

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

In Re: FRANCK'S LAB, INC. ,

MDL NO. 13-2454

PRODUCTS LIABILITY LITIGATION

**THIS DOCUMENT RELATES TO
ALL CASES**

SECTION "N" (4)

SPECIAL MASTER REPORT AND RECOMMENDATION

On June 2, 2014 an **ExParte/Consent Joint Motion for Appointment of Special Master and a Medical Expert (R. Doc. 112)** was filed by the Plaintiffs' Liaison Counsel for Appointment of Magistrate Judge Karen Wells Roby as Special Master in these proceedings for the purposes of allocation of settlement funds deposited into the registry of the Court by Evanston Insurance Company ("Evanston").¹ On June 4, 2014, Judge Kurt Engelhardt granted the Plaintiffs' Liaison Counsel's motion and issued an Order (R. Doc. 114) appointing the undersigned as Special Master.

The appointment was made due to the limited nature of the settlement funds and because the plaintiffs' collective general damages for alleged loss of vision greatly exceed the available settlement funds. Decisional authority concerning the allocation and distribution of the settlement funds was also granted by the Court to the undersigned as Special Master. *See* R. Doc. 114.

¹ The Order appointing the undersigned as Special Master only references the development of a protocol for allocating the Evanston Settlement Fund. The Special Master Order does not include the settlements of the Cincinnati Insurance Company, Those Interested Underwriters at Lloyd's, London, and American Casualty Company because each of those settlements was deposited into the Court's registry after the Special Master Order was issued. However, based on the intent of the Special Master Order to provide for the allocation of the settlement funds, it shall be construed to include the allocation of the subsequent settlements. Furthermore, hereinafter all settlements shall be collectively referenced as the Evanston Settlement Fund.

Per the Order, the Special Master was granted responsibility for the following:

1. Develop, with the assistance of court-appointed expert Lance Turkish M.D., a protocol for allocation of the Evanston Settlement Fund among participating claimants;
2. Implement the protocol for allocation of the Evanston Settlement Fund among participating claimants.
3. Communicate ex parte with the Court, with the attorneys or with the parties, without providing notice to the attorneys or the parties.
4. Make recommendations regarding which claimants, including future claimants shall be entitled to participate in the allocation of the Evanston Settlement Fund and the amounts to be allocated to participating claimants, subject to review by this Court but without further recourse on appeal;
5. Maintain records that support the basis of the recommendations to the District Judge.

Having set forth the scope of authority granted to the undersigned, the Court will proceed with the recommendations regarding the allocation of damages.

I. FACTUAL BACKGROUND

This action is a product liability dispute arising out of the manufacture and distribution of products known as “Brilliant Blue-G”, a surgical dye, and Triamcinolone acetonide,² which were manufactured by Franck’s Lab d/b/a Franck’s Compounding Lab, and/or Franck’s Pharmacy, Inc., a compounding pharmacy. The products were marketed to and used by ophthalmologists during cataract surgery and vitrectomy procedures. The compound was injected into the patient’s eyeball during surgery to help the doctor achieve the desired results of the procedure.

In March 2012 Franck’s Lab issued a recall which was followed by a FDA safety alert announcing the recall for the sterile human and veterinary prescriptions distributed by the

² In addition to the contamination of triamcinolone acetonide in its singular form, it also caused the contaminated of the mixture of bevacizumab/triamcinolone acetonide. However, bevacizumab in its singular form was not identified as a contaminated drug by the FDA.

pharmacy after it was discovered that there were microorganisms and fungal growth in the facility. The Center for Disease Control and Prevention (“CDC”) in May 2012, found more than 30 cases of fungal endophthalmitis in patients who underwent eye surgery that involved the products distributed by the pharmacy and Brilliant Blue-G was linked to 20 of the cases.³ Endophthalmitis is an eye infection that results in inflammation of the eye and can lead to vision loss and/or the loss of the entire eye.

In this case, thirty-eight claimants who were allegedly treated with contaminated compounds from Franck’s Lab have experienced fungal infections in the eye with complaints of varying degrees of damages, including in some instances blindness.

Evanston Insurance Company, Cincinnati Insurance Company, Those Interested Underwriters at Lloyd’s, London, and American Casualty Company entered into Memorandums of Understanding on behalf to the insureds⁴ memorializing settlement agreements with representatives of the court-appointed Plaintiff’s Steering Committee (“PSC”) regarding the matters, risks and claims asserted in the MDL proceeding. *See* R. Docs. 110; 135; 151; and 229. From May 30, 2014 to May 5, 2015, the insurance carriers deposited funds into the Court’s registry totaling six million four hundred eighty seven thousand three hundred forty nine dollars and ninety five cents (\$6,487,349.95).⁵

³The drug Triamcinolone acetonide was later recalled in March 31, 2012, due to contamination. Similar to Brilliant Blue-G, Triamcinolone acetonide and the combination bevacizumab/triamcinolone acetonide was later determined to have been administered to some of the claimants.

⁴ The insured include Franck’s Lab, Inc., Franck’s Pharmacy, Inc., Franck’s Infusion Pharmacy, Franck’s Home Care LLC and Franck’s Healthy Lifestyles and Franck’s Management LLC

⁵The deposit in the registry was in six amounts: (1) two million five hundred seventy seven thousand three hundred forty nine dollars and ninety five cents (\$2,577,349.95) from Evanston Insurance Company, *see* R. Doc. 111; (2) forty thousand dollars (\$40,000.00) from Evanston Insurance Company and the agreement provided that the PSC, without opposition by Evanston, could move the Court for leave to withdraw the sum listed pursuant to this Court’s order or the Court-appointed Special Master’s guidelines and protocols for the Court-appointed independent

On November 18, 2014, Dr. Turkish, the court-appointed medical expert with a specialty in Ophthalmology Diseases and Surgery of the Vitreous and Retina, submitted a report proposing a classification of the plaintiffs involved in this action. In rendering his decision, Dr. Turkish noted that one of the difficulties presented in evaluating the patients has been the inconsistencies in the medical records supplied. He further noted that the best standard for evaluating a patient's vision is known as best corrected visual acuity, which is the best vision that can be obtained with the best possible spectacle (i.e., glasses correction). Best corrected visual acuity was only available in a minority of patients, whether before or after the incident.

In an attempt to determine the best vision in the records, visual acuity tests were implemented with correction (contact lenses or glasses) and pinhole tests. For those patients who had their best vision with either glasses, contact lenses, a pinhole or glasses with a pinhole, and who subsequently lost vision, the best visual acuity in proximity to the incident was used and Dr. Turkish opined that this method would inure to the benefit of the claimant when determining the loss of vision.

Another group of patients are those who had a best corrected visual acuity after the incident and required the use of an aphakic spectacle correction in the involved eye. An aphakic spectacle is a very thick glass used to provide vision in patients who had undergone cataract surgery before present-day intraocular lenses, which have been in wide use in ophthalmology since the 1970's.

medical expert, *see* R. Docs. 110 and 111; (3) twenty thousand dollars (\$20,000.00) from Evanston Insurance Company, *see* R. Doc. 111; (4) four hundred seventy five thousand dollars (\$475,000.00) from Cincinnati Insurance Company, *see* R. Doc. 136; (5) one million eight hundred seventy five thousand dollars (\$1,875,000.00) from Those Interested Underwriters at Lloyd's, London, *see* R. Doc. 176; and (6) one million five hundred thousand dollars (\$1,500,000.00) from American Casualty Company, *see* R. Doc. 230.

An aphakic spectacle correction can cause image disparity and other distortions such that a patient with relatively good vision in one eye may require an aphakic spectacle in the other eye but may not be able to tolerate it. As a result, Dr. Turkish gave consideration for these patients where they were told by their physicians that they may be unable to have an intraocular lens implanted in the future because of the results of the incident and those who have not yet had the procedure performed since there is no guarantee that in the future the procedure would be able to be performed. Dr. Turkish also noted that these patients may also be fitted with a contact lens; but some of them may not be able to tolerate contact lenses and others who are elderly may be unable to use a contact lens because of physical limitations.

On November 20, 2014, the undersigned conducted a status conference reviewing the report from Dr. Turkish and the documents supporting his analysis of the injuries sustained by the plaintiffs. *See* R. Doc. 187. On December 3, 2014, the undersigned met with Dr. Turkish to evaluate and quantify the degree of damages sustained by each claimant. *Id.* On December 5, 2014, the undersigned issued an Order (R. Doc. 191) directing each individual plaintiff to furnish documentation supporting medical expenses on or before January 5, 2015. After reviewing and evaluating the medical records of the claimants, the medical treatment provided and the expenses of the claimants, the Court issues the following recommendation regarding (1) the allocation method to be used; (2) the claimants who are entitled to participate in the allocation of the Evanston Settlement Fund; and (3) the amount of allocation of the damages to the participating claimants.

II. THE CLAIMANTS

Each of the claimants contend that they suffered injury and damages as a result of receiving a surgical dye compounded by Franck's Lab. The claimants each had pre-existing eye

diseases that included age related macular degeneration, cataracts, macular edema, recurrent macular hole, macular pucker, vein occlusion, and vitreomacular traction secondary to proliferative diabetic retinopathy. In some instances the surgical dye used was easily traceable to the Lab, in other instances the lot number was not easily determined but the circumstances strongly suggest that the condition was caused by the dye. However, in other instances, the absence of the lot number and the lack of identifiable circumstances indicated that the condition and post-surgical interventions were not related to the surgical dye manufactured by Franck's Lab. Below is a summary regarding each claimant that includes the claimant's medical condition, diagnosis and background, organized by pre-existing eye disease.

A. Age Related Macular Degeneration-Diabetic Eye Disease

1. Julian Hendrix ("Hendrix")

Julian Hendrix is a seventy-year-old male and a retired commercial pilot who underwent an injection into the left eye of bevacizumab (lot number DC1113-14) for treatment of age-related macular degeneration. The injection was without complication. His best visual acuity in the records in the left eye in proximity to the injection was 20/30-2 as of January 9, 2012.

Post-operatively his treatment was complicated by the development of endophthalmitis and he underwent one procedure which was a major surgical procedure. A positive culture for Staphylococcus epidermidis was obtained although no positive culture for fungi was obtained. However, the rapid onset of this infection is consistent with a bacterial endophthalmitis. While Dr. Turkish concluded that Hendrix could expect to have the same or better vision following the injection, this finding was subject to his already preexisting age-related macular degeneration.

B. Cataracts

1. Josephine Bienick (“Bienick”)

Josephine Bienick, an eighty-six-year-old female, underwent cataract extraction of her right eye using Brilliant Blue-G (lot number 10102011@136) on November 20, 2011. Bienick’s surgery was without complication. Her best visual acuity in the right eye in proximity to the surgery was 20/30+2 as of October 27, 2011. Because Bienick experienced no complications during the surgical procedure, she could expect the same or better vision following surgery.

Bienick developed endophthalmitis during treatment and she underwent at least four procedures including three major surgical procedures. She took oral voriconazole with no complications noted in the record. A positive fungal culture result was obtained for a *Fusarium* species and the lot number matches with the Brilliant Blue-G that was identified as contaminated from Franck’s Pharmacy. Dr. Turkish concluded that it was more likely than not that Bienick’s endophthalmitis was caused by tainted Brilliant Blue-G obtained from Franck’s Pharmacy.

Bienick’s visual acuity in the right eye was light perception as of April 13, 2012. Her intraocular pressure, which is fluid pressure inside the eye, was zero, which indicates that there is little or no chance of recovery and significant risk of shrinkage of the eyeball. The visual acuity in the left eye, with correction, was 20/20. Based on her medical records, Dr. Turkish concluded it is possible that she may need removal of her right eye in the future.

2. Stephen Fulsom (“Fulsom”)

Stephen Fulsom is a fifty-nine-year-old male employed as a truck driver for Lawson Sanitation who underwent surgery of his left eye for treatment of a cataract on July 30, 2010. He was provided anesthesia by injection of hyaluronidase, a protein enzyme, from Franck’s Pharmacy. Fulsom’s best visual acuity of the left eye in proximity to the surgery was 20/200 as

of July 18, 2010. Cataract surgery, which Fulsom underwent, is a highly successful procedure with a low risk of complications.

Post-Operatively his recovery was complicated by the development of marked swelling that caused damage to the nerve of the left eye, which was the optic nerve. Despite treatment, Fulsom developed atrophy of the nerve of the left eye which Dr. Turkish concluded was more likely than not a reaction to the injection of local anesthetic with hyaluronidase from Franck's Pharmacy.

Fulsom ended up with a visual acuity of the left eye of no light perception as of September 27, 2010 and in the right eye his visual acuity was 20/30-2. Based upon the medical records, there is no chance of recovery of vision in the left eye.

3. Eldon McKinley ("McKinley")

Eldon McKinley is an eighty-two-year-old male who underwent surgery using Brilliant Blue-G (lot number 10102011@136) in his right eye for treatment of a cataract. The surgery was without complication and he could have expected to have the same or better vision following the surgery. McKinley's best visual acuity in the right eye in proximity to the surgery was 20/20 on October 27, 2011.

Post-operatively his treatment was complicated by the development of endophthalmitis and he underwent at least ten procedures including three major surgical procedures. He took oral voriconazole but for only five days. The lot number identified corresponded with the lot number that had fungal contamination from Franck's Pharmacy. Dr. Turkish noted that a positive culture result was not obtained. However, the lot number of the Brilliant Blue-G matched those having fungal contamination and he therefore concluded that it is more likely than not that McKinley's endophthalmitis was caused by tainted Brilliant Blue-G obtained from Franck's lab.

McKinley had visual acuity in the right eye of 20/40 as of May 14, 2014 with an aphakic contact lens and overcorrection. He had elevated pressure in both eyes and in the right eye as well. The impression of the right eye at the time was “open angle glaucoma with borderline findings-low risk” and “glaucoma suspect.” He was taking glaucoma drops once a day in the right eye. He also had a previous history of narrow angle glaucoma in both eyes since 2005. McKinley’s visual acuity in the left eye with correction was 20/25 and later 20/25-1 with no significant vision loss in the non-involved eye.

4. Bernice Tharp (“Tharp”)

Bernice Tharp is an eighty-two-year-old female who for decades was blind with a visual acuity of finger counting only in her left eye. Tharp underwent a surgical procedure to her right eye using Brilliant Blue-G (lot number 10102011@136) on November 8, 2011, for treatment of a cataract. The surgery was without complication.

Her best visual acuity in the records in the right eye in proximity to surgery was 20/60 on November 1, 2011. There were no complications during the surgical procedure and she could have expected to have the same or better vision following surgery according to her medical records.

Post-Operatively her treatment course was complicated by the development of endophthalmitis and she underwent forty-two procedures including three major surgical procedures. She took oral voriconazole. There was no positive culture result obtained but the lot number conformed to the contaminated lot from Franck’s Pharmacy.

Tharp had a visual acuity in the right eye of 20/30-2 on March 27, 2014, with an aphakic correction. She was found to have (1) mild macular edema; (2) epiretinal membrane/macular pucker that was stable; (3) a retinal detachment caused by traction not involving the central

retina that was stable; and (4) glaucoma. The visual acuity in the left eye was only counting fingers at three feet with no significant loss of vision in the non-involved eye from the time of the incident. Vision in her left eye was at this same level when the incident occurred secondary to scarring in the center of the retina in the left eye.

C. Macular Edema

1. Migdalia Aguilar (“Aguilar”)

Migdalia Aguilar is a sixty-one-year-old female that works as an administrative clerk and her duties require her to proof read all correspondence, documents and memos. On December 13, 2011, she underwent a surgical procedure called pars plana vitrectomy with membrane peel in the left eye using Brilliant Blue-G (lot number not available). Aguilar received the surgery to treat her macular edema, which is the swelling of the back of the eye, a disease secondary to diabetic eye disease. The surgical procedure was without complication. As of November 18, 2011, which was prior to the surgery, her best visual acuity in the left eye was 20/40-1.

