UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

EIGHTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

COVERING PERIOD FROM DECEMBER 5, 1997 TO JUNE 10, 1998

SPECIAL MASTERS/TRUSTEES

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

AGENDA

EIGHTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 10, 1998
3:00 P.M.

Hon. S. Arthur Spiegel

1. Introductory remarks by Judge Spiegel.
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 Spiegel.

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EIGHTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

To the Honorable S. Arthur Spiegel, Judge, United States District Court:

Your Special Masters/Trustees respectfully present their eighth periodic report, covering activities from December 5, 1997 to June 10, 1998.

I. CONSULTATION FUND

As previously reported, under Section 6 of the Settlement Agreement, the Consultation Fund, initially $80,000,000, is intended to provide Claimants with funds to obtain medical and psychological consultation as they deem best. It is to be divided equally among Claimants after paying or providing for fees and expenses to be paid out of this Fund. In addition, a $10,000,000 fund was established to be paid, after fees and expenses, equally among all Claimants who are spouses of Class Members. The final deadlines for filing Consultation Fund claims were March 31, 1996 for Class Members resident in the United States, and May 31, 1996, for Class Members resident in all other countries.

The Trustees received 15,907 proof of claim forms from implantee claimants. All of these claims have been processed and 13,351 have been approved. The other 2,556 have been rejected for various reasons (such as, lack of reasonable proof of an implanted BSCC valve, implantation of another type of heart valve, death or removal of the BSCC valve before January 23, 1992, etc.).

The approved distributions are as follows: $5,835 to implantees and $962 to spouses of implantees. To date $87,072,554 has been distributed to implantees and spouses of implantees from the Consultation Fund. There is in excess of $3,500,000 remaining in the Fund. It is anticipated that final nominal distributions will be paid to both implantees and spouses of implantees. The eventual total amount paid to implantees and spouses is estimated to exceed the $90,000,000 originally paid into the Fund by Defendants.

The timing of a final distribution from the Consultation Fund depends primarily on the settlement of Federal income tax matters. It will be remembered that the Trustees received a favorable revenue ruling regarding the taxability of the Settlement Fund (Fund) and the deductibility of certain expenses for Federal income tax purposes. Due to the revenue ruling, the Fund received refunds of taxes related to a net operating loss carryback for 1993 and a refund of 1996 estimated tax payments. In addition, amended returns were filed for 1994 and 1995 which have been audited by the Internal Revenue Service and the Trustees are awaiting refunds for these two years. The Consultation Fund will be liquidated as soon

as practical after receipt of these tax refunds.

II. PATIENT BENEFIT FUND

Under Section 5 of the Settlement Agreement, the Patient Benefit Fund was established for the following purposes, briefly stated: to conduct research on the diagnosis of the risks of strut fracture and the risks of surgical replacement of valves, to establish guidelines for valve replacement surgeries, and to create a publicly accessible repository of appropriate information concerning the status of research and the risks of valve fracture and valve replacement.

A. Dissemination of 1997 Guidelines. The Supervisory Panel has made extensive efforts to disseminate and publicize the Guidelines approved by the Court on August 28, 1997 (Document 1130). Using the procedure employed in the past and updated mailing lists, and with the Court's approval, a letter was sent by direct mail to physicians in most of the world enclosing the Guidelines (with the sole major exception of The Netherlands, where permission has not yet been granted for such mailing). This method of informing patients is the only method allowed in all contacted countries except the United States. In the U.S., a brief letter, approved by the Court, was mailed to all Class Members known to the Administrator through the filing of claims under the Consultation Fund or otherwise and to those implantees who are registered in Medic Alert and were not known to the Administrator. Appendix 1 shows the numbers of letters sent out, the countries to which they

were sent and the cost of this mailing.

The Supervisory Panel has written an article to be submitted to a leading U.S. medical journal describing the Guidelines in summary form and the procedures leading up to the promulgation thereof. A copy is attached as Appendix 2. It has been submitted to and reviewed by Class Counsel and Counsel for Defendants. The Supervisory Panel requests Court approval so that it may be submitted to prospective publishers.

Accompanying the medical article is a brief notice which the Supervisory Panel wishes to publish in leading medical journals, as is also shown in Appendix 3. Court approval is requested.

The U.S. Food and Drug Administration has placed the Guidelines in their web site, available to all through the internet. The Supervisory Panel is exploring the possibility of creating its own web site, but this cannot be done until after the Panel's public repository is in place. The Chairman continues to work on the questions of what will be in the repository and which parts of it will be available to public scrutiny and which parts must be kept confidential. Court approval will be sought before the establishment of either the repository and the web site.

B. Research. Projects are under way or planned in a number of different areas. With respect to imaging, a follow-up study of the approximate 1,000 patients imaged in the Stanford, Beaumont and Glasgow studies is close to being presented to the Court for approval. The purpose will be to study how patients have fared whose valves have been evaluated with respect to estimated risk of

valve failure. In addition, a project at Stanford will offer reimaging evaluation to all mitral patients (aortic patients are not included) who qualify for benefits for surgical replacement of a high risk valve under the Guidelines. Further, this imaging center will be available to all other patients (not qualifying under the Guidelines) who wish to have their valves x-rayed at their cost.

