

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 13-CV-3003 PAM/FLN

United States of America,)
ex rel. Kipp Fesenmaier,)

Plaintiffs,)

v.)

JURY TRIAL DEMANDED

The Cameron-Ehlen Group, Inc.,)
dba Precision Lens and)
Paul Ehlen,)

Defendants.)

UNITED STATES OF AMERICA’S COMPLAINT IN INTERVENTION

The United States of America (“United States” or “the Government”), for its Complaint, states and alleges as follows:

NATURE OF THE ACTION

1. The United States brings this action under the False Claims Act, 31 U.S.C. §§ 3729-3733 (“FCA”), and the common law against Defendants the Cameron-Ehlen Group, Inc. d/b/a Precision Lens (“Precision Lens” or “PL”) and Paul Ehlen (“Ehlen”).

2. PL and Ehlen engaged in a lengthy scheme to pay kickbacks, primarily to ophthalmologists, in order to induce the kickback recipients to utilize products supplied by PL and its corporate partner, Sightpath Medical, Inc. (“Sightpath”) in eye surgeries.

3. PL, Ehlen and PL’s corporate partner provided items of value, such as lavish hunting, fishing and golf trips, private plane flights, frequent-flyer miles and other items of value to ophthalmologists like Dr. Richard D. (physicians will typically be identified in

this Complaint by their first name and first initial of their last name). In return, ophthalmologists such as Dr. Richard D. arranged for ophthalmic products supplied by PL to be used in surgeries.

4. PL and Ehlen knew that providing these items of value in order to induce the recipients to utilize PL's products and services and those of their corporate partner was wrongful and violated the law.

5. In order to conceal their behavior, PL, Ehlen and Sightpath's CEO, Jim Tiffany, created and utilized what they referred to as a "slush fund" or "secret fund." The fund was used in part to fund lavish hunting and fishing trips with physicians.

6. The relevant time period ("RTP") for this Complaint is January 1, 2006 through December 31, 2015.

7. Defendants' conduct violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the FCA.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1345 and 1331.

9. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because all defendants operate and transact business in this district, all defendants committed acts that violated 31 U.S.C. §§ 3729-3733, PL is headquartered in Minnesota and the Relator and Ehlen lived in Minnesota during the relevant time period.

PARTIES

10. The Relator, Kipp Fesenmaier, is a resident of Minnesota. He worked for approximately fifteen years in various capacities for Sightpath Medical, Inc. and its corporate predecessor, Midwest Surgical Services, Inc. Mr. Fesenmaier served as a Vice President of Sightpath for many years.

11. PL is a distributor of intraocular lenses (“IOLs”), viscoelastics and other products related to ophthalmic surgeries. PL is headquartered in Bloomington, Minnesota.

12. Paul Ehlen is the founder and majority owner of Precision Lens.

LEGAL BACKGROUND

A. The False Claims Act

13. The relevant portion of the FCA states that:

any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B) ... or (G); ... or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government... is liable to the United States Government.

31 U.S.C. § 3729(a). *See also* 31 U.S.C. § 3729(a) (FCA, pre-2009 amendments, Pub.

L. 103-272). Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C 2461 and 64 Fed. Reg. 47099, 47103 (1999), FCA civil penalties were adjusted to a range of \$5,500 to \$11,000 per false claim for violations occurring on or after September 19, 1999. The FCA

also includes treble damages for three times the amount of damages the government sustained as a result of the defendant's false claims. *Id.*

14. Under the FCA, a person acts knowingly when he or she "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). The FCA does not require proof of specific intent to defraud. *Id.*

B. The Anti-Kickback Statute

15. The Anti-Kickback Statute ("AKS") prohibits any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, to induce or reward a person for, *inter alia*, purchasing, ordering, arranging for, or recommending the purchase or ordering of any goods or services for which payment may be made, in whole or in part, under a federal health program, including Medicare. 42 U.S.C. § 1320a-7b(b)(1),(2).

16. The AKS is intended to prevent arrangements that can lead to unfair competition, the distortion of medical decision-making, overutilization of services and supplies, and increased costs to Federal health care programs. *See* 65 Fed. Reg. 59,434, 59,440 (Oct. 5, 2000). To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a per se prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. The statute was first enacted in 1972, and was strengthened in 1977 and 1987, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No.

92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

17. For the purposes of the AKS, “remuneration” includes the transfer of anything of value, "directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(1).