After the surgery, Aguilar experienced complications as a result of endophthalmitis, an inflammatory condition of the intraocular cavities usually caused by infection. During the treatment of the endophthalmitis, Aguilar underwent at least seven procedures. Some of the procedures Aguilar underwent included, but were not limited to: periocular injections into the tissues around the eye; vitreous taps, which is removal of vitreous gel from the back of the eye to obtain cultures; intravitreal injections, which are injections into the vitreous gel in the posterior portion of the eye; and major surgical procedures such as pars plana vitrectomy, retinal detachment repair, and enucleation.

Aguilar also took oral voriconazole with no indication of any complications secondary to the medication according to the medical records. Her liver enzymes were elevated before she

took the voriconazole but returned to normal in June 2012 and there was no positive culture reported. Dr. Turkish concluded that it was more probable than not that Aguilar's endophthalmitis was caused by the tainted Brilliant Blue-G obtained from Franck's Pharmacy.

Aguilar ended up with visual acuity in her left eye varying from counting fingers on January 18, 2013, to hand motion on January 25, 2013, with no chance of recovery of vision and significant risk of shrinkage of the eyeball. Based on the information available, she is at risk of removal of the left eye. The visual acuity in the right eye was 20/20 on January 18, 2013.

2. Abraham Antenor ("Antenor")

Abraham Antenor is a sixty-four-year-old male and a retired accountant in the Philippines. He was given injections of triamcinolone acetonide (lot number 12192011@189) and bevacizumab into the right eye for treatment of macular edema, secondary to diabetic eye disease, on December 21, 2011. The injections were without complications. He had some degree of diabetic edema before the injection.

Antenor's best visual acuity in the right eye in proximity to the injections was 20/50 on December 21, 2011. Dr. Turkish opined that Antenor could have expected to have the same or better vision following the injections subject to diabetic eye disease.

Post-operatively his treatment was complicated by the development of endophthalmitis and as a result he underwent at least eight procedures including five major surgical procedures related to the treatment. He orally took voriconazole. His liver enzymes were elevated on September 3, 2012, but subsequent medical evaluation did not indicate the presence of complication from the treatment. The specimen from the surgery on July 26, 2012, was positive for fungi and the lot number from the injected triamcinolone acetonide is consistent with specimen identified as having fungal contamination from Franck's Pharmacy. Dr. Turkish

therefore concluded that Antenor's endophthalmitis was more likely than not caused by tainted triamcinolone obtained from Franck's Pharmacy.

Dr. Turkish concluded that based on the records, Antenor may need removal of his right eye in the future. The Court notes, nonetheless, that Antenor's counsel drafted a letter dated September 2, 2014, stating that Antenor had his right eye removed and replaced by an ocular prosthesis. However, counsel's assertion is not supported by proof in the record and the court-appointed medical expert, Dr. Turkish, did not indicate on November 2, 2014, that Antenor's eye was removed.

3. Mercedes Cabrera ("Cabrera")

Mercedes Cabrera, a sixty-two-year-old female, was given an injection into the right eye with bevacizumab/triamcinolone acetonide (lot number DC1129-101) for treatment of macular edema secondary to diabetic eye disease. The injection was without complication. At the time of the procedure, she was studying to become an insurance salesperson. While the course was free she was not able to complete it.

The best visual acuity in the record in her right eye in proximity to the injection was 20/40 and there were no complications during the injection. Cabrera could, according to Dr. Turkish, have the same or better vision following the injection subject to her diabetic eye disease.

Endophthalmitis developed post-operatively and Cabrera underwent at least three additional procedures related to the condition, which included one major surgical procedure. A surgical specimen obtained on March 29, 2012, was positive for the presence of fungi. Dr. Turkish concluded that based on the medical records, this case is more likely than not consistent

with fungal endophthalmitis caused by tainted bevacizumab/triamcinolone acetonide from Franck's Pharmacy.

Cabrera had a visual acuity in the right eye of 20/100 on September 15, 2012, and at that point, the physician's attention turned to treating the diabetic eye disease and macular edema with no evidence of the previously noted endophthalmitis. On August 12, 2013, Cabrera had a visual acuity in the right eye of 20/70-2. Her best visual acuity in the left eye on these dates was 20/40-1 and 20/30-2, respectively.

4. Cristina Caro ("Caro")

Cristina Caro is a fifty-seven-year-old female who was given an injection into the right eye of bevacizumab/triamcinolone acetonide (lot number DC1129-101) for treatment of macular edema, secondary to diabetic eye disease, on January 19, 2012. The injection was without complication. Her best visual acuity in the right eye closest to the injection was 20/50+ as of January 23, 2012. There was some improvement in the visual acuity following the injection and Caro could expect to have the same or better vision following the injection.

Her post-operative course was complicated by the development of endophthalmitis which resulted in Caro undergoing six procedures including one major surgical procedure. Caro took oral voriconazole and on October 27, 2012, she had an elevated liver enzyme. Additional laboratory results were not available in the medical records. Dr. Turkish concluded that Caro's condition is more likely than not consistent with fungal endophthalmitis caused by tainted bevacizumab/triamcinolone acetonide from Franck's Pharmacy.

Caro ended up with a visual acuity of no light perception in her right eye on April 14, 2014. Visual acuity in the left eye, without correction, was 20/80 on that same date. On January

15, 2014, her visual acuity of the left eye without correction and with a pinhole was 20/50+ which is the same as it had been on January 23, 2012.

Dr. Turkish concluded after reviewing her medical records that Caro has no chance of recovery of vision in the right eye. Additionally while the pressure in her eye was not low when she was last seen, there is still a risk that she could experience shrinkage of the right eyeball itself in the future.

5. David Corona (“Corona”)

David Corona is a fifty-two-year-old male who was given injections into the vitreous gel in the posterior portion of the right eye with triamcinolone acetonide (lot number 12192011@189) on January 12, 2012. He was also given bevacizumab for treatment of macular edema and diabetic eye disease. The injections were without complication.

The best visual acuity in the right eye in proximity to the injections was 20/80 as of February 1, 2012. Corona’s vision improved after the injection and since there were no complications during the injections, he could have expected to have the same or better vision following the injections subject to his underlying diabetic disease.

Post-operatively, his treatment was complicated by the development of endophthalmitis which resulted in Corona undergoing nine procedures, including three major surgical procedures. Corona took oral voriconazole and developed hallucinations that may have been secondary to voriconazole. A positive fungal culture was obtained (Bipolaris). The lot number from the injected triamcinolone actinide is consistent with the specimen identified as having fungal contamination from Franck’s Pharmacy. As a result, Dr. Turkish concluded that it is more likely than not that Corona’s endophthalmitis was caused by tainted triamcinolone acetonide obtained from Franck’s Pharmacy.

Corona ended up with a visual acuity in the right eye of 20/200-1 on January 9, 2014, and a visual acuity of no light perception in the left eye, but had significant loss of vision in the non-involved eye prior to the incident.

6. Raul Corrales, Jr. (“Corrales”)

Raul Corrales, a thirty-two-year-old man, underwent a surgical treatment which consisted of an injection of triamcinolone acetonide (lot number 12192011@189) and bevacizumab into the left eye for treatment of macular edema due to diabetic eye disease.

In proximity to the injections, Corrales’s best visual acuity in the left eye was 20/20+3 as of March 8, 2012. His vision improved after the injections and there were no complications such that he could expect to have the same or better vision following the injections subject to diabetic eye disease.

Post-operatively his treatment course was complicated by the development of endophthalmitis and he underwent at least seven procedures including three major surgical procedures. He took oral voriconazole without evidence of complication. A positive fungal culture was not obtained, but the lot number from the injected triamcinolone acetonide is consistent with specimens identified as having fungal contamination from Franck’s Pharmacy. Dr. Turkish concluded that based upon the information received, it is more likely than not that Corrales’s endophthalmitis was caused by tainted triamcinolone acetonide obtained from Franck’s Pharmacy.

Corrales’s visual acuity in the left eye without correction was 20/60 as of March 5, 2013, and in the right eye it was 20/20 with no significant loss of vision in the non-involved eye since the incident. According to the medical records, Corrales will need continued treatment of his diabetic eye disease and macular edema. Corrales will also need continued monitoring for as

long as he takes oral voriconazole, which he was taking orally as of the last medical record dated March 5, 2013.

7. Salvatore Ferrante (“Ferrante”)

Salvatore Ferrante is a seventy-seven-year-old male who was given an injection into the right eye using bevacizumab/triamcinolone acetonide (lot number DC1129-101) for treatment of macular edema, secondary to diabetic eye disease, on February 1, 2012. The injection was without complication.

Ferrante’s best visual acuity in proximity to the injection was 20/25-1 in the right eye as of December 28, 2011. Since there were no complications, following the injections he should have had the same or better vision subject to the underlying diabetic eye disease.

Post-operatively his course of treatment was complicated by the development of endophthalmitis and he underwent three procedures including one major surgical procedure. He also had two laser procedures to the right eye for treatment of diabetic eye disease in September and November 2012. He also took oral voriconazole without evidence of complication. Dr. Turkish concluded that while there is no record of a positive culture, it is more likely than not consistent with fungal endophthalmitis caused by tainted bevacizumab/triamcinolone acetonide from Franck’s Pharmacy.

Ferrante’s visual acuity in his right eye with correction was 20/30 as of November 12, 2013, and in the left eye with correction it was 20/30 with no significant loss of vision in the non-involved eye at the time of the incident. The medical records indicate that Ferrante will need future care in both eyes for diabetic retinopathy only.

8. Ester Gonzalez (“Gonzalez”)

Ester Gonzalez, a sixty-seven-year-old female retired factory worker, was given injections into the right eye of triamcinolone acetonide (lot number 12192011@?) and bevacizumab for treatment of macular edema and diabetic eye disease on January 18, 2012. The next day she was given injections in the left eye using the same medication with the same lot number.

Her best visual acuity in each eye in proximity to the injections on January 18, 2012, was 20/30-2 in the right eye and 20/60-1 in the left eye. There were no complications during the injections and Gonzalez could expect to have the same or better vision following the injections.

Post-operatively her treatment was complicated by the development of endophthalmitis in both eyes and she underwent at least nineteen procedures including five major surgical procedures related to the treatment for the fungal infection. She took voriconazole orally without any report of complications and no laboratory results were submitted with the records. The records indicate that the fungal endophthalmitis was caused by *Bipolaris hawaiiensis*,⁶ but no positive culture results were seen. The lot number from the injected triamcinolone acetonide used in each eye is consistent with specimens identified as having fungal contamination from Franck’s Pharmacy.

Gonzalez ended up with a visual acuity of no light perception in both eyes on December 16, 2013, with no chance of recovery of vision and significant risk of shrinkage of the eyeballs themselves. Based on her medical records, it is possible that she may need removal of both eyes in the future as well as continued monitoring for recurrence of the fungal infection.

⁶*Bipolaris hawaiiensis* is a species of dematiaceous fungi. Medical Dictionary for the Health Professions and Nursing. <http://medical-dictionary.thefreedictionary.com/Bipolaris+hawaiiensis> (last visited June 3, 2015).

9. Pamella Hosang , Ph.D. Nursing (“Dr. Hosang”)

Dr. Pamella Hosang, a seventy-seven-year-old female, was given an injection in the left eye of bevacizumab/triamcinolone acetonide (lot number DC1129-101) for treatment of macular edema, secondary to diabetic eye disease. The injection was without complication.

Dr. Hosang’s best visual acuity in proximity to the injection for the left eye was 20/30-1 on January 11, 2012. Therefore, following the injections she could have expected to have the same or better vision subject to the underlying diabetic eye disease.

Post-operatively her treatment was complicated by the development of endophthalmitis and she underwent at least eight procedures including two major surgical procedures. She also took oral voriconazole for a short time. The records do not report an elevation of Dr. Hosang’s liver enzymes. However, Dr. Hosang’s blood urea nitrogen (“BUN”), which is a measure of kidney function, was slightly elevated, but the cause of this condition was not determined. Her creatinine, another measure of kidney function, remained within normal limits but no follow up laboratory results were available. Also, a positive culture for *Exserohilum*⁷ species was obtained.

Dr. Turkish concluded that Dr. Hosang’s case is more likely than not consistent with fungal endophthalmitis caused by tainted bevacizumab/triamcinolone acetonide from Franck’s lab.

⁷ *Exserohilum* is a common mold that is found in soil and on plants, especially grasses. Additionally, *Exserohilum* thrives in warm and humid climates. *Exserohilum* is a very rare cause of infection in people, and has been connected to causing infections in the skin or the cornea, which are typically due to skin or eye trauma. Center for Disease Control and Prevention, <http://www.cdc.gov/fungal/diseases/other/exserohilum.html> (last visited June 3, 2015).

10. Levon Jingoian (“Jingoian”)

Levon Jingoian, a sixty-nine-year-old male, was given injections into the left eye of triamcinolone acetonide (partial lot number 1219201) and bevacizumab for treatment of macular edema and diabetic eye disease. The injections were without complication.

His best visual acuity in the left eye, with correction, in proximity to the injections was 20/30 on January 10, 2012. Jingoian could have expected to have the same or better vision following the injections.

Post-operatively his treatment course was complicated by the development of endophthalmitis and he underwent at least nine procedures including one major surgical procedure. He also took oral voriconazole without indication that there were complications. Although no positive fungal culture was obtain, Dr. Turkish found that the presumed lot number from the injected triamcinolone acetonide was consistent with specimens identified as having fungal contamination from Franck’s Pharmacy.

Jingoian ended up with a visual acuity in his left eye of 20/200-1 with correction as of December 11, 2013. There was also no clinical evidence of infection on that date. Atrophy of the nerve in the back of the left eye (optic nerve) was present. He continued on oral voriconazole. His visual acuity in the right eye was 20/40-2, with correction it was 20/40-2 as of December 11, 2013.

When he was last seen, he continued to be followed for recurrence of infection and problems related to the oral voriconazole. He would also need to be followed for his preexisting diabetic eye disease and associated macular edema.

11. Adolfo Lemus-Gonzalez (“Lemus-Gonzalez”)

Adolfo Lemus-Gonzales, a sixty-two-year-old man, was given injections into the right eye with triamcinolone acetonide (lot number 12192011@189) and bevacizumab for treatment of macular edema, secondary to diabetic eye disease. The injections were without complications and he could have expected to have the same or better vision following the injections subject to his underlying diabetic eye disease.

His best visual acuity in the right eye in proximity to the injections was counting fingers as of January 17, 2012. Post-operatively his treatment course was complicated by the development of endophthalmitis and he underwent at least eighteen procedures including one major surgical procedure. He also took oral voriconazole.

Lemus-Gonzales had a transient elevation of one of his liver enzymes in September 2012 which may or may not have been related to the oral voriconazole. Dr. Small noted in a report that a specimen obtain on April 20, 2012, was “positive for mold” and the lot number from the injected triamcinolone acetonide is consistent with specimens identified as having fungal contamination from Franck’s Pharmacy.

He ended up with a visual acuity in the right eye of 20/70 as of December 12, 2013, significantly improved from the pre-incident visual acuity of counting fingers, with “no evidence of infection.” Visual acuity in the left eye was 20/80 on December 13, 2013, with some decrease in vision in the non-involved eye since the incident, probably secondary to diabetic eye disease. He also had surgical procedures on the left eye out of fear that this eye would also get an infection even though he was informed that the vial of triamcinolone acetonide used for the left eye was not a contaminated vial. According to Dr. Turkish, based on the medical records, Lemus-Gonzalez will need continued treatment of his diabetic eye disease and macular edema.

12. Robert Magnet (“Magnet”)

Robert Magnet is a fifty-five-year-old male who works as a professional lighting designer who was given injections of triamcinolone acetonide (partial lot numbers 12192011@189 and ??192011@190) into his right eye for treatment of macular edema, secondary to diabetic eye disease. Magnet had a previous knife injury to the right eye, corneal scarring, aphakia and previous retinal detachment. The injections were without complication and he could have expected to have the same or better vision following the injections. Magnet’s best visual acuity in proximity to the injections was 20/200 in the right eye as of October 13, 2011.

