

**SUMMARY OF CONTINUING OPERATION PLAN
OF THE SUPERVISORY PANEL**

Background. The Supervisory Panel (Panel) was created by terms of the Settlement Agreement for the purpose of establishing and modifying Guidelines under which surgical benefits for Class Members will be provided. The Panel also was charged with the duties of conducting "research and development of diagnostic techniques to identify implantees who have a significant risk of strut fracture", and; conducting "research concerning the characterization and/or reduction of the risks of valve replacement surgery, including improvement of the techniques for such surgery." The Panel was appointed and began its work in 1994.

Part 5 of the Agreement creates the Patient Benefit Fund and sub-section 5.2 provides for Pfizer to provide a total of \$75 million for this fund. The following sub-sections stipulate the uses for the money including: research and development of diagnostic techniques to identify implantees who may have significant risk of strut fracture; research to reduce the risks of valve replacement surgery and improve surgical techniques; paying for the diagnostic techniques, and; paying for explant surgery as approved under the Guidelines. Sub-section 5.2.3.1 established that "the surgery must be in compliance with guidelines for C/C heart valve replacement as adopted from time to time by the Supervisory Panel, with the approval of the Court" (cross reference to 5.4.4.2)

Section 5.3.1 provides the Supervisory Panel may devote up to \$37.5 million of these funds to pay for the research, diagnostic tests, related expenses of the Panel, and the cost of the claims administrator. Further, this section states that if the \$37.5 million is exhausted and no diagnostic technique is approved, the Panel, with the approval of the Court may allocate additional incremental amounts to research and development.

The other half of the Patient Benefit Fund (\$37.5 million) provides for the operation of the Trustees office, fees and expenses of Class and Special Counsel, fees and expenses of Counsel for the Trustees, office administration and surgical expenses to class members. The Panel may have access to some of these funds, however, a large amount of these funds must be set aside to provide support to the Class members in the form of claims administration.

In the Status Conference of December 9, 2004 before Judge Weber, the issue of the continuing activities of the Panel was raised. The Court set a hearing for April 7, 2005 for the purpose of establishing a budget for the continued administration of the Settlement including the operation of the Bowling-Pfizer Trustees Office and a plan for the continuing operation of the Panel to include a time frame for when the Panel will cease its activities.

Overview of The Plan The Panel prepared a Plan for Continuing Operation which is based on three critical premises:

1. The need to preserve funds with which to operate a Claims Administration office to support the Class for the next 20 years.
2. The need to maintain the Guidelines for Class member eligibility for surgical benefits.
3. The need to determine if one or more diagnostic devices to detect single leg separation of the BSCC valves in Class members can be put to use.

The Court approved the Plan on April 28, 2005 and one aspect of the Plan is the creation of a Protocol for Funding Decisions, which follows:

The following are factors the Panel will consider as it makes decisions on research proposals. The underlying standard of this protocol for considering future projects is that of reasonable certainty. The

research project must demonstrate an ability to provide a direct benefit to the Class, and do so within a reasonable time frame.

1. The Panel will recommend funding of known technologies or study methodologies that have demonstrated reasonable certainty of resulting in a diagnostic device or technique, or improving the Guidelines. The Panel is at the point where it must focus on those research projects which have highly promising techniques with the potential to benefit the Class members in a reasonable period of time. It will not initiate new projects using different techniques or approaches unless some revolutionary method is introduced.
2. The Panel will focus on continuing to fund the projects which are now in place based upon a priority listing of projects it considers will most likely produce a diagnostic device or technique, or improve the Guidelines. The Panel will focus on a smaller number of highly promising projects which demonstrate the potential to produce results in a reasonable time frame. This Plan includes a listing of those projects.
3. As it relates to Imaging and Acoustics projects, the Panel will focus on those projects which have demonstrated "proof of concept" of their technology in either animal or human testing. This principle relates to in-vitro v. in-vivo test results. Favorable funding recommendations will be made based upon those projects which have demonstrated results in vivo, or which have a reasonable certainty of in-vivo success in the next funding cycle.
4. As it relates to Epidemiological or Guidelines related projects, the Panel will focus on those projects which have a reasonable certainty of providing meaningful data. The data obtained from these projects must be critical to assisting in the evaluation of the Guidelines.
5. The Panel will consider the issue of regulatory approval. The Panel must be mindful of the requirements of the FDA and other regulatory agencies abroad as it considers the viability of projects. These approval processes will be for use of any diagnostic techniques in the clinical trial setting as opposed to full FDA approval of any device as a diagnostic device.
6. The Panel will consider the issue of preservation of some funds for use with a diagnostic device or technique. The Panel must preserve money to implement any diagnostic device or technique, or in the absence of such a device or technique, consider how to use any remaining funds, such as establishing a medical monitoring program.

To further clarify the intent of the Panel regarding future diagnostic device research, the Panel determined any project it approves must have a clearly defined goal of meaningful application *in a patient within a 12-18 month time frame*. The Panel must now see if one or more diagnostic devices can be made available to patients soon or abandon these efforts.

The Plan set aside funds on which to operate a claims administration office for the next 20 years to support the Class members. In the Plan, the Panel outlined current epidemiological studies geared toward consideration of a revision of the Guidelines in 2005 and continuing work in this area. The Plan also identified several investigators, whose work has progressed to the point where the Panel is reasonably certain one or more diagnostic devices using acoustics methods will be developed for use in patients. The Court has allowed the Panel approximately 2 years to determine if such a device(s) can be developed for use in patients.

The Court has now given the Panel a specific plan for its continuing activities. Our focus remains on ensuring the Guidelines for providing surgical benefits are fair and appropriate and will give the most benefit to the Class. This follow up work is envisioned to continue for the next 10 years.

The Panel is also working to determine if a diagnostic device to detect the status of the BSCC valve in patients can be implemented. The studies to support these objectives will be fewer and must demonstrate, with reasonable certainty, a direct benefit to the Class in a relatively short time frame.