18. The AKS' legislative history confirms Congress' intent to interpret the term “remuneration” broadly. *See* 123 Cong. Rec. 30,280 (1977) (Statement of Rep. Rostenkowski), cited at 56 Fed. Reg. 35,952, 35,958 (July 29, 1991) (Final Rule regarding AKS Safe Harbors).

19. The knowing and willful payment of remuneration to a physician – or the knowing and willful receipt of remuneration by a physician - violates the AKS when even one purpose of the transaction is to induce the referral - or generation - of federal health program-related business. The term “referral” is used herein to stand in for the language in the AKS, including arranging for or recommending the ordering of goods for which Medicare pays.

20. An individual who violates the AKS is also subject to exclusion from participation in federal health care programs and, as of August 6, 1997, civil monetary penalties of \$50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

21. The United States Department of Health and Human Services Office of Inspector General (HHS-OIG) has promulgated “safe harbor” regulations that identify

payment practices that are not subject to the AKS because such practices are unlikely to result in fraud or abuse. *See* 42 C.F.R. § 1001.952. Safe harbor protection is afforded only to those arrangements that meet all of the specific conditions set forth in the safe harbor. Defendants’ conduct in this matter did not comply with any safe harbors.

22. In 2010, Congress amended the AKS to clarify that “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].” Patient Protection and Affordable Care Act of 2010 (“PPACA”), Pub. L. No. 111–148 § 6402(f), 124 Stat. 119, 759 (codified at 42 U.S.C. § 1320a–7b(g)). According to PPACA’s legislative history, this amendment to the AKS was intended to clarify “that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves.” 155 Cong. Rec. S10854.

23. Compliance with the AKS is a condition of payment under federal health care programs, and providers participating in the Medicare and Medicaid programs must agree to comply with the AKS and certify such compliance.

C. Medicare

24. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare Program, to pay for the costs of certain health care services. 42 U.S.C. § 1395, *et seq.* Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1.

25. The Department of Health and Human Services (HHS) is responsible for the administration and supervision of the Medicare Program. The Centers for Medicare &

Medicaid Services (CMS) is an agency of HHS and is directly responsible for the administration of the Medicare program.

26. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage of the fee schedule for physician services as well as a variety of “medical and other services.” *See* 42 U.S.C. §§ 1395j to 1395w-5.

27. In order to bill Medicare, physicians and facilities must certify that they will comply with all Medicare laws and regulations, including the AKS.

28. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statutes and regulations. 42 C.F.R. § 424.516(a)(1).

29. To participate in the Medicare Program, a health care provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the Medicare Program and in order to receive reimbursement from Medicare.

30. The Medicare Enrollment Application for physicians and non-physician practitioners specifically describes the FCA in the section titled “Penalties for Falsifying Information.” CMS Form 855I.

31. The application also states that compliance with the AKS and other similar statutes is a condition of receiving Medicare reimbursement. CMS Form 855I. Physicians and non-physician practitioners must certify that they will comply with these statutes.

32. Physicians, including those who received illegal remuneration from PL and Ehlen, were obligated to enter into these provider agreements, and did enter into them, in order to submit claims to Medicare.

33. The Medicare Program includes various “Parts,” including Medicare Part B. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and by contributions from the Federal Treasury. Eligible individuals who are 65 or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums. Payments under Medicare Part B are typically made to facilities and practitioners, such as physicians, rather than to the patient/beneficiary.

34. The United States provides reimbursement for Medicare Part B claims from the Medicare Trust Fund through CMS. To assist in the administration of the Medicare Part B Program, CMS contracts with Medicare Administrative Contractors (“MACs”). 42 U.S.C. § 1395u. MACs are responsible for processing the payment of Medicare Part B claims to providers on behalf of CMS.

35. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form (“CMS 1500”) or its electronic equivalent known as the 837P form. Among the information the provider or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes (“CPT codes”) and Healthcare Common Procedure Coding System (“HCPCS”) Level II codes, that identify the services rendered and for which reimbursement is sought, and the unique billing

identification number of the “rendering provider” and the “referring provider or other source.”

36. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the referring physician’s name and unique physician identification number. 42 U.S.C. § 1395l(q)(1).

