for a patient in NYHA functional class I or class II, with no associated cardiovascular (coronary artery disease, depressed LV function, myopathy, significant arrhythmia, 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. Although many factors should 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 explanation 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.

Rework status An indication of whether the valve is believed to have undergone a reweld, had a crack polished, or had one of several welder designations prior to its distribution.

Shop order The batch, sometimes referred to as a fab order, in which the valve was produced. Batch sizes ranged from 1 to 168 valves.

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 replacement surgery. The top 10% of facilities in the United States perform more than 30 primary valve replacement procedures a year. The Supervisory Panel strongly advises patients undergoing elective valve replacement surgery to consult with their physicians to obtain advice on referral to centers with greater experience and overall excellence in reoperative valve procedures because such centers can be presumed to have the lowest surgical mortality.

Supervisory Panel Consists of 7 members, 6 of whom are recognized scientific or medical experts (tenured professor, Board certified or equivalent) in fields relevant to the purposes of the Settlement. Currently, the six members include 2 cardio-thoracic surgeons, 2 cardiologists, and 2 epidemiologists. The seventh member, who serves as the Chairperson, is not a scientist or physician and has experience in Court processes and project management. The duties of the Panel include the development of Guidelines for payment of monetary benefits, and sponsoring and monitoring research and development of diagnostic techniques to identify implantees who may have a significant risk of outlet strut fracture. Guidelines developed by the Panel must be approved by the Court before they become effective.

Valve conduit (also known as graft valve) is a tube or graft used when the aorta is damaged. The BSCC heart valve is placed inside the valve conduit. To date, there have been no reported outlet strut fractures of valves implanted in valve conduits.

Welder group A categorization of valves into several groups defined by the identity of the welder(s) involved in the manufacture of the valve.

APPENDIX B: FORMULA FOR AND EXAMPLE OF CALCULATION OF THE ESTIMATED OSF (% 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 60° 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	$(.941)^{50-35} = 0.40165$
Gender	x	1.00
Rework	x	<u>1.00</u>
	=	0.711 % per year

Using the estimated annual fracture rate of 0.711% per year for this hypothetical Class Member calculated above, go to APPENDIX D, Table 3, Row 21 for a male with a mitral valve to find the outlet strut fracture qualification threshold rate of 0.630% per year. Thus, in this example, the person would qualify for monetary benefits under the 2007 Guidelines.

APPENDIX C: 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 (%)		
<u>Age</u>	<u>Single Valve</u>	<u>Multiple Valve</u>
35	4.4	5.4
40	4.4	5.5
45	4.5	5.5
50	4.6	5.6
55	4.8	5.8
60	5.0	6.0
65	5.4	6.4
70	6.1	7.2
75	7.3	8.4
80	9.4	10.8

APPENDIX D: STATISTICAL TABLES FOR USE IN DETERMINING QUALIFICATION UNDER THE GUIDELINES

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

Factor	Multiplier	Subgroup
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	$(.941)^{(\text{Age} - 35)}$
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

