

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

IN RE: : Case No. C-1-91-256

BOWLING-PFIZER LITIGATION : (Judge Spiegel)

FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES

COVERING PERIOD FROM FEBRUARY 28, 1992 TO FEBRUARY 28, 1995

SPECIAL MASTERS/TRUSTEES

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

AGENDA

FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES
MOTION FOR INTERPRETATION OF SETTLEMENT AGREEMENT

In Re: Bowling-Pfizer Litigation

March 3, 1995

10:00 A.M.

Hon. S. Arthur Spiegel

FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES

1. Introductory remarks by Judge Spiegel.
2. First Part of Report of Special Masters/Trustees.
3. Report of Foreign Fracture Panel (FFP).
4. Objections to FFP Report.
5. Comments from Counsel:

 Class Counsel.
 Counsel for Defendants.
6. Questions and comments from those in attendance.
7. Continued Report of Trustees.

 A. Consultation Fund: report of Trustees.
 B. Patient Benefit Fund: report of Supervisory Panel.
 C. Financial Reports: report of Trustees.
8. Comments from Counsel:

 Class Counsel.
 Counsel for Defendants.
9. Questions and Comments from those in attendance.
10. Request for date of next report of Trustees.
11. Closing remarks of Judge Spiegel.

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MOTION FOR INTERPRETATION OF SETTLEMENT AGREEMENT

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5. Invoice and listing of equipment and office furniture proposed to be purchased for the Research Management Group.
6. Proposed Epidemiology Research Consulting Agreement with International Epidemiology Institute, Ltd.
7. Proposed contract for members of the Guidelines Panel.
8. Combined unaudited balance sheet as of December 31, 1994 and an unaudited statement of income, benefit payments and contributions for the year ended December 31, 1994 for the Consultation Fund and the Patient Benefit Fund. Financial information from inception of the funds through December 31, 1993.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

IN RE:

:

Case No. C-1-91-256

BOWLING-PFIZER LITIGATION

:

(Judge Spiegel)

FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their first periodic report, covering activities from January 28, 1992 to February 28, 1995.

I. BEGINNINGS

The litigation in this case was terminated by the signing of an Agreement of Compromise and Settlement (the "Settlement Agreement") on January 23, 1992. On January 28, 1992, the Court appointed the Honorable Robert L. Black, Jr., as Special Master/Trustee, to receive, hold and invest the immediate payment by Defendants of \$80,000,000 into the Medical and Psychological

Consultation Fund (the "Consultation Fund"), one of the two funds created by the Settlement Agreement. After fairness hearings on June 5, 8 and 9 and July 22, 1992, the Court found the Settlement Agreement as supplemented during the hearings to be fair (Order of August 19, 1992), and on September 10, 1992, the Court certified a settlement class consisting of all living persons who were implanted with a Bjork/Shiley Convexo-Concave (C/C) Heart Valve on January 23, 1992, and their living spouses on January 23, 1992, and held that the Settlement Agreement was fair, adequate and reasonable. All objections thereto were overruled.

Appeals to the Sixth Circuit Court of Appeals were filed depriving this Court of jurisdiction of the case until March 15, 1994, when the Sixth Circuit Court of Appeals dismissed the appeals. Although a petition was filed in the United States Supreme Court to hear the case (which was later denied on October 3, 1994), this Court determined that it now had jurisdiction of the case and decided that it was "appropriate to provide a means whereby the proceeds of the settlement may be held for the benefit of the class." On April 13, 1994, the court appointed the Honorable Robert L. Black, Jr. and the Honorable Peter J. Strauss, Esq. as Special Masters/Trustees to implement the terms of the Settlement Agreement. On May 13, 1994, the Court appointed the two

expert panels provided for in the Settlement Agreement: the Foreign Fracture Panel and the Supervisory Panel.

In this First Report, the Special Masters/Trustees will review all activities under the Settlement Agreement since January 28, 1992, but since the Foreign Fracture Panel has completed its task and filed its final report, the Special Masters/Trustees, with the Court's consent, will present this report first, before all other reports, in the interest of time.

II. REPORT OF FOREIGN FRACTURE PANEL.

Pursuant to Subsection 7.3.1 of the Settlement Agreement, the Court appointed the Foreign Fracture Panel on May 13, 1994, whose task is to determine fair compensation for Fracture Claimants who are residents of countries other than the United States. A Fracture Claimant, under Subsection 3.7 of the Settlement Agreement, is "any Settlement Class Member whose C/C heart valve incurs a strut fracture after the date of this Agreement, and his or her estate, heirs, successors, legatees, and devisees." (The meaning of "strut fracture" will be argued to this Court later in this hearing.) Fracture Claimants residing in the United States may elect to receive from the defendants compensation determined in accordance with a formula set forth in Appendix C of the Settlement Agreement. Non-U.S. resident Fracture Claimants fall into one of

four groups depending on what country they reside in, the countries being divided into the four groups specified in Appendix D. The task of the Foreign Fracture Panel is to develop fair compensation formulae for each group of countries, which "shall be based upon, and consistent with, the amounts of compensatory damages generally awarded or agreed upon in settlements, in the countries comprising the groups, for comparable personal injury or wrongful death claims." The defendants have paid all costs and expenses of this Panel, not from either of the two funds created by the Settlement Agreement, but from other funds channelled through the Special Masters/Trustees.

The members of the Panel are:

Prof. Laurent Aynes

Prof. Gordon A. Christenson

Dennis R. Connolly, Co-Chair

Prof. Harold Luntz

Werner Pfennigstorf, Esq.

Prof. Basil Markesinis

Harvey Rosen, Ph. D., Co-Chair

Augustus R. Ullstein, Q.C.

The Foreign Fracture Panel met three times: in Cincinnati on June 29 and 30, 1994; in Paris, France on October 26, 27 and 28, 1994;

and in New York City on December 12 and 13, 1994.

Shiley has contributed \$260,000.00 for compensation of the Foreign Fracture Panel members and for travel and other expenses relating to the panel. As of February 28, 1995, compensation aggregating \$193,107 and expenses totalling \$65,850 had been paid from these funds. Additional funds will be requested from Shiley upon receipt of final billings for compensation and expenses.

The Final Report was written and signed at that last meeting; it was filed with the Court on January 9, 1995. Subsequently, the Panel members have agreed among themselves that certain corrections should be made in order to clarify meaning without changing the substance of the Report. A copy of the Amended Final Report is attached as Appendix 1. The Special Masters/Trustees suggest that the Court hear from Class Counsel and Counsel for Defendants with respect to the proposed arbitration clause before taking action thereon. The Special Masters/Trustees further suggest that the Court's action be by a separate order.

The Special Masters/Trustees report to the Court that this Panel undertook and completed its assigned task with exemplary professional thoroughness and efficiency.

A representative of the Panel will now present the Amended Final Report and the proposed arbitration clause. After that,

Charles Wolfson wishes to raise objections he has filed.

III. ADMINISTRATIVE ARRANGEMENTS

During the period between January 1992 when the defendant's first payment was made and April 1994 when the Court appointed the Special Masters/Trustees, the activity under the Settlement Agreement was limited to the investment and reinvestment (roll-over) of the Consultation Fund in United States Treasury Bills (T-Bills) and the payment of federal income taxes. This was managed by Special Master/Trustee Black for minimal expense out of an office at his residence. On May 2, 1994, the Consultation Fund had T-Bills and cash totalling \$85,195,276, after paying federal income taxes through the calendar year 1993.

When the Court directed that the Settlement Agreement be implemented, the Special Masters/Trustees set up and staffed an office at 525 Vine Street, Cincinnati, by an arrangement with the Fernald Trustees, who were winding down their activity. This arrangement allowed the Special Masters/Trustees to start up operations markedly faster, at much less expense and with more fully experienced personnel than would have been the case if they had created an office from scratch. The Trustees' Office shares space and some furniture with the Fernald Trustees, but has its own personnel, files, phone system, and computer system. The

Administrator is R. Wayne Smith. It is anticipated that the day will come when the Fernald Trustees close down their office entirely and the Special Masters/Trustees will be the sole occupant of the office space.

IV. CONSULTATION FUND

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 is created to be paid, after fees and expenses, equally among all Claimants who are spouses of Class Members.

On November 25, 1994 the Court ordered the Special Masters/Trustees to hold in reserve at least twenty-five percent (25%) of the Consultation Fund for the purposes of future payment of attorney's fees and expenses to Class Counsel. Furthermore, since the final date for submission of claim forms is July 1, 1995, the total number of eligible claimants will not be known until sometime after that date. As a result, it is necessary to pay those claimants who filed a claim form on or before October 31, 1994 in two installments. Due to the foregoing, the Trustees

determined that the initial payments would be \$1,500.00 to qualified implantees and \$250.00 to qualified spouses.

After the total number of eligible claimants is known and after providing for those fees and expenses that are directed by the Court to be paid out of the Consultation Fund, the second and final distribution will be made, including payments to those eligible claimants whose claim forms were filed after October 31, 1994 and on or before July 1, 1995. The balance in the class member portion of the Consultation Fund (after providing for fees and expenses) will be divided so that all eligible class member claimants shall have been paid equally. Likewise, the balance in the spousal portion of the Consultation Fund (after providing for fees and expenses) will be divided so that all eligible spousal claimants shall have been paid equally.

The Trustees received 9,860 claims for the Consultation Fund on or before October 31, 1994, and 538 claims have been received since then. As of February 28, 1995, 5,128 claims have been processed by the Trustees' Office, with 4,464 claims being approved and 664 denied. There have been 3,475 payments to implantees totalling \$5,212,500.00 and 2,569 payments to spouses totalling \$642,250.00. A schedule relating to the claims is appended as Appendix 2.

V. PATIENT BENEFIT FUND

Under Section 5 of the Settlement Agreement, the Patient Benefit Fund is created 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 diagnosis and valve replacement, and to reimburse Class Members for the expenses of diagnosis and valve replacement that comply with the guidelines.

The implementation of the purposes of the Patient Benefit Fund is given to a Supervisory Panel of seven persons, six of whom are scientific or medical experts, with the seventh neither a physician nor a scientist. They have a daunting task, because these seven persons must learn about, understand and evaluate the activities of a multinational company over a span of the fifteen years during which it manufactured the valves and then sought ways to detect the risks of strut fracture.

The members of the Supervisory Panel are:

Sir Donald Acheson

Dr. Donald Harrison

Dr. Michel Ibrahim

Dr. Tom C. Ivey

John Kermit Smith, Chair

Dr. Arthur E. Weyman

Dr. Robert L. White

To date, the Panel has met four times: June 29 and 30, 1994, in Cincinnati; August 5 and 6, 1994, in Cincinnati; November 10, 11, and 12, 1994, in Cincinnati; and January 19, 20 and 21, 1995, in Irvine, California (the location of the offices, documents and records of Shiley Heart Valve Research Center, ("Shiley") the manufacturing subsidiary of Pfizer Inc.).

To accomplish its goal of conducting research in appropriate ways, committees of Panel Members were created to make recommendations in the following fields:

Epidemiology

Acoustics

Imaging (Radiography)

Biomechanics.

Epidemiology deals with the probabilities of valve failure as derived from manufacturing data. Research in the fields of acoustics and imaging seeks to detect a single leg separation by non-invasive means while a valve is still implanted in the patient. Biomechanics studies the physical capabilities and endurance of the valves.

Under Subsection 5.4.3.1 of the Settlement Agreement, the Supervisory Panel's first charge was to consider and act on the research proposal made by Shiley. That proposal was presented at the August meeting; the requested funding was \$14,928,000. It was rejected at the November meeting. A modified proposal was submitted at the November meeting, and at the January meeting, Shiley reviewed for the Supervisory Panel its entire research program from the beginning to the present.

The Trustees, the Chair of the Supervisory Panel and most of the Supervisory Panel members have met with representatives of the FDA in Washington. A line of communication has been established with that agency. The Chair and certain members of the Supervisory Panel have travelled abroad to meet with governmental officials in the Netherlands, the UK and Sweden concerning research for implantees in those countries. Governmental officials and researchers from the Netherlands and a representative of the FDA have attended Supervisory Panel meetings in Cincinnati.

After considerable review of data and presentations concerning the research conducted by and proposed by Shiley and review of other research proposals, the Supervisory Panel decided to fund the following initial research projects: (a) the second phase of a cohort study of implantees in the Netherlands; (b) a cohort study

for implantees in the UK; (c) a program of aortic valve imaging at Glasgow; (d) an opportunistic program at Glasgow; (e) an initial valve imaging program at Stanford; and (f) to seek a modified proposal for a "feinfocus" X-Ray study at Hershey. The proposals and budgets for these research projects are currently under financial review and will be presented for approval of the Court when this process is satisfactorily completed.

In order to carry out their research efforts the Supervisory Panel proposes to engage four individuals who have been employees of Shiley. These four persons have been actively involved in Shiley's research and would bring a substantial amount of knowledge and expertise to the Supervisory Panel's research programs and would function as a research management group.

A list of the names and proposed compensation and benefits for the four individuals is attached as Appendix 3. Also included in the appendix is a resume, a summary of their duties and experience with Shiley and proposed job descriptions for each of the individuals. The Trustees recommend that the Court approve that the four persons be retained as a research management group with compensation and benefits as outlined in Appendix 3 and that three administrative persons who have supported them at Shiley be retained to support the research management group.

It is proposed that the four person research management group would be located in Irvine, California and occupy separate space in Shiley's business complex. A proposed sublease is attached as Appendix 4. The Chair of the Supervisory Panel has negotiated the purchase of equipment and office furniture from Shiley for \$64,500.00 to be utilized by the proposed research management group and their support personnel. An invoice and listing of this equipment and office furniture is attached as Appendix 5. The Trustees recommend that the Court approve the attached sublease and the purchase of the equipment and office furniture.

To assist in the epidemiological aspects of the research studies to be conducted, the Supervisory Panel proposes to engage the International Epidemiology Institute, Ltd. A copy of the proposed agreement including a budget is attached to this report as Appendix 6. The Trustees recommend that the Court approve the attached agreement.

The Supervisory Panel has requested that BioReview, Inc. prepare a proposal for preparation of a master research plan. BioReview has experience in monitoring research projects and has access to a great number of scientific experts in various fields of study.

Shiley had previously sponsored a panel to determine

guidelines for replacement surgery. This panel was dissolved in January, 1995.

The Supervisory Panel proposed to appoint a Guidelines Committee of medical experts to consider and recommend to the Panel guidelines for the use of diagnostic techniques and for replacement surgery. The proposed Members of the Panel are:

Dr. J.J.A.M.T. Defauw - Cardiothoracic Surgeon - Nieuwegein -
THE NETHERLANDS

Dr. Robert Frye - Chief of Medicine and Cardiology Mayo Clinic
U.S.A.

Dr. Carol Garrison - Professor and Chair of the Department of
Epidemiology, University of South Carolina School of Public
Health, U.S.A.

*Dr. Gary Grunkemeier, Ph.D. - Director of the Medical Data
Research Center at the Heart Institute at St. Vincent's
Hospital Oregon U.S.A.

Dr. J. O'Neal Humphries - Dean School of Medicine and Clinical
Cardiologist University of South Carolina, U.S.A.

*Dr. Dan Lindblom - Head of the Division of Cardiothoracic
Surgery at Karolinska Institute at Huddinge University
Hospital SWEDEN

*Dr. Craig Miller, M.D. - Chief of Cardiovascular Surgery
Stanford, U.S.A.

Mr. John Parker - Cardiothoracic Surgeon. St. Georges
Hospital LONDON. President of the British Cardiac Society.

Rev. Clyde Shallenberger - Chaplain (retired) John's Hopkins
Hospital Medical Ethicist, U.S.A.

* - These proposed panel members were members of the Shiley sponsored panel.

A copy of a proposed contract to be executed by each panel member is appended to this report as Appendix 7. The Trustees recommend that the Court approve the selection of the nine members of the Guidelines Committee and authorize the Trustees to enter into the agreement in Appendix 7 with each panel member. The Trustees intend to apply to the Court in the near future for indemnification of the Guidelines Committee members from the Patient Benefit Fund.

At the recommendation of the Special Masters/Trustees, on January 18, 1995, the Court appointed R. Wayne Smith as Claims Administrator, being the designee under Subsection 5.2.4.1 of the Settlement Agreement. Shiley, with the consent of the Trustees, had been performing this task in the interim period. At a conference between the Special Masters/Trustees, Class Counsel and Counsel for Defendants on February 22, 1995, it was agreed that Mr. Smith will handle all claims for reimbursement for valve replacement surgery, both foreign and domestic, from that date forward.

VI. FINANCIAL INFORMATION

At December 31, 1994, the total balance of cash and cash equivalents was \$92,304,299 for the Consultation Fund (class member

portion and spousal portion) and \$12,228,958 for the Patient Benefit Fund. These amounts include net interest earned from January 28, 1992 through December 31, 1994, in the aggregate amount of \$8,883,529 for the Consultation Fund and \$102,366 for the Patient Benefit Fund. A combined unaudited balance sheet as of December 31, 1994 and an unaudited statement of income, benefit payments and contributions for the year ended December 31, 1994 is attached as Appendix 8. Also appended is a copy of financial information from inception of the funds through December 31, 1993.

VII. COMMUNICATIONS

The Special Masters/Trustees continue to maintain open communication with Class Counsel and Counsel for Defendants. Communications with Class Members has been on a one-on-one basis, after the distribution of the notice and claim form for the Consultation Fund in August, 1994.

Class Counsel and Counsel for Defendants are working on a pamphlet or brochure that will inform Class Members about their rights and benefits under the Settlement Agreement. This communication with the Class must await the Court's decision about single leg separation and strut fracture. When ready, it will be sent to all physicians, medical associations and officials,

hospitals, and patients known to Counsel or to the Special Masters/Trustees.

VIII. APPROVALS

Your honor, the Trustees request that the Court approve this Report and the actions specifically referred to herein, and approve or provide further direction with respect to each of the Appendices to this Report.

Respectfully submitted,

Dated: March 3, 1995

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

January 4, 1995

**FOREIGN FRACTURE PANEL
BOWLING-PFIZER HEART VALVE SETTLEMENT**

Hon. Robert L. Black, Jr.
Trustees for the Bowling-Pfizer
Heart Valve Settlement Funds
P.O. Box 3598
Cincinnati, Ohio 45201-3598

Mr. Peter J. Strauss, Esq.
Graydon, Head & Ritchey
1900 Fifth Third Center
P.O. Box 6464
Cincinnati, Ohio, 45201

Dear: Judge Robert L. Black, Jr. and Peter J. Strauss,

Annexed hereto are our formulae which represent the strong consensus of the Foreign Fracture Panel.

We draw to your attention the following points:-

1. We have used Appendix C of the Settlement Agreement as the basis of the proposed formulae.
2. We have not sought to define/redefine the expression "strut fracture".
3. We have not used the word "resident" as a term of art or in any technical sense. It is and should be understood to be used in its ordinary English meaning.
4. The expression "the date of fracture" is used in accordance with the terms of the Settlement Agreement.

5. Since the formulation in clauses 1 and 2.1 may adversely affect a claimant who is habitually resident in a category 1 country but is, at the date of fracture, resident in a country within category 3 or 4, we propose that the claimant should be given a choice between the country of his residence and the country of his habitual residence.

For the reverse situation, however, namely the claimant habitually resident in a lower category country who happens to be working in a higher category country, we do not favor such a choice since it would lead to an undeserved windfall. That is the reason for the three year qualifying period which might also be helpful for the purpose of determining the lost income which, in accordance with paragraph (d), is to be calculated by reference to the Settlement Class Member's tax returns for the said three year period.

6. We have retained the word "spouse" which we understand to exclude co-habitees (of either gender) who might, under some jurisdictions, be allowed to claim in fatal accidents actions.

We are of the opinion that wherever possible, the formulae should be clear and certain so that there can be no doubt or dispute as to who is entitled to claim. We recognize, however, that even the retention of the word "spouse" does not necessarily achieve that end since it may have different meanings in different jurisdictions.

Equally, it is not clear to us whether the intention of the Settlement Agreement was to include or exclude the spouses of polygamous marriages. We say that because Appendix C uses the expression a spouse.

We recommend that the spouses of polygamous marriages should, in fact, be allowed to claim since they will simply divide the amount payable under paragraph (b). The formula does not provide for more than one payment under this heading.

In this context we also considered the issue of co-habitees, who in a number of countries might have claims. For example, in France such a claimant can not be excluded. For these reasons we recommend that cohabitees should be permitted to claim under this heading if the fracture claimant is claiming from a jurisdiction which allows such claims.

7. (a) We have extended the classes of children who are entitled to claim because we firmly believe that our form is more equitable than the bare reference to "minor children" in Appendix C. This is based on our appreciation of different laws and conditions in other prevailing jurisdictions and is consistent with the principle of parity.


(b) In Appendix C the expression "minor child" appears to us to include illegitimate children. We assume that that is correct and should certainly not suggest adopting a definition which excluded such children.
8. We have retained the words "lost income" which we understand to refer to pre-tax income.
- 9.a We believe we have devised formulae which will be easy to operate. Nevertheless, when one takes into account that the formulae are intended to deal with a multiplicity of claims from all over the world we recognize that there may be disputes as to the construction and/or interpretation of words, phrases and expressions used.
- 9.b Since there is no machinery in the Settlement Agreement for resolving such issues, and since we believe it would be inappropriate if Fracture Claimants were to reject the settlement simply because there was no means available to them to resolve disputes of the type to which we have referred, we propose an arbitration procedure to deal with such issues. The draft protocol is annexed hereto. We have chosen that particular form in order to attempt to ensure that such an arbitration (if it takes place) is dealt with as expeditiously and inexpensively as possible.

10. Finally, we have amended Appendix D in accordance with the provisions of Clause 7.3.3 of the Settlement Agreement. The information upon which the categories were originally based is now out of date. We have used the same source and moved countries into a higher group when it is appropriate to do so in accordance with the updated information.

Respectfully Submitted,

CO-CHAIRMEN

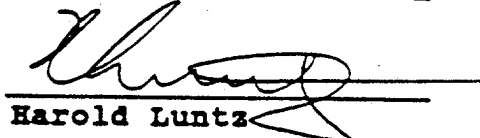

Dennis R. Connolly


Harvey S. Rosen

PANELISTS


Laurent Aynes


Gordon A. Christensen


Harold Luntz


Basil Markesinis


Werner Pfennigstorf


Augustus Ullstein

AMENDED FINAL REPORT OF THE FOREIGN FRACTURE PANEL

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

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

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

- 2.1 In the event that at the date of fracture the Fracture Claimant has not been resident in the country in which he is then resident for three years his claim will be determined by reference to the amount payable to a resident of the country of his habitual residence.
- 2.2 In the event that the habitual residence of a Fracture Claimant is a country in a higher Category than the country in which he has been resident for three years at the date of fracture, he or his personal representatives may elect, at their sole discretion, to receive compensation calculated as appropriate to the country of his habitual residence.
- 3.1 In the case of a Fracture Claimant resident or habitually resident (as may be appropriate to the claim) in a Category 1 or a Category 2 country if the fracture results in death or permanent total disability compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below provided that in no event shall the total payment exceed \$1 million US.
 - (a) \$160,000 US.
 - (b) \$60,000 US if the Fracture Claimant incurring the fracture has a "spouse" at the date of fracture.
 - (c) \$40,000 US multiplied by the number of children, if any, that the Fracture Claimant has at the time of fracture who fall into one or more of the following categories namely:
 - (i) Minors.