37. Medicare Part B authorizes CMS to pay for cataract surgeries and the lenses used in such surgeries. Medicare Claims Processing Man., ch. 14, § 40.3. As of January 1, 2008, the procedure and lens are paid in a single lump sum. *Id.* The most common CPT codes associated with cataract surgeries are 66982 and 66984. For each, there is a facility fee, paid to the facility where the service is performed, and a professional fee, paid to the physician. Both the facility fee and the professional fee are paid for by Medicare Part B.

SPECIFIC ALLEGATIONS

A. Precisions Lens’ Business and Relationship with Sightpath

38. PL provides ophthalmic supplies and equipment to ophthalmologists and facilities for use in various ophthalmology procedures. These procedures include cataract-related surgeries and refractive surgeries. Each cataract surgery requires the implantation of an IOL. Cataract surgery also involves the utilization of viscoelastic materials and other surgical supplies (viscoelastics, IOLs and other supplies will be referred to collectively as “Surgical Supplies”).

39. Following cataract surgeries, Yttrium-Aluminum Garnet (“YAG”) laser procedures are often performed in order to remove protein buildup around eyes.

40. Cataract surgeries are performed in outpatient hospital clinics or in ambulatory surgical centers (“ASCs”). Many ASCs are owned by ophthalmologists who perform ophthalmic procedures such as cataract surgeries and YAG procedures.

41. During the RTP, PL sold Surgical Supplies and equipment affiliated with eye surgeries to customers who used them in connection with those surgeries. Those customers could be the ASC, outpatient hospital clinic, a group of physicians, or an individual physician.

42. It is well understood in the industry, and was certainly well understood at PL, that the physicians performing the cataract surgeries were among the primary decisionmakers in determining what Surgical Supplies and equipment they would use in performing surgeries. Accordingly, PL and Ehlen targeted physicians with their marketing efforts, both directly and through PL’s corporate partner Sightpath.

43. Sightpath provides ophthalmic surgical services to ophthalmologists and healthcare facilities in connection with cataract and refractive surgeries. Its primary business model is to provide everything a practice needs to do eye surgery on a mobile basis. Sightpath trucks travel to different locations on the day the ophthalmologist performs eye surgeries, and Sightpath provides a surgical technician and all of the supplies and equipment needed for the surgery.

44. PL had close corporate relationships with two of the larger optical manufacturers in the ophthalmology industry, Abbott Medical Optics, Inc. (“AMO”) and Bausch and Lomb (“B&L”). Upon information and belief, PL had informal exclusive distributorships with those entities in a territory of certain states; in other states, PL could

sell their products on a non-exclusive basis. PL did not sell products manufactured by Alcon Laboratories, the manufacturer with the largest market share in the industry during most of the RTP.

45. PL therefore had a strong financial incentive to persuade physicians to use AMO and B&L products in their surgeries and to buy those products from PL. PL also had a strong financial incentive to sell large enough quantities of AMO and B&L products so that those companies would continue to do business with PL, and on terms that were favorable to PL.

46. PL was mindful of its need to sell enough of its aligned manufacturers' products to keep them satisfied. When PL's sales of a certain manufacturer's products' slipped, the manufacturer would convey its dissatisfaction to PL.

47. In many regions of the country, AMO sold its products directly rather than using a distributor like PL. If AMO wished, it could have terminated its relationship with PL and sold its products directly to customers in PL's territory as well. PL's AMO territory fluctuated over time but was principally focused on the Midwest.

48. Sightpath purchased Surgical Supplies and equipment manufactured by AMO and B&L through PL rather than directly from the manufacturers. The AMO and B&L Surgical Supplies that Sightpath purchased through PL included the IOLs that were included in Sightpath's surgical packs.

49. Sightpath and PL were closely linked together for many years. For most of the RTP, Sightpath and PL had their physical headquarters in the same building, right next

door to one another. Paul Ehlen was also an initial investor in Sightpath's predecessor entity, Midwest Surgical Services.

50. PL also served as Sightpath's sales representative, making sales and negotiating contracts on behalf of Sightpath. PL received a commission from Sightpath for the sales it made on Sightpath's behalf.

51. Accordingly, the relationship between PL and Sightpath was intertwined. Representatives of either PL, Sightpath, or both would approach prospective physician or facility customers in order to pursue sales. When physicians wanted to implant lenses manufactured by AMO or B&L in connection with a Sightpath-connected surgery, Precision Lens would supply the lens. In other instances, Precision Lens entered into contracts with the physicians or facilities directly.

