

to Class Counsel. James Capretz, Esq. served as Special Counsel to Class Counsel until his death in 2019. The Court extends its sympathies to Mr. Capretz's family and colleagues and its gratitude for his many years of service in this case.

On October 29, 2015, the Court entered an agreed order approving an amendment of the Settlement and a second distribution totaling almost \$17 million to all then-living implantee class members and their then-living spouses. (Doc. 3138.) The agreed order approving the second distribution required a holdback in the agreed amount of \$1,619,835.

Id. at 33. In that agreed order, the Court found that this holdback amount

would be more than sufficient to cover the reasonable and foreseeable (a) costs of reimbursing qualified class members' uninsured expenses related to explant surgeries under subsection 5.2.3, including those who qualify under the Supervisory Panel's guidelines and those later diagnosed with single-leg fractures; (b) fees and expenses of the Settlement Administrator; (c) fees and expenses of the Special Master/Trustee; (d) fees for any necessary tax return preparation and accounting and for a biennial review of the remaining funds by a qualified outside accounting firm; (e) costs associated with administering, implementing, and/or enforcing the terms of the Settlement, including any additional expenses of the Supervisory Panel or its members and any further work that the Court might ask of the Panel or any of its members; and (f) fees and expenses related to the distribution. This hold-back will cover the foregoing expenses and any other costs associated with carrying out the purposes of the Settlement Agreement in future years.

Id. at 32-33. With the payment of 17 late claims from the second distribution earlier this year totaling \$92,224.67, that distribution is now complete.

Over the past five years since the Court ordered the second distribution, no class member has been reimbursed for uninsured expenses related to explant surgeries under subsection 5.2.3 of the Settlement, including those who qualify under the Supervisory Panel's

guidelines and those later diagnosed with single-leg fractures. Although such reimbursements have totaled about \$1.3 million over the 28-year life of the Settlement and \$397,421.56 since 2001, they totaled only \$107,953.88 since 2003, \$3,083.97 between 2008 and 2012, and zero over the past seven years. *See* Exhibit A. Moreover, although Pfizer is not responsible for such reimbursements or the funds needed to cover them going forward, Pfizer nevertheless remains subject to certain other potential payment obligations to class members under the Settlement.

As of May 2020, the Settlement Fund's balance is \$1,606,499.00. If the trend lines evident since 2008 are projected into the future, virtually none of this reserve will be spent on direct benefits to class members, barring another distribution. Stated another way, it appears likely that the remainder of this reserve will be used exclusively to cover administrative costs. This makes it appropriate for the Court to consider a third distribution, especially in light of the advancing age of implantee class members and the availability of relatively up-to-date contact information for them as a result of the second distribution. This also makes it appropriate for the Court to consider further steps to minimize the costs of administering the Settlement. To achieve these ends, the Court has directed the Special Master/Trustee, Class Counsel, and Special Counsel to submit recommendations.

Recommendations of The Special Master/Trustee, Class Counsel, and Special Counsel

The Special Master/Trustee, Class Counsel, and Special Counsel jointly recommend that the Court approve a third distribution, this time in the amount of \$1,300,000.00, to be divided in equal shares among all living implantee class members who cashed checks as part

of the second distribution (including the late claimants paid earlier this year); and that once the third distribution has been completed, the remainder of the funds in the Settlement Fund be entrusted to the care and custody of HealthPath Foundation of Ohio, a non-profit foundation in Ohio, by means of the "Custodial Agreement Between HealthPath Foundation of Ohio and the Special Master/Trustee of the *Bowling/Pfizer* Heart Valve Settlement Fund," which is attached as Exhibit B for the Court's approval.

The Recommended Third Distribution

The second distribution was highly successful in that it resulted in payment of almost \$17 million to class members, including to then-living implantees and to spouses of living implantees. The total amount successfully distributed represents approximately 99 percent of the amount approved for distribution and issued in checks. Because there had been no mass distribution of settlement funds in this case since the 1990s, those charged with carrying out the second distribution faced the daunting task of locating implantees and their spouses two decades later. Thus, the second distribution must be considered a ringing success. Its success is a tribute to the work of those who have helped administer the fund and maintain the class member database, including Nancy Johnson and her staff at CAC (the current Claims Administrator), former Special Master/Trustee James Higgins and his then-counsel Nancy Lawson (the current Special Master/Trustee), former Claims Administrator Wayne Smith, and their assistants, Jeanine Hance and Cathy Lovely.

Along with the Special Master/Trustee, Class Counsel and Special Counsel are recommending that the Court build on the success of the second distribution by ordering a

third cash distribution to the implantees class members who cashed checks as part of the second distribution, this time with a more modest holdback. Five reasons are offered in the support of this aspect of the recommendations.

First, putting cash in the hands of qualified implantees, many of whom are of advanced age and in need, constitutes the highest and best use of the settlement fund, particularly during the current uncertain times.

Second, when the Court approved the amendment to the Settlement to permit cash distributions and ordered the second distribution in 2015, it determined that there were no other practical uses for the Patient Benefit Fund that were of comparable direct value to class members. This remains true today.

Third, in the light of the highly successful second distribution, which demanded accurate location information for class members who cashed checks, the class member database—which consists of the names, contact information, and payment information of all qualified implantees currently registered as class members—will never be more up-to-date and reliable than it is right now. Any significant delay in undertaking another distribution will necessarily weaken the accuracy of the database.