- (ii) Those who are undergoing full time education or training for a trade or profession and are under the age of 26 years.
 - (iii) Those who provide evidence in writing to satisfy the Defendants in accordance with Clause 7.5 of the Settlement Agreement that they are under a physical or mental disability which has reasonably required the Fracture Claimant to maintain and support them.
- (d) The Fracture Claimant's lost income, calculated as the sum of (1) a percentage of the adjusted current annual income equal to the number of days from the date of fracture to the end of the year divided by 365, and (2) the present value of future adjusted current annual income beginning with the first day of the calendar year following the fracture, ending the year of the Fracture Claimant's 65th birthday and discounted to the year of the fracture at a net interest rate of 1.5% (which percentage is calculated as the difference between 5.5% growth and a 7% discount rate).

3.2 "Adjusted current annual income" means 78.5% (which percentage is calculated to reflect fringe benefits as well as personal maintenance expenditures) of the Fracture Claimant's average actual income from wages, salary, personal services, personal business activities or other form of income from self employment as reported to relevant tax authorities in the three years immediately preceding the date of fracture or as evidenced by such other public records reasonably to be regarded as satisfactory proof of income over the three years prior to the year of the fracture. If the Fracture Claimant has not such income or if aged 65 or greater at the time of the fracture, then there is no payment under this component of the formula.

3.3 If the strut fracture does not result in death or permanent total disability, the compensation shall be equal to the sum of the amounts allowed under components (a), (b), (c) and (d) below; provided, that in no event shall the total payment exceed \$1.5 million US.

(a) \$160,000 US.

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

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

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

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

(a) \$80,000 US.

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

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

(i) Minors.

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

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

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

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

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

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

(a) \$80,000 US

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

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

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

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

(a) \$40,000 US

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

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

(i) Minors.

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

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

6.1 Pursuant to Clause 7.5 of the Settlement Agreement, the Defendants may require a Fracture Claimant (here defined in accordance with Clause 3.7 of the Settlement Agreement) to provide or cause to be provided to them either:

(a) a release of all claims by such Social Security Department, or any other legally obligated provider, appropriate to the claim; or

(b) satisfactory evidence that such Social Security Department, or any other legally obligated provider has no right to make any claim against the Defendants.

6.2 Pending receipt of a release or satisfactory evidence in accordance with Clause 6.1 hereof, the Defendants shall be entitled to withhold payment to the Fracture Claimant only of such sum as may reasonably be expected to be claimed by the Social Security department or other legally obligated provider as may be appropriate to the claim.

PROPOSED ARBITRATION CLAUSE

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

APPENDIX D

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

Group 1

Countries having a Common law tort system

Australia	
Canada	
New Zealand	
Including	Tokelau
United Kingdom	
Including	Guernsey, Isle of Man, Jersey

Group 2

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

Andorra	
Austria	
Bahamas	
Belgium	
Bermuda	
Cayman Islands	
Denmark	
Including	Faroe Islands, Greenland
Finland	
France	
Including	French Guiana, French Polynesia, Guadeloupe, Martinique, New Calendonia, Reunion, Saint Pierre and Miquelon, Wallis and Futana
Germany	
Gibraltar	
Greece	
Hong Kong	
Iceland	
Ireland	
Italy	
Japan	
Kuwait	
Liechtenstein	

Luxembourg
Monaco
Netherlands
Including Aruba
Netherlands Antilles

Norway
Portugal
Including Macau
Qatar
San Marino
Singapore
Spain
Sweden
Switzerland
United Arab Emirates

Group 3

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

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

Group 4

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

Afghanistan
Albania
Algeria

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

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

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

TRUSTEES FOR THE BOWLING PFIZER HEART VALVE SETTLEMENT FUNDS

STATUS OF CONSULTATION FUND CLAIMS AS OF FEBRUARY 28, 1995

Claims Received as of October 31, 1994 9860

Claims Approved	4464
Claims Denied	664
Claims Pending	4732

Of above Approved Claims, paid or
in process to be paid 4042

	Implantees	\$ Amount	Spouses	\$ Amount	Total
Group 1	1422	\$2,133,000.00	1088	\$272,000.00	\$2,405,000.00
Group 2	531	796,500.00	379	94,750.00	891,250.00
Group 3	906	1,359,000.00	658	164,500.00	1,523,500.00
Group 4	616	924,000.00	444	111,000.00	1,035,000.00
<u>Total</u>	<u>3475</u>	<u>5,212,500.00</u>	<u>2569</u>	<u>642,250.00</u>	<u>5,854,750.00</u>

Group 5	567	850,500.00	400	100,000.00	950,500.00*
<u>Total</u>	<u>4042</u>	<u>6,063,000.00</u>	<u>2969</u>	<u>742,250.00</u>	<u>6,805,250.00</u>

* = Tentative payment - Not yet approved by the Court.

Records Received after October 31, 1994
through February 28, 1995 538

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

**Proposed Compensation and Benefits for Four Individuals
for Research Management Group**

<u>NAME</u>	<u>ANNUAL COMPENSATION</u>
Amir Abolfathi	\$72,200
Jamie Lee Hirsch	67,400
Stefan Schreck	79,400
Mary Ann Soltis	54,300

<u>BENEFIT</u>	<u>AMOUNT OF COVERAGE</u>
Life Insurance	2 times annual earnings
Accidental Death & Dismemberment	2 times annual earnings
Dependent Life Insurance	(contributory)
Business Travel Accident	6 times annual earnings
Medical Insurance	Indemnity or HMO coverage for individual and family
Dental Insurance	Indemnity or prepaid for individual and family
Disability Insurance	60% replacement of income until age 65+
Savings and Investment Plan	Employer contribution: first 2% of pay: 100% next 4% of pay: 50%

NOTE - The above compensation and benefits provided to the four persons as employees of Shiley Incorporated.

AMIR H. ABOLFATHI

P.O. BOX 4048
IRVINE, CA 92716

HOME (714) 581-6824
FAX (714) 581-6051
WORK (714) 863-5716

SUMMARY

EXPERIENCE	<ul style="list-style-type: none"> •Pfizer/Shiley Heart Valve Research Center, Irvine, CA Project Manager / Senior Scientist / Project EngineerJan 1991-Present •Eli Lilly/Advanced Cardiovascular Systems, Santa Clara, CA Senior Engineer / Group Leader Dec 1989-Dec 1990 •Baxter/Edwards Cardiovascular Surgery, Irvine, CA R&D Engineer May 1988-Nov 1989
EDUCATION	<p>M.S. Engineering Management, (3.6/4.0) University of Southern California, May 1988.</p> <p>B.S. Biomedical Engineering, (3.1/4.0) University of California, San Diego, August 1986.</p>
MANAGEMENT	Five years of experience in project management, planning, budgeting, and managing technical and analytical personnel. Extensive experience in contract management and collaborating with outside research institutions/consultants. Lab manager of the Shiley Heart Valve Research Center Research & Development Laboratory, and group leader of the Instrumentation Engineering at Advanced Cardiovascular Systems. Managed research programs in excess of five million dollars in 1992-1994.
RESEARCH AND DEVELOPMENT	Six years of experience in conducting research. Work included development of new medical products, experimental protocols, designs of instrumentation and test facilities, conducting in vitro and in vivo experiments, data coordination and analysis, and development of mathematical prediction models.
CLINICAL AFFAIRS	Three years of experience in managing a diverse multi-center and multi-disciplinary clinical research program. Assessed feasibility of utilizing a newly developed radiographic and acoustic analysis technique for detection of incipient failure of heart valves implanted in patients. In the process of validating and qualifying a custom designed angiocardiology system for clinical application.
BIOMEDICAL ENGINEERING	Designed a dynamic radiological phantom for heart valve imaging. Investigated the fluid mechanics of various heart valves in pulse duplicators. Designed a patented hydraulic system to simulate the hemodynamics of the venous circulatory system. Conducted research to determine the effect of catheter geometry, surface coating, and material on the forces induced on an angioplasty catheter in an instrumented coronary model. Designed and fabricated a coronary stent fatigue tester for evaluation of metallic stents under dynamic loading.
REGULATORY AFFAIRS	Five years of experience in supporting PMA, IDE, and 510K application submissions to the U.S. FDA for medical device approval. Experience in collaborating with the FDA to discuss and resolve healthcare issues related to clinical research planning and compliance, patient stratification and notification, and medical device approval.
COMMUNICATION SKILLS	Experience in writing and presenting proposals, progress reports, technical papers, and publications. Adaptable and capable of working in a highly publicized letigious environment. Experience in collaborating with surgeons to convert ideas into workable devices and/or techniques.
MECHANICAL DESIGN	Six years of experience in mechanical design of instrumentation and experimental activities. Practical experience in drafting and machining.
COMPUTERS	Working knowledge of using Macintosh and PC (DOS) systems, programming in FORTRAN 77 and BASIC.
PERSONAL	Hobbies: Travel, Water Sports, Music

AMIR H. ABOLFATHI**COMPREHENSIVE****PROFESSIONAL • PROJECT MANAGER / SENIOR SCIENTIST, Pfizer Inc., Shiley Heart Valve
EXPERIENCE** Research Center, Irvine/CA, January 1991 to Present.

Responsibilities include: management of the radiographic diagnostic research and clinical programs; played a critical role in development, qualification, and validation of the x-ray technique for screening patient's heart valves, assisted in data analysis and preparation of the IDE and IRB submission for the approval of clinical use of the x-ray technique, coordinated all activities pertaining to patient stratification and notification, data and technology management, quality assurance, and archival storage. Other responsibilities include; assessing and investigating new technologies (i.e. ultrasound, angioscopy, MRI), foundation of the R&D Biomechanics laboratory, preparing and presenting progress reports to U.S. FDA & other international healthcare regulatory agencies (i.e. Australia, Germany, The Netherlands, United Kingdom), and litigation technical support. Establishment and maintenance of strategic clinical relationships. Managing and development of relationship with the consulting panels. Provide technical and strategic direction to my direct reports.

- **SENIOR ENGINEER**, Eli Lilly Company, Advanced Cardiovascular Systems Inc., Santa Clara/CA, December 1989 to December 1990.

Group Leader of a team of engineers and technicians responsible for the design of new equipment and fixtures for in vitro evaluation of new cardiovascular devices (Coronary Stents, Angioplasty Catheters, Guiding Catheters, Guide Wires, Inflators). Designed and implemented feasibility studies for testing new products for submission to the U.S. FDA for product approval. Assisted in the development and evaluation of perfusion angioplasty catheter, temporary stent, and coronary stent. Responsible for developing a pilot process for environmental testing of all ACS's products.

- **RESEARCH AND DEVELOPMENT ENGINEER**, Baxter Healthcare Corporation, Edward Cardiovascular Surgery, Irvine/CA, May 1988 to November 1989.

Project Engineer responsible for coordinating the research and development of a new biological valve for the venous circulatory system. Project planner, designer, and coordinator of all in vivo and in vitro research studies associated with venous valve project. Designed and fabricated a patented hydraulic system for simulating the venous hemodynamic loading on biological venous valves. Developed a full scale testing system for evaluation of small size biological grafts for CABG procedure. Supervised and conducted experimentation in support of PMA approval of several heart valves.

**ACADEMIC
EXPERIENCE**

Instructor, USC, Los Angeles/CA, Fall 1987.

- Taught a course in engineering economy, principles of finance, and treatment of risk and uncertainty.

Teaching Assistant, USC, Los Angeles/CA.

- Statistics, Spring 1988.
- Operation Research, Fall of 1987 & Spring 1988.

CREDENTIALS

State of California College Instructor Credentials:

- Engineering
- Industrial Management

Regulatory Affairs Certification Program -- In Training

AMIR H. ABOLFATHI

- PUBLICATIONS**
- Radiographic Detection of Single Leg Separations of the Outlet Strut of Mitral Björk-Shiley Convexo-Concave Heart Valves, W.W. O'Neill, J.G. Chandler, R.E. Gordon, A.H. Abolfathi, M. Castellani, H.J. Friedan, R.H. Seltzer, J.L. Hirsch, K.A. Powell, J.F. Cornhill, J.S. Bassett, D.M. Bakalyar, K.C. Beatty, M.A. Soltis, G.C. Timmis, C.L. Grines, William Beaumont Hospital, Shiley Heart Valve Research Center, Jet Propulsion Laboratory, Cleveland Clinic Foundation, submitted to The New England Journal of Medicine, August 1994.
 - New Cardiac Radiological Phantom for Heart Valve Imaging, H. Leyenaar, A.H. Abolfathi, C.H. Conlin, D.W. Wieting, D. Bakalyar, J.G. Chandler, submitted to Investigative Radiology on November 1994.
 - Effect of Valve Profiling and Increasing kVp on In Situ Radiographic Detection of Single Leg Separation of the Björk-Shiley Convexo-Concave Heart Valve, A.H. Abolfathi, Jamie Lee Hirsch, Steve E. Nissen, David W. Wieting, James G. Chandler, 16th Annual International Conference of IEEE Engineering in Medicine and Biology Society, Maryland, 1994.
 - Digital Radiographic Analysis of Single-Leg Separation (SLS) in the Outlet Struts of Björk Shiley Convexo-Concave (BSCC) Heart Valves, K.A. Powell, J.F. Cornhill, S.N. Nissen, J.G. Chandler, A.H. Abolfathi, E. LaPresto, E. Herderick, K. Mueller, E. Csmeli, S. Chandra, Cleveland Clinic Foundation, Shiley Heart Valve Research Center, and The Ohio State University, Computer Assisted Radiology (CAR), Berlin, 1993.
 - In-Vitro Testing of Venous Valves, D. Lee, A.H. Abolfathi, G.A. Delaria, T.J. Phifer, A.S. Nashef, R.C. Quijano, Baxter Healthcare Corporation, Transactions of American Society of Artificial Internal Organs, 1991.
 - Bioprosthetic Venous Valve: Lessons of in-vitro testing, G.A. Delaria, T.J. Phifer, A.S. Nashef, D. Lee, A.H. Abolfathi, R.C. Quijano, Presented: V European-American Symposium on Venous Diseases, 1990.
- PATENT**
- Method and Device for Testing Venous Valves, Inventors: T. Nguyen, A.S. Nashef, A.H. Abolfathi, D.W. Wieting, D. Lee, Baxter International Inc., Dec. 28, 93, U.S. 5,272,909.
- DISCLOSURES**
- | | |
|------|----------------------------------|
| 1993 | Continuos ACT Monitoring |
| 1992 | Self-Sealing Hypodermic Needle |
| 1992 | Endovascular Stent |
| 1991 | Perfusion Catheter Assist Device |
| 1991 | Instrumented Coronary Simulator |
- PROFESSIONAL TRAINING**
- | | |
|------|---|
| 1993 | Management Action Program |
| 1993 | Managing and Investigating Medical Device Incidents |
| 1992 | Achieving Excellence through Team Work |
| 1992 | Design of Experiments |
| 1991 | Cardiovascular Pathology |
| 1991 | Supervisory Training |
| 1990 | Biomedical Certification Program |
- SOCIETY AFFILIATIONS**
- Regulatory Affairs Professionals Society (RAPS)
 - Biomedical Engineering Society (BMES)
 - Society For Biomaterials
 - Association for the Advancement of Medical Instrumentation (AAMI)
- ACADEMIC HONORS**
- Vice president, USC Chapter, American Institute of Industrial Engineers, 1988.
 - Scholarship, Pahlavi Foundation, USC, Los Angeles, CA, USC, LA/CA, 1986-88.
 - Outstanding Services to the School of Engineering Award, USC, LA/CA, 1988.
 - Outstanding Leadership Award, USC, LA/CA, 1988.

AMIR H. ABOLFATHI'S ROLE IN SHILEY'S STUDIES OF SINGLE LEG SEPARATED VALVES

Although I manage a separate study to determine the SLS prevalence in a unique cohort of explanted valves examined by the Armed Forces Institute of Pathology, my major involvement is in the studies of radiographic SLS detection. I have participated in these studies since their inception. The highlights of my contributions to the development of SLS valve radiography follow:

Jun-Jul 1991: The first demonstration that an SLS could be visualized using an industrial magnification x-ray system and a biologic phantom. Definition of the importance of careful profiling and establishing the acceptable range for C/C valve tunnel views.

Aug-Oct 1991: Design of a Working Valve Phantom (WVP) for in vitro investigation of various radiographic systems. I evaluated General Electric, Siemens, and Philips neuro-angiography and cardio-angiography systems with the WVP, determining that the Siemens-Hicor system was the most facile. The first demonstration showed that a SLS could be identified in C/C valves functioning in sheep followed soon thereafter using a hybrid feinfocus industrial and clinical system. I then investigated single and double-emulsion film imaging in sheep with C/C valves using Siemens' neuro-angiography system and determined that images acquired in ≤ 20 msec had tolerable motion unsharpness, but that image intensification was necessary for adequate SLS visualization in this model.

Nov-Dec 1991: Assisted in the design and development of specifications for the feinfocus clinical cardiology prototype direct imaging magnification x-ray system.

Jan-May 1992: Determined that higher kVp favors SLS detection by partially penetrating the metal structure to differentiate differences in metal radiodensity and by diminishing the effect of background densities. Two oblique views for each leg, one from the internal and the other from the external aspect were defined within limits imposed by the dense flange rolls. I participated in the writing of the IDE application and was responsible for completing all in vitro and in vivo testing to support it.

May 1992-Aug 1993: I supervised the modification of the Beaumont Siemens-Hicor system in preparation for the start of clinical imaging and designed the basic Beaumont database and data coordination formats. I coordinated and oversaw the research with the Jet Propulsion Laboratory and Cleveland Clinic Foundation for development of an objective image analysis system. Various vendors were also surveyed in search of the best film duplication process.

Aug 1993-Present: I am responsible for training of the investigators, Expert Review Panel, and radiographers, and for modification and qualification of the x-ray systems prior to new studies at Academisch Zeikenhuis Leiden and Western Infirmary Glasgow. Overall management of the feinfocus study at Hershey Medical Center is now my principal assignment. Responsibilities have included facility design, preparation of import-export documents, installation and certification of the system, training and qualification of the investigators and expert reviewers, overseeing the sheep implant program, conducting WVP studies, assisting investigators in

acquiring optimal views in sheep, and assisting in development and evaluation of the digital image display unit for review of the feinfocus images. I managed the technical coordination of the recent sequestered comparative review of feinfocus and Siemens images. I am the author and co-author of three publications:

- (1) Powell KA, Cornhill JF, Nissen SN, Chandler JG, Abolfathi AH, LaPresto E, Herderick E, Mueller K, Cesmeli E, Chandra S, Cleveland Clinic Foundation, Shiley Heart Valve Research Center, and The Ohio State University. Digital Radiographic Analysis of Single-Leg Separation (SLS) in the Outlet Struts of Björk Shiley Convexo-Concave (BSCC) Heart Valves. Computer Assisted Radiology (CAR), Berlin, 1993.
- (2) Abolfathi AH, Hirsch JL, Nissen SE, Wieting DW, Chandler JG. Effect of valve profiling and increasing kVp on in situ radiographic detection of single leg separations of the Björk-Shiley convexo-concave heart valve. Proceedings of the 16th Annual International Conference of the IEEE Engineering in Medicine Biology and Society. 1994;16:528-529.
- (3) O'Neill WW, Chandler JG, Gordon RE, Abolfathi AH, Castellani M, Friedan HJ, Seltzer RH, Hirsch JL, Powell KA, Cornhill JF, Bassett JS, Bakalyar DM, Beatty KC, Soltis MA, Timmis GC, Grines CL, William Beaumont Hospital, Shiley Heart Valve Research Center, Jet Propulsion Laboratory, Cleveland Clinic Foundation. Radiographic Detection of Single Leg Separations of the Outlet Strut of Mitral Björk-Shiley Convexo-Concave Heart Valves. Submitted to The New England Journal of Medicine, August 1994.

I am currently writing a manuscript describing the development of a WVP with annulus motion for cardiac valve studies, and another on the application of specific films for cine-angiography duplicating in conjunction with several co-authors.

JOB DESCRIPTION OF AMIR H. ABOLFATHI

Working within the overall objective of developing and implementing a patient management program for Björk-Shiley Convexo-Concave valve patients who are at risk of outlet strut fracture:

- A) To assist the Supervisory Panel in developing programs which will help to identify patients who are at risk of outlet strut fracture:
 - 1. Providing expert knowledge to the Supervisory Panel.
 - 2. Assisting in developing a master plan for the clinical research.
 - 3. Evaluating and reviewing proposed research studies.
 - 4. Designing additional research studies if appropriate.
- B) To manage research studies sponsored by the Bowling Supervisory Panel:
 - 1. Set-up office for the Management Consultants in Irvine, California including staffing, furnishing, access to Shiley data base and documents, and communication.
 - 2. Manage research studies in the areas of BSCC radiographic SLS detection (Siemens and feinfocus technologies) including technical support, preparation of contracts and statements of work, monitoring of progress of work, visits of study sites, and documentation of research status.
 - 3. Responsible for expansion of the existing clinical programs, and clinical implementation of any future technologies/techniques developed for patient screening and/or diagnostic purposes.
 - 4. Where applicable, assist in preparing relevant documentation for approval by regulatory bodies and ensure regulatory compliance of pre-clinical and clinical studies.
 - 5. Prepare periodic status reports of the research studies and report status to the respective subcommittees, the Supervisory Panel, and other bodies.

Reporting Structure

- 1. Administration and Finances: to Kermit Smith, Chairman, Supervisory Panel
- 2. Scientific Research: to respective Subcommittees, Supervisory Panel

JAMIE LEE HIRSCH

Shiley Heart Valve Research Center
17671 Cowan Avenue
Irvine, CA 92714
(714) 863-5712

2 Deerwood East
Irvine, CA 92714
(714) 863-5712

EDUCATION:

University of Southern California
MBA degree program, August 1994 to present

University of California at Irvine
Department of Mechanical Engineering, January 1992 to June 1992
FOCUS: Robotics and Mechanism Synthesis.

University of Delaware, Newark, Delaware
Master of Mechanical Engineering, May 1990
THESIS: Studies in Solid Imaging: Optical Curing of Photopolymers to Create Three-Dimensional Solid Models.

Lafayette College, Easton, Pennsylvania
B.S. Mechanical Engineering with honors, May 1987
Art Concentration
THESIS: Personal Computer Modeling of Roman Concrete Structures.

EXPERIENCE:

Pfizer/Shiley Heart Valve Research Center, Irvine, CA

Project Manager - Clinical Research (February 1994 - present)

Senior Scientist (February 1993 - January 1994)

Reporting to Vice President of Clinical Affairs working on patient studies of techniques to detect valves that may be at high risk of incipient failure:

- Manage ongoing clinical IDE study involving x-ray and acoustic recording of heart valves, including digital data processing and expert panel reviews.
- Clinical studies computer database management.
- Analyze study data to calculate accuracies, sensitivities, specificities and predictive values for tests.
- Design/conduct engineering in vitro testing in support of IDE applications.
- Draft protocols, consent and case report forms for future clinical x-ray studies.
- Compose submissions and responses to FDA.
- Prepare and present reports regarding ongoing studies to expert review panels and FDA.

Project Engineer (December 1990 - January 1992; June 1992 - January 1993)

Member of a research and development team searching for a method to detect incipient failure of a mechanical heart valve implanted in patients:

- Responsible for developing protocols and coordinating consultants for metallurgical work related to heart valves and litigation support.
- Coordinator for ongoing research and testing on currently marketed mechanical heart valve, including residual stress, finite element and fatigue studies.
- Supervise testing and engineering reports on all explanted and returned heart valves (product complaint reporting).
- Member of team responsible for a submission to FDA for approval of a medical device.
- Prepare and present reports regarding ongoing studies.
- Manage technician support personnel.
- Co-supervise safety program for Heart Valve Research Center.

Pfizer/Shiley Heart Valve Research Center, Irvine, CA

Sorin Biomedical, Irvine, CA

Consultant (January 1992 - June 1992)

Heart valve research, testing, and submissions.