52. The companies worked cooperatively to pursue sales from prospective customers.

53. In 2013, Sightpath and PL's relationship became more adversarial, and resulted in litigation. PL continued to provide Surgical Supplies to Sightpath, however.

B. Precision Lens Inducements

54. PL is a distributor, not a manufacturer. Because it does not manufacture products, PL competes in the marketplace in other ways, including by building strong relationships with customers and prospective customers.

55. PL and Ehlen understood that the ophthalmologists performing the ophthalmic surgeries are quite influential in determining which products to use in various surgeries. This includes the choice of what type of cataract products to use, what types of

machines to use in surgeries, and whether products should be purchased directly from the manufacturers or from a distributor like PL.

56. PL and Ehlen, for years, used illegal kickbacks in order to persuade physicians to purchase Surgical Supplies and equipment distributed by PL in connection with eye surgeries, including surgeries paid for by Medicare.

- a. PL and Ehlen took physicians on lavish trips in order to persuade them to work with PL and Sightpath, and also facilitated trips that were used to induce doctors to use products distributed by PL and Sightpath. In many instances these physicians were allowed to take the trips free of charge. In numerous other instances these physicians were not asked to pay, and did not pay, the fair market value (“FMV”) of these trips.
- b. PL and Ehlen provided private flights to the physicians for free or at heavily discounted rates, below the FMV of the flight and often below even the incremental cost of the flight to PL.
- c. In connection with trips involving PL and also for physicians’ personal travel, PL provided frequent flyer miles to physicians for free or at heavily discounted rates, allowing the physicians to take trips for well below fair market value, in order to induce the physicians to work with PL and Sightpath.
- d. PL provided expensive meals and entertainment to physicians in order to induce them to work with PL and Sightpath.

57. Ehlen and PL had access to a variety of desirable luxurious accommodations and destinations. They made a regular practice of taking physicians to those locations without requiring the physicians to provide market-based reimbursement. They used these trips to curry favor with the physicians, inducing them to either begin purchasing IOLs and other Surgical Supplies and equipment from PL and sometimes Sightpath, or to continue doing so.

58. As time went on, PL often required physicians to repay PL for an amount that appears to resemble the full value of the trips. For many other trips, however, Precision Lens either did not require the physicians to make any payment, or sought payment for well below the FMV of the trip. This practice continued for some doctors even as PL was charging other physicians amounts approximating the full value of the trips.

59. Ehlen belonged to a private club in Montana called Stock Farm Club where he frequently entertained physicians. Stock Farm Club is an exclusive club in Montana, offering membership by invitation only. The club offers upscale hunting, fishing and golfing arrangements, with gourmet meals and luxury accommodations.

60. Ehlen was also a member at Sutton Bay, an exclusive club in South Dakota. Sutton Bay provides an upscale hunting, fishing, golf and dining experience. Membership is available by invitation only.

61. Ehlen's family owned a resort in Lake of the Woods, Ontario called Big Narrows Resort.

62. Ehlen also had an ownership stake in hunting land in White Lake, South Dakota.

63. Ehlen also had an ownership interest in multiple private planes.

64. Between 2004-2014, Ehlen and PL took a number of doctors on trips to Stock Farm Club, Sutton Bay, Big Narrows Resort, White Lake, and other locations. On many of these trips, Ehlen and PL took the physicians to the locations on one of Ehlen's private planes. On many occasions, Ehlen and PL paid for commercial flights or provided frequent flyer miles. In many instances, the doctors paid nothing for these trips. In others, the doctors paid Precision Lens or Ehlen a nominal amount that was well below the FMV of the trips.

65. Numerous such trips occurred between 2004-2014; a number of examples are set forth below.

66. These physicians then performed surgery using products supplied by PL and, in some cases, Sightpath. The physicians discussed below were PL customers during the RTP who performed cataract surgeries that were billed to Medicare.

1. Slush Fund Trips

67. To finance some of the above-referenced trips, PL created and used an account that it referred to as a "slush fund" or a "secret fund." The fund was maintained at PL and used to fund expensive trips involving Sightpath's CEO, Jim Tiffany, and various physicians that the companies did significant business with or hoped to do business with in the future.

68. Tiffany primarily dealt with Linda Norling, Ehlen's executive assistant, and Chris Reichert, PL's CFO, to request money from the slush fund.