As to acoustic research, further anechoic studies by Lawrence Livermore National Laboratories are under way (under the supervision of Drs. Weyman and Harrison), a contract with Information Systems Laboratories (formerly Quantum Magnetics) to study in vivo sounds is being conducted, and Dr. Wikswo's proposal to record induced sounds is under consideration. The purpose of these projects is to determine the advisability of pursuing the possibility of finding reliable acoustical detection of a high risk valve.

The Panel is also working on establishing a project to study the characteristics and durability of the metal from which the BSCC heart valve is manufactured. Past research projects have not turned up data of any useful significance, but the Panel desires to address this subject from a fresh point of view.

Epidemiological research continues and will be increased. Current and ongoing projects are the studies in the U.K. (which has the assistance of Dutch researchers trained in the examination and evaluation of Shiley's manufacturing records) and in the U.S. where Medic Alert and the International Epidemiology Institute, Ltd. are

conducting epidemiologic studies. The Second Dutch Follow-up Study has been completed and a final report was made to the Panel. Dr. Yolanda van der Graaf gave the Panel at its last meeting (March 1998) a detailed and impressive review of her conclusions, and her request for a follow up study was approved for a two year period. The Dutch cohort is, to date, the best defined and the most closely studied group of implantees in the world. The research in The Netherlands has been one of the most reliable and influential sources of information.

In this connection, the Supervisory Panel has approved the creation of a Data and Publication Committee consisting of the principal investigators of the three cohort studies (the Dutch, the U.K. and the U.S.) and others, to meet periodically to perform functions such as reviewing the consistency of definitions and groupings of data sets, facilitating the pooling of data, and arranging for combined data analysis. Court approval will be sought when this proposal is properly documented.

Under the guidance of Dr. Tom Ivey, studies of the rates of operative mortality and operative morbidity are in process of formation. This was promised last summer when the Supervisory Panel, the Chairman and the Trustees presented their Guidelines for court approval, because operative risks are key to the determination of which Class Members will qualify for valve replacement surgery. A contract with Health Data Research has been drawn up and will be submitted for court approval, and two other studies are being detailed and budgeted before they can be

submitted.

The Supervisory Panel has approved a proposal made by the Epidemiology Subcommittee to hold a workshop of leading epidemiological experts and professionals on the subjects of the synthesis of ongoing studies and recommendations of other studies.

C. Broad based Independent Review of Research. The Supervisory Panel has authorized the Chairman to find a group of qualified research experts (perhaps a think tank) to review all former research projects and reports that the Supervisory Panel has access to or knowledge of (whether done under its aegis or the aegis of Shiley or Pfizer), in order to determine and/or define other potential areas of research that would benefit the Class. This group will work closely with the Supervisory Panel and will have authority to consult with other experts worldwide.

D. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator has received 383 claims for valve replacement surgery and outlet strut fracture claims. The processing of many of these claims had been initiated by Shiley in the interim period from the date of the Settlement Agreement until the Claims Administrator was appointed. In addition, other qualified claims were settled by Shiley with the Settlement benefits during this interim period.

Of the above 383 claims, there are 58 qualified outlet strut fracture claims, 34 qualified single leg fracture claims and 43 qualified valve replacement surgery claims. Some of the claimants have elected other courses of action rather than to receive the

Settlement benefits. The remaining claims have been reviewed and they either do not qualify or additional information is needed and has been requested from the claimants.

As previously reported, the computer system in the Trustees' office has been upgraded in order to implement the new guidelines for valve replacement surgery. Software was installed which includes a data table consisting of selected manufacturing and implantation data derived from the Bjork-Shiley convexo-concave research data base of Shiley Incorporated. This data is needed to determine the eligibility of implantee Class Members for valve replacement surgery benefits under the Supervisory Panel's new guidelines formula.

The office of the Claims Administrator has provided, upon requests, the estimated annual fracture rates under the new guidelines formula for approximately 3,000 implantees. There are three known recent valve replacement surgeries that qualify for benefits under the new guidelines formula. By reviewing the valve replacement surgery claims and the Consultation Fund claims, there have been identified 213 implantees who may qualify for valve replacement surgery benefits under the new guidelines formula. Of these implantees, 42 have already had their BSCC heart valves explanted.

III. FINANCIAL INFORMATION

At April 30, 1998, the total balance of cash and cash equivalents was $3,642,232 for the Consultation Fund (class member

portion and spousal portion) and $11,690,668 for the Patient Benefit Fund. These amounts include net interest earned from January 28, 1992 through April 30, 1998, in the aggregate amount of $17,448,909 for the Consultation Fund and $1,844,188 for the Patient Benefit Fund.