Post-operatively his treatment was complicated by the development of endophthalmitis which resulted in at least thirteen procedures including three major surgical procedures. He took voriconazole orally which resulted in transient elevation of his liver enzymes that later returned to normal once he discontinued treatment of the voriconazole. While a positive culture result was not obtained, the partial lot number suggests that the specimen was contaminated and was from Franck’s Pharmacy.

On August 1, 2012, Magnet had to have his right eye removed. The visual acuity in the left eye, without correction, was 20/30-1 on September 23, 2013, with no significant loss of vision in the non-involved eye at the time of the incident.

13. Ricardo Medina (“Medina”)

Ricardo Medina, a fifty-seven-year-old male, was given an injection into the right eye using bevacizumab/triamcinolone acetonide (lot number DC1129-101) for treatment of macular edema, secondary to diabetic eye disease. The injection was successful and he could have expected to have the same or better vision following the injection except for his continued care for preexisting glaucoma and diabetic eye disease.

Medina's best visual acuity in the right eye, with correction, in proximity to the injection was 20/200-1. Post-operatively his treatment course was complicated by the development of inflammation in the right eye and fungal infection was suspected. He was started on oral voriconazole and had one major surgical procedure that did not appear related to the endophthalmitis. No culture was taken and no injections of antibiotics or antifungal agents were given. More likely than not Medina may have a mild case of fungal endophthalmitis caused by tainted surgical dye.

Medina ended up with a visual acuity in his right eye, with correction, of 20/400 and 20/30 in the left eye with correction. At the final visit included in the records, he was no longer receiving oral voriconazole or any other treatment relating to infection.

14. Pedro Ortiz ("Ortiz")

Pedro Ortiz is a sixty-four-year-old male who received an injection into the left eye of bevacizumab/triamcinolone acetonide (lot number not available) for treatment of macular edema secondary to diabetic eye disease. Since no injection complications were noted, he could have expected to have the same or better vision following injection limited by his underlying diabetic eye disease.

Ortiz's best visual acuity in the left eye, without correction, in proximity to the injection was 20/80. His visual acuity improved following the injection. Post operatively his treatment was complicated by the development of endophthalmitis and he had multiple procedures and one major surgical procedure. Culture results were not obtained but his treating physician Dr. Cohen was identified by the FDA as a physician who received tainted medications from Franck's Pharmacy such that his condition was likely caused by tainted dye.

Ortiz ended up with a visual acuity of light perception in the left eye on December 3, 2012, and visual acuity in the right eye, without correction, was 20/40. Based on his medical records it is possible that he may need removal of his left eye in the future.

15. Hyacinth Powell (“Powell”)

Hyacinth Powell is a sixty-five-year-old female who received an injection into the left eye of bevacizumab/triamcinolone acetonide (lot number DC1129-101) for treatment of macular edema secondary to diabetic eye disease on January 12, 2012. Powell’s best visual acuity in proximity to the injection was 20/40 in the left eye on January 4, 2012. Since there were no complications during the injection and she could have expected to have the same or better vision following the injection.

Post-operatively her treatment course was complicated by the development of endophthalmitis which resulted in at least eight procedures including three major surgical procedures. She also had one laser procedure to the left eye for treatment of diabetic eye disease on February 1, 2012.

Powell was prescribed voriconazole without evidence of complications and a positive fungal culture for *Exserohilum* species was obtained, which is more likely than not consistent with fungal endophthalmitis caused by tainted bevacizumab/triamcinolone acetonide from Franck’s Pharmacy.

She ended up having a visual acuity of no light perception in her left eye on May 2, 2014, with no chance of recovery and significant risk of shrinkage of the eyeball. Based on the medical records, Powell may need removal of her left eye in the future. Visual acuity in the right eye was 20/25-1, with correction.

16. Roy Romero (“Romero”)

Roy Romero is a sixty-four-year-old male who received an injection into the left eye of triamcinolone acetonide (partial lot number 12192011@1??) for treatment of macular edema secondary to diabetic eye disease. Romero’s best visual acuity in proximity to the injection was 20/40 in the left eye. There were no complications during the injection and as a result, Romero could have expected to have the same or better vision following the injection.

Post-operatively the treatment course was complicated by the development of endophthalmitis and he underwent at least nine procedures including seven major surgical procedures. Cultures were positive for fungi and following removal of the eye, the fungus was consistent with *Bipolaris hawaiiense* with no evidence of spread outside the eye.

The partial lot number was consistent with specimen identified having fungal contamination from Franck’s Pharmacy such that his endophthalmitis was more likely than not caused by tainted triamcinolone acetonide obtained from Franck’s Pharmacy.

Romero had his left eye removed on September 27, 2012, and will need routine maintenance on the prosthetic. In the right eye, he had a visual acuity, with correction, of 20/25+2 on April 5, 2012.

17. Nicholas Scunziano (“Scuniziano”)

Nicholas Scunziano is a seventy-two-year-old male who received an injection into the right eye of bevacizumab (lot number AG1124-7) for treatment of macular edema secondary to diabetic eye disease. The injection was without complication and he could have expected to have the same or better vision following the injection subject to the underlying diabetic eye disease.

Post-operatively his treatment course was complicated by the development of endophthalmitis, retinal detachment, and infection involving the scleral buckle. As a result of the infections, he underwent at least six procedures including three major surgical procedures. A positive culture for *Citrobacter koseri* was obtained and no positive culture for fungi was obtained. The rapid onset of his infection was consistent with a bacterial endophthalmitis.

The cause of the infection may not have been directly related to bevacizumab and could have occurred as a result of the injection procedure itself. The Root-Cause Report of the FDA did not list bevacizumab (Avastin) as one of the contaminated products from Franck's Pharmacy.

Scunziano ended up with a visual acuity in the right eye of 20/50-3 with an aphakic correction and without the aphakic correction in the range of counting fingers to 20/200. Scunziano's final visual acuity, with correction, in the left eye was 20/30 with no significant loss of vision in the non-involved eye since the time of the incident. The medical records suggest that it is possible that he may need a secondary intraocular lens implantation or an aphakic contact lens in the right eye because his cataract was removed as part of the treatment for his infection. He will also need continued treatment for his preexisting eye disease.

D. Macular Hole

1. Cheryl Avakian ("Avakian")

Cheryl Avakian, an eighty-five-year-old woman, underwent surgery in her right eye using Brilliant Blue-G (lot number not available) for treatment of a recurrent macular hole on November 30, 2011. The surgery was without complication.

Avakian's best visual acuity in the right eye in proximity to the surgery was 20/80+2 on November 22, 2011. She could have expected to have the same or better vision following surgery. Post-operatively her treatment was complicated by the development of endophthalmitis

and she underwent at least four procedures including three major surgical procedures. While there is no positive culture indicated in the records and no lot number was available for the Brilliant Blue-G, Dr. Turkish concluded that it is more likely than not responsible for the endophthalmitis.

Avakian ended up with a visual acuity of 20/200 in the right eye on October 25, 2012, and in her left eye it was 20/30 with no significant loss of vision in the non-involved eye at the time of the incident. The records did not indicate whether these visions were taken with or without corrective lenses.

2. Brenda Hess (“Hess”)

Brenda Hess, is a sixty-nine-year-old female who underwent surgery of her right eye for treatment of a macular hole using Brilliant Blue-G (lot number not available) on November 22, 2011. Her best visual acuity in the right eye in proximity to the surgery was 20/60 with correction as of November 30, 2011. Her vision improved after the surgery and she could have expected to have the same or better vision following surgery.

Post-operatively her course of treatment was complicated by the development of endophthalmitis and she underwent at least six procedures including three major surgical procedures. A positive culture for a *Fusarium* species was obtained from the specimen from surgery on January 24, 2012, as well as a positive bacterial culture. A second positive culture for a *Fusarium* species was obtained from the specimen from her surgery on March 8, 2012. It is therefore more likely than not consistent with fungal endophthalmitis caused by Brilliant Blue-G from Franck’s Pharmacy.

Hess ended up with a visual acuity in the right eye of counting fingers as of December 13, 2013, and a visual acuity in the left eye of 20/25-1, with correction, as of November 30,

2011. Her right eye appeared to be stable at the time of the most recent evaluation and eye pressure was not low in the right eye. Additionally, the retina was in place in her right eye.

3. James D. Johnson, Jr. (“Johnson”)

James Johnson, a sixty-eight-year-old male, underwent surgery of his right eye for treatment of a macular hole using Brilliant Blue-G (lot number 10112011@82) on November 28, 2011. The surgery was without complication. His best visual acuity in the right eye in proximity to the surgery was 20/80-2 as of November 10, 2011, and he could have expected to have the same or better vision following surgery.

Post-operatively his course of treatment was complicated by the development of endophthalmitis and he underwent at least ten procedures including three major surgical procedures. He took oral voriconazole and his liver enzymes were elevated on the last laboratory records. He obtained a follow up liver function test thereafter which indicated that he may have had pre-existing liver disease before using the voriconazole. No positive culture was obtained but the lot number was consistent with specimen identified to have fungal contamination from Franck’s Pharmacy. Dr. Turkish found that it is more likely than not that Johnson’s endophthalmitis was caused by tainted Brilliant Blue-G obtained from Franck’s Pharmacy.

Johnson’s final visual acuity in his right eye was 20/50- on July 11, 2013, and he maintained that visual acuity as of August 13, 2014. His visual acuity with correction in the left eye was 20/20 as of July 11, 2013, with no significant loss of vision in the non-involved eye at the time of the incident. Based on his medical records, it is recommended that in the future he have a secondary intraocular lens implant in the right eye because his intraocular lens had to be removed for his treatment.

4. Michele Laventhal (“Laventhal”)

Michele Laventhal, a sixty-three-year-old female, underwent surgery using Brilliant Blue-G (10112011@82) in her right eye for treatment of a macular hole. Her best visual acuity in the right eye in proximity to the surgery was 20/70-2 as of November 4, 2011. Surgery was without complication and she could have expected to have the same or better vision following surgery.

Post-operatively her treatment course was complicated by the development of endophthalmitis and she underwent at least twenty-six procedures including three major surgical procedures. She did not take oral voriconazole because she was undergoing treatment for lung cancer. A positive culture result was not identified in the records, but the lot number for the Brilliant Blue-G is consistent with specimens identified to have fungal contamination from Franck’s Pharmacy.

Laventhal ended up with a visual acuity of light perception in the right eye as of February 7, 2013. The pressure inside the right eye was so low it could not be measured, indicating that there is no chance of recovery of her vision and significant risk of shrinkage of the eyeball itself. Based upon Laventhal’s treatment records, it is possible that she will need removal of her right eye in the future.

5. Howard McMaster (“McMaster”)

Howard McMaster is a seventy-eight-year-old male who underwent surgery using Brilliant Blue-G (lot number not available) in his left eye for treatment of a macular hole. McMaster’s best visual acuity in the left eye, with correction, in proximity to the surgery was 20/70-2 on November 2, 2011. McMaster’s surgery was without complication and he could have expected to have the same or better vision following surgery.

Post-operatively McMaster's treatment was complicated by the development of endophthalmitis and he underwent at least six procedures including one major surgical procedure. A positive culture was not identified but his doctor was listed in the FDA documents as one of the physicians who received tainted surgical dye. Dr. Turkish concluded that this case is more likely than not consistent with fungal endophthalmitis caused by tainted Brilliant Blue-G from Franck's Pharmacy.

McMaster ended up with a visual acuity of no light perception in the left eye on August 15, 2013. The intraocular pressure, which is fluid pressure inside the eye, was zero in the left eye indicating that there was no chance of recovery of vision and significant risk of shrinkage of the eyeball itself. McMaster's acuity in the right eye, with correction, was 20/200 with decreased vision in the non-involved right eye from age-related macular degeneration, diabetic eye disease and optic atrophy, which is atrophy of the optic nerve in the back of the eye. McMaster may also need removal of his left eye in the future.

E. Macular Pucker/Epiretinal Membrane

1. Randy Brown ("Brown")

Randy Brown, a sixty-one-year-old male, is reported to have undergone surgery using Brilliant Blue-G (lot number not available) in his left eye for treatment of macular pucker/epiretinal membrane. The surgery was without complication. His best visual acuity in the left eye in proximity to the surgery was 20/40-2. Since there were no complications during the surgical procedure, he could have expected to have the same or better vision following surgery.

Post-operatively, endophthalmitis developed for which he underwent six procedures including four major surgical procedures. He took oral voriconazole with no indication of complications secondary to the oral voriconazole. A positive culture was not obtained and nor

was a lot number available, however, Dr. Turkish concluded that based upon the statement of Dr. Crews, Brown's case was consistent with fungal endophthalmitis caused by tainted Brilliant Blue-G from Franck's Pharmacy.

Brown ended up with a visual acuity of counting fingers in his left eye on October 8, 2013, and a best visual acuity in the right eye of 20/40. Based on the medical records, he will need continued treatment for inflammation in the left eye and follow-up evaluations of his retinal detachment following surgeries to treat the detachment on May 16, 2012, and July 18, 2012.

2. Corinne Child ("Child")

Corinne Child is a fifty-five-year-old female who underwent surgery on December 22, 2011, with Brilliant Blue-G in her right eye for treatment of macular pucker/epiretinal membrane, an irregularity of the surface of the retina caused by tissue on the surface of the retina. The operative report and lot number were not included in the records sent for review.

The best visual acuity in her right eye closest to the surgery was 20/40+1 on November 3, 2011. The post-operative records did not indicate that there were complications during the surgical procedure; therefore she could have expected to have the same or better vision following the surgery.

Her post-operative course was complicated by the development of inflammation in the right eye that was treated with a topical steroid which resolved the inflammation. Medical notes on Child indicate that the post-operative inflammation was possibly related to surgical dye used although it was resolved by the topical therapy alone. Further medical notes indicate that the inflammation was "unlikely" a fungal infection because inflammation occurs after surgical procedures without the presence of infection. Consequently, Dr. Turkish concluded that Child's

case was more likely than not a result of noninfectious inflammation rather than an infectious inflammation.

Child ended up with a visual acuity of the right eye, with correction, of 20/30 on March 28, 2013. Her visual acuity in the left eye, with correction was 20/30+1 as of March 20, 2013. Dr. Turkish concluded that Child required no continued treatment of the post-operative inflammation in the right eye

3. Joseph Cotugno (“Cotugno”)

Joseph Cotugno is a seventy-five-year-old machinist who retired from the Los Angeles Unified School District. He underwent surgery using Brilliant Blue-G (lot number not available) in his right eye for treatment of macular pucker. The surgery was without complications and he could have expected to have the same or better vision following surgery. His best visual acuity in proximity to the surgery was 20/40 according to a summary prepared by Dr. Michael Samuel, his personal doctor.

The post-operative course was complicated by the development of endophthalmitis. At first, Cotugno was noted to have inflammatory change on December 30, 2011, and the diagnosis of the fungal endophthalmitis occurred on February 17, 2012. He underwent five procedures, including three major surgical procedures. A positive culture was not reported. Based on the information received, Dr. Turkish concluded that it is more likely than not that Cotugno’s endophthalmitis was caused by tainted Brilliant Blue-G obtained from Franck’s Pharmacy.

Cotugno ended up with a visual acuity of hand motion in his right eye on July 17, 2013, with no chance of improvement. The records did not provide information regarding the status of the left eye which was the non-involved eye.

4. Barbara Farnsworth (“Farnsworth”)

Barbara Farnsworth, a sixty-nine-year-old female, underwent surgery in her right eye for treatment of macular pucker using Brilliant Blue-G (lot number not available). The surgery was without complication.

Farnsworth’s best visual acuity in the right eye in proximity to the surgery was 20/30 as of October 19, 2011, and her distance acuity was 20/200 without correction. Her distance visual acuity of the right eye was 20/80-1 as of November 29, 2011. Farnsworth uses monovision, which is the use of a contact lens for near vision on one eye, and if needed, a lens for distance vision on the other eye. The surgery was without complication such that Farnsworth could have expected to have the same or better vision following the surgery.