JAMIE LEE HIRSCH

Resume

Page Two

E.I. du Pont de Nemours & Company, Wilmington, DE

Senior Engineer - Imaging Systems (January 1990 - August 1990)

Assigned to SOMOS™ Venture, a project to develop a rapid prototyping system utilizing the polymerization of liquid monomers to produce models.

- Developed technology applications for various industries.
- Technical marketing to potential development partners (extensive travel throughout US and to Japan).
- Represented product to technical community in preparation for commercialization (conferences, trade shows, visits, etc).
- Provided customer technical support for prototype systems.
- Researched alternative "desktop manufacturing" technologies to improve company's competitive position.

Research Assistant - Engineering Technology Lab, Experimental Station (1988 - 1989)

Lab mission: develop and implement new technologies in existing Du Pont businesses.

- Oversaw operation of stereolithography lab including Aries solid modeling systems, finite element analysis, SLA and customer support.
- Designed optoelectronic devices for British Telecommunications and Du Pont joint venture.
- Conducted nondestructive testing using holographic interferometry.

Department of Mechanical Engineering, University of Delaware, Newark, DE

Teaching Assistant (Fall 1987)

Engineering Materials.

Lafayette College/Mack Trucks, Allentown, PA

Program Designer (Spring 1987)

- Created and networked programs using FORTRAN, ANSYS and a VAX system to calculate stress concentrations.
- Redesigned vehicle parts through finite element analysis.

Department of Mechanical Engineering, Lafayette College

Research Assistant (Spring, Summer 1986)

- Explored and demonstrated capabilities of a new finite element analysis program.
- Analyzed historic structures.
- Assisted at a SLOAN seminar for architectural historians at Princeton University.
- Created computer models that were filmed for a "NOVA" documentary.

PUBLICATIONS AND PRESENTATIONS:

O'Neill WW, Chandler JG, Gordon RE, Bakalyar DM, Abolfathi AH, Castellani M, Hirsch JL, Wieting DW, Bassett JS, Beatty KC, Soltis MA, Timmis GC, Grines CL. Radiographic detection of single leg separations of the outlet strut of mitral Björk-Shiley convexo-concave heart valves. 1994. (submitted to the N Engl J Med)

Abolfathi AH, Hirsch JL, Nissen SE, Wieting DW, Chandler JG. Effect of valve profiling and increasing kVp on in situ radiographic detection of single leg separations of the Björk-Shiley convexo-concave heart valve. Proceedings of the 16th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. 1994;16:528-529

Hirsch JL. Du Pont Solid Imaging System. Aries Users Group Meeting. Cambridge, MA, May 13-15, 1990.

Hirsch JL. Solid Imaging Systems. NTU Satellite Broadcast: *Desktop Manufacturing*. May 11, 1990.

Hirsch JL, Weaver KA. Rapid Prototyping from Du Pont. *MicroCAD News*, January/February 1990.

Hirsch JL, Van Gulick LA, Dey K, Feinberg K. Ansys-PC/Linear Modeling of the Roman Pantheon. ANSYS Conference Proceedings. 1989.

Hirsch JL, Van Gulick LA. Personal Computer Modeling of the Roman Pantheon. Post Conference Seminar, Computational Mechanics, Orlando, Florida, April 5-16, 1988.

JAMIE LEE HIRSCH

Resume

Page Three

HONORS:

Graduate	UCI Regents fellowship George W. Laird Graduate Merit Fellowship - Univ. of Del. DuPont Engineering Intern Fellowship
Undergraduate	Honors in Mechanical Engineering with Thesis Pi Tau Sigma - Mechanical Engineering Honors Society Jacqua Foundation Scholarship

SOCIETY AFFILIATIONS:

American Society of Mechanical Engineers
Sigma Xi - Scientific Research Society
ASM International - The Materials Information Society

JAMIE LEE HIRSCH
PROJECT MANAGER -- CLINICAL RESEARCH
SHILEY HEART VALVE RESEARCH CENTER

1990- 1992 -- Department of Research & Development

Principal engineer working on the Monostrut heart valve, the successor to the C/C valve, with primary responsibility for testing and analysis to support a PreMarket Approval Application to the US Food and Drug Administration. This work included finite element modeling, residual stress testing, fatigue and life analyses.

Prepared protocols and managed all BSCC valve metallographic studies.

Given responsibility for product complaint testing and engineering reporting. Reorganized the process to eliminate the backlog and ensure the capability for issuance of reports within six weeks of receipt of valve.

Participated in preparation of the initial draft of the Technical Proposal for submission to the Pfizer-Bowling Trust Supervisory Panel.

Jan 1993-Present -- Department of Clinical Affairs

Given responsibility for overall management of Shiley's clinical radiographic studies. Have operational responsibility for the overall strategy of the x-ray studies and direct management responsibility for the study at Stanford. In conjunction with Amir Abolfathi, developed Oracle database for clinical studies. Currently oversee new study programming, data input, and enhancements. Worked closely with Mary Ann Soltis in monitoring of the Beaumont study and current oversight of the Glasgow study. Work with Canadian Heart Valve Program to include Canadian 60° and 70° valve patients in US clinical studies. Serve as the primary resource for data for submissions to the FDA, Shiley's Medical Advisory Panel, and the Pfizer-Bowling Trust Supervisory Panel.

Work closely with Dr. Chandler in conceptual origination and preparation of manuscripts, presentations, protocols, submissions, and other documents.

In alliance with Amir Abolfathi, brought the Jet Propulsion Laboratory and Cleveland Clinic Foundation to one standardized program for analysis of radiographic images of C/C valves.

Developed and managed a blinded review by Lawrence Livermore National Laboratories to assess the role of apparent independent SLS motion as an additional criterion for SLS detection; the data justified concluding the effort.

Co-author of two publications:

- (1) Abolfathi AH, Hirsch JL, Nissen SE, Wieting DW, Chandler JG. Effect of valve profiling and increasing kVp on in situ radiographic detection of single leg separations of the Björk-Shiley convexo-concave heart valve. Proceedings of the 16th Annual International Conference of the IEEE Engineering in Medicine Biology and Society. 1994;16:528-529.

- (2) O'Neill WW, Chandler JG, Gordon RE, Bakalyar DM, Abolfathi AH, Castellani M, Hirsch JL, Wieting DW, Bassett JS, Beatty KC, Soltis MA, Timmis GC, Grines CL. Radiographic detection of single leg separations of the outlet strut of mitral Björk-Shiley convexo-concave heart valves. Submitted to the New England Journal of Medicine, August 1994.

Currently working with The Cleveland Clinic Foundation to prepare a manuscript describing the results of the digital analysis of all known status valves from the Beaumont study.

DRAFT

JOB DESCRIPTION OF JAMIE LEE HIRSCH

Working within the overall objective of developing and implementing a patient management program for Björk-Shiley Convexo-Concave valve patients who are at risk of outlet strut fracture:

- A) To assist the Supervisory Panel in developing programs which will help to identify patients who are at risk of outlet strut fracture:
 - 1. Providing expert knowledge to the Supervisory Panel.
 - 2. Assisting in developing a master plan for the clinical research.
 - 3. Evaluating and reviewing proposed research studies.
 - 4. Designing additional research studies if appropriate.
- B) To manage research studies sponsored by the Bowling Supervisory Panel:
 - 1. Manage clinical research studies including preparation of contracts and statements of work, patient recruitment, monitoring progress of work, visits to study sites, and documentation of research status.
 - 2. Continue management of Clinical Studies database, documents and communication.
 - 3. Prepare relevant documentation for approval by regulatory bodies and ensure regulatory compliance of pre-clinical and clinical studies.
 - 4. Prepare periodic status reports of the research studies and report status to the respective subcommittees, the Supervisory Panel, and other bodies.

Reporting Structure

- 1. Administration and Finances: to Kermit Smith, Chairman, Supervisory Panel
- 2. Scientific Research: to respective Subcommittees, Supervisory Panel

Stefan Schreck, Ph.D.

2057 White Birch Drive
Vista, CA 92083
(619) 727-8904

Shiley, Inc.
17672-B Cowan Avenue
Irvine, CA 92714
(714) 863-5770

SUMMARY

Research manager with strong background in biomedical engineering. Experienced in evaluating, planning, designing, budgeting, and managing research programs. Excellent oral and written communication skills. Uses strong analytical skills to provide creative solutions to scientific, organizational, and personnel problems. Demonstrated leadership by setting standards and achieving goals. Experienced in working in a multi-disciplinary setting.

EDUCATION

Doctor of Philosophy in Mechanical Engineering, University of Houston, Department of Mechanical Engineering, Houston, Texas, 1988.

Master's of Science in Aerospace Engineering, Technische Hochschule München, Munich, West Germany, 1985.

PROFESSIONAL EXPERIENCE

Project Manager, Shiley, Inc., Shiley Heart Valve Research Center, Irvine, California, Jan. 1993 - current

- Directed the Biomechanics Research program:

Gave the Biomechanics research program new focus; developed strategic research plan for clinical management of prosthetic heart valves patients, initiated new research studies in house and by external research contractors; prepared budgets; designed in vitro, animal, and clinical studies; managed an in-house research group of two engineers and two technicians and was contract manager of external research vendors; reported and presented new program and subsequent research findings to the FDA and national and international meetings; the new Biomechanics program became an integral part of Shiley's patient management strategy.

- In October 1993, took over responsibilities of the departing Associate Director of Research and reported directly to the Vice President of R&D.

Directed the Technical Research program which included the coordination of scientific meetings with international expert panels, preparation of scientific reports to the FDA, and management of the in-house support staff; integrated diverse research efforts into one unified multimillion dollar research proposal and headed a team of writers and researchers to prepare the proposal for submission; provided scientific expertise to the Legal Department.

- Formed a QA/QC team to assure regulatory compliance (GLP) of research studies; reorganized the product complaint group and removed backlog of product complaint reports; documented research studies sponsored by the Shiley Heart Valve Research Center.

Research Assistant Professor, University of Southern California, Department of Aerospace Engineering, Los Angeles, California, Oct. 1989 - Jan. 1993

- Designed and built innovative experimental facilities to study the upper respiratory system; developed first detailed theoretical model of the fluid mechanics of the upper airways; investigated and published research findings of the mechanics and physics of the human respiratory system in the Journal of Applied Physiology.
- Completely rebuilt and computer-automated an anechoic facility for tests of supersonic jets; won a \$90,000 research contract from NASA to develop noise control technology for supersonic jet engines; won a \$20,000 innovation research grant from the University of Southern California to develop technology for mixing enhancement in supersonic flows; successfully demonstrated new supersonic mixing technology to NASA representatives.
- Taught courses in aerospace engineering.

Research Associate, University of Houston, Department of Mechanical Engineering, Houston, Texas, and Georgia Institute of Technology, School of Mechanical Engineering, Atlanta, Georgia, Jan. 1986 - Aug. 1989.

- Assisted Krug International at the NASA Johnson Space Center in developing zero-gravity mammalian cell bioreactors; built innovative mixing chambers for culture of shear sensitive cells; Krug International received the NASA Innovation Award for the bioreactor design in 1992.
- Developed new methods to study two-phase flows by Laser Doppler velocimetry; designed study to investigate the interaction of freely suspended cells and turbulent media; published research findings in the Journal of Fluid Mechanics.
- Designed experimental facilities and image analysis software to quantify biomechanical changes in endothelial cells in response to fluid forces in blood vessels and grafts; significantly reduce failure rate of cell culture tests by redesigning test facilities and test procedures.
- Taught undergraduate laboratory courses.

Other Skills and Training

fluent in German;

enhanced management and communication skills by management and personal development courses;

completed a 26-week apprenticeship in manufacturing;

hands-on experience in drafting, machining, milling, welding, and manufacturing.

PUBLICATIONS

Schreck S, Kleis SJ, Nerem RM, "A Viscous Pump Bioreactor," Bioprocess Engineering Colloquium, ASME, 1987.

Kleis SJ, Schreck S, Nerem RM, "A Viscous Pump Bioreactor," Biotechnology and Bioengineering, 36 (8) 771-774, 1990.

Austin T., Schreck S., "Planar Imaging of a Heated Elliptic Jet by the Focusing Schlieren Method," Proceedings, 1990 Fall Meeting of the Western States Section/The Combustion Institute, La Jolla, CA, 11/1990.

Schreck S, Ho CM, "Coherent Structure Induced Pressure Fluctuations in an Elliptical Jet," AIAA paper No 90-3963, 1990.

Helminger G, R. Geiger RV, Schreck S, Nerem RM, "Effects of Pulsatile Flow Cultured Vascular Endothelia; Cell Morphology," J. Biomech. Eng. 113 (2), 123-131, 1991.

Schreck S, Ho CM, Sarmiento R, "Noise Radiated from Axisymmetric and Asymmetric Jets," DGLR/AIAA paper No 92-02-044, 1992.

Schreck S, Kleis SJ, "Modification of grid generated turbulence by solid particles," Journal of Fluid Mechanics, (1993), vol. 249, pp. 665-688.

Schreck S, Sullivan KJ, Ho CM, Chang HK, "Correlations between Flow Resistance and the Geometry in a Model of the Human Nose," Journal of Applied Physiology, 75 (4): 1767-1775, 1993.

Plemons TD, Schreck SG, Inderbitzen RS, "Stability of the BSCC Heart Valve Outlet Strut Resonant Frequency Under Changing Physiological Conditions and Observation Time," Proceedings, 1994 IEEE Seventh Symposium on Computer-Based Medical Systems, June 10-12, Winston-Salem, North Carolina, 1994.

Schreck S, Michaelian M, Ho CM, "Mixing Enhancement in a Supersonic Jet," AIAA Journal, Manuscript J21696, (in review)

ABSTRACTS

Schreck S, Kleis SJ, "Modification of Turbulence by High Concentrations of Neutrally Buoyant Particles", APS Fluid Dynamics Division Meeting, Eugene, Oregon, 11/87.

Schreck S, Kleis SJ, "Fluid and Particle Velocity Correlations in Liquid-Solid Two-Phase Turbulence", APS Fluid Dynamics Division Meeting, Buffalo, New York, 11/88.

Schreck S, Kleis SJ, "Effects of Solid Particles on Grid-Generated Turbulence", APS Fluid Dynamics Division Meeting, Palo Alto, California, 11/89.

Sullivan KJ, Schreck S, Ho CM, Chang HK, "Correlations between Nasal Geometry and Flow Resistance in Healthy Adults", Federation of American Societies for Experimental Biology, 75th Annual Meeting, Atlanta, Georgia, 4/91.

Schreck S, Sullivan KJ, Ho CM, Chang HK, "Fluid Dynamic Phenomena in a Scale Model of the Nasal Passage", Federation of American Societies for Experimental Biology, 75th Annual Meeting, Atlanta, Georgia, 4/91.

Schreck S, Sullivan KJ, Ho CM, Chang HK, "A Three-Compartment Model of the Flow Field in the Human Nose", APS Fluid Dynamics Division Meeting, Scottsdale, Arizona, 11/91.

Schreck S, Sullivan KJ, Ho CM, Chang HK, "Unsteady Flow Phenomena in the Human Nose", Federation of American Societies for Experimental Biology, 75th Annual Meeting, Anaheim, California, 4/92.

Auerbach AH, Sullivan KJ, Schreck S, Chang HK, "Nasal Flow Impedance and Flow Distribution Measured with Forced Oscillations", Federation of American Societies for Experimental Biology, 75th Annual Meeting, Anaheim, California, 4/92.

Thomas JD, Vandervoort PM, Schreck SG, Wieting DW, "Recordings of Opening Bounce Motion of Björk-Shiley Convexo-Concave Mitral Prostheses by Echocardiography: In Vitro Validation", American College of Cardiology, 43rd Annual Scientific Session.

Inderbitzen RS, Chin H, Schreck SG, Breznock E, Wieting DW, "Assessment of Dynamic Loading of Heart Valves In Vivo", AAMI Cardiovascular Science and Technology Conference, Washington, DC, December 10-12, 1993.

Eberhardt AC, Ward, MA, Lewandowski, SJ, Schreck SG, Wieting DW, "Duplication of Recorded Ventricular Pressure Waveforms for Characterization of Heart Valve Response", AAMI Cardiovascular Science and Technology Conference, Washington, DC, December 10-12, 1993.

Chandran KB, Lee CS, Aluri S, Dellsperger KC, Schreck S, Wieting DW, "Pressure Distribution Near the Occluders and Impact Forces on the Outlet Struts of Björk-Shiley Convexo-Concave Valves During Closing", Second World Congress of Biomechanics, Amsterdam, Netherlands, July 10-15, 1994.

Inderbitzen RS, Schreck SG, Wieting DW, "Non-Invasive Acoustic Detection of Implanted Mechanical Heart Valve Structural Integrity", Second World Congress of Biomechanics, Amsterdam, The Netherlands, July 10-15, 1994.

Schreck SG, Inderbitzen RS, Wieting DW, "Dynamics of Björk-Shiley Convexo-Concave Heart Valves in Sheep", Second World Congress of Biomechanics, Amsterdam, The Netherlands, July 10-15, 1994.

Eberhardt AC, Ward MA, Lewandowski SJ, Inderbitzen RS, Schreck SG, Wieting DW, "In Vitro Simulation of Mechanical Heart Valve Dynamics Using Left Ventricular Pressure Recordings from Humans with Arrhythmia", Second World Congress of Biomechanics, Amsterdam, The Netherlands, July 10-15, 1994.

Blick EF, Wieting DW, Inderbitzen RS, Schreck SG, Stein PD, "Velocity of Closure of Björk-Shiley Convexo-Concave Mitral Valves: Effects of Orientation of the Mitral Annulus and Left Ventricular Pressure Rise", IBEES, the 2nd Sheffield symposium, October 20-22, 1994.

Wieting DW, Schreck SG, Inderbitzen Breznock E, "Dynamics of the Björk-Shiley Heart Valve in Sheep", IBEES, the 2nd Sheffield symposium, October 20-22, 1994.

Pu M, Greenberg NL, Bibawy GA, Schreck S, Vandervoort PM, "Estimation of Load on Björk-Shiley Mitral Prostheses by Echocardiography", American Heart Association, 67th Scientific Sessions, Dallas, Texas, November 14-17, 1994.

Stefan Schreck, Ph.D.

Employment with the Shiley Heart Valve Research Center

Starting Date: January 1993

Current Position: Project Manager

Responsibilities: Biomechanics Research Program:

- refocused research effort toward identifying conditions indicative of increased outlet strut loading and clinical assessment of these conditions.
- managed the following studies: sheep implant program at BioSurg; echocardiography studies at Cleveland Clinic Foundation; in-vitro studies at Iowa University, Structural Acoustics Inc., Helmholtz Institute Aachen; fatigue studies at SHVRC.
- initiated collaboration of epidemiologic and biomechanics research in identifying patient specific risk factors.
- assisted Biomechanics research group in preparing proposals to the Bowling Panel.
- summarized findings and presented results to FDA and Technical Review Panel
- presented research findings at international meetings and prepared abstracts and manuscripts for publication.

Acoustics Research Program:

- provided scientific expertise to the Manager of the Acoustics Research Program.
- proposed and conducted vibrational measurements of valve components to identify vibro-acoustic responses unique to either intact or SLS valves.

Overall Research Management:

- took over administrative responsibilities for the overall non-clinical research program in Nov. 1993.
- prepared budgets and proposals.
- organized Review Panel Meetings.
- prepared summary reports of the research to the FDA.
- integrated x-ray, acoustics, epidemiological, and biomechanics research into one unified research proposal and prepared proposal for submission to the Bowling Panel.

Others:

- evaluated research proposals submitted to SHVRC.
- conducted feasibility study of SLS detection by microwaves.
- revised engineering evaluation of explanted valves (Product Complaint Reports).

DRAFT

JOB DESCRIPTION OF STEFAN SCHRECK, Ph.D.

Working within the overall objective of developing and implementing a patient management program for Björk-Shiley Convexo-Concave valve patients who are at risk of outlet strut fracture:

- A) To assist the Supervisory Panel in developing programs which will help to identify patients who are at risk of outlet strut fracture:
 - 1. Providing expert knowledge to the Supervisory Panel.
 - 2. Assisting in developing a master plan for the clinical research.
 - 3. Evaluating and reviewing proposed research studies.
 - 4. Designing additional research studies if appropriate.
- B) To manage research studies sponsored by the Bowling Supervisory Panel:
 - 1. Set-up office for the Management Consultants in Irvine, California including staffing, furnishing, access to Shiley data base and documents, and communication.
 - 2. Manage research studies in the areas of acoustics, biomechanics, and fracture mechanics including preparation of contracts and statements of work, monitoring of progress of work, visits of study sites, and documentation of research status.
 - 3. Where applicable, assist in preparing relevant documentation for approval by regulatory bodies and ensure regulatory compliance of pre-clinical and clinical studies.
 - 4. Prepare periodic status reports of the research studies and report status to the respective subcommittees, the Supervisory Panel, and other bodies.
 - 5. Provide administrative support to the management group including general communication, travel and meeting arrangements, and coordination of research efforts.

Reporting Structure

- 1. Administration and Finances: to Kermit Smith, Chairman, Supervisory Panel
- 2. Scientific Research: to respective Subcommittees, Supervisory Panel

MARY ANN SOLTIS, BSN, RN

1992 to Present - Clinical Research Associate
Shiley Heart Valve Research Center
Irvine, Calif.

Developed and initiated Patient Follow-Up Program for patients in radiographic SLS detection studies forming the basis for the patient/physician informational booklet being developed by Dr. James Chandler and myself.

Study Monitor for the Beaumont Study, establishing standard operating procedures which formed the basis for all in-house and external monitoring activities for this study as well as subsequent studies at Stanford and Western Infirmary, Glasgow.

Had primary responsibility for integrating activities at Western Infirmary, including training of study nurse, investigators, radiography techs and Expert Review panelists; facilitated liaison between study nurse and MTCE consultant.

Monitored travel and expenses of all Beaumont Study patients, identifying numerous billing discrepancies, including overbilling.

Established procedure for valve serial number/weld/ship date verification.

Participated in pre-study training and testing of investigators and panelists at Aachen and Stanford.

Worked with Tracor in developing of acoustic training manual for Western Infirmary. Assisted in training of cardiology technicians in acoustic recordings. As a result, became proficient in obtaining and evaluating quality of recordings. Independently obtained serial recordings from patient about to undergo explant of radiographically detected SLS valve.

Managed activities of data entry personnel. Co-managed clinical research database.

Performed ongoing analysis of medications and clinical characteristics of patients with known SLS and intact valves.

1991 to 1992 - Research Nurse

Western Regions Special Studies Group
Los Angeles - Long Beach, California

Completed intense training at Rand Corporation, Santa Monica, California.

On-site retroactive research of data pertinent to AIDS patients in Veterans Hospitals in the Western Region. Assimilation of data and analysis in preparation for final report.

**1988 to 1991 - Vice President Revenue Management and Audit Services
PARA - Pasadena, California**

Conducted feasibility studies for prospective client hospitals.

Compiled and analyzed data gathered, prepared report of analysis for final recommendation.

Interviewed, hired, and trained new employees at audit sites throughout United States.

Oriented key hospital personnel (Chief Financial Officer, Business Office Manager, etc.) to the Revenue Management Program and its process as it pertained to each hospital's specific needs.

Wrote Policy and Procedure Manual for the Revenue Management Program.

Performed financial analysis of the final billing process in order to assure accuracy of all commercially insured accounts.

**1985 to 1988 - Registered Nurse, Operating Room
El Camino Hospital - Mt. View, California**

Scrubbed and circulated all specialties.

Responsible for use and care of all surgical equipment.

Week-end Charge Nurse responsible for all aspects of a challenging trauma center O.R.

1986 to 1988 - Independent Nurse Specialist

Registered Nurse and Private Scrub Nurse for Plastic and Reconstructive Surgeons in private surgical as well as office surgical suites.