Attached as Appendix 4 are the following: an unaudited balance sheet as of April 30, 1998 and an unaudited statement of income and funds balance for the four months ended April 30, 1998 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 1998 through December 31, 1998).

Attached as Appendix 5 are the following: an unaudited balance sheet as of December 31, 1997 and an unaudited statement of income, benefit payments and funds balance for the year ended December 31, 1997 (which includes the budgeted amounts for expenses for the Research Management Group and the administrative office for the year ended December 31, 1997).

IV. COMMUNICATIONS

There is a daily contact with Class Members about a variety of their concerns. The Claims Administrator, the Chairman of the Supervisory Panel and the Trustees' office are in contact with Class Counsel.

V. APPROVALS

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

(a) approve this report, and

(b) approve the publication of the medical article and the notice to be published in medical journals, and

(c) approve or provide direction with respect to each of the other Appendices to this Report, and

(d) fix the date of the next Report.

Respectfully submitted,

Dated: June 10, 1998

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

"DEAR DOCTOR" LETTER
MAILING DIARY

1. Worldwide Registry - Mailed 1/26/98
   - Specified 60 degree or 70 degree or both
   - Also enclosed Brookmeyer's Report
   - List came from disk from Shiley
   - 105 total letters

2. U.S. Dear Doctor Letters - Mailed 1/29/98
   - 60 degree letter only
   - 22,615 total letters

3. Additional U.S. Doctor list from Shiley (Sherrie Sciacca) - Mailed 1/30/98
   - Combo letter only
   - 80 total letters

4. Australia and New Zealand Letters - Mailed 2/2/98
   - Combo letter only
   - 794 total letters

5. U.K. Letters - Mailed 2/3/98
   - Specified 60 degree or 70 degree letter
   - 529 total letters

6. Special Distribution - (Disk Names) - Mailed 2/3/98
   - Specified 60 degree or 70 degree letter
   - 307 total letters

7. Canadian Mailing (Drs. & Hospitals) - Mailed 3/24/98
   - 300 Total letters
   - 1 French Combo & 1 English Combo

8. 2nd Canadian Mailing - Mailed 4/10/98
   - Error in French Translation
   - 300 Letters

9. Shiley EMEA Database (Drs. & Hospitals) - Mailed 4/13/98
   - English Combo - 1,819 Letters
   - French Combo - 1,082 Letters
   - Spanish Combo - 10,191 Letters
   - German Combo - 850 Letters

10. S. America Database (Dr. & Hosp.) - Mailed 4/15/98
    - English Combo - 16 Letters
    - Spanish Combo - 8,025 Letters

11. Asia Pacific Database (Dr. & Hosp.) - Mailed 4/15/98
    - English Combo - 936 Letters
    - French Combo - 5 Letters

"DEAR PATIENT" LETTER
MAILING DIARY

1. Dear Patient Letters - Mailed in the U.S. only on 2/13/98
   - Mailed by Spectrum, Disk from our office
   - 6,608 letters mailed

2. Medic Alert's Dear Patient Letter mailing - Mailed 3/31/98
   - Mailed by Medic Alert
   - Total of 4,181 Letters (3,981 From Medic Alert, 200 Explanted Patients)

TOTAL SPENT ON "DEAR DOCTOR" AND "DEAR PATIENT" LETTER MAILINGS:

POSTAGE:	$ 77,901.00
OTHER OUTSIDE COSTS:	$ 79,607.00
	$ 157,508.00

6/1/98

New Guidelines for the Prophylactic Replacement of Bjork-Shiley Convexo-Concave Valves: A Clinical and Epidemiological Approach by the Bowling-Pfizer Supervisory Panel

Running Head: New Bjork-Shiley Heart Valve Guidelines

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The Supervisory Panel wishes to acknowledge the assistance of its consultants: William J. Blot, Ph.D., Chief Executive Officer, International Epidemiology Institute, Ltd.; Ronald Brookmeyer, Ph.D., Department of Biostatistics, Johns Hopkins University; Gary L. Grunkemeier, Ph.D., Director, Medical Data Research Center.

Abstract

Background: During the past two decades, reports of outlet strut fracture (OSF) of Bjork-Shiley Convexo-Concave (BSCC) valves have been received. Considerable clinical, legal, and media attention has been focused on the problem. In 1992 a class action lawsuit was settled between Pfizer and the Class of BSCC implantees with the unique provision of establishing a scientific Supervisory Panel under the jurisdiction of the Federal Court to develop guidelines for payment for prophylactic replacement of BSCC valves and to direct research on methods to detect and replace valves that may have a high risk of fracture.

Method: In 1994 a seven person Supervisory Panel composed of cardiologists, epidemiologists, a cardiovascular surgeon, a cardiovascular radiologist and a non-physician as Chairman was appointed by the Court. This Panel has directed epidemiological, acoustical, and image research and has developed new guidelines and recommendations for prophylactic replacement of BSCC valves.