69. Various internal PL documents reference paying for physician trips out of the “slush fund.”

70. In 2011, Reichert indicated to Ehlen in an email, “Tiff [Tiffany] is building up a very large slush fund – about \$40k right now and growing.”

71. In March 2012, PL discussed during an internal executive meeting that “PL has provided Tiff with a ‘marketing’ rebate fund for years where he has hid over \$100,000.” This was reflected in Reichert’s written meeting notes, which were circulated to Ehlen and the company’s other executives.

72. As an example of a trip funded by this slush fund, in 2008, Tiffany approached Reichert and wrote a handwritten note requesting \$2,000 from the slush fund to pay for Dr. J.S. to take a hunting excursion in Hawaii so the two of them could hunt goats.

73. Reichert provided Tiffany with a \$2,000 check written out to “Maui Hunting Safari,” and Tiffany took Dr. J.S. on the goat hunting trip in December 2008.

74. At the time, Dr. J.S. was Sightpath’s largest customer, and PL and Sightpath were discussing ways to increase his business with PL.

75. In November 2008, Ehlen and Reichert took at least two physicians, Dr. J.S. and Dr. Samuel S., to Sutton Bay on Ehlen’s private plane to for an upscale hunting trip. PL paid for their expenses, including food and lodging. PL estimated that the cost of this trip for Dr. Samuel S. was approximately \$7,000, which may well have underestimated the value of the trip. After the private flight returned to Minneapolis, PL took Dr. J.S. out to dinner at an expensive steakhouse in Minneapolis.

76. At the time, Dr. Samuel S. was a high volume PL cataract customer, and PL was working hard to retain his business.

77. Based on the close corporate relationship between Sightpath and PL, Sightpath obtained a fee for providing its mobile services and surgical pack for Dr. J.S.'s surgeries, and PL would receive a fee if Dr. J.S. implanted IOLs that PL supplied from companies like AMO and Bausch and Lomb. PL could also sell the machines used to perform the cataract surgeries to Dr. J.S. or the practices where he operated.

78. PL sometimes generated invoices to trip participants for the full or partial value of certain trips. For the November 2008 hunting trip to Sutton Bay, PL generated an invoice to Sightpath for several thousand dollars for the hunting trip expenses of Dr. Samuel S., one of the two physicians. PL then voided the invoice, writing, "Not paying invoice, taking out of slush fund instead." The companies also did not charge Dr. J.S. anything for the trip.

79. In the months leading up to the November 2008 Sutton Bay trip and the December 2008 goat hunting excursion, Sightpath and Precision Lens executives discussed Dr. J.S. at two quarterly meetings. At both meetings, the companies discussed attempting to convert Dr. J.S. to implanting IOLs provided by AMO or B&L, which PL supplied, and away from Alcon, which PL did not supply.

80. In early 2012, Tiffany wanted to take Dr. J.S. on a hunting trip. Tiffany reached out to Reichert and in January 2012, PL provided \$3,500 from the slush fund for a deposit for Dr. J.S.' December 2012 trip with Tiffany to a hunting lodge in Kansas.

81. In March 2012, a sales representative for AMO indicated to Ehlen that one of Dr. J.S.' facilities provided a good opportunity for Ehlen to distribute AMO products. The AMO representative told Ehlen that he believed it would be a productive sales tactic to continue to stay in Dr. J.S.' focus using dinners, lunch, or whatever form of attention would be a strong sales tactic. Ehlen forwarded the email to Mr. Tiffany and indicated, "This looks like with a little push from you, we should be good."

82. In August 2012, Sightpath and PL met concerning various business opportunities. One of the topics of conversation was a plan for Tiffany to attempt to persuade Dr. J.S. to convert to an AMO lens from an Alcon lens, a conversion that would benefit PL.

83. In December 2012, Mr. Tiffany and another Sightpath sales representative took Dr. J.S. on the hunting trip, using the deposit from the slush fund to fund part of the trip.

2. Representative Physician Examples

a. Dr. Richard D.

84. Dr. Richard D. received trips, frequent flyer miles, and other items of value from PL and Ehlen for the purpose of inducing him to use PL Surgical Supplies and equipment for his cataract surgeries.