1981 to 1985 - Registered Nurse, Operating Room
Good Samaritan Hospital - Portland, Oregon

Scrubbed and circulated all specialties

Organized and implemented new Neuro-Otology program.

1977 to 1981 - Registered Nurse, Operating Room
Roseville Community Hospital - Roseville, California

Scrubbed and circulated all specialties

Charge Nurse

Recovery Room relief nurse.

Education - Masters, Health Services Administration
University of San Francisco - Orange Campus
In progress.

Bachelor of Science, Nursing - 1974
San Jose State University - San Jose, California

Professional

Associations - Research Nurse Association
Southern California

Association of Operating Room Nurses

Orange County Regulatory Affairs Assoc.

**JOB DESCRIPTION/HISTORY
FOR
MARY ANN SOLTIS
@
SHILEY HEART VALVE RESEARCH CENTER**

1. As Study Monitor for the Beaumont Study, established standard operating procedures which formed the basis for all in-house and external monitoring activities for this study as well as subsequent studies at Stanford and Western Infirmary, Glasgow.
2. Monitored travel and expenses of all Beaumont Study patients, identifying numerous billing discrepancies, including overbilling.
3. Worked with Tracor in developing of acoustic training manual for Western Infirmary. Assisted in training of cardiology technicians in acoustic recordings. As a result, became proficient in obtaining and evaluating quality of recordings. Independently obtained serial recordings from patients about to undergo explant of radiographically detected SLS valves.
4. Managed activities of data entry person. Worked with J. Hirsch on management of clinical research database.
5. Developed and initiated Patient Follow-up Program for patients in radiographic SLS detection studies. Thus far, the program has yielded fourteen negatively-rated valves and formed the basis for the patient/physician informational booklet.
6. Had primary responsibility for integrating activities at Western Infirmary, including training of study nurse, investigators, radiography techs and Expert Review panelists; facilitated liaison between study nurse and MTCE consultant.
7. Established procedure for valve serial number verification and uncovered discrepancy between RS and C/C valves in Medic Alert and Bains databases. Instigated weld/ship implant date comparison and reporting to investigator when discrepancies appeared early in study, thereby avoiding any protocol deviations. Because of these discrepancies, suggested any valve thought to be questionable be imaged in alternate Cath Lab, using x-ray system without modifications, to establish valve type, thereby avoiding potential protocol violations.
8. Participated in pre-study training and testing of investigators and panelists at Aachen and Stanford.
9. Monitoring of clinical inquiries of patients and physicians.

JOB DESCRIPTION OF MARY ANN SOLTIS

Working within the overall objective of developing and implementing a patient management program for Bjork-Shiley Convexo-Concave valve patients who are at risk of outlet strut fracture:

A. To assist the Supervisory Panel in developing programs which will help to identify patients who are at risk of outlet strut fracture:

1. Provide expert knowledge to the Supervisory Panel.
2. Assist in developing a master plan for clinical research.
3. Evaluate and review proposed research studies.
4. Assist in design of additional research studies, if appropriate.

B. To manage research studies sponsored by the Bowling Supervisory Panel:

1. Co-manage imaging studies, monitoring progress of work, study site visits, and documentation of research progress.
2. Maintain patient follow-up program of applicable studies.
3. Prepare periodic status reports of the research studies and report status to the respective subcommittees, the Supervisory Panel, and others, where applicable.
4. Provide support to other members of the management group.

Reporting Structure:

1. Administration and Finances: Kermit Smith, Chairman, Supervisory Panel
2. Scientific Research: respective subcommittees, Supervisory Panel

SUBLEASE AGREEMENT

THIS SUBLEASE AGREEMENT ("Sublease") is entered into as of the _____, day of _____, 1995, by and between SHILEY INCORPORATED, a California corporation, a wholly owned subsidiary of Pfizer, Inc., a Delaware corporation (who took its interest as Lessee in the Master Lease described below as PFIZER HOSPITAL PRODUCTS GROUP DIVISION OF PFIZER, INC., a Delaware corporation) ("Sublessor") and SPECIAL MASTERS/TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS (referred to herein as the "Trustee" or "Sublessee"), as a sublease under that certain Standard Industrial Lease---Multi-Tenant ("Master Lease") dated November 16, 1992, entered into by the PRINCIPAL MUTUAL LIFE INSURANCE COMPANY, as "Lessor," and Sublessor, as "Lessee", a copy of which Master Lease is attached hereto as Exhibit A and incorporated herein by this reference.

NOW, THEREFORE, the parties hereto do agree as follows:

1. SUBLEASE OF PREMISES

Sublessor hereby leases to Sublessee and Sublessee hires from Sublessor the following described premises ("Sublease Premises") together with all appurtenances, situated in the City of Irvine, County of Orange, State of California, constituting a portion of the property commonly known as 17671 Cowan Avenue, comprising approximately 3,738 usable square feet of the total 16,635 usable square feet of the first floor of the building at said address. The configuration of the Sublease Premises is depicted on Exhibit B attached hereto.

2. PROVISIONS CONSTITUTING SUBLEASE

(a) This Sublease is subject to all of the terms and conditions of the Master Lease, and Sublessee shall assume and perform the obligations of Sublessor as Lessee in said Master Lease, to the extent said terms and conditions are applicable to the Sublease Premises. Sublessee shall not commit or permit to be committed on the Sublease Premises any act or omission which shall violate any term or condition of the Master Lease. In the event of the termination of Sublessor's interest as Lessee under the Master Lease for any reason, then this Sublease shall terminate coincidentally therewith without any liability of Sublessor to Sublessee.

(b) All of the terms and conditions contained in the Master Lease are incorporated herein, except as otherwise provided herein, as terms and conditions of this Sublease (with each reference therein to Lessor and Lessee to be deemed to refer to

Sublessor and Sublessee) and, along with all of the Sections set out in this Sublease, shall be the complete terms and conditions of this Sublease.

3. RENTAL

Sublessee shall pay to Sublessor as monthly rent for the Sublease Premises in advance on the first day of each calendar month of the term of this Sublease without deduction, offset, prior notice or demand, in lawful money of the United States, the sum of Two Thousand Four Hundred Thirty Dollars (\$2,430.00). If the commencement date is not the first day of the month, or if the Sublease termination date is not the last day of the month, a prorated monthly installment shall be paid at the then current rate for the fractional month during which the Sublease commences and/or terminates. Receipt of \$_____ is hereby acknowledged for rental for the period commencing March ____, 1995 through March 31, 1995. No security deposit shall be required from Sublessee under this Sublease.

4. TERM

(a) The term of this Sublease shall be for the period commencing March 10, 1995 and ending on February 29, 1996.

(b) In the event Sublessor is unable to deliver possession of the Sublease Premises at the commencement of the term, Sublessor shall not be liable for any damage caused thereby, nor shall this Sublease be void or voidable but Sublessee shall not be liable for rent until such time as Sublessor offers to deliver possession of the Sublease Premises to Sublessee. The term hereof shall not be extended by any such delay. If Sublessee, with Sublessor's consent, takes possession prior to the commencement of the term, Sublessee shall do so subject to all of the covenants and conditions hereof and shall pay rent for the period ending with the commencement of the term at the same rental as that prescribed for the first month of the term, prorated at the rate of 1/30th thereof per day.

5. USE

Sublessee shall use the Premises for general office purposes, and activities incidental thereto, and for no other purpose without the prior written consent of Sublessor. Sublessee's business shall be established and conducted throughout the term hereof in a first class manner. Sublessee shall not use the Sublease Premises for, or carry on, or permit to be carried on, any offensive, noisy or dangerous trade, business, manufacture or occupation nor permit any auction sale to be held or conducted on or about the Sublease Premises. Sublessee shall not do or suffer anything to be done upon the Sublease Premises which will cause structural injury to the Sublease Premises or the building of which the Sublease Premises form a part. The Sublease Premises shall not be overloaded and no machinery, apparatus or other appliance shall be used or operated in or upon the Sublease Premises which will in any manner injure, vibrate or shake the Sublease Premises or the building of which it is a part. No use shall be made of the Sublease Premises which will in any way

impair the efficient operation of the sprinkler system (if any) within the building containing the Sublease Premises. Sublessee shall not leave the Sublease Premises unoccupied or vacant during the term. No musical instrument of any sort, or any noise making device will be operated or allowed upon the Sublease Premises for the purpose of attracting trade or otherwise. Sublessee shall not use or permit the use of the Sublease Premises or any part thereof for any purpose which will increase the existing rate of insurance upon the building in which the Sublease Premises are located, or cause a cancellation of any insurance policy covering the building or any part thereof. If any act on the part of Sublessee or use of the Sublease Premises by Sublessee shall cause, directly or indirectly, any increase of Sublessor's insurance expense, said additional expense shall be paid by Sublessee to Sublessor upon demand. No such payment by Sublessee shall limit Sublessor in the exercise of any other rights or remedies, or constitute a waiver of Sublessor's right to require Sublessee to discontinue such act or use.

6. TENANT IMPROVEMENTS

Sublessor shall undertake to complete certain Tenant Improvements ("Tenant Improvements") at the Sublease Premises, as more particularly described in Exhibit C attached hereto, and as shown on Exhibit B. The cost of such Tenant Improvements shall be borne by Sublessor. Sublessor agrees to complete the Tenant Improvements as soon as possible to allow Sublessee's occupancy of the Sublease Premises.

7. UTILITIES

Sublessor shall bear the cost of all utilities for the Sublease Premises with the exception of electrical power, which shall be the obligation of the Sublessee. Sublessee agrees to pay its pro rata share of the cost of electrical power utilized for the first floor of the building containing the Sublease Premises, based upon the ratio of usable square footage of the Sublease Premises (3,738 square feet) as compared to the total usable square footage of the first floor of said building (16,635 usable square feet), which ratio equals 22.5%. Sublessor shall provide Sublessee with written notice of its share of the cost of electrical power for the Sublease Premises at such time as the Sublessor receives billings for the cost of electrical power, and Sublessee shall pay such billings to the Sublessor within ten (10) days of receipt thereof. It is agreed that Sublessee will not be required to reimburse Sublessor for any Operating Expenses paid by Sublessor pursuant to Section 4.2 of the Master Lease, nor will Sublessee incur a separate charge for the maintenance contracts specified at Section 7.2(a) of the Master Lease.

8. INSURANCE

(a) **Liability Insurance.** Sublessee shall maintain at its expense a policy of liability insurance with coverage of not less than \$2,000,000 per occurrence, consistent with the insurance requirements set forth at paragraph 8.1 of the Master Lease, which policy shall name Sublessee, Sublessor and the Lessor under the Master Lease as insured parties.

(b) **Property Insurance.** Sublessee shall not be required to maintain a policy of insurance covering loss or damage to the Sublease Premises or the building containing the Sublease Premises. Sublessee shall be responsible for maintaining full replacement cost insurance coverage for loss or damage to Sublessee's personal property, fixtures and equipment within the Sublease Premises, and Sublessor shall have no obligation in that regard.

9. REAL PROPERTY TAXES

Sublessee shall have no responsibility for reimbursement of real property taxes assessed against the Sublease Premises. Sublessee shall be responsible for payment of taxes assessed against and levied upon its fixtures, furnishings, equipment and all of the personal property of Sublessee contained in the Sublease Premises or elsewhere. If any of Sublessee's personal property shall be assessed with the real property taxes assessed against the Sublease Premises, Sublessee shall pay to Sublessor the taxes attributable to Sublessee's property within ten (10) days of receipt of a written statement from Sublessor setting forth such taxes.

10. PARKING

Sublessee shall have the right to utilize ten (10) parking spaces in connection with the occupancy of the Sublease Premises. Sublessee shall comply with all reasonable regulations and/or rules of Sublessor with regard to parking, including those which may be imposed in order to determine that Sublessee does not exceed its allotted number of parking spaces.

11. NO OPTIONS

Sublessee shall have no right to exercise any option to extend the term of the Sublease, notwithstanding the right of the Sublessor, if any, to extend the term of the Master Lease.

12. NO COMMISSIONS

Sublessor and Sublessee represent that no broker's or finder's fee is owed to any person or entity with respect to this Sublease, and each party indemnifies and holds harmless the other from any claim for a broker's fee or finder's fee arising out of the actions of the indemnifying party.

13. NOTICES

All notices or demands of any kind required or desired to be given by Sublessor or Sublessee hereunder shall be in writing and shall be deemed delivered forty-eight (48) hours after depositing the notice or demand in the United States mail, certified or registered, postage prepaid, addressed to the Sublessor or Sublessee respectively at the addresses set

forth after their signatures at the end of this Sublease. All rent and other payments due under this Sublease or the Master Lease shall be made by Sublessee to Sublessor at the address specified for notices.

14. COUNTERPARTS

This Sublease may be executed in counterparts, each of which shall be an original document, and all of which together shall constitute a single instrument.

15. LESSOR'S CONSENT

The effectiveness of this Sublease shall be subject to the prior approval of the Lessor under the Master Lease.

IN WITNESS WHEREOF, the undersigned have executed this Sublease Agreement as of the date first above written.

SHILEY INCORPORATED, a California corporation, a wholly owned subsidiary of PFIZER, INC., a Delaware corporation (who took its interest in the Master Lease as PFIZER HOSPITAL PRODUCTS GROUP DIVISION OF PFIZER, INC., a Delaware corporation)

By: _____

Its: _____

Address: 17671 Cowan Avenue
Irvine, California 92714

"Sublessor"

**SPECIAL MASTERS/TRUSTEES, FOR THE
BOWLING-PFIZER HEART VALVE
SETTLEMENT FUNDS**

By: _____

Judge Robert L. Black, Jr.

By: _____

Peter J. Strauss

Address: 17671 Cowan Avenue
Irvine, California 92714

"Sublessee"

LESSOR'S CONSENT TO SUBLEASE

The foregoing Sublease Agreement ("Sublease") is hereby approved by the undersigned Lessor under the Master Lease described in said Sublease.

This consent is given the _____ day of _____, 1995.

THE PRINCIPAL MUTUAL LIFE
INSURANCE COMPANY

By _____

Its _____

"Lessor"

EXHIBIT A
MASTER LEASE

STANDARD INDUSTRIAL LEASE — MULTI-TENANT

AMERICAN INDUSTRIAL REAL ESTATE ASSOCIATION



1. Parties. This Lease, dated, for reference purposes only, November 14, 1992, is made by and between The Principal Mutual Life Insurance Company (herein called "Lessor") and Pfizer Hospital Products Group Division of Pfizer, Inc., a Delaware Corporation (herein called "Lessee").

2. Premises, Parking and Common Areas.

2.1 Premises. Lessor hereby leases to Lessee and Lessee leases from Lessor for the term, at the rental, and upon all of the conditions set forth herein, real property situated in the County of Orange, State of California, commonly known as 17671 Canon Avenue, Suite 100, Irvine and described as Approximately 17,765 square feet of corporate headquarters/office space (see Exhibit "A" attached hereto).

herein referred to as the "Premises", as may be outlined on an Exhibit attached hereto, including rights in the Common Areas as hereinafter specified but not including any rights in the roof of the Premises or to any building in the Industrial Center. The Premises are a portion of a building herein referred to as the "Building." The Premises, the Building, the Common Areas, the land upon which the same are located, along with all other buildings and improvements thereon, are herein collectively referred to as the "Industrial Center."

2.2 Vehicle Parking. Lessee shall be entitled to 71 vehicle parking spaces, unreserved and unassigned, on those portions of the Common Areas designated by Lessor for parking. Lessee shall not use more parking spaces than said number. Said parking spaces shall be used only for parking by vehicles no larger than full size passenger automobiles or pick-up trucks, herein called "Permitted Size Vehicles." Vehicles other than Permitted Size Vehicles are herein referred to as "Over-sized Vehicles."

2.2.1 Lessee shall not permit or allow any vehicles that belong to or are controlled by Lessee or Lessee's employees, suppliers, shippers, customers, or invitees to be loaded, unloaded, or parked in areas other than those designated by Lessor for such activities.

2.2.2 If Lessee permits or allows any of the prohibited activities described in paragraph 2.2 of this Lease, then Lessor shall have the right to remove, without notice, in addition to such other rights and remedies that it may have, to remove or tow away the vehicle involved and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor.

2.3 Common Areas — Definition. The term "Common Areas" is defined as all areas and facilities outside the Premises and within the exterior boundary line of the Industrial Center that are provided and designated by the Lessor from time to time for the general non-exclusive use of Lessee, Lessee and other lessees of the Industrial Center and their respective employees, suppliers, shippers, customers and invitees, including parking areas, loading and unloading areas, trash areas, roadways, sidewalks, walkways, parkways, driveways and landscaped areas.

2.4 Common Areas — Lessee's Rights. Lessor hereby grants to Lessee, for the benefit of Lessee and its employees, suppliers, shippers, customers and invitees, during the term of this Lease, the non-exclusive right to use, in common with others entitled to such use, the Common Areas as they exist from time to time, subject to any rights, powers, and privileges reserved by Lessor under the terms hereof or under the terms of any rules and regulations or restrictions governing the use of the Industrial Center. Under no circumstances shall the right herein granted to use the Common Areas be deemed to include the right to store any property, temporarily or permanently, in the Common Areas. Any such storage shall be permitted only by the prior written consent of Lessor or Lessor's designated agent, whose consent may be revoked at any time. In the event that any unauthorized storage shall occur, Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove the property and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor.

2.5 Common Areas — Rules and Regulations. Lessor or such other persons as Lessor may appoint shall have the exclusive control and management of the Common Areas and shall have the right, from time to time, to establish, modify, amend and enforce reasonable rules and regulations with respect thereto. Lessee agrees to abide by and conform to all such rules and regulations, and to cause its employees, suppliers, shippers, customers, and invitees to so abide and conform. Lessor shall not be responsible to Lessee for the non-compliance with said rules or regulations by other lessees of the Industrial Center.

2.6 Common Areas — Changes. Lessor shall have the right, in Lessor's sole discretion, from time to time:

(a) To make changes to the Common Areas, including, without limitation, changes in the location, size, shape and number of driveways, entrances, parking spaces, parking areas, loading and unloading areas, ingress, egress, direction of traffic, landscaped areas and walkways; (b) To close temporarily any of the Common Areas for maintenance purposes so long as reasonable access to the Premises remains available; (c) To designate other land outside the boundaries of the Industrial Center to be a part of the Common Areas; (d) To add additional buildings to the Industrial Center, or any portion thereof; (e) To use the Common Areas while engaged in making additional improvements, repairs or alterations to the Industrial Center; or (f) To do and perform such other acts and make such other changes in or to or with respect to the Common Areas and Industrial Center as Lessor may, in the exercise of sound business judgment, deem to be appropriate.

2.6.1 Lessor shall at all times provide the parking facilities required by applicable law and in no event shall the number of parking spaces that Lessee is entitled to under paragraph 2.2 be reduced.

3. Term. The term of this Lease shall be for three (3) years, commencing on March 1, 1993 and ending on March 1, 1996, unless sooner terminated pursuant to any provision hereof.

3.1 Delay in Possession. Notwithstanding said commencement date, if for any reason Lessor cannot deliver possession of the Premises to Lessee on said date, Lessor shall not be subject to any liability therefor, nor shall such failure affect the validity of this Lease or the obligations of Lessee hereunder or extend the term hereof, but in such case, Lessee shall not be obligated to pay rent or perform any other obligation of Lessee under the terms of this Lease except as may be otherwise provided in this Lease, until possession of the Premises is tendered to Lessee. However, if Lessor shall not have delivered possession of the Premises within sixty (60) days from said commencement date, Lessee may, at Lessee's option, by notice in writing to Lessor within ten (10) days thereafter, cancel this Lease, in which event the parties shall be discharged from all obligations hereunder provided further, however, that if such written notice of Lessee is not received by Lessor within said ten (10) day period, Lessee's right to cancel this Lease hereunder shall terminate and be of no further force or effect.

3.2 Early Possession. If Lessee occupies the Premises prior to said commencement date, such occupancy shall be subject to all provisions of this Lease, such occupancy shall not advance the termination date, and Lessee shall pay rent for such period at the initial monthly rates set forth in Section 4.

4. Rent.

4.1 Base Rent. Lessee shall pay to Lessor, as Base Rent for the Premises, without any offset or deduction, except as may be otherwise expressly provided in this Lease, on the first day of each month of the term hereof, monthly payments in advance of \$ 12,566.48 (see Addendum Paragraph (1)).

Lessee shall pay Lessor upon execution hereof \$ 12,566.48 as Base Rent for the first month of the term and for any period during the term hereof which is for less than one month shall be a pro rata portion of the Base Rent. Rent shall be payable in legal tender of the United States to Lessor at the address stated herein or to such other persons or at such other places as Lessor may designate in writing.

4.2 Operating Expenses. Lessee shall pay to Lessor during the term hereof, in addition to the Base Rent, Lessee's Share, as hereinafter defined, of all Operating Expenses, as hereinafter defined, during each calendar year of the term of this Lease, in accordance with the following provisions:

(a) Lessee's Share is defined, for purposes of this Lease, as 77.5 percent.

(b) Operating Expenses is defined, for purposes of this Lease, as all costs incurred by Lessor, if any, for:

(i) The operation, repair and maintenance, in rent, clean, good order and condition, of the following:

(i)(a) The Common Areas including parking areas, loading and unloading areas, trash areas, roadways, sidewalks, walkways, parkways, driveways, landscaped areas, striping, bumpers, irrigation systems, Common Area lighting facilities and fences and gates.

(i)(b) Trash disposal services.

(i)(c) Tenant directories.

(i)(d) Fire detection systems including sprinkler system maintenance and repair.

1001 Security Services
(10) Any other service to be provided by Lessor that is elsewhere in this Lease stated to be an Operating Expense
(11) The cost of the premiums for the liability and property insurance policies to be maintained by Lessor under paragraph 6 hereof
(12) The cost of water, gas and electricity to be provided by Lessor under paragraph 6 hereof
(13) The inclusion of the improvements, facilities and services set forth in paragraph 4.2(b)(ii) at the definition of Operating Expenses shall not be deemed to impose an obligation upon Lessor if a similar service or improvement or facilities or to provide those services unless the Industrial Center already has the same. Lessor already provides the services or Lessor has agreed elsewhere in this Lease to provide the same or some of them.

(14) Lessee's Share of Operating Expenses shall be payable by Lessee within ten (10) days after a reasonably detailed statement of actual expenses is presented to Lessee by Lessor. At Lessor's option, however, an amount may be estimated by Lessor from time to time of Lessee's Share of annual Operating Expenses and the same shall be payable monthly or quarterly, as Lessor shall designate during each twelve-month period of the Lease term on the same day as the Base Rent is due hereunder. In the event that Lessee pays Lessor's estimate of each twelve-month period of Operating Expenses as aforesaid, Lessor shall deliver to Lessee within sixty (60) days after the expiration of each calendar year a reasonably detailed statement showing Lessee's Share of the actual Operating Expenses incurred during the expiration of each calendar year. If Lessee's payments under this paragraph 4.2(d) during said preceding year exceed Lessee's Share as indicated on said statement, Lessee shall be entitled to credit the amount of such overpayment against Lessee's Share of Operating Expenses next falling due. If Lessee's payments under this paragraph during said preceding year were less than Lessee's Share as indicated on said statement, Lessee shall pay to Lessor the amount of the deficiency within ten (10) days after delivery by Lessor to Lessee of said statement.