Results: The New Guidelines are based on balancing the risk for OSF as estimated from epidemiological findings from worldwide data banks on patients having implanted BSCC valves and

manufacturing characteristics of the valves versus the risk of mortality from reoperation. The guidelines require the use of a formula which permits a determination of the likelihood of increasing life expectancy by two years if BSCC valves are explanted. Additional recommendations are included which may aid physicians managing patients with BSCC valves. Patients qualifying under the previous guidelines for benefits from the settlement funds are generally also included.

Conclusion: Patients with BSCC valves who are deemed to be at high risk upon application of the new Guidelines are recommended for consideration for BSCC explantation based upon individual decisions by patients and their physicians.

Key words: Bjork-Shiley valves, outlet strut fracture, single leg separation, Bowling-Pfizer, guidelines, meaningful extension of life.

Introduction

The replacement of damaged heart valves with prosthetic devices was first attempted in the 1930s but was not successfully introduced until the early 1960s. Since that time considerable effort has been devoted to producing replacement heart valves that would have a longer life cycle and result in fewer hemodynamic complications.[1] Both mechanical valves of various designs and tissue valves have been developed for this purpose. Mechanical valves have been the most widely used in the past decade, because some tissue valves have been shown to deteriorate after 5-7 years and have frequently required explantation.[2-8] Many designs of mechanical valves have been introduced in the past three decades with varying degrees of clinical success.[1] Most have functioned quite well clinically and produced hemodynamic improvements, but their implantation may result in thrombosis on the valve, systemic embolization, stroke, endocarditis, perivalvular leaks, and, in rare instances, mechanical failure of the valve.[1] The results of valve replacement on life survival and the mechanisms and frequency of valve failure have recently been summarized.[1]

In 1969, the Bjork-Shiley tilting disk prosthesis was introduced with the claim of improved

hemodynamic function and fewer thrombogenic properties. During the next decade, several modifications were made. The 60 degree BSCC valve was distributed from 1979 to 1986, and the 70 degree BSCC valve from 1980 to 1983.[9] These modifications to the orifice ring struts supporting the disk incorporated the design of the valve ring and a major strut machined as one piece. However, the minor strut was still inserted and fused with the ring afterwards by an arc welding technique, as had been done for both struts on previous tilting disk valves. Soon thereafter, several fractures of the minor strut with escape of the disk into the peripheral circulation or into the heart were reported.[10-12] During the past 15 years, the fracture rate of the series of valves manufactured between 1978 and 1986 has attracted the attention of cardiologists, cardiovascular surgeons, epidemiologists, lawyers, and the media.

Several approaches were initiated to estimate the potential to fracture of the valve's minor strut, which became known as an outlet strut fracture (OSF).[1,13-17] These approaches examined a series of manufacturing characteristics, the size of the valve, the location of the implant, and whether the valve was a 60 or 70 degree valve.[13-17] Pfizer (the company that had acquired the stock of Shiley in 1979) appointed two independent panels of professional persons; in 1985 the 70 degree Medical

Advisory Panel was appointed, and the 60 degree Medical Advisory Panel in 1986.

Many lawsuits were initiated as a result of this valve's reported propensity toward OSF and the actual occurrence of OSF. In addition, a class action suit brought on behalf of BSCC implantees was filed in 1991 and this suit has become known as the Bowling-Pfizer Heart Valve Litigation. In 1992, the class action case was settled by an agreement approved in a federal court decision in Cincinnati, Ohio. Part of this Settlement mandated the appointment of a Supervisory Panel charged with studying the clinical and epidemiological data and developing a new set of guidelines for prophylactic BSCC valve replacement, which would be provided benefits by a settlement fund.

The purpose of this article is, first, to review the background and demographics of the worldwide experience with the BSCC valves; second, to outline the process to modify the guidelines that the Supervisory Panel has developed since its appointment in 1994; and third, to present a new set of guidelines for use by patients with BSCC valves and the physicians who manage them. These new guidelines are the basis for providing benefits to Class Members from the settlement funds for replacement surgery (Appendix I).

Background and Demographics

The BSCC valves considered in this report are the 60 degree valves distributed 1979-1986 and the 70 degree valves distributed 1980-1983. The specific changes in design from the previous Bjork-Shiley tilted disk valve included: first, making the inlet strut an integral part of the orifice ring, which was thought to improve the durability of the strut; second, moving the occluder disk away from the orifice ring in the open position to reduce stasis and valve thrombosis; and third, producing a design to increase blood flow through the minor flow orifice of the valve to improve its hemodynamic performance. A later modification was made to permit a 70 degree opening angle of the occluder disk and further improve hemodynamic performance.[9]

Approximately 86,000 of the BSCC valves, manufactured by Shiley, are estimated to have been implanted between 1979 and 1986, of which approximately 82,000 were 60 degree valves and approximately 4,000 were 70 degree valves. The 70 degree valve was never approved for use in the United States and had limited distribution in Europe, Australia, South Africa, and Canada. Rates of outlet strut fracture for the 60 and 70 degree BSCC valves differ considerably and have resulted in considerable difference in the clinical experience of elective explantation.