85. Dr. Richard D. met Ehlen on one of the PL trips in 2004.

86. Dr. Richard D. went on numerous trips with PL and Ehlen since 2004, including at least one trip every year.

87. Each year, PL and Ehlen would fly Dr. Richard D. from Minneapolis to White Lake on a private plane for an annual hunting trip.

88. For most of the RTP, PL and Ehlen did not charge Dr. D. for the private flights. They often paid for his other trip expenses as well.

89. On trips that Dr. Richard D. took in 2008 and 2009, for example, PL paid for Dr. Richard D's hunting fee, food and accommodations as well as for his transportation. In 2009, PL paid for a \$474 flight from Myrtle Beach to Minneapolis, flew Dr. D. to South Dakota on a private plane, and then paid for his accommodations and hunting fees in South Dakota.

90. During the RTP, Dr. Richard D. used products from multiple companies, including Alcon and AMO. The great majority of his IOLs were AMO IOLs.

91. From 2006 through early 2009, Dr. D. purchased his AMO IOLs from PL.

92. In early 2009, Dr. D. began purchasing IOLs directly from AMO rather than PL, at AMO's request.

93. Between May 2009 and September 2011, Dr. D. ordered IOLs directly from AMO.

94. Beginning in September 2011, and continuing through 2015, Dr. D. ordered all of his AMO IOLs through PL.

95. Ehlen and PL paid considerable attention to Dr. Richard D. and used various types of illegal remuneration in an effort to persuade him to convert his business back to ordering IOLs through PL.

96. Between October 2010 and December 2011, PL and Ehlen took Dr. Richard D. on two hunting trips, paid for a \$500 birthday meal for him, and took him out for a dinner that cost just under \$400.

97. In 2010 and 2011, Dr. D. paid for a portion of the hunting trips and the associated travel, but at an amount below fair market value.

98. Since 2011, Dr. D., sometimes with his family, also took at least three trips using frequent flyer miles that he obtained from PL or Ehlen.

99. In 2011, PL approached Dr. Richard D. with a proposal: if Dr. Richard D. would agree to implant at least 10,200 cataract lenses over the next three years, PL would give Dr. Richard D.'s practice a Zeiss IOL Master machine valued at \$30,000 (PL applied a per lens surcharge for each implant towards the cost of the machine). Under this arrangement, Dr. D. would order his IOLs from PL, rather than from AMO.

100. Dr. Richard D's practice agreed to PL's proposal with a slightly adjusted volume requirement and entered into the arrangement in late 2011.

101. From late 2011 through the end of 2015, Dr. Richard D. ordered the vast majority of his cataract lenses through PL.

102. During the late 2011-2015 period, PL continued to take Dr. Richard D. on trips, and facilitated his personal travel using frequent flier miles, without asking him to pay the fair market value of those trips.

103. During the late 2011-2015 period, PL and Ehlen took Dr. D. out to a number of expensive dinners, including a \$632 steak dinner with Ehlen, Dr. D. and Dr. T. (one of Dr. D's medical partners with whom Dr. D. frequently traveled on PL trips) in December

2012 in connection with one of the hunting trips and a \$372 dinner in South Carolina in October 2012.

b. Dr. Kurt W.

104. During the RTP, PL and Ehlen spent considerable amounts of money providing trips and other forms of entertainment in order to persuade Dr. Kurt W. to do business with PL.

105. In January 2009, PL and Ehlen took Dr. W. and his wife to the national championship college football game in Miami, Florida. PL documents indicate that Dr. W. was not charged for the trip.

106. Reichert told another PL executive that month that the trip had cost PL just under \$25,000.

107. PL documents indicate that Ehlen took Dr. Kurt W. to Stock Farm Club, once with Dr. W's wife and once with a group of other doctors, without asking Dr. W. to pay for either trip. The trips occurred in 2006 and 2008.

108. In January 2010, PL spent \$1,073 to take Dr. W. and two others out to a steak dinner in Oklahoma.

109. In early April 2011, Ehlen took a group of ophthalmologists, including Dr. Kurt W., to the Masters Golf Tournament in Augusta, Georgia. The group traveled to Augusta on PL's private plane.

110. PL estimated in an internal document that the private plane flights alone cost Precision Lens approximately \$20,000. Ehlen went on the flight and picked up three

ophthalmologists in Kansas City (along with Brendan Sheil, a PL independent sales rep) and another ophthalmologist in Oklahoma.