5. Security Deposit. Lessee shall deposit with Lessor upon execution hereof \$ 50,000.00 as security for Lessee's faithful performance of Lessee's obligations hereunder. If Lessee fails to pay rent or other charges due hereunder or otherwise defaults with respect to any provision of this Lease, Lessor may use, apply or retain all or any portion of said deposit for the payment of any rent or other charge in default or for the payment of any other sum to which Lessor may become obligated by reason of Lessee's default or to compensate Lessor for any loss or damage which Lessor may suffer thereby. If Lessor so uses or applies all or any portion of said deposit, Lessee shall, within ten (10) days after written demand from time to time, reimburse Lessor in an amount sufficient to restore said deposit to the full amount then required of Lessee. If the monthly rent shall increase during the term of this Lease, Lessee shall, at the time of such increase, deposit with Lessor additional money as a security deposit so that the total amount of the security deposit held by Lessor shall at all times bear the same proportion to the then current Base Rent as the initial security deposit bears to the initial Base Rent set forth in paragraph 4. Lessor shall not be required to keep said security deposit separate from its general accounts. If Lessee performs all of Lessee's obligations hereunder, said deposit, or so much thereof as has not theretofore been applied by Lessor, shall be returned, without payment of interest or other increment for its use, to Lessee (or, at Lessor's option, to the last assignee) hereof between Lessor and Lessee with respect to said Security Deposit.

6. Use.
6.1 Use. The Premises shall be used and occupied only for general office and storage use,
or any other use which is reasonably comparable and for no other purpose.

6.2 Compliance with Law.
(a) Lessor warrants to Lessee that the Premises, in the state existing on the date that the Lease term commences, but without regard to the use for which Lessee will occupy the Premises, does not violate any covenants or restrictions of record, or any applicable building code, regulation or ordinance in effect on such Lease commencement date. In the event it is determined that this warranty has been violated, then it shall be the obligation of the Lessor, after written notice from Lessee, to promptly, at Lessor's sole cost and expense, rectify any such violation. In the event Lessee does not give to Lessor written notice of the violation of this warranty within six months from the date that the Lease term commences, the correction of same shall be the obligation of the Lessee at Lessee's sole cost. The warranty contained in this paragraph 6.2(a) shall be of no force or effect if prior to the date of this Lease, Lessee was an owner or occupant of the Premises and, in such event, Lessee shall correct any such violation at Lessee's sole cost.

(b) Except as provided in paragraph 6.2(a), Lessee shall, at Lessee's expense, promptly comply with all applicable statutes, ordinances, rules, regulations, orders, covenants and restrictions of record, and requirements of any life insurance underwriters or rating bureaus, now in effect or which may hereafter come into effect, whether or not they reflect a change in policy from that now existing, during the term or any part of the term hereof, relating in any manner to the Premises and the occupation and use of the Premises and of the Common Areas. Lessee shall not use nor permit the use of the Premises or the Common Areas in any manner that will tend to create waste or a nuisance or shall tend to disturb other occupants of the Industrial Center.

6.3 Condition of Premises.
(a) Lessor shall deliver the Premises to Lessee clean and free of debris on the Lease commencement date (unless Lessee is already in possession) and Lessor warrants to Lessee that the plumbing, lighting, air conditioning, heating, and loading docks in the Premises shall be in good operating condition on the Lease commencement date. In the event that it is determined that this warranty has been violated, then it shall be the obligation of Lessor, after receipt of written notice from Lessee setting forth with specificity the nature of the violation, to promptly, at Lessor's sole cost, rectify such violation. Lessee's failure to give such written notice to Lessor within thirty (30) days after the Lease commencement date shall cause the conclusive presumption that Lessor has complied with all of Lessor's obligations hereunder. The warranty contained in this paragraph 6.3(a) shall be of no force or effect if prior to the date of this Lease, Lessee was an owner or occupant of the Premises.

(b) Except as otherwise provided in this Lease, Lessee hereby accepts the Premises in their condition existing as of the Lease commencement date and the date that Lessee takes possession of the Premises, whenever is earlier, subject to all applicable zoning, municipal, county and state laws, ordinances and regulations governing and regulating the use of the Premises, and any covenants or restrictions of record and accepts this Lease subject thereto and to all matters disclosed thereby and by any exhibits attached hereto. Lessee acknowledges that neither Lessor nor Lessor's agent has made any representation or warranty as to the present or future suitability of the Premises for the conduct of Lessee's business.

7. Maintenance, Repairs, Alterations and Common Area Services.
7.1 Lessor's Obligations. Subject to the provisions of paragraphs 4.2 (Operating Expenses), 6 (Use), 7.2 (Lessee's Obligations) and 9 (Damage or Destruction), and except for damages caused by any negligent or intentional act or omission of Lessee, Lessee's employees, suppliers, shoppers, customers, or visitors, in which event Lessee shall repair the damage, Lessor, at Lessor's expense, subject to reimbursement pursuant to paragraph 4.2, shall keep in good condition and repair the foundations, exterior walls, structural condition of interior bearing walls, a roof of the Premises, as well as the parking lots, walkways, driveways, landscaping, fences, signs and utility installations of the Common Areas and all parts thereof as well as providing the services for which there is an Operating Expense pursuant to paragraph 4.2. Lessor shall not, however, be obligated to repair the exterior or interior surfaces of exterior walls, nor shall Lessee be required to maintain, repair or replace windows, doors or plate glass of the Premises. Lessor shall have no obligation to make repairs under the paragraph 7.1 until a reasonable time after receipt of written notice from Lessee of the need for such repairs. Lessee expressly waives the benefits of any statute now or hereafter in effect which would otherwise afford Lessee the right to make repairs at Lessor's expense or to terminate the Lease because of Lessor's failure to keep the Premises in good order and condition and repair. Lessor shall not be liable for damages or loss of any kind or nature by reason of Lessor's failure to furnish any Common Area Services when such failure is caused by accident, breakage, repairs, strikes, riots, or other labor disturbances or disputes of any character, or by any other cause beyond the reasonable control of Lessor.

7.2 Lessee's Obligations.
(a) Subject to the provisions of paragraphs 6 (Use), 7.1 (Lessor's Obligations) and 9 (Damage or Destruction), Lessee, at Lessee's expense, shall keep in good order condition and repair the Premises and every part thereof (whether or not the damaged portion of the Premises or the means of repairing the same are reasonably or readily accessible to Lessee) including, without limiting the generality of the foregoing, all plumbing, heating, ventilating and air conditioning systems (Lessee shall procure and maintain, at Lessee's expense, a ventilating and air conditioning system maintenance contract), electrical and lighting facilities and equipment within the Premises, fixtures, interior walls and interior surfaces of exterior walls, windows, doors, plate glass, and skylights located within the Premises. Lessor reserves the right to procure and maintain the ventilating and air conditioning system/maintenance contract and if Lessor so elects, Lessee shall reimburse Lessor upon demand for the cost thereof.

(b) If Lessee fails to perform Lessee's obligations under the paragraph 7.2 or under any other paragraph of this Lease, Lessor may enter upon the Premises after ten (10) days prior written notice to Lessee (except in the case of emergency in which no notice shall be required) perform such obligations on Lessee's behalf and put the Premises in good order condition and repair and the cost thereof together with interest thereon, at the maximum rate then allowable by law shall be due and payable as additional rent to Lessor together with Lessee's next Base Rent installment.

(c) On the last day of the term hereof or on any sooner termination, Lessee shall surrender the Premises to Lessor in the same condition as received, ordinary wear and tear excepted, clean and free of debris. Any damage or deterioration of the Premises shall not be deemed ordinary wear and tear if the same could have been prevented by good maintenance practices. Lessee shall repair any damage to the Premises occasioned by the installation or removal of Lessee's trade fixtures, alterations, furnishings and equipment. Notwithstanding anything to the contrary herein, the cost of the plumbing and heating on the Premises in good operating condition.

7.3 Alterations and Additions.
(a) Lessee shall not, without Lessor's prior written consent, make any alterations, improvements, additions or utility installations in or about the Premises or the Industrial Center, except for structural alterations to the Premises not exceeding \$2,500 in cumulative cost. In the event that Lessee makes any alterations, improvements, additions or utility installations in or about the Premises or the Industrial Center, the cost thereof shall not exceed \$2,500 in cumulative cost. Lessee shall make no change or alteration to the

(ii) "Insured Loss" shall mean damage or destruction which was caused by an event required to be covered by the insurance described in paragraph 8. The fact that an insured Loss has a deductible amount shall not make the loss an uninsured loss.

in. **Replacement Cost** shall mean the amount of money necessary to be spent in order to repair or rebuild the damaged area to the condition that existed immediately prior to the damage occurring excluding all improvements made by lessee.

§ 2 Promises Partial Damage; Promises Building Partial Damage.

4. Insured Loss Subject to the provisions of paragraphs 3 and 5, if at any time during the term of this Lease there is a damage which is an Insured Loss and which falls into the classification of either Premises Partial Damage or Premises Building Partial Damage then the Lease shall be deemed to be terminated, repair such damage to the Premises, but not Lessee's fixtures, equipment, stock, contents, etc. as soon as reasonably possible and this Lease shall continue in full force and effect.

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1a) Subject to the provisions of paragraphs 2.4 and 2.5, the following shall apply:

18) Subject to the provisions of paragraphs 8 and 9.5, if at any time during the term of this Lease there is damage whether or not as insured loss and when falls into the classifications of either i) Premises Total Destruction or ii) Premises Building Total Destruction or iii) Industrial Center Building Total Destruction then Lessor may at Lessor's option either i) repair such damage or destruction but not Lessee's fixtures/equipment or ~~rebuild~~ as soon as reasonably possible at Lessor's expense, and this Lease shall continue in full force and effect or ii) give written notice to Lessee within thirty (30) days after the date of occurrence of such damage or destruction of Lessor's intention to cancel and terminate this Lease, in which case this Lease shall be canceled and terminated as of the date of the occurrence of such damage

9.4 Damage Near End of Term.

3.4 Damage Near End of Term

(8) Subject to Paragraph 9.4(a), if at any time during the last six months of the term of this Lease there is substantial damage, whether or not an insured loss, which falls within the classification of Premises Partial Damage, Lessor may at Lessor's option cancel and terminate this Lease as of the date of occurrence of such damage by giving written notice to Lessee of Lessor's election to do so within 30 days after the date of occurrence of such damage.

(b) Notwithstanding paragraph 9 (a), in the event that Lessee has an option to extend or renew this Lease, and the time within which said option may be exercised has not yet expired, Lessee shall exercise such option, if it is to be exercised at all, more than twenty (20) days after the occurrence of an insured loss falling within the classification of Premises Partial Damage during the last six months of term of this Lease if Lessee fully exercises such option during said twenty (20) day period. Lessor shall, at Lessor's expense, repair such damage to the Leasehold Equipment and Leasehold Improvements, as soon as reasonably practicable and this Lease shall continue in full force and effect if Lessee exercises such option during said twenty (20) day period. If Lessee does not exercise such option, then Lessor may, at Lessor's option, terminate and cancel this Lease as of the expiration of said twenty (20) day period by giving written notice to Lessee of Lessor's election to so terminate this Lease as of the expiration of said twenty (20) day period notwithstanding any term or provision in the grant of option to the contrary.

9.3 Abatement of Month Lessee's Remittance.

18) In the event Lessor repairs or restores the Premises pursuant to the provisions of this paragraph 8 the rent payable hereunder for the period during which such damage, repair or restoration continues shall be abated in proportion to the degree to which Lessee's use of the Premises is impaired. Except for abatement of rent, if any, Lessee shall have no claim against Lessor for any damage suffered by reason of such fire or destruction, repair or restoration.

(b) If Lessor shall be obligated to repair or restore the Premises under the provisions of this paragraph 8 and shall not commence such repair or restoration within ninety (90) days after such obligation shall accrue, Lessee may at Lessee's option cancel and terminate this Lease by giving Lessor written notice of Lessee's election to do so at any time prior to the commencement of such repair or restoration. In such event, this Lease shall terminate as of the date of such notice.

9.6 Termination — Advance Payments. Upon termination,

concerning advance rent and any advance payments made by Lessee to Lessor. Lessor shall, in addition, return to Lessee so much of Lessee's security deposit as has not theretofore been applied by Lessor.

§ 7 Waiver, Lease and

and agree that such event shall be governed by the terms of the Lease.

12. Real Property Taxes

18.1 Payment of Taxes. Lessor shall pay the real property tax, as defined in paragraph 10.3, applicable to the Industrial Center located at the address of the Property, and shall reimburse Lessee for Lessee's share of such taxes in accordance with the provisions of paragraph 4.3, and in accordance with paragraph 10.3.

10.2 Additional Improvements. Lessee shall not be responsible for paying Lessee's Share of any increase in real property tax specified in the tax assessor's records and work sheets as being caused by additional improvements placed upon the Industrial Center by either Lessee or the Lessor for the exclusive enjoyment of such other Lessees. Lessee shall, however, pay to Lessor at the time that Operating Expenses are payable under paragraph 2.1(e) the entirety of any increase in real property tax if said increase is by reason of additional improvements placed upon the Premises by Lessee or all Lessees' request.

[illegible]

10.4 Joint Assessment. If the Industrial Center is not separately assessed, Lessee's Share of the real property tax liability shall be an equitable proportion of the real property taxes for all of the land and improvements included within the tax parcel assessed, such proportion to be determined by Lessee from the respective valuations assigned in the Assessor's work sheets or such other information as may be reasonably available. Lessee's reasonable determination thereof, in good faith, shall be conclusive.

10.5 Personal Property Taxes

141. Lessee shall pay prior to delinquency all taxes assessed against and levied upon trade fixtures, furnishings, equipment and all other personal property of Lessee contained in the Premises or elsewhere. When possible, Lessee shall cause said taxes, trade fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lessor.

10. If any of Lessee's said personal property shall be destroyed with Lessee's real property, Lessee shall pay to Lessor the 'share' attributable to Lessee within ten (10) days after receipt of a written statement setting forth the losses applicable to Lessee's property.

19. Utilities. Lessee shall pay for all water, gas, heat, light, power, telephone and other utilities and services supplied to the Premises together with any taxes thereon if any such services are not separately metered to the Premises. Lessee shall pay all other charges jointly metered with other premises in the Building.

12. Assignment and Submitting

12. **Lessors Consent Required.** Lessor shall not voluntarily or by operation of law assign, transfer, mortgage, sublet or otherwise transfer, encumber, or in any part of Lessor's interest in the Lease or in the Premises without Lessor's prior written consent. When Lessor shall be requested by the assignee or subtenant to execute any assignment, transfer, mortgage, sublease or subletting without such consent shall be void and shall constitute a breach of this Lease without the need for notice to Lessor under paragraph 13.1

12.3 Lessee Affidavit. Notwithstanding the provisions of paragraph 12.1 hereof Lessee may assign or sublet the Premises or any portion thereof without Lessor's consent to any corporation which controls, is controlled by or is under common control with Lessee or to any corporation resulting from the merger or consolidation with Lessee or to any person or entity which acquires all the assets of Lessee as a going concern or the business or is being conducted on the Premises, all of which are referred to as Lessee Affidavit. Provided that before such assignment or subletting, Lessee shall assume in full the obligations of Lessee under this Lease. Any such assignment shall be in

way affect or limit the liability of Lessee under the terms of this Lease even if after such assignment or subletting the terms of this Lease are materially changed or altered without the consent of Lessee, the consent of whom shall not be necessary.

12.3 Terms and Conditions of Assignment. Regardless of Lessor's consent, no assignment shall release Lessee of Lessee's obligations hereunder or alter the primary liability of Lessee to pay the Base Rent and Lessee's Share of Operating Expenses, and to perform all other obligations to be performed by Lessee hereunder. Lessor may accept rent from any person other than Lessee pending approval or disapproval of such assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of rent shall constitute a waiver or estoppel of Lessor's right to exercise its remedies for the breach of any of the terms or conditions of this paragraph 12 or the Lease. Consent to an assignment shall not be deemed consent to any subsequent assignment in the event of default by any assignee of Lessee or any successor of Lessee in the performance of any of the terms hereof. Lessor may proceed directly against Lessee without the necessity of exhausting remedies of Lessee without notifying Lessee, or any successor of Lessee, and without obtaining its or their consent thereto and such action shall not relieve Lessee of liability under this Lease.

12.4 Terms and Conditions Applicable to Subletting. Regardless of Lessor's consent, the following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be included in any sublease.

(a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all rentals and income arising from any sublease hereof and hereafter made by Lessee, and Lessor may collect such rent and income and apply same toward Lessee's obligations under this Lease, provided, however, that until a default shall occur in the performance of Lessee's obligations under this Lease, Lessee may receive, collect and enjoy the rents of the sublease from a sublessee. Lessee shall not, by reason of this or any other assignment of such sublease to Lessor, be relieved of the obligation to pay the Base Rent and to perform all other obligations to be performed by Lessee hereunder. Lessee hereby irrevocably authorizes and directs any such sublessee, upon receipt of a written notice from Lessor stating that a default exists in the performance of Lessee's obligations under this Lease, to pay to Lessor the rents due and to become due under the sublease. Lessee agrees that such sublessee shall have the right to rely upon any such statement and request from Lessor and that such sublessee shall pay such rents to Lessor without any obligation or right to inquire as to whether such default exists and notwithstanding any notice from or claim from Lessee to the contrary. Lessee shall have no right or claim against such sublessee or Lessor for any such rents so paid by said sublessee to Lessor.

(b) No sublease entered into by Lessee shall be effective unless and until it has been approved in writing by Lessor. In entering into any sublease, Lessee shall use only such form of sublease as is satisfactory to Lessor, and once approved by Lessor, such sublease shall not be changed or modified without Lessor's prior written consent. Any sublease shall, by reason of entering into a sublease under this Lease, be deemed, for the benefit of Lessor, to have assumed and agreed to conform and comply with each and every obligation herein to be performed by Lessee other than such obligations as are contrary to or inconsistent with provisions contained in a sublease to which Lessor has expressly consented in writing.

(c) If Lessee's obligations under this Lease have been guaranteed by third parties, then a sublease, and Lessor's consent thereto, shall not be effective unless said guarantors give their written consent to such sublease and the terms thereof.

(d) The consent by Lessor to any subletting shall not release Lessee from its obligations or alter the primary liability of Lessee to pay the rent and perform and comply with all of the obligations of Lessee to be performed under this Lease.

(e) The consent by Lessor to any subletting shall not constitute a consent to any subsequent subletting by Lessee or to any assignment or subletting by the sublessee. However, Lessor may consent to subsequent sublettings and assignments of the sublease or any amendments or modifications thereto without notifying Lessee or anyone else liable on the Lease of sublease and without obtaining their consent and such action shall not release such persons from liability.

(f) In the event of any default under this Lease, Lessor may proceed directly against Lessee, any guarantors or any one else responsible for the performance of this Lease, including the sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefor to Lessor, or any security held by Lessor or Lessee.

(g) In the event Lessee shall default in the performance of its obligations under this Lease, Lessor, at its option and without any obligation to do so, may require any sublessee to affirm to Lessor, in which event Lessor shall undertake the obligations of Lessee under such sublease from the time of the exercise of said option to the termination of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to Lessee or for any other prior defaults of Lessee under such sublease.

(h) Each and every consent required of Lessee under a sublease shall also require the consent of Lessor.

(i) Lessor's written consent to any subletting of the Premises by Lessee shall not constitute an acknowledgment that no default then exists under this Lease or the obligations to be performed by Lessee nor shall such consent be deemed a waiver of any then existing default except as may be otherwise stated by Lessor at the time.

(j) With respect to any subletting to which Lessor has consented, Lessor agrees to deliver a copy of any notice of default by Lessee to the sublessee. Such sublessee shall have the right to cure a default of Lessee within ten (10) days after service of said notice of default upon such sublessee, and the sublessee shall have a right of reimbursement and offset from and against Lessee for any such defaults cured by the sublessee.

12.5 Attorney's Fees. In the event Lessee shall assign or sublet the Premises or request the consent of Lessor to any assignment or subletting or if Lessee shall request the consent of Lessor for any act Lessee proposes to do then Lessee shall pay Lessor a reasonable attorney's fees incurred in connection therewith, such attorney's fees not to exceed \$350.00 for each such request.

13. Default Remedies.

13.1 Default. The occurrence of any one or more of the following events shall constitute a material default of this Lease by Lessee:

(a) The vacating or abandonment of the Premises by Lessee.

(b) The failure by Lessee to make any payment of rent or any other payment required to be made by Lessee hereunder, as and when due, where such failure shall continue for a period of thirty (30) days after written notice thereof from Lessor to Lessee. In the event that Lessor so notifies Lessee with a Notice to Pay Rent or Quit pursuant to applicable Unlawful Detainer statutes such Notice to Pay Rent or Quit shall also constitute the notice required by this subparagraph.

(c) Except as otherwise provided in this Lease, the failure by Lessee to observe or perform any of the covenants, conditions or provisions of this Lease to be observed or performed by Lessee, other than described in paragraph (b) above, where such failure shall continue for a period of thirty (30) days after written notice thereof from Lessor to Lessee; provided, however, that if the nature of Lessee's nonperformance is such that more than thirty (30) days are reasonably required for its cure, then Lessee shall not be deemed to be in default if Lessee commences such cure within said thirty (30) day period and thereafter diligently prosecutes such cure to completion. To the extent permitted by law, such thirty (30) day notice shall constitute the sole and exclusive notice required to be given to Lessee under applicable Unlawful Detainer statutes.

(d) (i) The making by Lessee of any general assignment or transfer of all or substantially all of its assets for the benefit of creditors, (ii) Lessee becomes a "debtor" as defined in 11 U.S.C. § 101 or any successor statute thereto (unless, in the case of a petition filed against Lessee, the same is dismissed within sixty (60) days), (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within thirty (30) days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in the Lease, where such seizure is not discharged within thirty (30) days in the event that any provision of this paragraph 13.1(d) is contrary to any applicable law, such provision shall be of no force or effect.

(e) The discovery by Lessor that any financial statement given to Lessor by Lessee, any assignee of Lessee, any subtenant of Lessee, any successor in interest of Lessee or any guarantor of Lessee's obligation hereunder, was materially false.

13.2 Remedies. In the event of any such material default by Lessee, Lessor may at any time thereafter, with or without notice or demand and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such default:

(a) Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease and the term hereof shall terminate and Lessee shall immediately surrender possession of the Premises to Lessor. In such event Lessor shall be entitled to recover from Lessee all damages incurred by Lessor by reason of Lessee's default including, but not limited to, the cost of recovering possession of the Premises, including necessary renovation and alteration of the Premises, reasonable attorney's fees, and any real estate commission actually paid, the worth at the time of award by the court having jurisdiction thereof of the amount by which the unpaid rent for the balance of the term after the time of such award exceeds the amount of such rental less for the same period that Lessee proves could be reasonably avoided; that portion of the leasing commission paid by Lessor pursuant to paragraph 15 applicable to the unexpired term of this Lease.

(b) Maintain Lessee's right to possession in which case this Lease shall continue in effect whether or not Lessee shall have vacated or abandoned the Premises. In such event Lessor shall be entitled to enforce all of Lessor's rights and remedies under this Lease, including the right to recover the rent as it becomes due hereunder.

(c) Pursue any other remedy now or hereafter available to Lessor under the laws or judicial decisions of the state wherein the Premises are located. Unpaid installments of rent and other unpaid monetary obligations of Lessee under the terms of this Lease shall bear interest from the date due at the maximum rate then allowable by law.

13.3 Default by Lessor. Lessor shall not be in default unless Lessor fails to perform obligations required of Lessor within a reasonable time, but in no event later than thirty (30) days after written notice by Lessee to Lessor and to the holder of any first mortgage or deed of trust covering the Premises where name and address shall have theretofore been furnished to Lessee in writing, specifying wherein Lessor has failed to perform such obligation. Provided, however, that if the nature of Lessor's obligation is such that more than thirty (30) days are required for performance, Lessor shall not be in default if Lessor commences performance within such thirty (30) day period and thereafter diligently prosecutes the same to completion.