Post-operatively her treatment course was complicated by the development of endophthalmitis and she underwent one major surgical procedure. A positive culture was not obtained but she responded to treatment with virectomy and injections of antibiotics into the eye without the use of antifungal agents. As a result of the treatment she received, the endophthalmitis was most probably not caused by a fungal infection.

However, Dr. Turkish noted that Dr. Friedlander is identified as a FDA physician who received tainted Brilliant Blue-G from Franck’s Pharmacy. Therefore based upon the timing of the occurrence, Dr. Turkish concluded that it is more likely than not that tainted Brilliant Blue-G was responsible for the endophthalmitis even if the causative organism was not fungal in nature.

On May 18, 2012, Fansworth ended up with a visual acuity of 20/60-2 in the right eye, without correction, with a pinhole, and 20/20 in the left eye, without correction, with a pinhole. She had no significant loss of vision in the non-involved eye at the time of the incident.

5. Jim Hermanson (“Hermanson”)

Jim Hermanson, a seventy-two-year-old male, underwent surgery using Brilliant Blue-G (lot number not available) in his left eye for treatment of macular pucker/epiretinal membrane. The surgery was without complication. Hermanson’s best visual acuity in the left eye in proximity to the surgery was 20/40-2 as of December 2, 2011. He could have expected to have the same or better vision following surgery.

Post-operatively his treatment course was complicated by the development of endophthalmitis which resulted in an initial diagnosis of inflammation on December 30, 2011, and ultimately a diagnosis of fungal endophthalmitis on February 17, 2012. He underwent at least six procedures including two major surgical procedures and took oral voriconazole without evidence of complication. A positive culture result was not obtained but his case was more likely than not consistent with fungal endophthalmitis caused by tainted Brilliant Blue-G according to Dr. Turkish.

On October 24, 2013, Hermanson’s final visual acuity in his left eye was of no light perception, with no chance of recovery and significant risk of shrinkage of the eyeball. In the right eye, his visual acuity was 20/20, with correction. Based on the medical records, it is possible that he will need his left eye removed in the future.

6. Susan Kappelman (“Kappelman”)

Susan Kappelman is a sixty-three-year-old female who underwent surgery using Brilliant Blue-G (lot number not available) in her right eye for treatment of macular pucker/epiretinal membrane. The surgery was without complication. Her best visual acuity in the right eye, without correction, in proximity to the surgery was 20/40-2 as of November 29, 2011. Her

vision improved following surgery and she could have expected to have the same or better vision following the surgery.

Post-operatively her treatment was complicated by the development of endophthalmitis and she underwent thirteen procedures including six major surgical procedures. A positive fungal culture for a *Fusarium* species was obtained, which suggests that the case is more likely than not consistent with fungal endophthalmitis caused by tainted Brilliant Blue-G from Franck's Pharmacy.

Kappelman ended up with a visual acuity of counting fingers in the right eye on April 16, 2012, with low pressure inside the eye and a number of other problems that indicate that there is no chance of recovery of vision and significant risk of shrinkage of the eyeball. Based on the medical records she will need removal of her right eye in the future. Visual acuity in the left eye, without correction, was 20/20.

7. Natividad Lopez (“Lopez”)

Natividad Lopez, a sixty-nine-year-old female, underwent surgery in the right eye using Brilliant Blue-G (lot number not available) for treatment of macular pucker/epiretinal membrane, blood in the eye secondary to diabetic eye disease and vitreous traction. Surgery was without complication. Her best visual acuity in the right eye in proximity to the surgery was 20/70-2 as of November 8, 2011. Since there were no complications during the surgical procedure, Lopez could have expected to have the same or better condition as a result of the surgery subject to the underlying condition.

Post-operatively Lopez's treatment course was complicated by the development of endophthalmitis and she underwent at least five procedures including two major surgical procedures. Lopez also took oral voriconazole with transient elevation of liver enzymes which

were within normal limits on April 10, 2012, with no evidence of persistent sequelae from the use of voriconazole. Although a positive culture result was not obtained, Dr. Turkish concluded that this case is more likely than not consistent with fungal endophthalmitis caused by tainted Brilliant Blue-G from Franck's Pharmacy.

Lopez ended up with a visual acuity of no light perception in the right eye on November 22, 2013, with no chance of recovery. Based on the medical records, Dr. Turkish indicates that she may have had her right eye removed because she was referred to Dr. Alice for removal of the eye on October 9, 2013, but no records indicate the procedure was performed. Visual acuity in the left eye, with correction, was 20/100 on November 22, 2013.

F. Vein Occlusion

1. Ema Arakelian ("Arakelian")

Ema Arakelian, a seventy-two-year-old female, was given injections of triamcinolone acetonide (lot number 12192011@189) in the back of the left eye for treatment of macular edema secondary to vein occlusion, which is compromised circulation in the retina.

Arakelian's best visual acuity in the left eye in proximity to the injections was 20/50 on January 11, 2012. There were no complications and Arakelian could have expected to have the same or better vision following the injections.

Post-operatively her treatment was complicated by the development of endophthalmitis and Arakelian underwent at least thirteen procedures including four major surgical procedures related to treatment. Arakelian took oral voriconazole without evidence of complication. A positive fungal culture was obtained. The lot number from the injected triamcinolone acetonide is consistent with specimen identified as having fungal contamination from Franck's Pharmacy.

Dr. Turkish concluded that Arakelian's endophthalmitis was more likely than not caused by tainted triamcinolone acetonide obtained from Franck's Pharmacy.

Arakelian ended up having her left eye removed on October 3, 2012. In the right eye, her best visual acuity was 20/60 on July 10, 2013, with no significant loss of vision in the non-involved eye at the time of the incident.

2. Arnulfo Gonzalez ("Gonzalez")

Arnulfo Gonzalez, a sixty-three-year-old male, was given injections of triamcinolone acetonide (lot number 12192011@189) and bevacizumab into the right eye for treatment of macular edema, secondary to vein occlusion. The injections were without complication. Gonzalez's best visual acuity in the right eye in proximity to the injections was 20/100 on January 31, 2012. Gonzalez could have expected to have the same or better vision following the injections subject to his vein occlusion.

Post-operatively his treatment was complicated by the development of endophthalmitis and Gonzalez underwent at least fourteen procedures including seven major procedures. He orally took voriconazole and he had a transient elevation of his liver enzymes which returned to normal range with no other evidence of complications from the oral voriconazole.

Although a positive fungal culture was not obtained, the presumed lot number from the injected triamcinolone acetonide is consistent with specimens identified as having fungal contamination from Franck's Pharmacy. Dr. Turkish concluded that it is more likely than not that the endophthalmitis was caused by tainted triamcinolone acetonide obtained from Franck's Pharmacy.

Gonzalez ended up having his right eye removed on May 15, 2013. The visual acuity in the left eye, with correction, was 20/25-1 as of February 3, 2014, with no significant loss of

vision in the non-involved eye. The medical records further suggest that Gonzalez will need care for his prosthesis in the right eye and also continue to need follow-ups as long as he is taking oral voriconazole.

3. Sergio Hambav (“Hambav”)

Sergio Hambav a seventy-two-year-old male was given injections into the left eye of triamcinolone acetonide (lot number 12192011@189) and bevacizumab for treatment of macular edema, secondary to vein occlusion. The injections were without complication.

Hambav’s best visual acuity in the left eye, without correction, in proximity to the injections was 20/60 as of January 31, 2012, and his vision improved after the injections. He could have expected to have the same or better vision following the injections subject to his preexisting conditions.

Post-operatively Hambav’s treatment was complicated by the development of endophthalmitis which resulted in at least six procedures including three major surgical procedures related to treatment of the condition. He took oral voriconazole which was discontinued secondary to the development of headaches. There were no lasting complications from use of oral voriconazole noted in the records. The surgical specimen stains were positive for fungal organisms as of April 17, 2012, and the pathology report following removal of the left eye on July 23, 2012, also indicated the presence of fungal organisms and Hambav’s endophthalmitis was more likely than not caused by tainted triamcinolone acetonide from Franck’s Pharmacy.

Prior to the removal of the left eye, Hambav complained of extreme pain and indicated improvement of the pain following the removal. Visual acuity in the right eye was 20/20 on October 11, 2012.

G. Vitreomacular Traction

1. Ruth Smith (“Smith”)

Ruth Smith is a sixty-one-year-old female who underwent surgery on November 21, 2011, in her right eye using Brilliant Blue-G (lot number not available) for treatment of vitreomacular traction, secondary to proliferative diabetic retinopathy. Her best visual acuity in the right eye in proximity to the surgery was 20/400 on November 15, 2011. Since there were no complications, she could have expected to have the same or better vision subject to her preexisting diabetic retinopathy.

Post-operatively her treatment course was complicated by the development of endophthalmitis and she underwent at least eleven procedures including one major surgical procedure. She also took voriconazole without evidence of long-lasting complication. A positive PCR for *Fusarium equiseti* was obtained from the University of Washington in Seattle, which more likely than not was consistent with endophthalmitis caused by tainted Brilliant Blue-G from Franck’s Pharmacy.

Smith ended up with a visual acuity of no light perception in her right eye on February 28, 2013, with no chance for recovery and significant risk of shrinkage of the eyeball. She complained of pain in the right eye when she was seen in January 2013 and stated that she wanted to “poke it out.” Based on the medical records, it is possible that she may need her right eye removed in the future. Her visual acuity in the left eye was 20/200 on February 28, 2013.

III. ALLOCATION PROTOCOL

In connection with assessing the claim, the undersigned is responsible for developing a method for the allocation of the settlement funds which have been placed in the registry of the Court. *See* R. Doc. 114. Dr. Turkish, the expert retained by the PSC, prepared two charts to

determine the appropriate allocation of damages. The first chart presents each claimant's description, medical condition, and the clinical outcomes. The second chart compares the claimants to one another. He then developed a point system that proposed an allocation based upon the severity of the damages sustained.

The points have no monetary value but is an attempt to distinguish between the damages and the pain and suffering each patient experienced. For example, the loss of an eye is worth 250,000 points while having a minor surgery is worth 5,000 points. The maximum points that any patient could get is 950,000, subject to the addition of points for each procedure a patient had, which amounts to additional pain and suffering.

Under Dr. Turkish's proposed allocation process, loss or removal of an eye is allocated 250,000 points; risk of loss or removal of an eye is allocated 225,000 points; and best visual acuity before the incident in the non-involved eye of less than or equal to 20/200⁸ with loss of vision in the involved eye to 20/200 or less is allocated 300,000 points. Claimants who had loss of vision in the non-involved eye before the incident of less than or equal to 20/200 with loss of vision in the involved eye of less than or equal to 20/400⁹ are allocated 25,000 points. Claimants whose visual acuity before the incident in the non-involved eye was less than or equal to 20/200 and no loss of vision in the involved eye are allocated 25,000 points. Claimants whose visual acuity in the non-involved eye before the incident was 20/40 with loss of vision in the involved eye of 20/200 are allocated 100,000 points.

⁸20/200 vision means that your best distance with eyeglass or contact lenses is 20/200 or worse and considered "legally blind." Liz Segre, *Eye Testing - The Eye Chart and 20/20 Vision*, All About Vision, <http://www.allaboutvision.com/eye-test/> (last visited May 12, 2015).

⁹20/200 to 20/400 is considered severe visual impairment, or severe low **vision**. 20/500 to 20/1,000 is considered profound visual impairment, or profound low vision. Less than 20/1,000 is considered near-total visual impairment, or near total blindness. American Optometric Association, <http://www.aoa.org/patients-and-public/caring-for-your-vision/low-vision?sso=y> (last visited May 12, 2015).

For each major surgical procedure, the claimants were allocated 15,000 points. Claimants who had minor surgical procedures were allocated 5,000 points. Claimants who sustained a loss of vision from the best recorded visual acuity in the involved eye in proximity to the incident, excluding patients who lost their eye or are at risk of losing the involved eye from 20/40¹⁰ or better to less than or equal to 20/800,¹¹ are allocated 175,000 points.

Claimants whose loss of vision from the best recorded visual acuity in the involved eye in proximity to the incident excluding those claimants who are at risk of loss of the involved eye from 20/40 but greater than 20/200 are allocated 150,000 points. Claimants who sustained a loss of vision excluding those patients who lost the involved eye or are at risk of losing the involved eye from 20/40 but greater than 20/200 are allocated 75,000 points. Claimants whose best visual acuity loss vision, excluding those who have lost involved eye from less than 20/40 and greater than 20/200 to less than or equal to 20/200, are allocated 100,000 points.

Claimants who lost vision, excluding patients who lost vision in the involved eye or are at risk of loss of the involved eye or are at risk of loss of the involved eye from less than 20/40 and greater than 20/200 to less than or equal to 20/800, are allocated 125,000 points. Claimants who sustained a loss of vision and whose best visual acuity in the involved eye in proximity to the incident, excluding patients who have lost the involved eye or are at risk of loss of the involved eye from 20/200 to less than or equal to 20/800, are allocated 50,000 points.

¹⁰20/40 vision means that the test subject sees at 20 feet what a normal person sees at 40 feet. This applies that the test subject has poorer vision and must come closer the object before he can see well. *What Does 20-20 Vision Mean?*, Sky Vision Centers Blog, <http://skyvisioncenters.com/what-does-20-20-vision-mean/> (last visited May 12, 2015).

¹¹20/800 is the ability to see a blur or glare. Seriously impaired, but still with travel vision and reduced but useful object vision. People in this group can read with low-vision aids. *The Seven Steps of the Visual Scale*, Blind World Magazine (Aug. 3, 2006), <http://www.home.earthlink.net/~blindworld/NEWS/6-08-30-01.htm>

Claimants who lost vision following cataract surgery that should have resulted in the return of vision without underlying eye disease are allotted 25,000 points. Claimants who lost vision following surgery of macular pucker/epiretinal membrane or repair of macular hole, which could have resulted in improvement of vision without the underlying eye disease are allocated 12,500 points. Claimants whose pending surgical procedures at the time of the last medical records received related to the incident, excluding possible removal of the eye, but had major surgical procedures are allocated 10,000 points. Claimants whose pending surgical procedures at the time of the last medical records received related to the incident for which a minor procedure was performed are allocated 5,000 points.

Claimants who had ongoing eye disease in the non-involved eye that has the possibility to result in significant loss of vision in the future were allocated 25,000 points. Claimants who had aphakia in the involved eye that cannot or has not yet had a secondary intraocular lens implanted were allocated 35,000 points. Claimants who experienced bilateral vision loss less than 20/400 in both eyes from two involved eyes are allocated 400,000 points.

Considering the proposed system, the Court finds that the damages shall be apportioned by a ratio of the points per claimant divided by the total of all points for all claimants multiplied by the total funds in the registry of the Court.¹² Having set forth the points system recommended by Dr. Turkish and the damage apportionment formula utilized by the Court, the Court will proceed with describing the total points for each claimant and then apportion the damages.

¹²The equation is as follows: $\text{Points per claimant} / 10,577,500 * \$6,487,349.95 = \text{Claimant's general damages}$. $10,577,500 = \text{Total Points Available}$ and $\$6,487,349.95 = \text{Total Funds deposited into the Court's Registry}$.

IV. POINTS ALLOCATED PER CLAIMANT AND APPORTIONMENT OF DAMAGES

A. Five claimants experienced a loss of an eye: Ema Arakelian, Arnulfo Gonzalez, Sergio Hambav, Robert Magnet and Roy Romero.

Ema Arakelian ended up having her left eye removed on October 3, 2012. Her best visual acuity in the right eye was 20/60 on July 10, 2013, with no significant loss of vision in the non-involved eye at the time of the incident. Arakelian had vein occlusion with macular edema in the right eye on this date, but it was noted that the swelling had improved. She will need follow-up evaluations of the prosthesis for the left eye. Her medical specials total \$11,410.55¹³ with \$15,221.91 owed to Medicare and \$1,567.60 owed to Medi-Cal.¹⁴

Dr. Turkish concluded that Arakelian's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. A positive fungal culture was obtained and the lot number from the injected triamcinolone acetonide is consistent with contaminated fungal specimen from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Arakelian experienced was medically caused by Brilliant Blue-G dye from Franck's.