111. In addition to the flight, PL paid for an \$867 steak dinner and spent \$500 for clothing for the physicians at the gift shop of Augusta National, the home of the Masters.

112. The physicians were only invoiced \$500 apiece for the entire trip.

113. In September 2011, PL spent \$618 on in-room dining for Dr. W. in Las Vegas.

114. In February 2012, Reichert and Sheil took Dr. W. and his clinical director out to an \$1,100 steak dinner. When Dr. W. requested that PL take him there again in 2014, a PL executive told another PL employee that Dr. W. loved that steakhouse.

115. In May 2013, a PL executive took Dr. W. and another physician out for a \$439 dinner in Oklahoma City.

116. PL was successful in obtaining a greater share of Dr. W's business over time, and converting more of that business to lucrative deluxe, or premium, IOLs. Because the deluxe IOLs were more profitable to PL, PL worked to convert physicians from standard IOLs to deluxe IOLs. These are Dr. W's PL IOL purchases by year:

Year	Amount Paid	Standard IOLs	Deluxe IOLs
2008	\$ 211,257.72	1113	0
2009	\$ 229,600.81	1309	0
2010	\$ 300,345.30	1430	41
2011	\$ 684,702.73	1581	422
2012	\$ 806,700.69	1552	562
2013	\$ 995,780.73	1586	785

c. Minnesota Eye Consultants

117. Minnesota Eye Consultants (“MEC”) has been one of Precision Lens’ largest customers. Precision Lens spent considerable money providing financial inducements to MEC’s physicians during the relevant time period in order to incentivize them to order through PL. A few select examples are provided below.

118. Shortly after the November 2008 Sutton Bay trip that was paid for at least in part by the slush fund, Tiffany emailed another physician, Dr. Richard L. Tiffany suggested that Dr. L. needed to try Sutton Bay, which Tiffany described as having excellent hunting, country club amenities and a great wine cellar. Dr. L. responded that he was indeed planning on going the following September.

119. In September 2009, Ehlen took a group of physicians, including Dr. Richard L., to Sutton Bay. PL and Ehlen flew Dr. L. and a guest to Sutton Bay on a private plane and hosted them for Sutton Bay activities from September 18-20. In an email after the trip, Norling, Ehlen’s assistant, asked Tiffany if Sightpath was going to pay for Dr. L’s trip or if Reichert should use the “secret fund” to pay for the private flight and the remainder of the trip expenses. PL’s records indicate that Dr. L. was not charged for the trip.

120. In 2007, PL flew Dr. Elizabeth D. of MEC to New York City on a private plane and paid for her hotel room. The purpose of the trip was apparently for Dr. D. to attend a Broadway musical with Paul Ehlen and his wife. Ehlen’s assistant coordinated the trip. PL’s records indicate that Dr. D. did not reimburse the company for these expenses.

121. PL provided Dr. D. with two international trips at below FMV in 2012. In April 2012, PL and Ehlen provided her with 325,000 SkyMiles for a trip to Munich. She was invoiced for the miles at .05 cents per mile, well below fair market value. It is not clear whether she paid the invoice; the company does not have a record of any payment. She was not invoiced for the \$150 the company paid to book the flight.

122. In September 2012, PL paid for Ehlen, Ehlen's wife and Dr. Elizabeth D. to take a trip to Quebec. Ehlen charged to the company credit card numerous meals, ranging from \$95-\$598, along with a receipt for clothing. PL's credit card receipts also indicate that PL paid for each traveler's flights with frequent flyer miles, and further reflect a \$164 payment for a tour and a \$169 payment for clothes. Ehlen also paid for \$3,300 in hotel fees for the trip. There is no indication that Dr. D. was asked to pay for any portion of the trip. PL categorized the hotel fees, the clothing payment and all of the various meals as meals and entertainment.

123. In December 2012, PL paid for Dr. D.'s birthday party at a popular Minneapolis steakhouse. PL paid \$1,878 for the party, but asked Ehlen to pay \$570 of that amount for wine.

124. PL provided Dr. D. with access to private flights on various other occasions, charging her below FMV on some occasions and nothing on others.