The first reported BSCC 60 degree OSF was in an aortic valve prosthesis that occurred during clinical trials in September 1978. The manufacturer subsequently carried out a series of engineering and quality control analyses aimed at testing and increasing the strength of the outlet strut in the area where it was welded to the flange, on the hypothesis that the weak welds might be the cause of OSF. These efforts included implementation of a load deflection test. We are told that revised quality control and inspection procedures and modification to the manufacturing processes, implemented in April 1984, ensured that on closing, the disk could not strike the tip of the outlet strut, thereby preventing loads on the tip in excess of the material's fatigue endurance limit. No BSCC valve manufactured after April 1984 has been reported fractured. The new guidelines treat such valves as having no fracture risk.

In November 1986, all unimplanted BSCC heart valves were withdrawn from the market. Prior to that there were selective withdrawals from the market: all 70 degree valves in 1982-83, and the 29, 31, and 33mm 60 degree valves in 1985.

Approximately 86,000 BSCC valves are estimated to have been implanted in patients. The exact number of implanted valves cannot be known because there is no complete registry of

implantees. Implant cards that were designed to be returned to the manufacturer were not returned for approximately 60% of the valves, with the percentage of non-returns being even higher from sites outside the U.S. Therefore, it has been difficult to identify all patients having BSCC valves or to communicate directly with them or their physicians. Starting in late 1990, we understand that Pfizer undertook to create worldwide retrospective registries of BSCC valve patients. In the U.S. and United Kingdom, those registries are administered by Medic Alert and in other countries by surgeons, medical associations and government agencies. These registries provide a confidential means of communicating with BSCC valve patients and physicians as new information becomes available. In addition, Pfizer has maintained a worldwide database for reporting outlet strut fracture and the condition of any BSCC valve explanted electively. Explanted valves returned to Pfizer have been subjected to extensive evaluation, and their characteristics are recorded in this database. In several other countries, additional databases have been developed for reporting outlet strut fractures and the condition of any valves electively explanted. In The Netherlands, there has been extensive tracking of patients implanted with BSCC valves which has been reported.[19-22]

Data from the Shiley BSCC database are reported quarterly to the FDA. The November 30,

1997 Quarterly Report noted 606 OSF occurrences, with 150 being in the BSCC 70 degree valves, 445 in the 60 degree BSCC valves, and 11 in valves of unknown type. It is generally accepted that the reported rate for outlet strut fracture is an underestimate of the true fracture rate, and correction factors have been developed to account for this in estimating the risk of fracture. Extensive analysis of the worldwide experience with outlet strut fracture in the BSCC valves will be further detailed in a subsequent publication.

Previous Guideline Development

The independent Medical Advisory Panels for 60 degree and 70 degree valves, composed of American and European cardiologists, cardiovascular surgeons, biostatisticians, and epidemiologists, met at least twice yearly from 1985 through 1994, the last meeting being in January 1995. They reviewed the worldwide experience with BSCC valves as reported to the Shiley BSCC database and issued guidelines to the medical community from 1987 until 1995.[23,24] These guidelines were based on estimates of risk of OSF primarily according to various characteristics of the BSCC valves. The risk estimates were derived from epidemiological studies and manufacturing data obtained from

company records. These guidelines, which rated the risk of OSF for specific valve categories, were reviewed by the FDA and were presented to patients and physicians in the U.S. in letters approved by the agency.[23,24] Specific guideline distribution in other countries was regulated by various governmental agencies in those countries.

Bowling-Pfizer Settlement

The Settlement negotiated between opposing attorneys in the class action and entitled Bowling v. Pfizer in the United States District Court in Cincinnati, Ohio, approved by that Court, is an extraordinary breaking of new ground in bringing mass litigation to a conclusion. The Settlement Agreement includes in the Class all persons throughout the world who were implanted with a BSCC valve as of January 23, 1992, and who have not opted out of the Settlement. It should be noted that the Court has retained jurisdiction over all aspects of the Settlement, and thus this oversight will continue until terminated in accordance with the Settlement Agreement.

Among the features of the Settlement Agreement is the creation of a Supervisory Panel composed of six physicians and a lay chairman. Class Counsel and Counsel for Defendants each

recommended three physicians, who were appointed by the court without objection, and the court appointed the lay chairman. The Panel has three major responsibilities:

1. to conduct research in two areas: diagnostic techniques to identify implantees with significant risk of strut fracture of the BSCC valve, and the reduction of the risks of valve replacement surgery;

2. to develop, and to amend from time to time, guidelines for replacement surgery due to the risk of strut fracture; and

3. to create a publicly accessible repository of information useful to the medical community about the research (i.e. risks of valve failure and risks of surgical replacement), and the availability, use, and evaluation of any diagnostic techniques.