After the surgery she is no longer able to do many of the things she previously did. She must now be accompanied to her doctor appointments, grocery shopping and to visit family. She is also now agitated because objects, like a telephone or remote control, are no longer easy for her to locate after she sets them down.

Arakelian's allocated points for determining the general damages total 480,000 points. This number was derived by allocating: 250,000 points for the loss of the involved eye; 100,000

¹³The medical specials were provided by the plaintiff's attorney by email dated November 13, 2014, but are not verified by any back up medical bills.

¹⁴ Letter from CMS dated January 5, 2015.

points for the loss of vision in the non-involved eye and loss of vision in involved eye of 20/200 or less; 60,000 points for the number of major surgical procedures she underwent; 45,000 points for minor surgical procedures; and 25,000 points for the existence of ongoing eye disease in the non-involved eye that may result in significant vision loss in the future. The general damages awarded to Arakelian total **\$294,391.68 plus 65.5% of the Medicare lien of \$15,221.91 and 65.5% of the Medi-Cal lien of \$1,567.60.**¹⁵

Arnulfo Gonzalez ended up having his right eye removed on May 15, 2013. His best visual acuity in the left eye, with correction, was 20/25-1 on February 3, 2014, with no significant loss of vision in the non-involved eye. Gonzalez will continue to need follow-up for his prosthesis in the right eye. Gonzalez's medical specials totaled \$3,580.00 with \$1,332.96 being paid by insurance.¹⁶ The Medicare lien totals \$19,995.21.¹⁷

Dr. Turkish concluded that Gonzalez's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. While the culture did not confirm that it was contaminated, the timing of the surgery as compared to the lot's production date is consistent with the use of contaminated dye. As a result, the Court finds that the endophthalmitis Gonzalez experienced was medically caused by triamcinolone acetonide from Franck's.

Before the surgery he was an avid fisherman and formerly knitted his own fishing nets. He is unable to thread a needle and now feels that fishing is more of a burden than a pleasure. Additionally, he once enjoyed working around his home but due to his distorted vision he can no

¹⁵In allocating the special damages, the Court notes that the total cost of the Medicare and other liens would have resulted in an award in excess of the funds available in the registry of the Court. As a result, in order to compensate the claimants as fairly as possible given the insufficient resources available, the Court finds that it is necessary to adjust the lien awards of each claimant by 65.5%.

¹⁶Gonzalez's medical specials per attorney, no back-ups provided.

¹⁷CMS letter dated January 16, 2015.

longer use tools such as a hammer, a screwdriver, or a pair of pliers. He also finds driving difficult and rarely drives unless it is daytime and no one is available to drive him.

Gonzalez's allocated points for determining the general damages total 390,000 points. This number was derived by allocating: 250,000 points for the loss of the involved eye; 105,000 points for the number of major surgical procedures he underwent; and 35,000 points for minor surgical procedures. The general damages awarded to Gonzalez **total \$239,193.24 plus 65.5% of the Medicare lien of \$19,995.21.**

Sergio Hambav ended up having his left eye removed on July 23, 2012, and he complained of extreme pain in the left eye before its removal. After his left eye was removed, he reported improvement in the pain. His visual acuity in the right eye was 20/20 as of October 11, 2012, with no significant loss of vision in the non-involved eye since the incident. The medical specials total \$13,093.77.¹⁸ The Medicare lien totals \$28,729.26.¹⁹ His Medi-Cal lien is \$485.26.

Dr. Turkish concluded that Hambav endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. Surgical stains were positive for fungal organisms and the pathology report also indicated the presence of fungal organisms. As a result, the Court finds that the endophthalmitis Hambav experienced was medically caused by triamcinolone acetonide dye from Franck's.

Hambav is a medical doctor originally from Armenia who immigrated to America in 1988. Although retired, prior to the surgery he would travel back and forth to Armenia to provide medical care to impoverished communities. Hambav's current condition makes it challenging for

¹⁸ Attorney hand written amount on Medicare lien report.

¹⁹ CMS Letter dated January 13, 2015.

him to read, watch television, and use the computer. It has also ended his ability to practice medicine and provide needed care to people in his native country.

Hambav's allocated points for determining the general damages total 310,000 points. This number was derived by allocating: 250,000 points for the loss of the involved eye; 45,000 points for the number of major surgical procedures he underwent; and 15,000 points for minor surgical procedures. There was no loss of vision or risk of future loss in the non-involved eye. The general damages awarded to Hambav **total \$190,127.96 plus 65.5% of the Medicare lien of \$28,729.26 and 65.5% of the Medi-Cal lien of \$485.26.**

Robert Magnet ended up having his right eye removed on August 1, 2012, and his visual acuity in the left eye without correction was 20/30-1 on September 23, 2013, with no significant loss of vision in the non-involved eye. Magnet was recommended for follow-up of possible orbital involvement but the pathology report did not indicate the presence of any fungal organism in the removed eye. He was also provided a prosthetic. His medical specials total \$162,129.75.²⁰ He did not have Medicare. However, he does have a lien from Kent Small, MD Medical Corporation in the amount of \$4,324.81.²¹

Dr. Turkish concluded that Magnet's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. Although no positive culture was obtained, Dr. Turkish opined that the presumed lot number from the injected triamcinolone acetonide was consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result,

²⁰Itemized summary provided by counsel but supporting documentation was not included.

²¹Letter from Fidelity Creditor Service dated June 9, 2014. The claimant also submitted to the Court a UCLA bill dated October 22, 2014 and claimed that the bill was an additional lien amount. However, it is a medical bill and it was for gastrointestinal services performed on February 13, 2014, which is unrelated to the claimant's injury caused by contaminated products from Franck's Pharmacy. Therefore, it is not included as a lien.

the Court finds that the endophthalmitis Magnet experienced was medically caused by triamcinolone acetonide from Franck's.

When he first lost his eye, he was unbalanced, lacked depth perception and was afraid of walking outside. Having a prosthetic eye has affected how he interacts with people and has lowered his self-esteem. He could not attend his father's funeral because he could not fly a plane for a period after the surgery.

Magnet's allocated points for determining the general damages total 345,000 points. This number was derived by allocating: 250,000 points for the loss of the involved eye; 45,000 points for the number of major surgical procedures he underwent; and 50,000 points for minor surgical procedures. There was no loss of vision or risk of future loss in the non-involved eye. The general damages awarded to Magnet **total \$211,594.02 plus 65.5% of the Kent Small, MD Medical Corporation lien of \$4,324.81.**

Roy Romero ended up having his left eye removed on September 27, 2012, and the visual acuity of the right eye, with correction, was 20/25+2 with no significant loss of vision in the non-involved eye as of April 5, 2012. The medical records indicate that Romero should have routine maintenance for the prosthesis in the left eye. No medical bills were submitted. There is a Medicare lien of \$31,945.65.²²

Dr. Turkish concluded that Romero's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. A positive fungi culture was obtain and the fungus was consistent with *Bipolaris hawaiiense*. As a result, the Court finds that the endophthalmitis Romero's experienced was medically caused by triamcinolone acetonide from Franck's.

²² CMS letter January 13, 2015.

Romero is able to drive with the prosthetic eye but his vision is limited to driving during the daytime because he does not see well on his left side and the darkness seems to make it worse. He experiences anxiety when he attends the doctor's office for a checkup. At the time of the surgery, he had been restoring an old car but now finds it difficult to do many things due to the loss of depth perception. He tried to resume his hobby of coaching softball after the surgery but after being hit more than once because he could not see the ball coming at him, he had to stop coaching.

Romero's allocated points for determining the general damages total 390,000 points. This number was derived by allocating: 250,000 points for the loss of the involved eye; 105,000 points for the number major surgical procedures he underwent; 10,000 points for minor surgical procedures; and 25,000 points for the existence of ongoing eye disease in the non-involved eye that may result in significant vision loss in the future. There was no loss of vision or risk of future loss in the non-involved eye. The general damages awarded to Romero **total \$239,193.24 plus 65.5% of the Medicare lien of \$31,945.65.**

B. Eleven claimants are at risk of loss of an eye: Migdalia Aguilar, Abraham Antenor, Josephine Bienick, Jim Hermanson, Susan Kappelman, Michele Laventhal, Natividad Lopez, Howard McMaster, Pedro Ortiz, Hyacinth Powell and Ruth Smith.

Migdalia Aguilar after receiving treatments for the infection, ended up with a visual acuity in her left eye varying from counting fingers on January 18, 2013, to hand motion on January 25, 2013, to no chance for recovery of vision and significant risk of shrinkage of the eyeball itself. Due to the condition and poor vision in her left eye, she is considered to have monocular vision. As to her right eye, her visual acuity was 20/20 on January 18, 2013 with no

significant loss of vision in the non-involved eye. Aguilar's total medicals are \$54,742.00²³ with her out of pocket expense totaling \$200.00 for drug copays and \$120.00 for a bill she personally paid to Jules Stein Eye Institute. She also incurred \$120 for consulting services.²⁴

Dr. Turkish concluded that Aguilar's endophthalmitis was caused by Brilliant Blue-G from Franck's. While there was no positive culture, the lot number and type of endophthalmitis is consistent with the use of contaminated dye. As a result, the Court finds that the endophthalmitis Aguilar experienced was medically caused by Brilliant Blue-G dye from Franck's.

Since the injury, Aguilar is much slower in her ability to get around, has poor balance, and is less confident due to her disfigured face. She has trouble coming down stairs, getting on an escalator, and she is afraid to board a bus. Although she has been told that she can legally drive with one eye, she chooses to not drive because she cannot see anything from her left eye and fears not seeing an on-coming car.

Aguilar allocated points for determining the general damages total 315,000 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 45,000 points for the number of major surgical procedures she underwent; 20,000 points for minor surgical procedures; and 25,000 points for the existence of ongoing eye disease in the non-involved eye that may result in significant vision loss in the future. There was no loss of vision

²³Email from Steven P Goldberg, counsel for Migdalia Aguilar, (Dec. 18, 2014, 12:23 P.M. CST). The total amount of medical bills Aguilar incurred according to a letter from her lawyer was \$54,742.00. The bills consist of \$29,440.00 from the San Gabriel Ambulatory Surgery Center; \$21,296.00 from the Retina Institute; \$3,381.00 from the California Eye & Ear Specialists; \$505.00 from the Western University/Western Diabetes Institute; and the \$120.00 she paid out of pocket for Jules Stein Eye Institute. The actual backups which would support the itemization were not submitted.

²⁴Email from Steven P Goldberg, counsel for Migdalia Aguilar, (Dec. 3, 2014, 19:15 CST) with UCLA Health Systems Receipt.

or risk of future loss in the non-involved eye. The general damages awarded to Aguilar **total \$193,194.54.**

Abraham Antenor ended up with a visual acuity of no light perception in the right eye on March 12, 2014. There is no chance for vision recovery in the right eye and the eyeball is already undergoing shrinkage. Visual acuity in his left eye, with correction, was 20/70+1 as of March 12, 2014, with some decrease vision in the non-involved eye since the incident, most probably secondary to diabetic eye disease. The medical records indicate that Antenor may need removal of his right eye in the future and that he will also need continued care of the preexisting diabetic eye disease in the left eye.

Dr. Turkish concluded that Aguilar's endophthalmitis was caused by Brilliant Blue-G from Franck's. There was a positive culture, the lot number and type of endophthalmitis is consistent with the use of contaminated dye. As a result, the Court finds that the endophthalmitis Antenor experienced was medically caused by Brilliant Blue-G dye from Franck's.

Before the infection, Antenor was able to live a very independent life. He drove every day, enjoyed reading, enjoyed cooking meals for his wife and daughter, and enjoyed bowling once or twice a week. Now he is unable to do any of the things he once enjoyed doing. His total medical expenses were \$36,521.26 with \$15,931.74 paid by insurance.²⁵ He has a Medicare lien of \$11,592.52.²⁶

Antenor's allocated points for determining the general damages total 440,000 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 100,000 points for the loss of vision in the non-involved eye and loss of vision in involved eye of

²⁵A chart summary was submitted by counsel; however supporting documentation was not submitted.

²⁶Medicare charges and conditional payment confirmed by letter dated April 15, 2015.

20/200 or less; 75,000 points for the number of major surgical procedures he underwent; 15,000 points for minor surgical procedures; and 25,000 points for the existence of ongoing eye disease in the non-involved eye that may result in significant vision loss in the future. There was no loss of vision or risk of future loss in the non-involved eye. The general damages awarded to Antenor **total \$269,859.04 plus 65.5% of the Medicare lien of \$11,592.52.**

Josephine Bienick was found to have visual acuity in the right eye of light perception on April 13, 2012. The intraocular pressure (eye pressure) was zero indicating that there was no or little chance for recovery and significant risk of shrinkage of the eyeball itself. The final visual acuity in the left eye, with correction, was 20/20 with no significant loss of vision in the non-involved eye at the time of the incident. Dr. Turkish concluded that based upon Bienick's medical records, it is possible that she may need removal of her right eye in the future.

After Bienick post-operatively developed endophthalmitis, a positive fungal culture result was obtained for a *Fusarium* species. Additionally, the Brilliant Blue-G lot number matches with the Brilliant Blue-G that was identified as contaminated from Franck's Pharmacy. Therefore, the Court finds that the endophthalmitis Bienick experienced was medically caused by Brilliant Blue-G dye from Franck's.

Bienick lives independently and until November 30, 2012, she was still working at Excel Supply in Kendallville, Indiana where she worked as an office manager. She worked for the company for 25 years and was required to use a computer terminal for the majority of the workday. She had always been an avid reader and crossword puzzle enthusiast. However, the loss of her right eye made it more difficult for her to read and she now tires easily when reading and doing crossword puzzles.

Activities which were normal for her before the procedure, such as pouring coffee or adding cream and sugar to her cup, has become more difficult and results in frequent spills. Driving a car has also become considerably more difficult particularly in either bright sunlight conditions or low light conditions due to her loss of depth perception. She does not drive at night and is no longer able to park her car in the garage by herself.

At the time of Bienick's eye surgery, she was working as an office manager which she had to quit after the surgery. She seeks lost earnings for two years totaling \$25,000.²⁷ Bienick's medical specials total \$71,696.41.²⁸ The Medicare lien totals \$8,628.86.²⁹ Also, Bienick indicates that there is an AARP subrogation lien of \$2,103.31.³⁰

Bienick's allocated points for determining the general damages total 300,000 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 45,000 points for the number of major surgical procedures she underwent; 5,000 points for minor surgical procedures; and 25,000 points for the loss of vision following cataract surgery which should have resulted in return of vision without the underlying eye disease. There was no loss of vision or risk of future loss in the non-involved eye. The general damages awarded to Bienick **total \$183,994.80 plus 65.5% of the Medicare lien of \$8,628.86 and 65.5% of the AARP subrogation lien of \$2,103.31.**

Jim Hermanson ended up with a final visual acuity in his left eye of no light perception, with no chance of recovery and significant risk of shrinkage of the eyeball. In the right eye, his

²⁷Letter from David Farnbauch, 08/29/14. Her wages for 2011 was \$13,566 and 2012 it was \$12,229.

²⁸Medical expense summary provided by counsel dated November 3, 2011.

²⁹CMS letter dated January 5, 2015.

³⁰Email dated January 9, 2015 regarding AARP lien and the presence of a subrogation policy.

visual acuity was 20/20, with correction. Based on the medical records, Dr. Turkish concluded that it is possible that he will need his left eye removed in the future. The Medicare lien totals \$12,721.21³¹ with out of pocket costs totaling \$1,446.24. Hermanson's medical expenses are - \$23,733.04.³²

Dr. Turkish concluded that Hermanson's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. While the culture did not confirm that it was contaminated, the timing of the surgery as compared to the lot's production date is consistent with the use of contaminated dye. As a result, the Court finds that the endophthalmitis Hermanson experienced was medically caused by Brilliant Blue-G dye from Franck's.