Fourth, having carried out a cash distribution in recent years, Nancy Johnson and her staff at CAC should be able to replicate it with the least difficulty and at the lowest possible cost to the Settlement Fund. Ms. Johnson estimates that the cost of another distribution to living implantees would be about \$30,000.

Fifth, over the past decade, fund expenses have been greatly reduced, with very little paid out to class members for reimbursement of qualified uninsured expenses, all of which supports a more modest holdback this time around. To demonstrate this, attached as Exhibit A is a chart showing all amounts paid out of the Patient Benefit Fund to reimburse class members for uninsured medical expenses related to qualifying valve replacement surgeries since 2000. Since 2004, the amount paid to all class members in reimbursement claims totals only \$4,310.03. There have been no reimbursement claims submitted by class members since 2012. The Special Master/Trustee, Class Counsel, and Special Counsel have stated that they expect the trends toward reduced costs—*i.e.*, average annual fund expenses in the \$15,000-20,000 range and few, if any, viable claims for reimbursement of medical expenses payable from the Patient Benefit Fund—to continue into the foreseeable future.

Based on the foregoing data, the Special Master/Trustee, Class Counsel, and Special Counsel recommend that \$1,300,000.00 be distributed to the living implantees who cashed checks in the second distribution, and that whatever remains in the Settlement Fund and from this third distribution be held back to cover future administrative expenses and potential reimbursement claims. The rationale for paying only living implantees this time around, as opposed to including their spouses again in the distribution, is that the funds to be used for this proposed distribution principally were held back in 2015 to provide for potential reimbursement payments to implantees (and not their spouses), which have never materialized and appear unlikely to do so, based on Exhibit A.

The 2015 order amending the Settlement Agreement provided that Shiley and Pfizer would no longer have any liability or responsibility to pay additional money into the Patient Benefit Fund if that Fund ever has insufficient funds to pay claims. After this additional distribution, Shiley and Pfizer will still have no responsibility to make any further payments into the Patient Benefit Fund under any circumstances. This proposed distribution imposes no new or additional liabilities, obligations, or responsibilities on Shiley or Pfizer.¹

The Recommended Custodial Agreement

Once the third distribution has been completed, the parties recommend, and it makes abundant sense to the Court, that steps be taken to ensure the costs of administering the Settlement are being reduced to, and maintained at, the lowest possible levels. Before the Court for approval is the “Custodial Agreement Between HealthPath Foundation of Ohio and the Special Master/Trustee of the *Bowling/Pfizer* Heart Valve Settlement Fund,” which is attached as Exhibit B for the Court’s approval. In substance, this Custodial Agreement would help to reduce administrative costs by placing the monies remaining in the Settlement Fund after the third distribution in the care and custody of HealthPath Foundation of Ohio (HealthPath).

HealthPath is an affiliate of the Greater Cincinnati Foundation and has resources for and expertise in managing funds and in making grants, particularly in the health care arena.

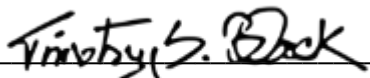
¹ As noted in the Amended Order Approving Amendment and Distribution, Pfizer and Shiley retain certain other payment obligations under the Settlement Agreement. *See* Doc. 3141, pp. 9-10.

Under the Custodial Agreement, HealthPath would be obligated to manage and, where necessary, pay out funds according to instructions issued by the Court, all within a ten-year timeframe. Within that ten-year window, HealthPath would make use of its internal resources to perform administrative responsibilities previously covered by outside vendors such as tax preparers and accountants; and to the extent given responsibilities cannot be brought in-house at HealthPath, the foundation would use the funds entrusted to it to cover them. At all times within that ten-year window, for example, HealthPath would ensure that CAC is paid for continuing to act as Settlement Administrator. At the end of this ten-year period, HealthPath will distribute the then-remaining funds in the form of grants in support of public health projects and/or research for improving cardiovascular health. The Custodial Agreement provides for such final distributions on “the earlier of (1) the date on which the Court determines and advises HealthPath that sufficient funds exist within the Fund that making such grants from the income thereon will not jeopardize any amount reasonably anticipated to pay claims under sub-paragraph 2(a)(1) above or (2) ten years from [the effective date of the Custodial Agreement].” Exhibit B, p. 2, Sec. 2(b). If the Custodial Agreement is approved, the expectation is that HealthPath, utilizing its expertise in grant making within the health care arena, in the near term would work in collaboration with the Special Master/ Trustee, Class Counsel, and Special Counsel to formulate a plan for automatically making the grants described above and in the Custodial Agreement at the end of the ten-year period.

Approval by the Court

The Court accepts these recommendations and orders as follows:

1. The Special Master/Trustee and the Settlement Administrator shall distribute forthwith a total of \$1,300,000.00, to be divided in equal shares among all living implantee class members who cashed checks in the second distribution, reserving the remainder in the Settlement Fund to cover (a) through (f) at pages 32-33 of Doc. 3138.
2. The Court approves, and authorizes the Special Master/Trustee to sign, the Custodial Agreement attached as Exhibit B.
3. The Court retains jurisdiction over the administration of the Settlement, including the implementation and enforcement of the Custodial Agreement, once it has been executed. IT IS SO ORDERED.



Timothy S. Black, United States District Judge

Agreed:

/s/ Nancy Lawson
Special Master/Trustee

/s/ Paul De Marco
Class Counsel

/s/ Brian Wolfman
Special Counsel to Class Counsel

/s/ Jack Harrison
Counsel for Pfizer and Shiley