13.4 **Late Charges.** Lessee hereby acknowledges that late payments by Lessee to Lessor of Base Rent, Lessee's Share of Operating Expenses or other sums due hereunder will cause Lessor to incur costs not contemplated by this Lease, the cost amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and assessing charges, and late charges which may be imposed on Lessor by the terms of any mortgage or trust deed covering the Property. Accordingly, if any installment of Base Rent, Operating Expenses or any other sum due from Lessee shall not be received by Lessor or Lessor's designee within ten (10) days after such amount shall be due then, without any requirement for notice to Lessee, Lessee shall pay to Lessor a late charge equal to 6% of such overdue amount. The period hereby agreed to such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of late payment by Lessee. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's default with respect to such overdue amount nor prevent Lessor from exercising any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, no further Lessor from exercising consecutive installments of any of the aforesaid monetary obligations of Lessee, then Base Rent shall automatically become due and payable quarterly in advances, rather than monthly, notwithstanding paragraph 4.1 or any other provision of the Lease to the contrary.

14. **Condemnation.** If the Premises or any portion thereof is taken by eminent domain, the Lease shall terminate on the date of such taking.

14. **Condemnation.** If the Premises or any portion thereof or the Industrial Center are taken under the power of eminent domain or sold under the threat of the exercise of such power all of which are herein called "condemnation"), the Lessee shall terminate as to the part so taken as of the date the condemning authority takes title or possession, whichever first occurs. If more than ten percent of the floor area of the Premises or more than twenty-five percent of that portion of the Common Areas designated as parking for the Industrial Center is taken by condemnation or more than five percent of the floor area of the Premises or more than fifteen percent of that portion of the Common Areas designated as parking for the Industrial Center is taken by condemnation, Lessee may, at its election, to be exercised in writing only within ten (10) days after the taking of the premises, terminate this Lease as of the date of the taking. In the absence of such notice within ten (10) days after the taking, the concerning Authority shall have taken possession; termination of such taking of the full force and effect as to the portion of the premises remaining except that the rent shall be reduced in the proportion that the floor area of the premises taken bears to the total floor area of the Premises. No reduction of rent shall occur if the only area taken is that which does not constitute over one-third of the value of the leasehold or for the taking of the fee or as severance damages provided, however, that Lessee shall be entitled to any award for diminution of value or damage to Lessee's trade fixtures and removable personal property in the event that this Lease is not terminated as a result of such taking. If condemnation, Lessee shall to the extent of severance damages received by Lessee in connection with such condemnation, repair any damage to the Premises caused by such condemnation except to the extent that Lessee has been reimbursed thereby by the condemning authority. Lessee shall pay any amount in excess of such severance damages required to complete such repair.

15. **Broker's Fee.**

12. Broker's Fee.

(A) Upon execution of this Lease by both parties Lessor shall pay to Grubb & Ellis Company Commercial Real Estate Brokers

(b) Lessor further agrees that if Lessor receives any Commission or fee for brokerage services rendered by said broker(s) to Lessor in this transaction

(b) Lessor further agrees that if Lessee exercises any Option, as defined in paragraph 3B.1 of this Lease, which is granted to Lessee under the Lease, or if any subsequently granted option which is substantially similar to an Option granted to Lessee under this Lease, or if Lessee acquires any rights to the Premises or any Premises described in this Lease which are substantially similar to what Lessee would have acquired had an Option herein granted to Lessee been exercised, or if Lessor remains in possession of the Premises after the expiration of the term of this Lease after having failed to exercise an Option, or if said broker(s) are the procuring cause of any other lease or sales entered into between the parties pertaining to the Premises and/or any adjacent property in which Lessor has an interest then as to any of said transactions, Lessor shall pay said broker(s): a fee in accordance with the schedule of said broker(s) in effect at the time of execution of this Lease.

(c) Lessor agrees to pay said fee not only on behalf of Lessor but also on behalf of any person, corporation, association, or other entity having an ownership interest in said real property or any part thereof, when such fee is due hereunder. Any transfer of Lessor's interests in this Lease, whether such transfer is by agreement or by operation of law, shall be deemed to have assumed Lessor's obligation under this paragraph 15. Said broker shall be a third party beneficiary of the provisions of this paragraph 15.

12. Escaped Certificate

(d) Each party (as "responding party") shall, at any time upon not less than ten (10) days' prior written notice from the other party, requesting party 1 execute, acknowledge and deliver to the requesting party a statement in writing (i) certifying that this Lease is unmodified and in full force and effect (or if modified, stating the nature of such modification and certifying that this Lease, as so modified, is in full force and effect; and in: 2 date to which the rent and other charges are paid in advance, if any; and (ii) acknowledging that there are not, in the responding party's knowledge 3 any uncured defaults on the part of the requesting party, or specifying such defaults if any are claimed. Any such statement may be conclusive, 4 relied upon by any prospective purchaser or encumbrancer of the Premises or of the business of the requesting party.

(b) At the requesting party's option, the failure to deliver such statement within such time shall be a material default of this Lease by the party, who is in response, without any further notice to such party, or it shall be conclusively upon such party that (i) the Lease is in full force and effect, without modification except as may be represented by the requesting party, (ii) there are no uncured defaults in the requesting party's performance, and (iii) if Lessor is the requesting party, not more than one month's rent has been paid in advance.

(c) If Lessor desires to finance, refinance, or sell the Property, or any part thereof, Lessor hereby agrees to deliver to any lender or purchaser designated by Lessor or financial statements of Lessee as may be reasonably required by such lender or purchaser. Such statements shall include the past three (3) years' financial statements of Lessee. All such financial statements shall be received by Lessor and such lender, seller, purchaser or confidence and shall be used only for the purposes herein set forth.

17. **Lessee's Liability.** The term "Lessee" as used herein shall mean any the owner or owners, at the time in question of the fee title or a lesser interest in a ground lease of the Industrial Center, and except as expressly provided in Paragraph 13, in the event of any transfer of such title or interest, Lessee herein named (and in case of any subsequent transfers then the grantor) shall be relieved from and after the date of such transfer of all liability as respects Lessee's obligations thereunder to be performed, provided that any funds in the hands of Lessee at the then grantor at the time of such transfer, in which Lessee has an interest, shall be delivered to the grantee. The obligations contained in this Lease to be performed by Lessee shall, subject as aforesaid, be binding on Lessee's successors and assigns, only during their respective periods of ownership.

18. **Severability.** The invalidity of any provision of this Lease as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.

19. **Interest on Past-due Collections.** Except as expressly herein provided, any amount due to Lessor not paid when due shall bear interest at the maximum rate then allowable by law from the date due. Payment of such interest shall not excuse or cure any default by Lessee under this Lease provided, however, that interest that not be payable on late charges incurred by Lessee nor on any amounts upon which late charges are paid.

20. **Time of Exercise.** Time is of the essence with respect to the obligations to be performed under this Lease.

31. **Additional Rent.** All monetary obligations of Lessee to Lessor under the terms of this Lease, including but not limited to Leasehold Improvements, Operating Expenses and Insurance and tax expenses payable shall be deemed to be rent.

22. Incorporation of Prior Agreements; Amendments. This Lease contains all agreements of the parties with respect to any matter relating to the use and enjoyment of the Premises. No prior or contemporaneous agreement or understanding pertaining to any such matter shall be effective. This Lease may be modified or amended only by a written instrument signed by the parties to this Lease at the time of the modification. Except as otherwise stated in this Lease, Lessee hereby agrees that neither the real estate broker listed in Article 1 nor any other person acting as a broker in this transaction nor the lessor or any other person acting as an agent of any of said persons has made any oral or written promises or representations to Lessee relative to the condition or use of Lessee's Premises or the Property and Lessee acknowledges that Lessee assumes all responsibility regarding the Occupational Safety Health Act, the use and adaptability of the Premises and the compliance thereof with all applicable laws and regulations in effect during the term of this Lease, except as otherwise specifically stated in this Lease.

23. **Notices.** Any notice required or permitted to be given hereunder shall be in writing and may be given by personal delivery or by certified mail and if given personally or by mail, shall be deemed sufficiently given if addressed to Lessee or to Lessor at the address below (the signatories to the respective parties, as the case may be) either party may by notice to the other specify a different address for notice purposes (provided that Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for notice purposes). A copy of all notices required to be given to Lessor hereunder shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate by notice to Lessee.

14. **Waivers.** No waiver by Lessor of any provision hereof shall be deemed a waiver of any other provision hereof or of any subsequent breach by Lessee of the same or any other provision. Lessor's consent to, or approval of, any act shall not be deemed to constitute a waiver of any subsequent act by Lessee or approval of any subsequent act by Lessee. The acceptance of rent hereunder by Lessor shall not be a waiver of any breach by Lessee of any provision hereof other than the failure of Lessee to pay the particular rent so accepted, regardless of Lessor's knowledge of such preceding breach at the time of acceptance of such rent.

25. Recording. Either Lessor or Lessee shall, upon request of the other, execute, acknowledge and deliver to the other a separate memorandum of this Lease for recording purposes.

28. **Holding Over.** If Lessee with Lessor's consent, remains in possession of the Premises or any part thereof after the expiration of the term of such occupancy shall be a tenancy from month to month upon all the provisions of this Lease pertaining to the obligations of Lessee. Any Options if any granted under the terms of this Lease shall be deemed terminated and be of no further effect during and after the term of such holding over.

27. **Cumulative Remedies.** No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.
28. **Covenants and Conditions.** Each provision of this Lease performable by Lessee shall be deemed both a covenant and a condition.
29. **Binding Effect: Choice of Law.** Subject to any provisions hereof respecting assignment or assignment by Lessee and subject to the provisions of paragraph 17, this Lease shall bind the parties, their personal representatives, successors and assigns. This Lease shall be governed by the laws of the State where the Industrial Center is located and any litigation concerning this Lease between the parties hereto shall be initiated in the county in which the Industrial Center is located.
30. **Subordination.**
- (a) This Lease, and any Option granted hereby, at Lessor's option, shall be subordinate to any ground lease, mortgage, deed of trust, or any other hypothecation or security now or hereafter placed upon the Industrial Center and to any and all advances made on the security thereof and to the possession of the Premises shall not be disturbed if Lessee is not in default and so long as Lessee shall pay the rent and observe and perform all of the provisions of this Lease, unless this Lease is otherwise terminated pursuant to its terms. If any mortgage, trustee or ground lease shall elect to have this Lease and any Options granted hereby prior to the lien of its mortgage, deed of trust or ground lease, and then give written notice to Lessee, this Lease and such Options shall be deemed prior to such mortgage, deed of trust or ground lease, whether this Lease or such Options are dated prior or subsequent to the date of said mortgage, deed of trust or ground lease or the date of recording thereof.
- (b) Lessee agrees to execute any documents required to effectuate an assignment, a subordination or to make this Lease or any Option granted herein prior to the lien of any mortgage, deed of trust or ground lease, as the case may be. Lessee's failure to execute such documents within ten (10) days after written demand shall constitute a material default by Lessee hereunder without further notice to Lessee or, at Lessor's option, Lessor shall execute such documents on behalf of Lessee as Lessee's attorney-in-fact. Lessee does hereby make, constitute and irrevocably appoint Lessor as Lessee's attorney-in-fact and in Lessee's name, place and stead, to execute such documents in accordance with this paragraph 30(b).
31. **Attorney's Fees.** If either party or the broker(s) named herein bring an action to enforce the terms hereof or declare rights hereunder, the prevailing party in any such action, on trial or appeal, shall be entitled to his reasonable attorney's fees to be paid by the losing party as fixed by the court. The provisions of this paragraph shall inure to the benefit of the broker named herein who agrees to enforce a right hereunder.
32. **Lessor's Access.** Lessor and Lessor's agents, lenders, or lessees, and making such alterations, repairs, improvements or additions to the Premises or to the building of which they are part as Lessor may deem necessary or desirable. Lessor may at any time place on or about the Premises any ordinary "For Lease" signs and Lessor may at any time during the last 120 days of the term hereof place on or about the Premises any ordinary "For Lease" signs. All activities of Lessor pursuant to this paragraph shall be without abatement of rent, nor shall Lessor have any liability to Lessee for the same.
33. **Auctions.** Lessee shall not conduct, nor permit to be conducted, either voluntarily or involuntarily, any auction upon the Premises or the Common Areas without Lessor's prior written consent. Notwithstanding anything to the contrary in this Lease, Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to grant such consent.
34. **Signs.** Lessee shall not place any sign upon the Premises or the Industrial Center without Lessor's prior written consent. Under no circumstances shall Lessee place a sign on any roof of the Industrial Center.
35. **Merger.** The voluntary or other surrender of this Lease by Lessee, or a mutual cancellation thereof, or a termination by Lessor, shall not work a merger, and shall, at the option of Lessor, terminate all or any existing subtenancies or may, at the option of Lessor, operate as an assignment to Lessor of any or all of such subtenancies.
36. **Consent.** Except for paragraph 33 hereof, wherever in this Lease the consent of one party is required to an act of the other party such consent shall not be unreasonably withheld or delayed.
37. **Guarantor.** In the event that there is a guarantor of this Lease, said guarantor shall have the same obligations as Lessee under this Lease.
38. **Quiet Possession.** Upon Lessee paying the rent for the Premises and observing and performing all of the covenants, conditions and provisions on Lessee's part to be observed and performed hereunder, Lessee shall have quiet possession of the Premises for the entire term hereof subject to all of the provisions of this Lease. The individuals executing this Lease on behalf of Lessor represent and warrant to Lessee that they are fully authorized and legally capable of executing this Lease on behalf of Lessor and that such execution is binding upon all parties holding an ownership interest in the Property.
39. **Options.**
- 39.1 **Definition.** As used in this paragraph the word "Option" has the following meaning: (1) the right or option to extend the term of this Lease or to renew this Lease or to extend or renew any lease that Lessee has on other property of Lessor; (2) the option or right of first refusal to lease the Premises or the right of first offer to lease the Premises or the right of first refusal to lease other property of Lessor; (3) the right or option to purchase the Premises or the Industrial Center, or the right of first refusal to purchase the Premises or the Industrial Center, or the right of first offer to purchase the Premises or the Industrial Center, or the right of first refusal to purchase other property of Lessor, or the right of first offer to purchase other property of Lessor.
- 39.2 **Options Personal.** Each Option granted to Lessee in this Lease is personal to the original Lessee and may be exercised only by the original Lessee while occupying the Premises who does so without the intent of thereafter assigning this Lease or substituting the Premises of any portion thereof, and may not be exercised or be assigned, voluntarily or involuntarily, by or to any person or entity other than Lessee. Provided, however, that an Option may be assigned or be assigned to any Lessee's affiliate as defined in this Lease. The Options, if any, herein granted to Lessee are not assignable separate and apart from this Lease, nor may any Option be separated from this Lease in any manner either by reservation or otherwise.
- 39.3 **Multiple Options.** In the event that Lessee has any multiple options to extend or renew this Lease a later option cannot be exercised unless the prior option to extend or renew this Lease has been so exercised.
- 39.4 **Effect of Default on Options.**
- (a) Lessee shall have no right to exercise an Option, notwithstanding any provision in the grant of Option to the contrary, (i) during the time commencing from the date Lessor gives to Lessee a notice of default pursuant to paragraph 13.1(b) or 13.1(c) and continuing until the noncompliance alleged in said notice of default is cured, or (ii) during the period of time commencing on the date after a monetary obligation to Lessor is due from Lessee and unpaid (without any necessity for notice thereof to Lessor) and continuing until the obligation is paid, or (iii) at any time after an event of default described in paragraphs 13.1(a), 13.1(b), or 13.1(c) without any necessity of Lessor to give notice of such default to Lessee, or (iv) in the event that Lessor has given to Lessee three or more notices of default under paragraph 13.1(b), or paragraph 13.1(c), whether or not the defaults are cured, during the 12 month period of time immediately prior to the time that Lessee attempts to exercise the Subject Option.
- (b) The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of paragraph 39.4(a).
- (c) All rights of Lessee under the provisions of an Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and during the term of this Lease, (i) Lessee fails to pay to Lessor a monetary obligation of Lessee for a period of thirty (30) days after such obligation becomes due (without any necessity of Lessor to give notice thereof to Lessee), or (ii) Lessee fails to commence to cure a default specified in paragraph 13.1(c) within thirty (30) days after the date that Lessor gives notice to Lessee of such default and/or Lessee fails thereafter to diligently prosecute and cure to completion, or (iii) Lessee commits a default described in paragraph 13.1(a), 13.1(b) or 13.1(c) (without any necessity of Lessor to give notice of such default to Lessee), or (iv) Lessor gives to Lessee three or more notices of default under paragraph 13.1(b), or paragraph 13.1(c), whether or not the defaults are cured.
40. **Security Measures.** Lessee hereby acknowledges that Lessor shall have no obligation whatsoever to provide guard service or other security measures for the benefit of the Premises or the Industrial Center. Lessee assumes all responsibility for the protection of Lessee's agents and Lessee's sole option, from providing security protection for the Industrial Center of any part thereof, in which event the cost thereof shall be included within the definition of Operating Expenses, as set forth in paragraph 4.2(b).
41. **Easements.** Lessor reserves to itself the right, from time to time, to grant such easements, rights and dedications that Lessor deems necessary or desirable and to cause the recordation of PLAT Maps and restrictions, so long as such easements, rights, dedications, maps and restrictions do not unreasonably interfere with the use of the Premises by Lessee. Lessee shall sign any of the aforementioned documents upon request of Lessor and failure to do so shall constitute a material default of this Lease by Lessee without the need for further notice to Lessee.
42. **Performance Under Protest.** If at any time a dispute shall arise as to any amount or sum of money to be paid by one party to the other under the provisions hereof the party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment, and there shall survive the right on the part of said party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said party to pay such sum or any part thereof, said party shall be entitled to recover such sum or so much thereof as it was not legally required to pay under the provisions of this Lease.

43. Authority. If Lessee is a corporation, trust, or general or limited partnership, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on behalf of said entity. If Lessee is a corporation, trust or partnership, Lessee shall, within thirty (30) days after execution of this Lease, deliver to Lessor evidence of such authority satisfactory to Lessor.
44. Conflict. Any conflict between the printed provisions of this Lease and the typewritten or handwritten provisions, if any, shall be controlled by the typewritten or handwritten provisions.
45. Offer. Preparation of this Lease by Lessor or Lessor's agent and submission of same to Lessee shall not be deemed an offer to lease. This Lease shall become binding upon Lessor and Lessee only when fully executed by Lessor and Lessee.
46. Addendum. Attached hereto is an addendum or addenda containing paragraphs 1 through 2 which constitute a part of this Lease.

LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN AND, BY EXECUTION OF THIS LEASE, SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

THIS LEASE HAS BEEN PREPARED FOR SUBMISSION TO YOUR ATTORNEY FOR APPROVAL. NO REPRESENTATION OR RECOMMENDATION IS MADE BY THE AMERICAN INDUSTRIAL REAL ESTATE ASSOCIATION OR BY THE REAL ESTATE BROKER OR ITS AGENTS OR EMPLOYEES AS TO THE LEGAL SUFFICIENCY, LEGAL EFFECT, OR TAX CONSEQUENCES OF THIS LEASE OR THE TRANSACTION RELATING THERETO. THE PARTIES SHALL RELY SOLELY UPON THE ADVICE OF THEIR OWN LEGAL COUNSEL AS TO THE LEGAL AND TAX CONSEQUENCES OF THIS LEASE.

LESSOR

THE PRINCIPAL MUTUAL LIFE INSURANCE COMPANY

By



By

TIMOTHY E. MINIMUM
Assistant Director & Secretary
Commercial Real Estate Division

Executed on

(Date)

ADDRESS FOR NOTICES AND RENTThe Principal Mutual Life Insurance Company
Real Estate Equity Management

711 Main Street, Suite 6-21

Des Moines, Iowa 50392-1370

LESSEEPFIZER HOSPITAL PRODUCTS GROUP DIVISION OF PFIZER,
INC., A DELAWARE CORPORATION

By



By

Executed on

(Date)

ADDRESS

Pfizer Hospital Products Group

17622-B Corner Avenue

Irvine, California 92714

NOTE: These forms are often modified to meet changing requirements of law and needs of the industry. Always write or call to make sure you are using the most current form. AMERICAN INDUSTRIAL REAL ESTATE ASSOCIATION 345 So Figueroa St. M-1 Los Angeles, CA 90071 (213) 687-6777

ADDENDUM TO THAT CERTAIN LEASE DATED NOVEMBER 16, 1992 BY AND BETWEEN THE PRINCIPAL MUTUAL LIFE INSURANCE COMPANY ("LESSOR") AND PFIZER HOSPITAL PRODUCTS GROUP DIVISION OF PFIZER, INC., A DELAWARE CORPORATION ("LESSEE").

1. Rent:

The monthly rent payable by Lessee under the terms and provisions of Paragraph (4) of the lease ("Basic Monthly Rent") shall be subject to adjustment per the following:

<u>Months</u>	<u>Rent PSF</u>	<u>Rent Per Month</u>
01 - 12	\$0.713 NNN	\$12,666.45
13 - 24	\$0.765 NNN	\$13,590.23
25 - 36	\$0.817 NNN	\$14,514.00

2. Tenant Improvements:

Lessor shall provide Lessee a Tenant Improvement Allowance in the sum of \$100,000 for costs of all design, permitting and construction for the alterations to the interior of the premises per a mutually approved plan. Lessee intends to spend substantial funds of its own in excess of Lessor's allowance of \$100,000 to construct tenant improvements. Lessor shall have the right to approve the general contractor selected by Lessee for the tenant improvements, but such approval shall not be unreasonably withheld. Lessee shall be responsible for overseeing the work of its contractor, and will indemnify Lessor with respect to any errors or omissions resulting from modifications to the premises. Lessor shall reimburse Lessee monthly for work which Lessee certifies has been performed prior to such reimbursement. Lessor shall (a) require suitable progress payment and final payment lien releases from all parties furnishing labor, services, equipment or material in connection therewith, and (b) have the right to confirm by inspection that such work has been performed, prior to its disbursement of funds, but such inspection shall be completed within forty-eight (48) hours after Lessee's request for disbursement. Funds shall be disbursed promptly thereafter. Any costs in excess of the allowance shall be paid by Lessee. In the event the improvements costs are less than the Allowance, any unused amount up to \$25,000 shall be credited to Lessee's rent obligation. Any unused amount greater than \$25,000 shall remain the Lessor's. At the end of the term of the Lease, Lessee shall not be required to remove from the premises any tenant improvements included in the tenant improvement allowance or paid for by Lessee and approved by Lessor.


3. See Attached Addendum

4. Signs:

Lessee shall have the right to install its sign at the parking lot entrance and/or on the face of the subject building at the lobby entrance facing the premises parking lot subject to compliance with any applicable ordinance, law, rule, or regulation of any governmental authority having jurisdiction thereof, and subject to Lessor's reasonable approval.

5. Access:

Lessee shall have unrestricted access to the premises 24 hours per day, 365 days per year.



Addendum, Page Two

6. Roof/HVAC:

Lessee shall pay to Lessor, as a part of Operating Expenses, Lessee's Share of the cost of standard independent roof and HVAC service agreements as reasonably required by Lessor throughout the term of the Lease. However, Lessor shall throughout the term perform, at its sole cost and expense, all necessary repairs and replacements for the roof and HVAC system which are not covered by such standard service agreements.

Lessor acknowledges receipt of certain roof repair work proposals and the HVAC work proposals. Lessor agrees to make all necessary repairs to Lessor and Lessee's mutual satisfaction as soon as practicable following execution of this Lease. Lessor shall exercise due diligence in its roof and HVAC obligations and shall provide rapid response in the event of equipment malfunction.

Lessee shall independently determine to its satisfaction that there are sufficient HVAC system zones to handle all exposures and provide a comfortable temperature throughout the premises. Modifications to the HVAC system may be paid for out of the Tenant Improvement Allowance discussed in paragraph (2) above.