Hermanson is a restaurant owner but is no longer able to run his small business as he had in the past. His business partner had to play a greater role and they have also had to hire help. His loss of vision resulted in a loss of \$21,000 catering revenue, and increased expenses of \$119,000 for having to hire a general manager.

While Hermanson seeks to recover for the increased expenses incurred in connection with running his restaurant, there is no evidence of the actual expenses, such as evidence of the particularized payroll expense. Nor is there evidence of loss of catering revenue. As a result, the Court denies his request for increased business expenses. While there was a change in the quality of the enjoyment of his life, there is not enough funds in the registry of the Court to compensate him for the change.

³¹ CMS letter dated January 22, 2015.

³² Medical bill summary prepared by plaintiff's counsel was submitted. However, there is no supporting documentary evidence.

Hermanson's allocated points for determining the general damages total 312,500 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 30,000 points for the number of major surgical procedures he underwent; 20,000 points for minor surgical procedures; 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without the underlying disease; and 25,000 points for having ongoing eye disease in the non-involved eye that has the potential for significant loss of vision in the future. The general damages awarded to Hermanson **total \$191,661.25 plus 65.5% of the Medicare lien of \$12,721.21.**

Susan Kappelman ended up with a visual acuity of counting fingers in the right eye. She also experienced low pressure inside the right eye along with a number of other problems that indicated that there was no chance of recovery of vision and significant risk of shrinkage of the eyeball itself. Kappelman's visual acuity in the left eye, without correction, was 20/20 on April 16, 2012, with no significant loss of vision in the non-involved eye at the time of the incident. The medical records suggest that it is possible that Kappelman will need removal of her right eye in the future.

Dr. Turkish concluded that Kappelman's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. A positive fungal culture for a *Fusarium* species was obtained. As a result, the Court finds that the endophthalmitis Kappelman experienced was medically caused by Brilliant Blue-G dye from Franck's.

Prior to the incident Kappelman was extremely athletic and a very active woman who taught an activities class that included weight lifting, Pilates, and aerobics. She also played tennis daily and would engage in running, biking, and water sports. Since the incident she has not been

able to engage in the physical activities she once participated in because of her lack of depth perception and her inherent fall and trip hazards. There is no Medicare lien.

Kappelman's allocated points for determining the general damages total 387,500 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 90,000 points for the number of major surgical procedures she underwent; 35,000 points for minor surgical procedures; 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without underlying disease; and 25,000 points for having ongoing eye disease in the non-involved eye that has the potential for significant loss of vision in the future. The general damages awarded to Kappelman **total \$237,659.95**.

Michele Laventhal ended up with a visual acuity of light perception in the right eye as of February 7, 2013. The pressure inside the right eye was so low it could not be measured, indicating that there is no chance of recovery of her vision and significant risk of shrinkage of the eyeball itself. Dr. Turkish concluded that based upon Laventhal's treatment records, it is possible that she will need removal of her right eye in the future. Laventhal's medical specials totaled \$61,227.91 and she does not have a Medicare lien.³³

Dr. Turkish concluded that Laventhal's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. Although no positive culture was obtained, Dr. Turkish opined that the presumed lot number from the injected Brilliant Blue-G was consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds

³³Medical bill summary prepared by plaintiff's counsel was submitted. However, there is no supporting documentary evidence.

that the endophthalmitis Laventhal experienced was medically caused by Brilliant Blue-G from Franck's.

Laventhal's allocated points for determining the general damages total 397,500 points. This number was derived by allocating: 225,000 points for risk of loss or removal of the eye; 45,000 points for the number of major surgical procedures she underwent; 115,000 points for minor surgical eye procedures; and 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without the underlying disease. The general damages awarded to Laventhal **total \$243,793.11.**

Natividad Lopez ended up with a visual acuity of no light perception in the right eye on November 22, 2013, with no chance for recovery. Her visual acuity with correction in the left eye was 20/100. She had advanced neovascular glaucoma and diabetic retinopathy in the non-involved left eye. The medical records indicated that her right eye may have been removed because she was referred to Dr. Alice on October 9, 2013, for enucleation but it is unclear whether the procedure was performed. Her medical specials totaled \$68,194.00.³⁴ There is a Medicare lien of \$14,309.67.³⁵

Dr. Turkish concluded that Lopez's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. While the culture did not confirm that it was contaminated, the timing of the surgery as compared to the lot's production date is consistent with the use of

³⁴Medical specials identified by counsel were submitted. However, no supporting documentation or itemization of bills were provided.

³⁵CMS letter dated January 13, 2015.

contaminated dye. As a result, the Court finds that the endophthalmitis Lopez experienced was medically caused by Brilliant Blue-G dye from Franck's.

Lopez was retired at the time of her surgery and is not making a loss of earnings claim. Lopez is now very reluctant to have the surgery she needs on her right eye due to the loss of her left eye caused by the contaminated dye.

Lopez's allocated points for determining the general damages total 417,500 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 100,000 points for having visual acuity in non-involved eye of less than 20/40 and greater than 20/200, with loss of vision in the involved eye of 20/200 or less; 30,000 points for the number of major surgical procedures she underwent; 15,000 points for minor surgical procedures; 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without the underlying disease; 10,000 points for pending major surgical procedure; and 25,000 points for having ongoing eye disease in the non-involved eye that has the potential for significant loss of vision in the future. The general damages awarded to Lopez **total \$256,059.43 plus 65.5% of the Medicare lien of \$14,309.67.**

Howard McMaster ended up with a visual acuity of no light perception in the left eye on August 15, 2013. The intraocular pressure inside his left eye was zero, indicating that there was no chance of recovery of vision and significant risk of shrinkage of the eyeball. McMaster's acuity in the right eye, with correction, was 20/200 with decreased vision in the non-involved right eye from age-related macular degeneration, diabetic eye disease and optic atrophy. Dr.

Turkish concluded that he may need removal of his left eye in the future. His medical specials total \$40,198.14 and the Medicare lien totals \$5,728.87.³⁶

Dr. Turkish concluded that McMaster's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. Although no positive culture was obtained, Dr. Turkish opined that the presumed lot number from the injected Brilliant Blue-G was consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis McMaster's experienced was medically caused by Brilliant Blue-G from Franck's.

As a result of the incident, McMaster can no longer drive due to his vision loss. He is a retired Fire Chief for the City of Sparks. McMaster's left leg was amputated in 2012 due to complications from diabetes. His loss of depth perception has made walking on uneven ground extremely challenging. Before the injury he was a handyman and performed maintenance for his home including the home for his handicapped daughter. He no longer is able to avidly read or engage in everyday life matters.

McMaster's allocated points for determining the general damages total 602,500 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 300,000 points for a decrease in the visual acuity in the involved after the surgery with less than or equal to 20/200 visual acuity in the non-involved eye; 15,000 points for the number of major surgical procedures he underwent; 25,000 points for minor surgical procedures; 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without underlying disease; and 25,000

³⁶The attorney submitted a medical cost summary but with no back up supporting documents. However, there is a letter from CMS dated February 19, 2015 concerning the lien.

points for having ongoing eye disease in the non-involved eye that has the potential for significant loss of vision in the future. The general damages awarded to McMaster **total \$369,522.89 plus 65.5% of the Medicare lien of \$5,728.87.**

Pedro Ortiz ended up with a visual acuity in the left eye of light perception and visual acuity in the right eye, without correction, of 20/40 with no significant loss of vision in the non-involved eye since the incident. The records also indicate that it is possible that Ortiz may need removal of his left eye in the future and also continued treatment for diabetic eye disease and glaucoma in his right eye. Ortiz does not have a Medicare lien.³⁷

Dr. Turkish concluded that Ortiz's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. Although no positive culture was obtained, Dr. Turkish noted that Ortiz's treating physician was identified by the FDA as a physician who received tainted medications from Franck's Pharmacy and his condition was more likely than not caused by tainted dye. As a result, the Court finds that the endophthalmitis Ortiz experienced was medically caused by triamcinolone acetonide from Franck's.

Since the incident, Ortiz has experienced strong pains, stinging sensation, and some hallucinations. He has not been able to sleep and remains in the dark to avoid the sunlight or wears dark glasses to avoid the sun. He frequently trips over things and does not go out after dark for fear of falling.

Ortiz's allocated points for determining the general damages total 265,000 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 15,000

³⁷CMS letter January 28, 2015.

points for the number of major surgical procedures he underwent; and 25,000 points for minor surgical procedures. The general damages awarded to Ortiz **total \$162,528.74**.

Hyacinth Powell ended up with a visual acuity in her left eye of no light perception, with no chance for recovery of vision and significant risk of shrinkage of the eyeball. Powell's visual acuity in the right eye, with correction was 20/25-1, with no significant loss of vision in the non-involved eye at the time of the incident. It was noted that Powell may need removal of her left eye in the future. Her summary of medical expenses total \$27,461.50.³⁸ As of February 5, 2015, Medicare indicates that it made no payments related to the incident.³⁹ The National Benefit Fund by letter provided notice of its lien in the amount of \$29,939.29.⁴⁰

Dr. Turkish concluded that Powell's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. A positive fungal culture for *Exserohilum* was obtained, and according to Dr. Turkish, the positive culture was consisted with tainted bevacizumab/triamcinolone acetonide from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Powell experienced was medically caused by triamcinolone acetonide from Franck's.

Powell retired from her job at NYU due to vision. She experienced complete loss of vision in the left eye. As a result, she has experienced difficulty walking due to not being able to see out of her left eye. She has also had difficulty with steps, reading and watching TV and has experienced anxiety and depression.

³⁸The attorney submitted a medical bill summary with no supporting documents.

³⁹CMS letter dated February 5, 2015.

⁴⁰National Benefit Fund letter dated January 2, 2015.

Powell's allocated points for determining the general damages total 320,000 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 45,000 points for the number of major surgical procedures she underwent; 25,000 points for minor surgical procedures; and 25,000 points for having ongoing eye disease in the non-involved eye that has the potential for significant loss of vision in the future. The general damages awarded to Powell **total \$196,261.12 plus 65.5% of the National Benefit Fund lien of \$29,939.29.**

Ruth Smith ended up with a visual acuity of no light perception in her right eye with no chance for recovery and significant risk of shrinkage of the eyeball. Smith complained of pain in the right eye in January 2013 and complained that she wanted to "poke it out." Her visual acuity of the non-involved eye was 20/200. The medical records also suggest that it is possible that Smith may need her right eye removed in the future. Smith has not provided evidence of her medical specials. There is no Medicare lien. There is, however, a Blue Cross Blue Shield lien in the amount of \$55,532.71.⁴¹

Dr. Turkish concluded that Smith's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. A positive PCR for *Fusarium equiseti* was obtained. As a result, the Court finds that the endophthalmitis Smith experienced was medically caused by Brilliant Blue-G dye from Franck's.

Since the incident, Smith has been unable to perform activities of daily living, including computer work on a large screen monitor, handling finances and counting money, driving, shopping at the grocery store, and reading product labels.

⁴¹Blue Cross BlueShield of Louisiana Fax dated December 11, 2014.

Smith's allocated points for determining the general damages total 340,000 points. This number was derived by allocating: 225,000 points for the risk of loss of the involved eye; 25,000 points for loss of vision in the non-involved eye and the involved eye; 15,000 points for the number of major surgical procedures she underwent; 50,000 points for the minor surgical procedures; and 25,000 points for having ongoing eye disease in the non-involved eye that has the potential for significant loss of vision in the future. The general damages awarded to Smith total **\$208,527.44 plus 65.5% of the Blue Cross Blue Shield lien of \$55, 532.71.**

C. One claimant before the incident had a visual acuity of less than or equal to 20/200 (legally blind) in the non-involved eye with loss of vision in the involved eye of 20/200: David Corona.

David Corona ended up with a visual acuity in the involved right eye of 20/200-1 as compared to 20/80 prior to the injections. The non-involved left eye had significant loss of vision prior to the incident and he ended up with a visual acuity of no light perception in left eye after the incident. His total medical expenses are \$154,673.62 and his Medicare lien totals \$29,866.84.⁴² There is also a lien in the amount of \$696.19 from Medi-Cal.⁴³

Dr. Turkish concluded that Corona's endophthalmitis was caused by tainted triamcinolone acetonide obtained from Franck's Pharmacy. A positive fungal culture was obtained for Bipolaris and the lot number from the injected triamcinolone actinide is consistent with specimen identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Corona experienced was medically caused by triamcinolone acetonide from Franck's.

⁴²A medical bill summary was provided by the plaintiff's attorney but no back-up documentation was included. CMS provided a letter dated April 15, 2015.

⁴³Medi-Cal lien letter dated February 6, 2015.

Although Corona could not see out of his left eye prior to the incident, he was able to maintain his independence and did not require assistance for his daily activities. Since the incident he is effectively sightless due to the loss of vision in his right eye from the incident and the preexisting loss of vision in his left eye. Corona now requires assistance for his daily living including feeding, showering, cooking, cleaning, and hygiene. He is cared for by his sister who moved in with him to provide full-time assistance.

Corona's allocated points for determining the general damages total 500,000 points. This number was derived by allocating: 300,000 points for the loss of vision in the involved eye with preexisting visual acuity in the non-involved eye of less than or equal to 20/200; 45,000 points for the number of major surgical procedures he underwent; 30,000 points for minor surgical procedures; 100,000 points for loss of vision in the involved eye from less than 20/40 and greater than 20/200 to less than or equal to 20/200;⁴⁴ and 25,000 points for having ongoing eye disease in the non-involved eye that has the potential for significant loss of vision in the future. The general damages awarded to Corona **total \$306,658.00 plus 65.5% of the Medicare lien of \$29,866.84 and 65.5% of the Medi-Cal lien of \$696.19.**

D. One claimant loss vision in both eyes to less than 20/400 from two involved eyes: Ester Gonzalez

Ester Gonzalez ended up with a final visual acuity of no light perception in both eyes, and according to a report from Dr. Chu dated December 16, 2013; she is rendered blind in both eyes. Dr. Chu also concluded that Gonzalez had no chance for recovery of vision and significant risk of shrinkage of the eyeballs themselves. Based upon Gonzalez's medical records, Dr. Turkish

⁴⁴This category excludes claimants who have lost their eye or are at risk of losing an eye.

concluded that she may need removal of both eyes in the future and she will also need continued monitoring for recurrence of the fungal infection. As of December 16, 2013, she was still on oral voriconazole and will need continued monitoring as long as she is taking the medication.

After the surgery, Gonzalez became withdrawn and reluctant to leave her home. She is now virtually a recluse and is incapable of performing everyday chores. Her total medical expenses are \$39,827.31. She has a Medicare lien of \$32,940.90.⁴⁵

Dr. Turkish concluded that Gonzalez's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. The records indicated that the endophthalmitis was fungal in nature and caused by *Bipolaris hawaiiensis*. He further noted that the lot number of the injected triamcinolone acetonide used in each eye was consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Gonzalez experienced was medically caused by triamcinolone acetonide from Franck's.

Gonzalez's allocated points for determining the general damages total 845,000 points. This number was derived by allocating: 75,000 points for the number of major surgical procedures she underwent; 70,000 points for minor surgical procedures; 175,000 points for loss of vision from 20/40 or better in proximity to the incident to less than or equal to 20/800 after the incident;⁴⁶ 125,000 points for loss of vision in proximity to the incident of less than 20/40 and greater than 20/200 to less than or equal to 20/800 after the incident;⁴⁷ and 400,000 points for

⁴⁵CMS letter dated January 13, 2015.

⁴⁶This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁴⁷This category excludes claimants who have lost their eye or are at risk of losing an eye.

bilateral loss of vision to less than 20/400 in both involved eyes. The general damages awarded to Gonzalez **total \$518,252.02 plus 65.5% of the Medicare lien of \$32,940.90.**⁴⁸

E. Eight claimants had significant vision loss in the involved eye after the incident: Cheryl Avakian, Mercedes Cabrera, Raul Corrales, Jr., Joseph Cotugno, Barbara Fansworth, Brenda Hess, Pamella Hosang, and Levon Jingoian.