With respect to the first two responsibilities, the Panel was directed to review both the research and the guidelines previously established under the aegis of Shiley-Pfizer and approved by the FDA.[23,24] These guidelines were to remain in effect until amended by those of the Supervisory Panel. An addendum to the Settlement provided that in establishing its guidelines, the Panel should, if possible, identify those circumstances in which prophylactic replacement of a BSCC heart valve

"would reasonably offer a meaningful extension of life expectancy because of the risk of strut fracture."

The provisions for monetary benefits for Class Members are several. If a surgical replacement due to risk of strut fracture complies with the guidelines, the benefits are payment for all unreimbursed costs of the surgery with the optional benefits of a lump sum of $38,000 and lost income.

If a removed valve is found to have one broken leg of the outlet strut (known as a single leg separation, or SLS), unreimbursed costs of the surgical procedure are paid from the settlement fund and all other compensation or benefits are subject to negotiation.

If a complying surgical replacement results in the death or total permanent disability of a patient with an implant, the case is treated as though there had been a total fracture of the valve (an OSF). The compensation payable for OSF is determined for a U.S. resident by a formula incorporated in the Settlement Agreement, which awards a lump sum depending on the patient's family status, age and income at the time of fracture. While the stated formula is applicable to U.S. residents, non-U.S. residents are compensated on an equivalent basis by formulas recommended by

an independent Foreign Fracture Panel and approved by the Court for each of four groups of countries.

There is an open end to the Settlement in that if the settlement funds are exhausted, Pfizer must continue to furnish funds to pay for complying replacement surgeries. Further, in cases of OSF, Pfizer pays from its own funds all compensation to which the patient or the survivors are entitled, and the settlement funds are not diminished.

Activity of the Bowling-Pfizer Supervisory Panel

The Supervisory Panel members were appointed in Spring 1994 and held their first meeting in June 1994. The Panel is composed of cardiologists, epidemiologists, a cardiovascular surgeon, a cardiovascular radiologist, and a Chairman, a non-physician. The Supervisory Panel has subsequently met at least three times per year. Several subcommittees of the Panel have been established and continue to work actively, including subcommittees for epidemiology, imaging and acoustics, and surgical oversight.

The Panel continues to seek input and advice from appropriate experts. The activities of the

Supervisory Panel have included visits to the Shiley Heart Valve Research Center, discussions and advisory sessions with both Shiley and Class Counsel, meetings with the physicians associated with and directing research protocols. The Panel has carried out an extensive review and analysis of the worldwide BSCC database maintained by Shiley. The Panel has also supported research aimed at better detection of patients with BSCC valves at risk for outlet strut fracture. Several imaging and acoustic studies have been undertaken in an attempt to define methods to detect the risk for fracture. Epidemiological studies in The Netherlands and Great Britain have also been supported. These studies are ongoing and will be the subject of subsequent reports.

The New Guidelines

In January 1995 the Panel began planning the new guidelines. Extensive data analysis and discussion followed, and more than one dozen drafts of guidelines were developed. A working draft was submitted for review by regulatory agencies from several countries and other professional medical organizations as had been directed by the Settlement Agreement. By early 1997 the Supervisory Panel had reached consensus on guidelines to be submitted to the Federal Court for

approval.

As required by the Settlement Agreement, the proposed guidelines were distributed to, and responses obtained from medical societies, institutions, government agencies, and relevant individuals noted in the Settlement Agreement, specifically including Class Counsel, Counsel for Defendants, and the U.S. FDA. Every comment submitted was presented to and considered by the Panel. The resulting final draft was approved by the Panel on April 23, 1997, filed in the U.S. District Court, explained and discussed in two open hearings May 2, 1997, and June 4, 1997. Class Counsel and Counsel for Amicus (Public Citizen) raised certain objections and made certain counter proposals, which were extensively briefed for the Court during the summer months. After thorough review, the Court approved the Panel's final draft of the guidelines on August 28, 1997, without any change or amendment.

Specific Features of the New Guidelines

A new model to aid in deciding which patients with implanted BSCC valves might benefit from elective explantation was developed.[25] In this model, the risk of reoperation was weighed

against the potential risk of OSF. The basic approach was to compute the potential gains in life expectancy from reoperation to replace the valve with another prosthesis. Life expectancies with and without elective explantation were calculated and compared. These calculations accounted for the possibilities of competing causes of death, outlet strut fracture (which was assumed to result in death) and reoperative mortality. Separate models for 60 and 70 degree BSCC valves were developed to predict the risk of outlet strut fracture based on valve size, implant position, manufacturing characteristics and patient age. The risk of death from competing causes is related to the patient's age and gender. Reoperative mortality is markedly influenced by the patient's age. A new set of simplified tables and formulae were developed and are outlined in the guidelines (Appendix I).

Several considerations merit further explanation. First, the analyses used by the Panel were based on the worldwide data in the Shiley BSCC database as of August 1996. It has been well known that the reporting of OSF is under-reported, Shiley having first taken this into account in 1992. The estimated fracture rates used by Shiley since 1992 and by the Panel were adjusted for this under-reporting, using the experience in The Netherlands as a standard. This resulted in using a multiplier

which has increased the fracture rates reported to Shiley Pfizer. In addition, the calculation of individual estimates of rates of OSF took into account two new risk factors not previously included: valve shop order and the patient's current age.