Lessor warrants that the air conditioning units comprising the HVAC system will produce at least ninety percent (90%) of the cooling capacity for which they are rated. Lessor will be responsible for repair or replacement of any units that do not produce such capacity on a consistent basis. Any costs incurred by Lessor for roof and/or HVAC system repairs or replacements shall not be included in "Operating Expenses" under the Lease.

7. Indemnity Regarding Hazardous Materials:

Lessee has been informed that the Premises may be affected by a subsurface plume of toxic material from an adjacent property. Lessee desires an indemnification from Lessor in connection with such contamination and with regard to any other hazardous material which may be present on the premises during the term of this lease which is not the result of Lessee's activities or failure to act. Accordingly, Lessor hereby agrees to indemnify, protect, defend and hold harmless Lessee and its directors, officers, employees, shareholders, lenders, agents, contractors and each of their respective successors and assigns from and against any known and unknown claims, judgments, causes of action, damages, penalties, fines, taxes, liabilities, losses and expenses (including, without limitation, court costs, attorney's fees, and damages to any person or property) arising at any time during or after the term of this Lease as a result (directly or indirectly) of the presence of hazardous materials on, under or about the premises which are not the result of Lessee's activities, or failure to act, or the activities or failure to act of any of the parties indemnified herein. Lessee hereby agrees to indemnify, protect, defend and hold harmless Lessor and its directors, officers, employees, shareholders, lenders, agents, contractors and each of their respective successors and assigns from and against any known and unknown claims, judgments, causes of action, damages penalties, fines, taxes, liabilities, losses and expenses (including, without limitation, court costs, attorney's fees, and damages to any person or property) arising at any time during or after the term of this Lease as a result (directly or indirectly) of the presence of hazardous materials on, under or about the premises which are the result of Lessee's activities, or failure to act. These indemnities shall include, but shall not be limited to, the cost of any required or necessary pre-clean-up investigation, repair, clean-up or detoxification, and the preparation and implementation of any closure, monitoring or other required plan, whether such action is required or necessary prior to or following the termination of this Lease. As used herein, "hazardous materials" means any substance or material which is hazardous to human health or safety or to the environment which is now or in the future becomes listed, defined or regulated in any manner by any environmental law based upon, directly or indirectly, its properties or effect. As used herein, "environmental laws" means any and all federal, state or local environmental,

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Addendum, Page Three

health and/or safety related laws, regulations standards, decisions of courts, ordinances, rules, codes, orders, decrees, directives, guidelines, permits or permit conditions, currently existing and as amended, inactive, issued or adopted in the future which are or become applicable to the Premises. Lessor's and Lessee's obligations, pursuant to the foregoing indemnities, shall survive the termination of this Lease.

8. Code Compliance:

Lessor shall be responsible for compliance with all applicable building codes and regulations affecting the Premises, including without limitation all applicable requirements of the Americans with Disabilities Act and all code-required smoke detection equipment.

AGREED AND ACCEPTED:**LESSOR:**

The Principal Mutual
Life Insurance Company

By: _____

By: _____

Date: _____

Timothy E. Munton
TIMOTHY E. MUNTON
Assistant Director & Secretary
Commercial Real Estate Group

LESSEE:

Pfizer Hospital Products Group
Division of Pfizer, Inc.

By: _____

By: _____

Date: _____

~~i) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new MRV within the next 30 days. Any associated costs will be split equally between the parties, or~~
~~ii) Both Lessor and Lessee shall each immediately select and pay the appraiser or broker of their choice to establish a MRV within the next 30 days. If, for any reason, either one of the appraisals is not completed within the next 30 days, a stipulated, then the appraisal that is completed at that time shall automatically become the new MRV. If both appraisals are completed and the two appraisers/brokers cannot agree on a reasonable average MRV then they shall immediately select a third mutually acceptable appraiser/broker to establish a third MRV within the next 30 days. The average of the two appraisals closest in value shall then become the new MRV. The costs of the third appraisal will be split equally between the parties.~~

2) In any event, the new MRV shall not be less than the rent payable for the month immediately preceding the date for rent adjustment.

(b) Upon the establishment of each New Market Rental Value as described in paragraph A(i);

- 1) the monthly rental sum so calculated for each term as specified in paragraph A(i)(a) will become the new "Base Rent" for the purpose of calculating any further Cost of Living Adjustments as specified in paragraph A(i)(a) above and
- 2) the first month of each Market Rental Value term as specified in paragraph A(i)(a) shall become the new "Base Month" for the purpose of calculating any further Cost of Living Adjustments as specified in paragraph A(i)(b).

☐ III. Fixed Rental Adjustment(s) (FRA)

The monthly rent payable per paragraph 1.5 ("Base Rent") of the attached Lease shall be increased to the following amounts on the dates set forth below:

On (Fill in FRA Adjustment Date(s)):

The New Base Rental shall be:

_____	\$ _____
_____	\$ _____
_____	\$ _____

B. NOTICE: Unless specified otherwise herein, notice of any escalations other than Fixed Rental Adjustments shall be made as specified in paragraph 23 of the attached Lease.

~~C. BROKER'S FEE~~

~~The Real Estate Brokers specified in paragraph 1.10 of the attached Lease shall be paid a Brokerage Fee for each adjustment specified above in accordance with paragraph 15 of the attached Lease.~~

C. Lessee's occupancy during such extended term(s) shall be governed by all of the other terms, conditions, covenants and provisions of this lease except as otherwise provided in this Addendum and as this lease may be hereafter amended, if at all, except that:

- (i) There shall be no free rent or other rent concession;
- (ii) Except as otherwise provided herein, Lessee shall accept the premises "as is" and "with all faults" and Lessor shall have no obligation to improve the same in any way, provided, however, that this shall not excuse Lessor from the Lessor's repair and maintenance obligations set forth in this lease.

Initials: _____

OPTION(S) TO EXTEND
Page 2 of 2


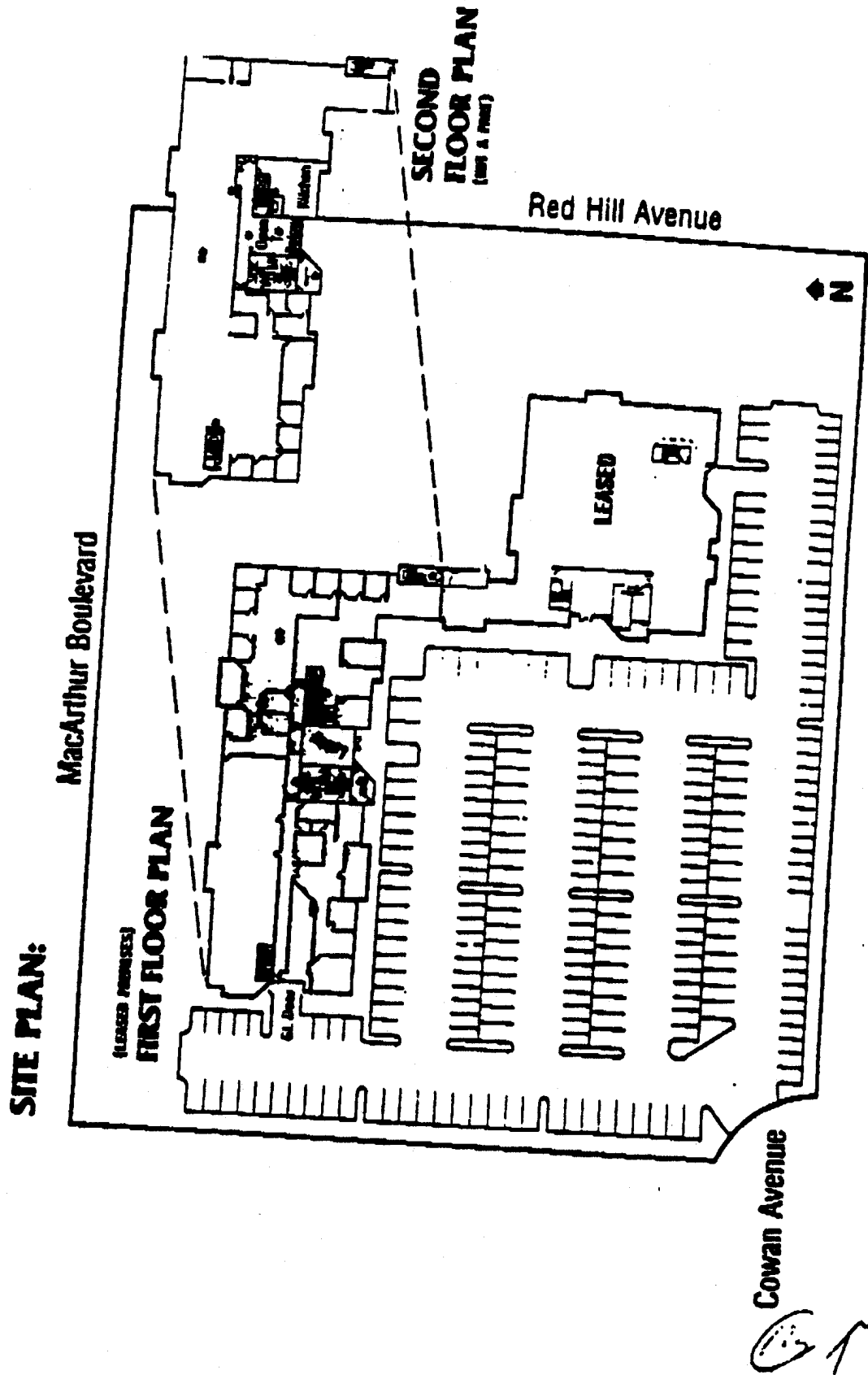
Initials: 

EXHIBIT "A"



No warranty with the information contained is given with the understanding that all measurements relating to the purchase, rental or leasing of the property described above shall be conducted through this office. The above information while not guaranteed has been secured from sources we believe to be reliable.

EXHIBIT B

FLOOR PLAN OF SUBLEASE PREMISES

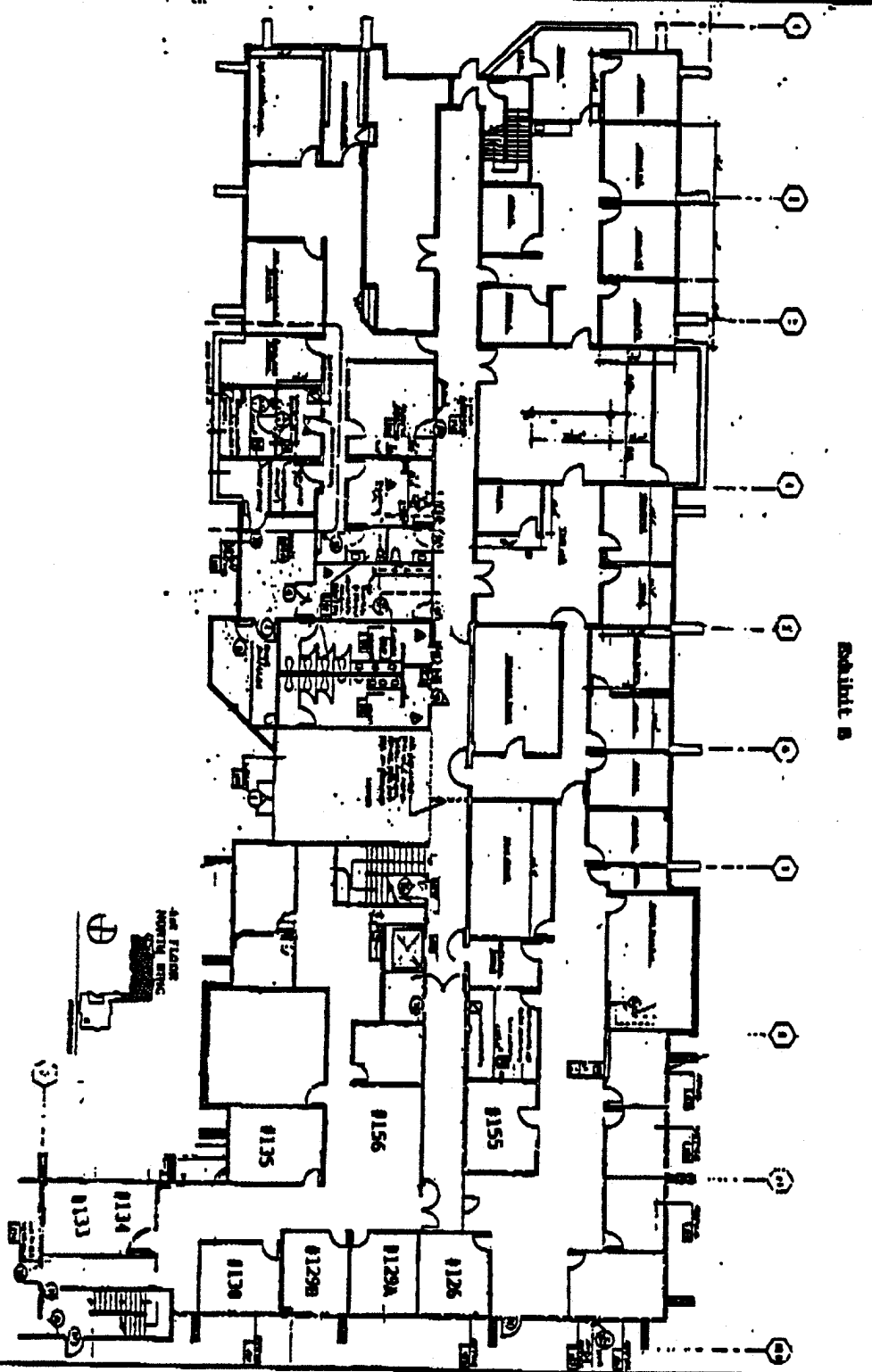
EXHIBIT C**Tenant Improvements for Sub-Lease on First Floor of 17671 Cowan Avenue Facility**

The following modifications are to be made by Shiley Incorporated at their expense for the Special Masters/Trustees for the Bowling-Pfizer Heart Valve Settlement Funds ("the Trustees") (Exhibit #2):

1. Construct a dividing wall from office #155 to office #126 to subdivide the suite of offices from the Shiley offices.
2. Construct two new offices, #129A and #129B, of approximately equal size and dimension in existing open secretarial area.
3. Enlarge office #135 by removing a secretarial area and enclosing with new walls.
4. Move the location of the existing door in office #130.
5. For office #156 remove two walls to form an open secretarial area.
6. Change offices #133 and #134 into one storage room.
7. Provide an intrusion control system for the perimeter doors of the Trustees space.
8. Provide moving labor for the furniture and equipment of Trustee employees who are transferring from the Shiley Heart Valve Research Center.

EXHIBIT C

DESCRIPTION OF TENANT IMPROVEMENTS



Shiley Heart Valve Research Center
Shiley Incorporated
17671 Cowan Avenue
Irvine, California 92714
Tel 714 863 5400 Fax 714 863 5420



Shiley Heart Valve Research Center

INVOICE

Bill to :

Mr. Wayne Smith
Bowling Supervisory Panel
525 Vine Street
Cincinnati, OH. 45201

Invoice No.: 95-0217b

Date 02/17/95

Furniture & Equipment

1). Furniture and Equipment per attached list	39,500
2). Laser Vibrometer & Portable Acoustic System	<u>25,000</u>
Total	64,500

Make check payable to:

Shiley, Inc.
17671 Cowan Avenue
Irvine, Ca. 92714

SOURCE	ITEM	SHILEY TAG #	BOOK VALUE
A. ABOLFATHI OFFICE:			
	DESK	5336	\$552
	MACINTOSCH POWERBOOK:	4164	\$764
	-6MB RAM	1894	\$2,999
	BOOKCASE	5319	\$107
	FILE CABINET	5365	\$353
	MACINTOSH COMPUTER/ACC	1383	\$2,910
	MONITOR	1384	\$406
	SMALL TABLE	N.T.	\$100
	CHAIRS @3	N.T.	\$225
	HANGER	N.T.	\$71
	BOOK SHELF	5319	\$106
	BOOKS/DOCUMENTS		\$1,000
	PICTURE FRAME	5532	\$108
	POWERBOOK ACCESSORIES	1894 A&B	\$687
	MACINTOSH ACCESSORIES	1383A	\$201
S. SCHRECK OFFICE:			
	DESK	5335	\$552
	MACINTOSCH COMPUTER/AC	2059	\$829
	MACINTOSCH COMPUTER	2060	\$3,035
	MACINTOSCH MONITOR	2058	\$420
	FILE CABINET	5313	\$346
	BOOKSHELVES	N.T.	\$107
	TABLE (SMALL)	N.T.	\$100
	CHAIR	5435	\$93
	CHAIR	5434	\$93
	CHAIR	N.T.	\$225
	BOOKS/DOCUMENTS	N.T.	\$1,000
	HANGERS	N.T.	\$4
	MACINTOSH ACCESSORIES	2060 A&B	\$340
J. HIRSCH OFFICE:			
	DESK	4648	\$1,122
	MACINTOSCH COMPUTER/AC	1385	\$2,960
	MACINTOSCH MONITOR	1229	\$356
	FILE CABINET	5310	\$346
	BOOKSHELVES	5325	\$106
	CHAIR	0110	\$199
	BOOKS/DOCUMENTS	N.T.	\$1,000
	HANGERS	N.T.	\$71
	LABEL MAKER	2068	\$123
	MICRONET BACK UP	2069	\$370
	CHAIR	5432	\$72
	CHAIR	5431	\$72

[illegible]

SOURCE	ITEM	SHILEY TAG #	BOOK VALUE
	MACINTOSH DUO (BECKY IND)	2054	\$3,030
	MONITOR (BECKY IND.)	2052	\$404
	CHAIR	5770	\$121
	CHAIR	5414	\$121
	TABLE	5576	\$383
	TABLE	5577	\$383
	CREDENZA	4906	\$1,261
	DOCUMENTS/BOOKS	N.T.	\$200
	MAC POWERBOOK ACCESS.	2054 A&B	\$792
DATA ENTRY OFFICE:			
	DESK	5480	\$246
	COMPUTER/MODEM	2056	\$2,238
	MONITOR	2055	\$296
	FILE CABINET	4772	\$632
	FILE CABINET	4771	\$632
	FILE CABINET	5530	\$904
	FILE CABINET	5707	\$147
	CHAIR	4553	\$257
ADMINISTRATIVE:			
GENERAL EQUIPMENT	COLOR PRINTER	1382	\$3,842
GENERAL EQUIPMENT	VELO BINDER	4217	\$2,776
GENERAL EQUIPMENT	PRO600 PRINTER	C-2114	\$2,030
GENERAL EQUIPMENT			
GENERAL EQUIPMENT	COMPUTER (DOS)	C2142	\$2,331
GENERAL EQUIPMENT	MONITOR (DOS)	C2141	\$318
GENERAL EQUIPMENT	POWER BOX (DOS)	C2211	\$361
GENERAL EQUIPMENT			
GENERAL EQUIPMENT			
GENERAL EQUIPMENT	MACINTOSH FILESHARE	C1454	\$2,904
GENERAL EQUIPMENT	TYPEWRITER	4213	\$361
GENERAL EQUIPMENT	FAX MACHINE	5080	\$2,512
GENERAL EQUIPMENT	DICTAPHONE	4146	\$489
GENERAL EQUIPMENT	SHREDDER	4358	\$730
GENERAL EQUIPMENT	TRANSCRIBING MACHINE	4079	\$409
GENERAL EQUIPMENT	TRANSPARENCY PROJECTOR	4156	\$305
	SEIKO LASER PRINTER-JLH	2068	\$120
	SEIKO LASER PRINTER-AHA	0103	\$120
	SEIKO LASER PRINTER-LDC	0104	\$120
	HP LASERJET 4 PRINTER	2113	\$1,904
KITCHEN	MICROWAVE	N.T.	\$280
KITCHEN	COFFEE MAKER	N.T.	\$400
KITCHEN	REFRIGERATOR	5010	\$534
CONFERENCE ROOM	TRANSPARENCY TABLE	5768	\$277

SOURCE	ITEM	SHILEY TAG #	BOOK VALUE
CONFERENCE ROOM	CREENZA	5386	\$339
CONFERENCE ROOM	TABLE	5381	\$1,332
CONFERENCE ROOM	CHAIR	5602	\$241
CONFERENCE ROOM	CHAIR	5592	\$241
CONFERENCE ROOM	CHAIR	5594	\$241
CONFERENCE ROOM	CHAIR	5606	\$241
CONFERENCE ROOM	CHAIR	5601	\$241
CONFERENCE ROOM	CHAIR	5596	\$241
CONFERENCE ROOM	CHAIR	5603	\$241
CONFERENCE ROOM	CHAIR	5598	\$241
CONFERENCE ROOM	CHAIR	5610	\$241
CONFERENCE ROOM	CHAIR	5608	\$241
CONFERENCE ROOM	CHAIR	5600	\$241
CONFERENCE ROOM	CHAIR	5593	\$241
CONFERENCE ROOM	CHAIR	5595	\$241
CONFERENCE ROOM	CHAIR	5604	\$241
CONFERENCE ROOM	CHAIR	5597	\$241
CONFERENCE ROOM	BOARD	5785	\$1,124
CONFERENCE ROOM	TV CABINET	5804	\$1,147
CONFERENCE ROOM	TOSH. TV	4385	\$357
CONFERENCE ROOM	SLIDE PROJECTOR	4185	\$338
ENERAL FURNITURE	CINE CABINET@4	5827	\$349
ENERAL FURNITURE	FILE CABINET	5772	\$472
ENERAL FURNITURE	FILE CABINET	5773	\$472
ENERAL FURNITURE	FILE CABINET	5774	\$472
ENERAL FURNITURE	FILE CABINET	3994	\$479
ENERAL FURNITURE	FILE CABINET	3993	\$479
ENERAL FURNITURE	FILE CABINET	3995	\$479
ENERAL FURNITURE	FILE CABINET	4775	\$729
ENERAL FURNITURE	FILE CABINET	5530	\$904
ENERAL FURNITURE	FILE CABINET	4773	\$729
ENERAL FURNITURE	FILE CABINET	4911	\$763
ENERAL FURNITURE	FILE CABINET	4912	\$763
ENERAL FURNITURE	FILE CABINET	5505	\$1,031
ENERAL FURNITURE	FILE CABINET	4776	\$665
ENERAL FURNITURE	FILE CABINET	4777	\$665
ENERAL FURNITURE	FILE CABINET	4145	\$798
ENERAL FURNITURE	FILE CABINET	3999	\$871
ENERAL FURNITURE	FILE CABINET	5075	\$789
ENERAL FURNITURE	FILE CABINET	5069	\$782
ENERAL FURNITURE	FILE CABINET	5074	\$789
ENERAL FURNITURE	FILE CABINET	5747	\$234
ENERAL FURNITURE	FILE CABINET	5748	\$234
ENERAL FURNITURE	FILE CABINET	5749	\$234
ENERAL FURNITURE	FAX MACHINE CABINET	5375	\$182

SOURCE	ITEM	SHILEY TAG #	BOOK VALUE
ENERAL FURNITURE	FAX MACHINE CABINET	5376	\$182
ENERAL FURNITURE	DESK	5824	\$824
ENERAL FURNITURE	DESK	3924	\$584
ENERAL FURNITURE	DESK	4885	\$865
ENERAL FURNITURE	DESK	4905	\$1,249
ENERAL FURNITURE	DESK	TBD	\$865
ENERAL FURNITURE	CHAIR	5015	\$220
ENERAL FURNITURE	CHAIR @10	TBD	\$2,410
ENERAL FURNITURE	CREDENZA	5386	\$339
ENERAL FURNITURE	CREDENZA @4	TBD	\$1,469
ENERAL FURNITURE	BOOKSHELVES (CHANDLER) @	4986-90	\$1,744
ENERAL FURNITURE	BOOKSHELVES @2	TBD	\$214
RESEARCH:			
X-RAY	WVP:		
X-RAY	-MOCKLOOP	CP-010	\$5,000
X-RAY	-PHILADRIE	ED-006	\$2,201
X-RAY	-PHILADRIE (BACK UP)	M3929	\$2,201
X-RAY	-AIR COMPRESSOR/220V	N.T.	\$250
X-RAY	-AIR COMPRESSOR/110V	N.T.	\$250
X-RAY	-CO2 REGULATOR	M4143	\$201
X-RAY	-FLIGHTCASE	GA-048	\$600
X-RAY	-FLIGHTCASE	GA-047	\$600
X-RAY	-DOLLY	M4148	\$223
X-RAY	CINE-PROJECTOR	M4108	\$29,413
X-RAY	X-RAY SYSTEM	M2834	\$5,179
X-RAY	DENSITOMETER	EA-001	\$833
X-RAY	DIAMENTOR	N.T.	\$2,812
X-RAY	NIKON CAMERA/FLASH/TRIPO	N.T.	\$577
ACOUSTIC	GOULD OSCILLOSCOPE 1604	4130	\$542
ACOUSTIC	VALIDYNE CONDITIONER	N.T.	\$800
ACOUSTIC	CD90 DEMODULATOR	916	\$250
ACOUSTIC	FLUKE 77 MULTIMETER	BR-001	\$250
ACOUSTIC	ELECTROMEDIC MS-20 P.T.	N.T.	\$250
ACOUSTIC	DYNATECH DIGITAL P.T.	3629	\$200
GENERAL	SOLDERING IRON	N.T.	\$200
GENERAL	ANGLE BLOCKS	N.T.	\$500
GENERAL	POLAROID CAMERA	FE-017	\$250
GENERAL	MICROSCOPE	1674	\$1,300
GENERAL	TOOL BOX	4721	\$330
GENERAL	TOOL KIT	N.T.	\$300
GENERAL	WORK BENCH	6D-017	\$505
GENERAL	STORAGE CABINET	N.T.	\$250
GENERAL	STORAGE CABINET	N.T.	\$250

SOURCE	ITEM	SHILEY TAG #	BOOK VALUE
	TOTAL NET BOOK VALUE		\$172,452
	SALES PRICE		\$39,500

EPIDEMIOLOGY RESEARCH CONSULTING AGREEMENT

This is an Agreement effective the date last signed between the International Epidemiology Institute, Ltd., 1550 Research Blvd., Suite 200, Rockville, Maryland 20850 (hereafter "IEI") and the Trustees for the Bowling-Pfizer Heart Valve Settlement Funds, 525 Vine Street, Suite 1300, Cincinnati, Ohio 45202 (hereafter "Trustees").