Cheryl Avakian before the incident had a best visual acuity in the right eye of 20/80+2 and after the incident she ended up with a visual acuity of 20/200 in the right eye. Her visual acuity in the non-involved left eye was 20/30 after the incident with no significant loss of vision in the non-involved eye at the time of the incident. The records did not indicate whether these visions were taken with or without corrective lenses. The records indicate Avakian will need follow-up ophthalmologic evaluations and treatment for macular edema in the right eye. It should also be noted that macular edema was present in the right eye prior to the original surgery. No evidence of medical expenses was provided. However, there is a Medicare lien of \$4,836.90.⁴⁹

Dr. Turkish concluded that Avakian's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. Although no positive culture was obtained, Dr. Turkish opined that the dye was contaminated. In so doing, he noted that Avakian's physician, Dr. Tom Chang, was identified by the FDA as a physician who received tainted Brilliant Blue-G from Franck's Pharmacy, that the timing of the occurrence is suggestive, and that the records of treatment with surgery and antifungal agents is further suggestive. As a result, the Court finds that the endophthalmitis Avakian experienced was medically caused by Brilliant Blue-G from Franck's.

⁴⁸CMS letter dated January 13, 2015.

⁴⁹CMS report issued in January 5, 2015.

Avakian's allocated points for determining the general damages total 162,500 points. This number was derived by allocating: 45,000 points for the number of major surgical procedures she underwent; 5,000 points for minor surgical eye procedures; 100,000 points for loss of vision in the involved eye from less than 20/40 and greater than 20/200 before the incident to less than or equal to 20/200 after the incident;⁵⁰ and 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without underlying disease. The general damages awarded to Avakian **total \$99,663.85 plus 65.5% of the Medicare lien of \$4,836.90.**

Randy Brown before the incident had a best visual acuity in the left eye of 20/40-2 and after the incident he ended up with a visual acuity counting fingers in his left eye. His visual acuity in the non-involved right eye was 20/40 after the incident. The medical records indicated that he will need continued treatment for inflammation in the left eye and follow-up evaluations of his retinal detachment following surgeries to treat the detachment. Brown's medical specials are \$46,441.47.⁵¹ He also has a lien from the American Postal Workers Union, AFL-CIO Health Plan of \$27,957.08.⁵²

The medical records indicate that no positive culture was obtained and nor was a lot number available linking it to Franck's Pharmacy. Dr. Turkish concluded that this case is more likely than not consistent with fungal endophthalmitis caused by Franck's Pharmacy. In so doing, he relied upon the opinion of Brown's treating physician Dr. Kent Crews. The Court

⁵⁰This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁵¹Medical Summary written by attorney with no medical bills attached.

⁵²Letter dated December 22, 2014, on behalf of the American Postal Workers Union, AFL-CIO Health Plan.

therefore finds that Brown's endophthalmitis was medically caused by contaminated Brilliant Blue-G.

Brown's allocated points for determining the general damages total 207,500 points. This number was derived by allocating: 60,000 points for the number of major surgical procedures he underwent; 10,000 points for minor surgical eye procedures; 125,000 points for loss of vision in proximity to the incident of less than 20/40 and greater than 20/200 to less than or equal to 20/800 after the incident;⁵³ and 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without underlying disease. The general damages awarded to Brown **total \$127,263.07 plus 65.5% of the American Postal Workers Union lien of \$27,957.08.**

Mercedes Cabrera before the incident had a best visual acuity in her right eye of 20/40 and after the incident her visual acuity in the right eye was 20/100 on September 15, 2012, and 20/70-2 on August 12, 2013. Her best visual acuity in her left eye on these dates was 20/40-1 and 20/30-2, respectively. Cabrera now cannot read, use the computer, work, or cook. She also suffers from depression since losing the vision in her right eye. She itemizes her medical costs at \$40,750.00.⁵⁴ She did not have a Medicare lien or any other liens.⁵⁵

Dr. Turkish concluded that Cabrera's endophthalmitis was caused by bevacizumab/triamcinolone acetonide from Franck's. There was a positive culture for the presence of fungi caused by tainted bevacizumab/triamcinolone acetonide which is included in the FDA's Root cause analysis as one of the contaminated compounds from Franck's. As a

⁵³This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁵⁴Medical Summary written by attorney with no medical bills attached.

⁵⁵The New York Social Services Administration by letter dated January 2, 2015.

result, the Court finds that the endophthalmitis Cabrera experienced was medically caused by bevacizumab/triamcinolone acetonide dye from Franck's.

Cabrera's allocated points for determining the general damages total 130,000 points. This number was derived by allocating: 15,000 points for the number of major surgical procedures she underwent; 15,000 points for minor surgical eye procedures; 75,000 points for loss of visual acuity in the involved eye from 20/40 or better before the incident to less than 20/40 but greater than 20/200 after the incident;⁵⁶ and 25,000 points for having ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The general damages awarded to Cabrera **total \$79,731.08**.

Cristina Caro before the incident had a best visual acuity in the right eye of 20/50+ and after the incident she ended up with a visual acuity of no light perception in her right eye. The visual acuity in the left eye after the incident was 20/80, without correction. Caro's medical specials are \$83,296.65 and she has no documented liens.⁵⁷

Dr. Turkish concluded that the endophthalmitis Caro developed post-operatively was likely consistent with fungal endophthalmitis caused by tainted bevacizumab/triamcinolone acetonide from Franck's Pharmacy. Although there is no record of a positive culture, the lot number is consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Caro experienced was medically caused by bevacizumab/triamcinolone acetonide from Franck's.

⁵⁶This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁵⁷The attorney submitted a medical bill summary with no supporting medical receipts. Additionally, the New York Human Resources by letter dated January 27, 2015, indicated that it will not assert a lien against the proceeds of Caro's personal-injury claim.

Caro's allocated points for determining the general damages total 290,000 points. This number was derived by allocating: 100,000 points for the loss of vision in the non-involved eye and loss of vision in involved eye of 20/200 or less; 15,000 points for the number of major surgical procedures she underwent; 25,000 points for minor surgical eye procedures; 125,000 points for loss of vision in proximity to the incident of less than 20/40 and greater than 20/200 to less than or equal to 20/800 after the incident;⁵⁸ and 25,000 points for ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The general damages awarded to Caro **total \$177,861.64**.

Raul Corrales, Jr. before the incident had a best visual acuity in the left eye of 20/20+3. After the incident Corrales's visual acuity in the left eye was 20/60 and his visual acuity in the right eye was 20/20 with no significant loss of vision in the non-involved eye since the incident. According to the medical records, Corrales's will need continued treatment of his diabetic eye disease and macular edema. His medical specials total \$102,341.25 and \$46,369.29 was paid by insurance.⁵⁹ According to counsel there is a lien of \$34,728.18. However, no letter has been received from the insurer to verify the amount and presence of a lien.

Dr. Turkish concluded that Corrales' endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. While the culture did not confirm that it was contaminated, the lot number and type of endophthalmitis is consistent with the use of a contaminated product. As a result, the Court finds that the endophthalmitis Corrales experienced was medically caused by triamcinolone acetonide from Franck's.

⁵⁸This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁵⁹The attorney submitted a medical bill summary with no supporting medical receipts.

Corrales's allocated points for determining the general damages total 165,000 points. This number was derived by allocating: 45,000 points for the number of major surgical procedures he underwent; 20,000 points for minor surgical eye procedures; 75,000 points for loss of visual acuity in the involved eye from 20/40 or better before the incident to less than 20/40 but greater than 20/200 after the incident;⁶⁰ and 25,000 points for ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The general damages awarded to Corrales **total \$101,197.14**.

Joseph Cotugno before the incident had a best visual acuity in the right eye of 20/40 and a visual acuity of hand motion in his right eye after the incident. Cotugno experienced anxiety, stress and pain. He is now left with loss of vision in his right eye and decreased depth perception as a result of the infection. Before losing sight in his right eye, he regularly played golf, repaired jewelry as a hobby, and performed household chores. His Medicare lien totals \$18,002.39.⁶¹

Dr. Turkish concluded that Cotugno's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. Although the culture did not confirm that it was contaminated and the lot number was not available, Dr. Turkish concluded that the infection was consistent with the use of contaminated dye. The Court notes that the timing of the surgery is consistent with the production date of the contaminated dye, which was August 23, 2011.⁶² As a result, the Court finds that the endophthalmitis Cotugno experienced was medically caused by Brilliant Blue-G dye from Franck's.

⁶⁰This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁶¹CMS Report dated January 5, 2015.

⁶²Centers for Disease Control and Prevention: Notes from the Field: Multistate Outbreak of Post procedural Fungal Endophthalmitis Associated with a Single Compounding Pharmacy-United States, March-April 2012. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6117a5.htm?s_cid=mm6117a5_w. May 4, 2012.

Cotugno's allocated points for determining the general damages total 242,500 points. This number was derived by allocating: 45,000 points for the number of major surgical procedures he underwent; 10,000 points for minor surgical eye procedures; 175,000 points for loss of vision from 20/40 or better in proximity to the incident to less than or equal to 20/800 after the incident;⁶³ and 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement of vision without the underlying disease. The general damages awarded to Cotugno **total \$148,729.13 plus 65.5% of the Medicare lien of \$18,002.39.**

Barbara Farnsworth before the incident had a best visual acuity in the right eye of 20/30. After the incident she had a visual acuity of 20/60-2 in her right eye and a visual acuity of 20/20 in the left eye, without correction, with a pinhole. Farnsworth has medical specials of \$41,013.00.⁶⁴ There is a Medicare lien of \$763.02.⁶⁵

Dr. Turkish concluded that Farnsworth's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. While the culture did not confirm that it was contaminated, Dr. Turkish noted that Dr. Friedlander, her treating physician, was identified as a FDA physician who received tainted Brilliant Blue-G from Franck's Pharmacy. Further the Court notes that the timing of the surgery is further consistent with the tainted dye's production date. As a result, the Court finds that the endophthalmitis Farnsworth experienced was medically caused by Brilliant Blue-G dye from Franck's.

⁶³This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁶⁴The Attorney submitted a medical bill summary with no medical back up documents.

⁶⁵CMS letter dated January 5, 2015.

Farnsworth's allocated points for determining the general damages total 90,000 points. This number was derived by allocating: 15,000 points for the number of major surgical procedures she underwent and 75,000 points for loss of visual acuity in the involved eye from 20/40 or better before the incident to less than 20/40 but greater than 20/200 after the incident.⁶⁶ The general damages awarded to Farnsworth **total \$55,198.44 plus 65.5% Medicare lien of \$763.02.**

Brenda Hess before the incident had a best visual acuity in the right eye of 20/60, with correction. After the incident she ended up with a visual acuity in the right eye of counting fingers and a visual acuity in the left eye of 20/25-1, with correction. Her medical specials total \$102,037.95 and she does not have a Medicare lien.⁶⁷

Dr. Turkish concluded that Hess's endophthalmitis was caused by contaminated Brilliant-Blue-G from Franck's. A positive culture for a *Fusarium* species was obtained on two separate dates. As a result, the Court finds that the endophthalmitis Hess experienced was medically caused by Brilliant Blue-G from Franck's.

Hess's allocated points for determining the general damages total 207,500 points. This number was derived by allocating: 45,000 points for the number of major surgical procedures she underwent; 15,000 points for minor surgical eye procedures; 125,000 points for loss of vision in proximity to the incident of less than 20/40 and greater than 20/200 to less than or equal to 20/800 after the incident;⁶⁸ 12,500 points for loss of vision following surgery for macular pucker/epiretinal membrane or repair of macular hole which could have resulted in improvement

⁶⁶This category excludes claimants who have lost their eye or are at risk of losing an eye.

⁶⁷Her medicals were provided in summary form with no backs. A CMS letter dated January 23, 2015, indicated that it has not paid any portion of her medicals.

⁶⁸This category excludes claimants who have lost their eye or are at risk of losing an eye.

of vision without the underlying disease; and 10,000 points for pending surgical procedures at the time of the last medical records received related to incident. The general damages awarded to Hess **total \$127,263.07.**

Pamella Hosang before the incident had a best visual acuity in the left eye of 20/30-1 and after the incident her visual acuity in the left eye was 20/50+2. In the non-involved right eye her visual acuity was 20/30+2 with no significant loss of vision. She will need continued treatment due to her pre-existing diabetic eye disease and glaucoma. Dr. Hosang's medical specials total \$16,074.63 and the Medicare lien is \$9,229.57.⁶⁹

Dr. Turkish concluded that Dr. Hosang's endophthalmitis was caused by contaminated bevacizumab/triamcinolone acetonide from Franck's Pharmacy. A positive culture for Exserohilum species was obtained and the lot number was consistent with the Franck's products that caused fungal infections. As a result, the Court concludes that the endophthalmitis Dr. Hosang experienced was medically caused by bevacizumab/triamcinolone acetonide from Franck's.

Dr. Hosang's allocated points for determining the general damages total 160,000 points. This number was derived by allocating: 30,000 points for the number of major surgical procedures she underwent; 30,000 points for minor surgical eye procedures; 75,000 points for loss of visual acuity in the involved eye from 20/40 or better before the incident to less than 20/40 but greater than 20/200 after the incident;⁷⁰ and 25,000 points for ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The

⁶⁹CMS letter dated January 28, 2015.

⁷⁰This category excludes claimants who have lost their eye or are at risk of losing an eye.

general damages awarded to Hosang **total \$98,130.56 plus 65.5% of the Medicare lien of \$9,229.57.**

Levon Jingoian before the incident had a best visual acuity in the left eye of 20/30 and after the incident Jingoian ended up with a visual acuity in his left eye of 20/200-1 and a visual acuity in the right eye of 20/40-2. Jingoian's medical specials total \$67,986.08.⁷¹ The Medicare lien totals \$3,018.08 and the Medi-Cal lien totals \$359.35.⁷²

Dr. Turkish concluded that Jingoian's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. Although no positive culture was obtained, Dr. Turkish opined that the presumed lot number from the inject triamcinolone acetonide was consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Jingoian experienced was medically caused by triamcinolone acetonide from Franck's.

Jingoian's allocated points for determining the general damages total 230,000 points. This number was derived by allocating: 15,000 points for the number of major surgical procedures he underwent; 40,000 points for minor surgical eye procedures; 150,000 points for loss of vision in the involved eye from 20/40 or better before the incident to less than or equal to 20/200 after the incident;⁷³ and 25,000 points for ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The general damages awarded to Jingoian **total \$141,062.68 plus 65.5% of the Medicare lien of \$3,018.08 and 65.5% of the Medi-Cal lien of \$359.35.**

⁷¹A summary of the medical specials were provided by the plaintiff's attorney but no back-up documentation was provided.

⁷²CMS provided a letter dated January 28, 2015, and Medi-Cal provided a letter dated April 29, 2013.

⁷³This category excludes claimants who have lost their eye or are at risk of losing an eye.

F. Six claimants had major surgery with less significant vision loss or vision improvement in the involved eye: Salvatore Ferrante; James Johnson, Jr., Adolfo Lemus-Gonzalez, Eldon McKinley, Ricardo Medina, and Bernice Tharp.

Salvatore Ferrante experienced difficulty driving after the incident, especially at night because the lights from cars would bother him. He has difficulty reading newspapers and books due to blurry vision and has fallen five times as a result. He recently fell down the back yard steps and injured his meniscus and underwent 18 months of physical therapy for his knee. He also experienced anxiety for a while after the incident. His medical specials total \$7,866.78 and his own pocket total \$100.⁷⁴ The Medicare lien totals \$3,565.87.⁷⁵

Ferrante's allocated points for determining the general damages total 50,000 points. This number was derived by allocating: 15,000 points for the number of major surgical procedures he underwent; 10,000 points for minor surgical eye procedures; and 25,000 points as a patient with ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The general damages awarded to Ferrante **total \$30,665.80 plus 65.5% of the Medicare lien of \$3,565.87.**

James Johnson, Jr. before the incident had a visual acuity in the right eye of 20/80-2 and after the incident his visual acuity, with correction, was 20/50-1 in his right eye and 20/20 in his left eye. The medical records indicate that in the future Johnson will likely need a secondary intraocular lens implant in his right eye because his intraocular lens was removed as part of his treatment. The records further indicate that he also had difficulty wearing a contact lens in his right eye and he had not been able to have a secondary intraocular lens implant in his right eye.