Second, there was considerable controversy about the surgical mortality for reoperation in patients with different levels of heart failure, different ages, and different associated co-morbidities. The two specific approaches that were used were to review the data on in-hospital mortality from prosthetic valve reoperation in three American centers, and to review the experience with prophylactic replacement of the BSCC valves. The information specific to BSCC valves was derived from the nearly 1,000 patients undergoing imaging and acoustic studies within the United States and Great Britain and the experience in The Netherlands. Based on the reported data available for patients with BSCC valves undergoing explantation and replacement of the valves, the reoperative mortality for a theoretical patient, age 58, was calculated and adjusted downward for patients younger than 58 and upward for patients older than 58. Such calculations based on the available data directly related to BSCC valves yielded a mortality at 90 days of 9%. Since certain data for patients undergoing prophylactic reoperations for other types of valves predicted a reoperative mortality rate

lower than this, a modification was made by the guidelines subcommittee to adjust the theoretical patient's average mortality at age 58 to be 6%, adjusting downward for younger patients and upward for older patients.

These analyses of surgical mortality did not take into account the fact that patients undergoing elective explantation still had a prosthetic valve in place with the high risk of thromboembolism, perivalvular leak, stroke, and endocarditis. In addition, the serious morbidity and recovery from second and/or multiple heart operations was not figured into the equation.

Third, the Panel determined that a gain in life expectancy of two years or more would be meaningful and significant. This conservative approach was taken because of the inexact data that were available to calculate surgical mortality associated with elective explantation, the failure to take into account co-morbidity in many of these patients as it relates to reoperative mortality, the fact that serious morbidity from reoperation could not be considered with available data, and the fact that the risk factors for OSF in individual patients were not clearly known, with all data on such risk factors based on epidemiology and thus inexact for any particular patient. Furthermore, if a patient has elective explantation, he or she must receive another prosthetic valve and is at risk for all the

associated complications and the risk of anticoagulation, which is considerable. The fact that some patients survive outlet strut fracture, particularly those with mitral valve replacement, could not be taken into account, and for practical purposes it was assumed that all outlet strut fractures resulted in death.

Fourth, the potential benefit obtained in terms of increasing life expectancy occurred primarily among young patients. Current data indicates that it is probable that outlet strut fracture rates decline with age and reoperative mortality rates increase with age. It is important to recognize that gains in life expectancy are extremely sensitive to assumptions about reoperative mortality, and the Panel plans further data collection and studies that will aid in refining the estimates for gain in life expectancy.

Finally, those patients who had qualified for benefits under the previous guidelines were generally included as qualifying for benefits under the new guidelines. Some patients who were reasonable candidates for elective explantation have already undergone it, and patients who qualify for benefits under the old guidelines have either serious co-morbidity or advanced stages of heart failure. Further, benefits once granted are legally difficult to take away. Irrespective of whether an

implantee qualifies for benefits, the judgment of physicians advising these individual patients will prevail. Thus, the new guidelines generally maintain benefits for Class Members who qualify under the previous guidelines, while increasing the number of younger patients who qualify for BSCC valve replacement surgery benefits.

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IMPORTANT NOTICE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

To Medical Professionals with Patients with Bjork-Shiley Convexo-Concave (BSCC) Heart Valves

New guidelines for prophylactic explantation of BSCC heart valves have been issued, with United States District Court approval, by the Trustees and the Supervisory Panel appointed and acting under the Bowling-Pfizer Settlement Agreement. These new guidelines use additional determinative factors not found in previously issued guidelines (January 1995 for 60 degree heart valves, and August 1994 for 70 degree heart valves). The guidelines are used to determine when valve replacement surgery should be considered and when valve replacement benefits under the Settlement Agreement will be paid.

To receive a copy of the new guidelines, contact the Trustees or the Claims Administrator at the Bowling-Pfizer Settlement Funds office:

525 Vine Street, Suite 1300
Cincinnati, Ohio 45202-3124
Telephone: 513/421-4415
800/977-0779
Facsimile: 513/421-7696

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF APRIL 30, 1998

UNAUDITED

ASSETS

CASH:	
Consultation Fund	$ 68,086
Patient Benefit Fund	20,310
U.S. TREASURY BILLS:	
Consultation Fund (Par Value $3,615,000)	3,574,146
Patient Benefit Fund (Par Value $11,752,000)	11,670,358
OTHER ASSETS	24,990
	$ 15,357,890

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	$ 745,399(1)
FUNDS BALANCE	14,612,491
	$ 15,357,890

(1) - Does not include any provision for fees and expenses relating to applications filed with the Court in November 1997 by Class Counsel and Special Counsel and Public Citizen, Inc. that basically covered the period October 1996 - October 1997.