Background

The Trustees are interested in developing additional epidemiological information that may help improve the estimation of risk of valve fracture among patients with Bjork-Shiley CC heart valve implants and the efficacy of guidelines for these patients and their physicians regarding elective explantation. IEI has the ability to assess epidemiologic data and identify and evaluate structures for the conduct of epidemiologic studies and is willing to assist the Trustees upon certain terms. Accordingly, the parties agree as follows:

Terms

1. IEI agrees to use its best efforts to undertake evaluation of the risks of fracture and the guidelines for explantation of BSCC Heart Valves, in accordance with the protocol attached to this agreement as Attachment A. It is understood that should any deviations from the protocol be required, these should be agreed

upon by both parties in writing prior to work in accordance with any such deviations.

2. IEI shall maintain reasonably complete written records which document the work performed in conducting the program and records shall be made reasonably available for the Trustees' inspection during normal business hours. Progress on the project will be verbally reported to the Trustees from time to time and will also be reported in writing to the Trustees and the Supervisory Panel on at least a quarterly basis. When appropriate IEI will have Dr. Blot available to meet with the Supervisory Panel to report on progress of the program. Results shall also be summarized in a final report to be submitted to the Trustees within 90 days of completion of the project.

3. IEI agrees to conduct their work in conformity with all applicable governmental agency codes, regulations, and guidelines.

4. The Trustees agree to pay IEI for its services an amount not to exceed \$405,000.00. These costs will be paid upon invoices submitted monthly indicating the personnel performing the services, along with appropriate reimbursable expenses, consistent with the budget attached hereto and describing the nature of the services performed for the month; said invoices must be approved by the court before payment.

It is understood that mutually agreed upon changes in requirements under this Agreement may result in changes in payments due.

5. Neither party will use the name of the other in any advertising or other form of publicity without the written permission of the other party. The Supervisory Panel, or IEI, after approval by the Supervisory Panel, may disclose preliminary findings and final conclusions to third parties.

6. Any notices required to be given under this Agreement shall be in writing and delivered by first class mail or fax addressed to the parties as follows:

International Epidemiology Institute, Ltd.

Researcher's Name	William J. Blot, Ph.D.
Title	Chief Executive Officer
Address	1550 Research Blvd., Suite 200 Rockville, Maryland 20850
Fax	301-517-4063

Trustees for the Bowling-Pfizer Heart Valve Settlement Funds and the Supervisory Panel.

Representative's Name	Robert L. Black, Jr. and Peter J. Strauss, Trustees of the Bowling-Pfizer Heart Valve Settlement Funds
Address	J. Kermit Smith, Chair, Supervisory Panel 525 Vine Street, Suite 1300 Cincinnati, Ohio 45202
Fax	513-421-7696

7. Notwithstanding anything to the contrary contained herein, this Agreement shall not become effective until approved by court order in the case entitled Arthur Ray Bowling, et al. v. Pfizer, Inc., et al., case number C-1-91-256, United States District Court, Southern District of Ohio, Western Division.

8. (a) Except for obligations with respect to reports and to transmission of information to third parties, this Agreement shall terminate two (2) years from its effective date, unless extended by mutual agreement.

(b) Performance of services under this Agreement may be terminated at any earlier date by mutual agreement at any time or by either party upon sixty (60) days advance written notice. Upon such termination, IEI will be reimbursed by the Trustees for all appropriate costs and noncancellable commitments incurred up to the effective date of termination of the performance of services. Everything purchased by IEI will be transferred to the Trustees and will become property of the Trustees, including but not limited to, equipment, furniture, supplies and all records and documents.

(c) The law of the state of Ohio shall control. Disputes will be arbitrated in Cincinnati, Ohio by a panel of three arbitrators: One chosen by each party to the dispute, and another chosen by those arbitrators. The arbitrators shall follow the Rules of Conciliation and Arbitration of the International Chamber

9. This Agreement shall be binding upon the parties and upon their successors in business but shall not otherwise be assignable. Accordingly, the parties have executed this Agreement as of the effective below date.

By: _____, Trustee

By: _____, Trustee

International Epidemiology Institute, Ltd.

By: William J. Blot, Ph.D., its
Chief Executive Officer

Date: _____

ATTACHMENT A

Further Evaluation of the Risks of Fracture and Explantation of BSCC Heart Valves

A Proposal Submitted to:

Trustees for the Bowling-Pfizer

Heart Valve Settlement Funds

Submitted by:

International Epidemiology Institute, Ltd.

I. Purpose

The International Epidemiology Institute, Ltd. (IEI) will, working within the overall objectives of the Biostatistics and Epidemiology Subcommittee for the Trustees for the Bowring-Pfizer Heart Valve Settlement Funds, assist in the development of programs that will improve the efficacy of guidelines regarding elective explantation for patients and their physicians by:

1. Improving the estimates of absolute risk of valve fracture in implantees;
2. Identifying and evaluating factors relating to the risk of valve fracture associated with:
 - events in the manufacturing process;
 - characteristics and location of the valve;
 - patient demographic and clinical characteristics; and
 - various types of medical treatment.
3. Improving estimates of fatality rates due to elective explantation.

II. Activities to be completed by IEI:

Year 1

1. Become familiar with the BSCC manufacturing process and with detailed data on the manufactured valves.
2. Study published and unpublished literature on risk factors for BSCC heart valve fractures.
3. Study published and unpublished literature on risks of explantation of BSCC heart valves.
4. Evaluate the data bases used by Drs. Brookmeyer and Walker for completeness, integrity, and their value for further studies.
5. With the assistance of the Subcommittee, determine the current status of BSCC implant cohort data bases in the US, UK, Sweden and the Netherlands. Assess their comparability, accessibility, and usefulness for rapidly generating data for defining guidelines.
6. Develop and supervise procedures for the commissioning of coordinated multi-national cohort studies or other relevant additional biostatistical and epidemiological work to be conducted within the overall objective.

7. For the parallel multi-national cohort studies in the US, UK, Sweden and the Netherlands, (pending acceptability by the Subcommittee of data bases in each country) establish a common protocol for data collection and analysis, providing assistance within approved budgets to each center so that standardized methods are used and the resultant data can be combined in a joint analysis.
8. Develop and supervise procedures for the commissioning of multi-national studies, in the same populations as in item 7 above and/or in additional BSCC patient groups, to yield improved estimates of the absolute risk of mortality following elective valve explantation.
9. For the parallel multi-national explant followup studies, (pending acceptability by the Subcommittee of the relevant data bases) develop a common protocol and assure standardized methods so that the resultant data can be combined in a joint analysis.

Year 2

10. Monitor the progress of the studies, lending epidemiologic and biostatistical assistance as needed and as within approved budgets. Identify potential problems and make recommendations for their resolution.
11. Coordinate the receipt, editing, and checking of data in preparation for pooling for joint analysis.
12. Assist centers, to the extent requested (likely to be variable) and as within approved budgets, in the statistical analysis of data generated at that center.
13. Coordinate and assist as requested and as within approved budgets in the conduct of statistical analyses of the pooled data. Utilize appropriate methods to provide estimates (point estimates and confidence intervals) of relative and absolute risks of fracture, and of mortality following elective valve explantation, according to various patient/valve characteristics.
14. Assist in the preparation of reports describing results of analyses of the combined data sets.
15. Assist the Subcommittee in the interpretation of the study findings and in revising medical guidelines for elective explantation.

III. Deliverables

IEI will provide to the Subcommittee the following:

Year 1

1. A report summarizing the relevant literature on absolute rates and on risk factors for BSCC heart valve fractures.
2. A report summarizing the relevant literature on rates of mortality following explantation of BSCC valves, distinguishing elective from emergency or unelective explants.
3. A report on the adequacy of the data bases used by Drs. Brookmeyer and Walker and a recommendation on the value of the data for further studies.
4. Recommendations regarding the appropriateness of national implant cohort data bases in the US, UK, Sweden and the Netherlands for studies to improve estimates of absolute rates of valve fracture.
5. Recommendations regarding the appropriateness of data bases for studies to improve estimates of mortality following elective valve explantation.
6. A plan for the commissioning of parallel multi-national studies to achieve Subcommittee objectives.
7. Contributions to, working with the Subcommittee and the participating centers, a detailed protocol describing methods of study for parallel national cohort studies to improve estimates of fracture rates.
8. Contributions to, working with the Subcommittee and the participating centers, a detailed protocol describing methods of study for parallel investigations of mortality following elective valve explantation.

Year 2

9. Quarterly progress reports describing study progress and identifying any potential problem areas.
10. A plan, developed in consultation with the Subcommittee and the participating centers, describing the proposed statistical analyses of the pooled data.
11. Contributions to, working with the Subcommittee and the participating centers, a report describing the results of the pooled analyses of the cohort studies on fracture rates.
12. Contributions to, working with the Subcommittee and the participating centers, a report describing the results of the pooled analyses of mortality rates following explantation.
13. Recommendations, based on the combined data, for revising medical guidelines for implant patients.

IV. Budget

	Year 1				Year 2			
	-----Annual-----				-----Annual-----			
	% time	Salary	Fringe	Cost	% time	Salary	Fringe	Cost
A. Personnel								
Dr. Blot	40	\$160,000	\$49,600	\$83,840	30	\$168,000	\$52,800	\$66,240
Senior assistant	35	\$57,000	\$17,670	\$26,134	20	\$59,850	\$18,554	\$15,681
Data manager/programmer	20	\$42,000	\$13,020	\$11,004	40	\$44,100	\$13,671	\$23,109
Secretary	10	\$23,000	\$7,130	\$2,967	10	\$24,150	\$7,486	\$3,164
Overhead				\$49,313				\$45,341
Total				\$173,258				\$153,535
B. Travel								
Within US				\$16,000				\$8,000
Europe				\$20,000				\$11,500
C. Computer								
				\$7,500				\$15,000
Total				\$216,758				\$188,035

**AGREEMENT BETWEEN TRUSTEES FOR THE
BOWLING-PFIZER HEART VALVE SETTLEMENT
FUNDS AND Member OF THE GUIDELINES COMMITTEE**

This Agreement made this ____ day of _____, 1995 (the "Agreement") by and between the Special Masters/Trustees for the Bowling-Pfizer Heart Valve Settlement Funds ("Trustees") and _____ ("Member") of the Guidelines Committee.

1.0 Purposes.

The Bowling-Pfizer Settlement Agreement sets forth the basis upon which patient claims can be asserted against Pfizer and Shiley in a worldwide class action brought in the Federal District Court in Cincinnati, Ohio involving the Bjork-Shiley Convexo-Concave 60° and 70° heart valves ("BSCC"). Among other things, the Settlement Agreement creates:

- (1) a Patient Benefit Fund to pay for research on diagnostic techniques and valve replacement surgery, and
- (2) a Supervisory Panel whose task is (a) to approve diagnostic research programs and (b) to develop guidelines for physicians and surgeons (i) about the use of any diagnostic techniques that may be developed, and (ii) the conditions under which elective replacement surgery may be appropriate. The Guidelines Committee's task is to bring its combined skills and experiences to bear in order to recommend to the Supervisory Panel guidelines for diagnostic techniques and valve replacement surgery.

The Supervisory Panel carries out its tasks under the supervision of Hon. Robert L. Black, Jr., and Peter J. Strauss, Special Masters/Trustees, who are responsible to the court.

Shiley appointed a Medical Advisory Committee that established guidelines for valve replacement surgery based on epidemiological data derived from known valve failures. The Medical Advisory Committee's guidelines have been changed from time to time, the latest being issued January 31, 1995. They will remain in effect until the Supervisory Panel, on recommendation of the Guidelines Committee, establishes its own guidelines and the Court approves them.

In the absence of any reliable diagnostic technique to gauge the risk of complete valve failure, the guidelines serve to identify those groups of valves for which the risk of failure is sufficiently high as to warrant consideration of valve replacement surgery, and those patients whose condition suggests meaningful extension of life expectancy after survival of that surgery. The Guidelines Committee should be aware that the guidelines as adopted will determine which patients are eligible for reimbursement from the Patient Benefit Fund for surgical, hospital and related expenses and for lost income.

The Supervisory Panel will refer to the Guidelines Committee any relevant scientific or medical literature about the valves, will provide all results of research relating to the valve whether developed by Shiley or by the Supervisory Panel, and will transmit any relevant unpublished literature or studies that may be of assistance in setting the guidelines. The Guidelines Committee will independently assess the reliability and applicability of all such information, and may seek relevant data from any other source.

2.0 Services.

2.1 At the Supervisory Panel's request, Member is serving on the Guidelines Committee.

2.2 The Committee monitors and evaluates medical, statistical and related information regarding BSCC valves for the purpose of rendering recommendations to the medical community and government regulatory agencies, for the benefit of BSCC heart valve recipients. To fulfill this important objective, panel members agree to the following duties and responsibilities:

- ◆ To exercise independent professional judgment based on their knowledge, skill and experience;
- ◆ They shall review professional literature in their respective fields and keep abreast of developments within their disciplines bearing on the BSCC heart valve;
- ◆ To meet and confer with other members in an open exchange of ideas and views; and render recommendations for the sole benefit of patients with implanted valves. The Members shall be free to exercise discretion as to the methods and means of performance of those services.

2.3 Member shall be free to exercise discretion as to the methods and means of performance of services hereunder and shall in no sense be considered an employee or agent of Trustees.

3.0 Payment.

3.1 Member is to be compensated for services the sum computed at the rate of Two Hundred Dollars (US\$200.00) per hour up to a

maximum of Two Thousand Dollars (US\$2,000.00) per day. Payment should be limited to _____ Thousand Dollars (US\$_____) per annum.

3.2 Trustees shall also pay Member's reasonable expenses, to include travel and lodging, as well as research and communication support relevant to all Committee activities.

3.3 Consulting fees, together with any reimbursable expenses of Member, shall be payable within thirty (30) days of the end of the month upon presentation by Member of a suitable invoice.

4.0 Indemnification.

The Trustees agree to apply to the Court for indemnification of Member from the Patient Benefit Fund (as defined in the Settlement Agreement), from any claim, lawsuit, judgment or other award of damages including attorney's fees based on or arising out of the actions or omissions of such Member while acting in his capacity as a Member of the Committee.

This Agreement to apply for and obtain indemnity is subject to the following conditions:

(a) Member will cooperate fully with Trustees and their representatives in defending any such claim or lawsuit;

(b) This Agreement does not cover or extend to any claim or lawsuit based upon any alleged actions or omissions on the part of Member which are not directly related to or arise from Member's activities as a member of the Committee; and

(c) Member agrees to be represented in connection with any such claim or lawsuit by counsel selected and retained by Trustees with respect to the same claim or lawsuit.

5.0 Term and Termination.

The services of Member may be terminated at the discretion of the Supervisory Panel, on 30 days' advance written notice. Any Member may resign at any time by sending a written notice (including the date of resignation) to the Chair of the Guidelines Committee and the Chair of the Supervisory Panel by certified mail or personal delivery. Unless sooner terminated as provided in this paragraph, this Agreement shall terminate on March 1, 1997.

6.0 Entire Agreement, Modification, etc.

This instrument contains the entire and only agreement between the parties respecting the subject matter hereof, and any representation, promise or condition in connection therewith not incorporated herein shall not be binding upon either party. No waiver, alteration, modification, renewal or extension of this Agreement shall be valid unless made in writing and signed on behalf of Trustees.

7.0 Effective Date.

This Agreement is to be effective as of the date signed by the last party provided.

8.0 Court Approval.

Notwithstanding anything to the contrary contained herein, this Agreement shall not become effective until approved by court order in the case entitled Arthur Ray Bowling, et al. v. Pfizer, Inc., et al., case number C-1-91-256, United States District Court, Southern District of Ohio, Western Division.

TRUSTEES FOR THE BOWLING-PFIZER HEART
VALVE SETTLEMENT FUNDS

By: _____
Peter J. Strauss, Trustee

Robert L. Black, Jr., Trustee

MEMBER

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF DECEMBER 31, 1994

UNAUDITED

ASSETS

CASH:		
Consultation Fund	\$	145,050
Patient Benefit Fund		123,480
U.S. TREASURY BILLS:		
Consultation Fund (Par Value \$92,900,000)		92,159,249
Patient Benefit Fund (Par Value \$12,162,000)		12,105,478
PREPAID FEDERAL TAXES		108,280
OTHER ASSETS		<u>46,177</u>
		<u>\$104,687,714</u>

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES:		
Supervisory Panel Members' Compensation	\$	234,900
Other		<u>76,413</u>
Total Liabilities		311,313
FUNDS BALANCE		<u>104,376,401</u>
		<u>\$104,687,714</u>

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND CONTRIBUTIONS
FOR THE YEAR ENDED DECEMBER 31, 1994
UNAUDITED

INTEREST INCOME:

U.S. Treasury Bills:	
Consultation Fund	\$ 3,562,564
Patient Benefit Fund	101,211
Other:	
Consultation Fund	5,731
Patient Benefit Fund	<u>1,155</u>
	<u>3,670,661</u>

BENEFIT PAYMENTS:

Consultation Fund:	
Implantees	2,134,500
Spouses	<u>272,000</u>
	<u>2,406,500</u>

EXPENSES:

Notification expense	407,606
Supervisory Panel:	
Panel Members' compensation	481,500
Consultants' compensation	16,975
Travel and other expenses	73,118
Trustees' compensation	93,117
Trustees' expense	311
Professional fees	44,954
Other Administration Expenses:	
Rents	13,428
Office payroll	53,113
Payroll taxes	5,789
Employee benefits	1,821
Outside services	10,636
Printing and postage	7,733
Telephone	3,283
Office supplies and expense	2,077
Depreciation	1,019
Miscellaneous	<u>342</u>
	<u>1,216,822</u>

PROVISION FOR FEDERAL TAXES 971,720

CONTRIBUTIONS BY SHILEY INCORPORATED 22,500,000

NET CHANGE IN FUNDS BALANCE \$21,575,619

ARTHUR
ANDERSEN

ARTHUR ANDERSEN & CO. S.C.

TRUST OF BOWLING-PFIZER HEART VALVE

CONSULTATION FUND

FINANCIAL STATEMENTS

AS OF DECEMBER 31, 1993

TOGETHER WITH ACCOUNTANTS'

COMPILATION REPORT

ARTHUR ANDERSEN & CO.

Honorable Robert L. Black, Jr.
Trustee
Trust of Bowling-Pfizer Heart Valve Consultation Fund
5900 Drake Road
Cincinnati, Ohio 45243

We have compiled the accompanying balance sheet of Trust of Bowling-Pfizer Heart Valve Consultation Fund, as of December 31, 1993, and the related statement of income and contributions from inception (January 31, 1992) to December 31, 1993 and for the year then ended in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants.

A compilation is limited to presenting, in the form of financial statements, information that is the representation of management. We have not audited or reviewed the financial statements referred to above and, accordingly, do not express an opinion or any other form of assurance on them.

Management has elected to omit substantially all of the disclosures and the statement of cash flows required by generally accepted accounting principles. If the omitted disclosures were included in the financial statements, and the statement of cash flows presented, they might influence the user's conclusions about the Company's financial position, results of operations and cash flows. Accordingly, the financial statements presented are not designed for those who are not informed about such matters.

Cincinnati, Ohio
March 2, 1994

Arthur Andersen PC.

TRUST OF BOWLING-PFIZER HEART VALVE

CONSULTATION FUND

BALANCE SHEET

AS OF DECEMBER 31, 1993

ASSETS

CASH	\$ 112,114
U.S. TREASURY BILLS (PAR VALUE \$83,650,000)	<u>82,773,103</u>
	<u>\$82,885,217</u>

LIABILITIES AND FUND BALANCE

ACCRUED EXPENSES	\$ 1,162
FEDERAL TAXES PAYABLE	<u>83,273</u>
Total liabilities	84,435
FUND BALANCE	<u>82,800,782</u>
	<u>\$82,885,217</u>

The accompanying accountants' compilation report should
be read in conjunction with this statement.

TRUST OF BOWLING-PFIZER HEART VALVE

CONSULTATION FUND

STATEMENT OF INCOME AND CONTRIBUTIONS

FROM INCEPTION (JANUARY 31, 1992) TO DECEMBER 31, 1993

	<u>Year Ended December 31, 1993</u>	<u>Inception (January 31, 1992) to December 31, 1993</u>
INTEREST INCOME:		
U.S. Treasury Bills	\$ 2,577,869	\$ 5,258,012
Other	<u>22,224</u>	<u>57,222</u>
	<u>2,600,093</u>	<u>5,315,234</u>
TRUSTEE/ADMINISTRATION EXPENSES:		
Notification expense	-	900,000
Trustee's compensation	7,800	18,600
Trustee's expense	451	2,318
Bank charges	1,057	1,960
Professional fees	11,764	11,764
Interest expense	<u>50</u>	<u>50</u>
	<u>21,122</u>	<u>934,692</u>
Net Income Before Taxes	<u>2,578,971</u>	<u>4,380,542</u>
PROVISION FOR FEDERAL TAXES	<u>1,021,273</u>	<u>1,579,760</u>
Net income	1,557,698	2,800,782
CONTRIBUTION BY SHILEY INCORPORATED	<u>-</u>	<u>80,000,000</u>
Net income and contribution	<u>\$ 1,557,698</u>	<u>\$82,800,782</u>

The accompanying accountants' compilation report should
be read in conjunction with this statement.