⁷⁴The attorney submitted a medical summary with no medical bills attached.

⁷⁵CMS fax dated May 22, 2015.

According to Dr. Turkish, there were ongoing issues that may delay or prevent the secondary intraocular lens implantation in the future. The medical specials total \$95,424.55 and the Medicare lien totals \$117.42.⁷⁶

Dr. Turkish concluded that Johnson's endophthalmitis was caused by contaminated Brilliant Blue-G from Franck's. Although no positive culture was obtained, Dr. Turkish opined that the presumed lot number from the injected Brilliant Blue-G was consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Johnson experienced was medically caused by Brilliant Blue-G from Franck's.

Johnson's allocated points for determining the general damages total 125,000 points. This number was derived by allocating: 45,000 points for the number of major surgical procedures he underwent; 35,000 points for minor surgical eye procedures; 10,000 points for pending surgical procedures at the time of the last medical records received related to the incident; and 35,000 points for aphakia in the involved eye in patients that cannot or have not yet had a secondary intraocular lens implanted. The general damages awarded to Johnson **total \$76,664.50 plus 65.5% of the Medicare Lien of \$117.42.**

Adolfo Lemus-Gonzalez before the incident had a best visual acuity in the right eye of counting fingers. After the incident he ended up with a visual acuity in the right eye of 20/70, which was a significant improvement from the pre-incident visual acuity of counting fingers. The visual acuity in the left eye was 20/80 after the incident, with some decrease in vision in the non-

⁷⁶A medical summary and accompanying medical bills were submitted by the claimant, as well as a CMS letter dated January 13, 2015, was also provided.

involved eye since the incident, probably secondary to diabetic eye disease. Lemus-Gonzalez's medical specials total \$109,335.97.⁷⁷ The Medicare lien totals \$27,700.24.⁷⁸

Dr. Turkish concluded that Lemus-Gonzalez's endophthalmitis was caused by contaminated triamcinolone acetonide from Franck's. Dr. Small, the treating physician, noted in a report that a specimen obtain on April 20, 2012, was "positive for mold." Additionally, the lot number from the injected triamcinolone acetonide is consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Lemus-Gonzalez's experienced was medically caused by contaminated triamcinolone acetonide from Franck's.

Lemus-Gonzalez's allocated points for determining the general damages total 125,000 points. This number was derived by allocating: 15,000 points for the number of major surgical procedures he underwent; 85,000 points for minor surgical eye procedures; and 25,000 points for ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The general damages awarded to Lemus-Gonzalez **total \$76,664.50 plus 65.5% of the Medicare lien of \$27,700.24.**

Eldon McKinley before the incident had a best visual acuity in the right eye of 20/20 and after the incident his visual acuity in the right eye was 20/40 with an aphakic contact lens and overcorrection. His visual acuity in the non-involved left eye with correction was 20/25. McKinley received a recommendation to have a secondary intraocular lens implantation in the right eye in the future because the lens had to be removed as a part of the treatment. It was also recommended that McKinley continue to use glaucoma medication once a day in the right eye

⁷⁷A medical specials summary was provided but no back-up documentation was provided.

⁷⁸CMS letter dated February 6, 2015.

and return in three months for a follow-up evaluation. His total medical specials were \$65,821.89.⁷⁹ The Medicare lien totals \$11,059.15⁸⁰ and other liens total \$2,980.43.

In considering the evidence, the Court notes that the lot number of the dye used for McKinley's cataract surgery was identified as contaminated Brilliant Blue-G, although a positive culture was not obtained. Additionally, he developed endophthalmitis after the Brilliant Blue-G injections. Based on these factors, Dr. Turkish concluded that his endophthalmitis was more likely than not medically caused by the Brilliant Blue-G obtained from Franck's lab. The Court agrees and finds that McKinley's endophthalmitis was medically caused by Brilliant Blue-G from Franck's.

McKinley's allocated points for determining the general damages total 175,000 points. This number was derived by allocating: 45,000 points for the number of major surgical procedures he underwent; 35,000 points for the minor surgical eye procedures; 25,000 points for loss of vision following cataract surgery which should have resulted in return of vision without underlying eye disease; 10,000 points for pending surgical procedures at the time of the last medical records received related to the incident; 25,000 points for ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future; and 35,000 points for aphakia in the involved eye in patients that cannot or have not yet had a secondary intraocular lens implanted. The general damages awarded to McKinley **total \$107,330.30 plus 65.5% of the Medicare lien of \$11,059.15 and 65.5% of the other lien of \$2,980.43.**

⁷⁹A medical summary of the medical specials and accompanying medical bills were submitted by the claimant.

⁸⁰CMS letter dated January 13, 2015.

Ricardo Medina before the incident had a best visual acuity in the right eye of 20/200-1 and after the incident he ended up with a visual acuity in his right eye, with correction, of 20/400 and 20/30 in the left eye with correction. Medina's medical specials total \$23,098.83.⁸¹ While he has Medicare, there is no lien.⁸²

Dr. Turkish concluded that Medina's endophthalmitis was caused by contaminated bevacizumab/triamcinolone acetonide from Franck's. Although no positive culture was obtained, Dr. Turkish opined that the lot number from the injected bevacizumab/triamcinolone acetonide was consistent with specimens identified as having fungal contamination from Franck's Pharmacy. As a result, the Court finds that the endophthalmitis Medina experienced was medically caused by bevacizumab/triamcinolone acetonide from Franck's.

Medina's allocated points for determining the general damages total 40,000 points. This number was derived by allocating: 15,000 points for the number of major surgical procedures he underwent and 25,000 points for ongoing eye disease in the non-involved eye that has the potential to result in significant loss of vision in the future. The general damages awarded to Medina **total \$24,532.64.**

Bernice Tharp before the incident had a best visual acuity in the right eye of 20/60 and after the incident she had a visual acuity of 20/30-1 in the right eye with an aphakic correction. In the non-involved left eye she had a visual acuity of counting fingers with no significant loss of vision in the non-involved eye from the time of the incident. The medical records indicate that Tharp may be in need of further intravitreal injections, continued oral antifungal medication, and eye drops for treatment of glaucoma. A secondary intraocular lens implantation or contact lens

⁸¹The attorney created a chart but no medical bills were attached.

⁸²CMS letter dated January 28, 2015.

may be needed for the right eye in the future because her intraocular lens had to be removed as part of her treatment.

Prior to the incident Tharp cared for herself and her home. She lived independently and drove herself everywhere she needed to go. She was also an active volunteer in the Fort Wayne area and at the time of the incident she had been volunteering several days a week at Building Blocks Day Care as Grandma Bernice. Due to the incident, she lost her independence and can no longer drive her car or engage in any of the things she once enjoyed. Tharp's medical specials are \$120,002.58.⁸³ There is also a \$17,273.00 Medicare lien.⁸⁴

Dr. Turkish concluded that Tharp's endophthalmitis was caused by Brilliant Blue-G from Franck's. While the culture did not confirm that it was contaminated, the lot number and type of endophthalmitis is consistent with the use of contaminated dye. As a result, the Court finds that the endophthalmitis Tharp experienced was medically caused by Brilliant Blue-G dye from Franck's.

Tharp's allocated points for determining the general damages total 320,000 points. This number was derived by allocating: 25,000 points for loss of vision in the non-involved eye without loss of vision in the involved eye; 45,000 points for the number of major surgical procedures she underwent; 195,000 points for minor surgical eye procedures; 10,000 points for pending major surgical procedures at the time of the last medical records received related to incident; 10,000 points for pending minor surgical procedures at the time of the last medical records received related to incident; and 35,000 points for loss of vision following surgery for aphakia in the involved eye in patients that cannot or have not yet had a secondary intraocular

⁸³An attorney medical summary chart was submitted with no supporting medical bills.

⁸⁴CMS letter dated February 18, 2015.

lens implanted. The general damages awarded to Tharp total **\$196,261.12 plus 65.5% of the Medicare lien of \$17,273.00.**

G. Four claimants receive no points: Julian Hendrix, Corinne Child, Nicholas Scuniziano and Stephen Fulsom.

A close review of the medical records and the opinion of Dr. Turkish reveal that the inflammations or resulting endophthalmitis of four claimants, Julian Hendrix, Corinne Child, Nicholas Scuniziano, and Stephen Fulsom, were not medically caused by tainted dye from Franck's Pharmacy.

Julian Hendrix had a positive culture for Staphylococcus epidermidis but no positive culture for fungi was obtained. According to Dr. Turkish, he may have either been injured by the bevacizumab from Franck's Pharmacy or he could have been injured as a result of having the injection procedure itself. The Root-Cause Report of the FDA does not list bevacizumab (Avastin) as one of the contaminated products from Franck's Pharmacy. Dr. Turkish noted that the FDA report indicated that the contamination was detected in the combination bevacizumab /triamcinolone acetonide product. The FDA report also noted multiple deficiencies at Franck's Pharmacy. Considering the medical evidence, the FDA report, and the report of Dr. Turkish, the Court finds that Hendrix's endophthalmitis was not medically caused by the contaminated bevacizumab because it is not a listed contaminated product from Franck's Pharmacy. Additionally, Hendrix was injured by a bacterial infection rather than a fungal infection, however, the type of infection caused by Franck's lab was fungal endophthalmitis.

Corinne Child, according to the medical evidence, developed inflammation that was "unlikely" a fungal infection. Dr. Turkish noted that inflammation can occur after surgical procedures without the presence of infection. Dr. Turkish concluded that this case is more likely than not a result of noninfectious inflammation rather than infectious inflammation. As

previously noted, the type of infection caused by Franck's lab was fungal endophthalmitis. Therefore, the Court finds that Child's injury was not medically caused by the contaminated Brilliant Blue-G from Franck's Pharmacy.

Nicholas Scunziano's post-operative treatment was complicated as a result of endophthalmitis, retinal detachment, and infection involving the scleral buckle. A positive culture was obtained for *Citrobacter koseri* but no positive culture was obtained for fungi. Dr. Turkish concluded that the rapid onset of his infection was more consistent with bacterial endophthalmitis and not fungal endophthalmitis. Dr. Turkish further opined that the infection may have been the result of the injection procedure itself, rather than tainted dye. As previously noted, that the Root-Cause Report of the FDA did not list bevacizumab (Avastin) as one of the contaminated products from Franck's Pharmacy. As a result, the Court finds that the bacterial endophthalmitis that Scunziano had was not caused by Franck's Pharmacy's.

Stephen Fulsom before the incident had a best visual acuity in the left eye of 20/200 and ended up with a visual acuity in left eye of no light perception after the incident. However, in considering the medical evidence and the opinion of Dr. Turkish, the Court notes that Fulsom unlike the other claimants was injected with hyaluronidase, which is a protein enzyme anesthesia. In response to the injection, Fulsom experienced optic nerve damage which is a known complication of ophthalmic surgery.⁸⁵ Further, the medical evidence also failed to show any evidence of the development of endophthalmitis which is the known complication of using the contaminated products from Franck's Pharmacy. Also noticeably absent from Dr. Turkish's opinion is any reference to the inclusion of hyaluronidase in the FDA Root-Cause Analysis

⁸⁵ See EyeWiki, http://eyewiki.aao.org/Ocular_anaesthesia, (last visited June 2, 2015).

report or any reference to the testing of hyaluronidase for any contamination. As a result, the Court finds that Fulsom's optic nerve damage is not medically caused by any contaminated product from Franck's Pharmacy.

V. CONCLUSION:

It is therefore Recommended that the claimants be awarded the following:

	<u>Plaintiff</u>	<u>General Damages Awarded</u>	<u>Medicare Lien @ 65.5%</u>	<u>Other Lien @ 65.5%</u>
1	Aguilar, Migdalia	\$193,194.54	\$0.00	\$0.00
2	Antenor, Abraham	\$269,859.04	\$7,593.10	\$0.00
3	Arakelian, Emma	\$294,391.68	\$9,970.35	\$1,026.78
4	Avakian, Cheryl	\$99,663.85	\$3,168.17	\$0.00
5	Bienick, Josephine	\$183,994.80	\$5,651.90	\$1,377.67
6	Brown, Randy	\$127,263.07	\$0.00	\$18,311.89
7	Cabrera, Mercedes	\$79,731.08	\$0.00	\$0.00
8	Caro, Christina	\$177,861.64	\$0.00	\$0.00
9	Child, Corrine	\$0.00	\$0.00	\$0.00
10	Corona, David	\$306,658.00	\$19,562.78	\$456.00
11	Corrales, Jr., Raul	\$101,197.14	\$0.00	\$22,746.96
12	Cotugno, Joseph	\$148,729.13	\$11,791.57	\$0.00
13	Farnsworth, Barbara	\$55,198.44	\$499.78	\$0.00
14	Ferrante, Salvatore	\$30,665.80	\$2,335.64	\$0.00
15	Fulsom, Stephen	\$0.00	\$0.00	\$0.00
16	Gonzalez, Arnulfo	\$239,193.24	\$13,096.86	\$0.00
17	Gonzalez, Ester	\$518,252.02	\$21,576.29	\$0.00
18	Hambav, Sergio	\$190,127.96	\$18,817.67	\$317.85
19	Hendrix, Julian James	\$0.00	\$0.00	\$0.00
20	Hermanson, Jim	\$191,661.25	\$8,332.39	\$0.00
21	Hess, Brenda	\$127,263.07	\$0.00	\$0.00
22	Hosang, Pamella	\$98,130.56	\$6,045.37	\$0.00
23	Jingoian, Levon	\$141,062.68	\$1,976.84	\$235.37
24	Johnson, James Jr.	\$76,664.50	\$76.91	\$0.00
25	Kappelman, Susan	\$237,659.95	\$0.00	\$0.00
26	Laventhal, Michele	\$243,793.11	\$0.00	\$0.00
27	Lemus-Gonzalez, Adolfo	\$76,664.50	\$18,143.66	\$0.00
28	Lopez, Natividad	\$256,059.43	\$9,372.83	\$0.00
29	Magnet, Robert	\$211,594.02	\$0.00	\$2,832.75

30	McKinley, Eldon	\$107,330.30	\$7,243.74	\$1,952.18
31	McMaster, Howard	\$369,522.89	\$3,752.41	\$0.00
32	Medina, Ricardo	\$24,532.64	\$0.00	\$0.00
33	Ortiz, Pedro	\$162,528.74	\$0.00	\$0.00
34	Powell, Hyacinth	\$196,261.12	\$0.00	\$19,610.23
35	Romero, Roy	\$239,193.24	\$20,924.40	\$0.00
36	Scunziano, Nicholas	\$0.00	\$0.00	\$0.00
37	Smith, Ruth	\$208,527.44	\$0.00	\$36,373.93
38	Tharp, Bernice	<u>\$196,261.12</u>	<u>\$11,313.82</u>	<u>\$0.00</u>
	Totals	\$6,180,691.99	\$201,246.48	\$105,241.61

The Combined total award for all the claimants is **\$6,487,180.08**

A party's failure to file written objections to the proposed findings, conclusions, and recommendation in a Magistrate Judge's Report and Recommendation within **fourteen (14) days** after being served with a copy shall bar that party, except upon grounds of plain error, from attacking on appeal the unobjected-to proposed factual findings and legal conclusions accepted by the District Court, provided that the party has been served with notice that such consequences will result from a failure to object. *Douglass v. United Servs. Auto. Ass'n*, 79 F.3d 1415, 1430 (5th Cir. 1996).⁸⁶

New Orleans, Louisiana, this 5th day of June 2015



KAREN WELLS ROBY
UNITED STATES MAGISTRATE JUDGE

⁸⁶*Douglass* referenced the previously applicable ten-day period for the filing of objections. Effective December 1, 2009, 28 U.S.C. § 636(b)(1) was amended to extend the period to fourteen days.