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME AND FUNDS BALANCE

FOR THE FOUR MONTHS ENDED APRIL 30, 1998

UNAUDITED

INCOME:		
Investment interest:		
Consultation Fund	$	62,698
Patient Benefit Fund		210,364
Total		273,062
RESEARCH PROGRAMS		284,163
EXPENSES:		
Supervisory Panel (1)		558,376
Trustees' fees and expenses		64,950
Professional fees		15,084
Administrative office (1)		138,653
Total		777,063
NET CHANGE IN FUNDS BALANCE		(788,164)(2)
FUNDS BALANCE, DECEMBER 31, 1997		15,400,655
FUNDS BALANCE, APRIL 30, 1998	$	14,612,491

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

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

SCHEDULE OF EXPENSES
UNAUDITED

	BUDGET 1/1/98-12/31/98	ACTUAL 1/1/98-4/30/98
SUPERVISORY PANEL:		
Panel members' compensation		$ 236,400
Consultants' compensation		118,973
Travel expenses		39,156
Miscellaneous		6,339
Notification expenses		157,508
Total		$ 558,376
ADMINISTRATIVE OFFICE:		
Rents	$ 54,000	$ 18,772
Office payroll	298,000	86,028
Payroll taxes	18,000	7,488
Employee benefits	18,000	5,086
Outside services	96,000	11,323
Printing and postage	48,000	420
General insurance	3,000	900
Telephone	24,000	5,892
Office supplies and expense	12,000	786
Travel	6,000	
Depreciation	4,000	1,669
Miscellaneous	12,000	289
Total	$ 593,000	$ 138,653

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF DECEMBER 31, 1997

UNAUDITED

ASSETS

CASH:	
Consultation Fund	$ 76,658
Patient Benefit Fund	75,000
U.S. TREASURY BILLS:	
Consultation Fund (Par Value $3,615,000)	3,605,202
Patient Benefit Fund (Par Value $12,652,000)	12,588,169
OTHER ASSETS	25,793
	$ 16,370,822

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	$ 970,167(1)
FUNDS BALANCE	15,400,655
	$ 16,370,822

(1) - Does not include any provision for fees and expenses relating to applications filed with the Court in November 1997 by Class Counsel and Special Counsel and Public Citizen, Inc. that basically covered the period October 1996 - October 1997.

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE YEAR ENDED DECEMBER 31, 1997

UNAUDITED

INCOME:	
Investment interest:	
Consultation Fund	$ 1,022,406
Patient Benefit Fund	458,365
Miscellaneous	11,928
Total	1,492,699
BENEFIT PAYMENTS:	
Consultation Fund:	
Implantees	38,416,910
Spouses	4,546,644
Total	42,963,554
Patient Benefit Fund:	
Valve Replacement Surgery	43,279
Total	43,006,833
RESEARCH PROGRAMS	1,002,147
LITIGATION ATTORNEYS-FEES & EXPENSES	737,765(1)
EXPENSES:	
Supervisory Panel (2)	1,462,435
Trustees' fees and expenses	206,563
Professional fees	58,130
Research Management Group (2)	67,754
Administrative office (2)	487,321
Total	2,282,203
PROVISION FOR FEDERAL TAXES	(388,064)
CONTRIBUTION BY SHILEY INCORPORATED	6,250,000
NET CHANGE IN FUNDS BALANCE	(38,898,185)
FUNDS BALANCE, DECEMBER 31, 1996	54,298,840
FUNDS BALANCE, DECEMBER 31, 1997	$ 15,400,655

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

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

SCHEDULE OF EXPENSES
UNAUDITED

	BUDGET 1/1/97-12/31/97	ACTUAL 1/1/97-12/31/97
SUPERVISORY PANEL:		
Panel members' compensation		$ 931,440
Guidelines Committee compensation		39,491
Consultants' compensation		300,685
Travel and other expenses		190,819
Total		$ 1,462,435
RESEARCH MANAGEMENT GROUP:		
Rents	$ 62,000	$ 25,606
Office payroll	84,000	18,826
Payroll taxes	8,000	1,734
Employee benefits	12,000	1,021
Outside services	12,000	1,015
Computer and telephone support	24,000	625
Travel	12,000	
Printing and postage	24,000	8,763
General insurance	3,000	
Telephone	12,000	2,696
Research supplies and expense	12,000	4,667
Office supplies and expense	9,000	2,470
Depreciation	8,000	
Miscellaneous	3,000	331
Total	$ 285,000	$ 67,754
ADMINISTRATIVE OFFICE:		
Rents	$ 54,000	$ 49,359
Office payroll	298,000	269,772
Payroll taxes	24,000	15,891
Employee benefits	24,000	15,864
Outside services	102,000	66,501
Printing and postage	54,000	47,117
General insurance	6,000	1,357
Telephone	24,000	12,541
Office supplies and expense	12,000	1,971
Travel	6,000	
Depreciation	4,000	2,792
Miscellaneous	12,000	4,156
Total	$ 620,000	$ 487,321