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 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.

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	1.00
	=	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 (%)	
Age	Single Valve	Multiple Valve
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	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. Factors for Calculation of Estimated 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 3. Outlet strut fracture threshold 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**
Row 1	30	0.349	0.365	0.338	0.352
Row 2	31	0.368	0.385	0.355	0.371
Row 3	32	0.389	0.407	0.376	0.392
Row 4	33	0.413	0.432	0.398	0.416
Row 5	34	0.440	0.461	0.425	0.443
Row 6	35	0.472	0.495	0.455	0.475
Row 7	36	0.478	0.501	0.460	0.481
Row 8	37	0.484	0.508	0.466	0.488
Row 9	38	0.490	0.516	0.472	0.494
Row 10	39	0.497	0.523	0.477	0.501
Row 11	40	0.503	0.531	0.484	0.508
Row 12	41	0.510	0.539	0.490	0.515
Row 13	42	0.518	0.547	0.496	0.522
Row 14	43	0.525	0.556	0.503	0.530
Row 15	44	0.533	0.565	0.511	0.538
Row 16	45	0.542	0.574	0.518	0.547
Row 17	46	0.550	0.584	0.526	0.556
Row 18	47	0.560	0.595	0.534	0.565
Row 19	48	0.569	0.606	0.543	0.575
Row 20	49	0.579	0.618	0.552	0.586
Row 21	50	0.590	0.630	0.562	0.597
Row 22	51	0.602	0.643	0.572	0.608
Row 23	52	0.614	0.657	0.583	0.621
Row 24	53	0.626	0.671	0.594	0.634
Row 25	54	0.640	0.687	0.607	0.648
Row 26	55	0.655	0.704	0.620	0.663
Row 27	56	0.670	0.721	0.634	0.679
Row 28	57	0.687	0.740	0.649	0.696
Row 29	58	0.705	0.761	0.665	0.714
Row 30	59	0.724	0.783	0.683	0.734
Row 31	60	0.745	0.807	0.702	0.755
Row 32	61	0.768	0.832	0.722	0.778
Row 33	62	0.793	0.860	0.745	0.804
Row 34	63	0.819	0.890	0.769	0.831
Row 35	64	0.848	0.924	0.795	0.861

Table 3. Outlet strut fracture threshold 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 (continued)

		Male		Female	
	Age	**Aortic**	**Mitral**	**Aortic**	**Mitral**
Row 36	65	0.880	0.960	0.824	0.893
Row 37	66	0.915	0.999	0.856	0.929
Row 38	67	0.954	1.043	0.891	0.968
Row 39	68	0.996	1.090	0.929	1.011
Row 40	69	1.043	1.143	0.971	1.059
Row 41	70	1.095	1.202	1.018	1.112
Row 42	71	1.152	1.267	1.071	1.171
Row 43	72	1.217	1.340	1.129	1.236
Row 44	73	1.289	1.422	1.195	1.310
Row 45	74	1.370	1.513	1.268	1.393
Row 46	75	1.461	1.616	1.351	1.486
Row 47	76	1.565	1.733	1.445	1.592
Row 48	77	1.682	1.866	1.552	1.712
Row 49	78	1.816	2.018	1.674	1.849
Row 50	79	1.970	2.192	1.814	2.006
Row 51	80	2.147	2.392	1.974	2.187
Row 52	81	2.352	2.624	2.160	2.396
Row 53	82	2.591	2.894	2.377	2.639
Row 54	83	2.869	3.209	2.630	2.924
Row 55	84	3.197	3.580	2.927	3.258
Row 56	85	3.584	4.018	3.279	3.654
Row 57	86	4.045	4.539	3.697	4.124
Row 58	87	4.595	5.162	4.197	4.686
Row 59	88	5.258	5.912	4.798	5.363
Row 60	89	6.061	6.820	5.528	6.183
Row 61	90	7.040	7.927	6.417	7.182

Table 4. Outlet strut fracture threshold 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
Row 1	30	0.463	0.446
Row 2	31	0.487	0.469
Row 3	32	0.513	0.494
Row 4	33	0.544	0.523
Row 5	34	0.579	0.557
Row 6	35	0.620	0.596
Row 7	36	0.627	0.602
Row 8	37	0.634	0.609
Row 9	38	0.642	0.615
Row 10	39	0.650	0.622
Row 11	40	0.658	0.630
Row 12	41	0.667	0.638
Row 13	42	0.676	0.646
Row 14	43	0.686	0.654
Row 15	44	0.696	0.663
Row 16	45	0.706	0.672
Row 17	46	0.717	0.682
Row 18	47	0.729	0.692
Row 19	48	0.741	0.703
Row 20	49	0.754	0.715
Row 21	50	0.767	0.727
Row 22	51	0.782	0.740
Row 23	52	0.797	0.753
Row 24	53	0.813	0.768
Row 25	54	0.831	0.783
Row 26	55	0.850	0.800
Row 27	56	0.869	0.818
Row 28	57	0.891	0.837
Row 29	58	0.914	0.858
Row 30	59	0.939	0.880
Row 31	60	0.965	0.904
Row 32	61	0.994	0.930
Row 33	62	1.026	0.958

Table 4. Outlet strut fracture threshold rates (per cent per year), by age and gender, above which the patient with multiple BSCC valves will qualify for valve replacement surgery benefits (continued)

	Age	Male	Female
Row 34	63	1.060	0.989
Row 35	64	1.098	1.023
Row 36	65	1.139	1.060
Row 37	66	1.184	1.100
Row 38	67	1.233	1.145
Row 39	68	1.288	1.194
Row 40	69	1.348	1.248
Row 41	70	1.415	1.309
Row 42	71	1.489	1.376
Row 43	72	1.573	1.451
Row 44	73	1.666	1.536
Row 45	74	1.772	1.631
Row 46	75	1.891	1.738
Row 47	76	2.026	1.860
Row 48	77	2.179	1.999
Row 49	78	2.355	2.157
Row 50	79	2.557	2.340
Row 51	80	2.791	2.551
Row 52	81	3.062	2.796
Row 53	82	3.379	3.081
Row 54	83	3.750	3.417
Row 55	84	4.189	3.812
Row 56	85	4.709	4.282
Row 57	86	5.330	4.842
Row 58	87	6.077	5.517
Row 59	88	6.981	6.332
Row 60	89	8.082	7.326
Row 61	90	9.431	8.544