3. Additional Trip Examples

125. PL and Ehlen routinely took groups of physicians from the same practice on trips in order to foster relationships with those practices to induce future purchases. They also often scheduled trips with physicians who were friendly with one another and then

invited similar groups on future trips to the same destinations. Examples of these trips follow below.

a. Beaver Creek Ski Trips

126. In January 2010, PL took a group of three doctors from the Eye Clinic of Wisconsin, Matthew H., Douglas E., and Kevin F., on a ski trip to Beaver Creek, Colorado. PL flew the doctors out on a private plane and paid for assorted other expenses, including a \$592 sushi dinner. PL documents indicate that the doctors were not charged for this trip.

127. In January 2011, PL took that same group skiing to Beaver Creek again. This time the physicians were invoiced but paid amounts well below FMV. For a private flight to Beaver Creek from northern Wisconsin, then helicopter transportation to the ski area, accommodations, food and wine, the doctors each paid a total of \$800. Ehlen also purchased ski jackets on the trip for more than \$2,500.

b. Stock Farm Club

128. Ehlen and PL hosted ophthalmologist customers at Stock Farm Club in various years, including 2006, 2007 and 2008. The physicians were in various instances flown to Stock Farm Club. They were not charged for the vacations.

129. To provide a sense of the value of these trips, the company billed others for the use of the company's accommodations alone at Stock Farm during a later time period at a rate of \$550/night.

c. Big Narrows Resort

130. In 2008, Ehlen took multiple physicians who worked at a clinic in Western Wisconsin to Big Narrows Resort, flying them there on his private plane. PL's records do

not indicate that these ophthalmologists, Dr. Michael M. and Dr. Christopher W., made any payment for this expensive trip.

131. In 2010, Ehlen took several physicians to Big Narrows Resort. Norling, Ehlen's assistant, wrote one of the trip participants, Michael M, giving Dr. M. instructions on what to pack and where to catch the private flights. Dr. M. reimbursed PL for a portion of the trip cost, but well below FMV.

d. Hunting Trips

132. Ehlen regularly took groups of physician customers on a pheasant hunting trip to White Lake, South Dakota during the RTP. Ehlen typically flew the physicians there on a private plane. In many instances, the physicians paid nothing for the trip. In others, particularly in more recent years, some of the physicians paid for a portion of the trip, but often well below the FMV.

133. PL took several doctors on hunting trips to South Dakota in 2006. PL took Dr. Larry W., Ray, B., Richard L., and Vance T. on a hunting trip in early November 2006. Then PL took multiple doctors on a hunting trip in mid-November 2006, including Dr. Kent C., and two doctors named Mark S. PL then took Dr. Michael G., Paul K., Richard D. and Ron L. on a hunting trip in December 2006. There is no indication that any of the physicians were charged for these trips.

134. In 2007, Ehlen and Tiffany took Dr. J.S. on a pheasant hunt in White Lake, South Dakota. PL paid \$480 for Dr. J.S.' flight to Minnesota, then flew Dr. J.S. on a private plane to White Lake. The companies also paid for Dr. J.S.' lodging, hunting and food,

including a steak dinner at a well-known Minneapolis steakhouse. Dr. J.S. was not charged for this trip.

135. In 2004, Ehlen took several doctors including Vance T., David W., and Frank E. on a duck hunt in Flin Flon, Manitoba, Canada. In an accounting of the trip costs, there is a notation that PL will pay \$1000 of the \$3104 cost for two of the doctors, who would be invoiced for the remainder. The third doctor's expenses were paid in full by PL.

136. In 2005, Ehlen took several doctors including David W, Kevin L., and Vance T., on a hunt in Canada referred to as the "Specklebelly hunt." Ehlen's assistant sent a note to each of the participating doctors telling them their flight information and informing them of the car rental reservation she had made for them. PL's records do not indicate that any of the physicians were charged for this trip.

137. In December 2009, Drs. Richard D., Richard L., Vance T., John B., Frank E., and Gerald T. participated in the White Lake pheasant hunt. A flight log shows that Ehlen transported Drs. D. and L. to the hunt in Ehlen's personal aircraft. PL's records do not indicate that any of the physicians were charged for this trip.

138. The pheasant hunting trip to White Lake was repeated in December 2010. Doctors E., D., L., and T. again participated in the hunt. The flight log shows that Ehlen transported Dr. D., T., and L. to the hunt in Ehlen's personal aircraft. PL's records do not indicate that any of the physicians were charged for this trip.

139. A similar trip occurred in December 2011, with the flight log indicating that Drs. D., T., and L. were flown to South Dakota in Ehlen's plane. Dr. D., who lives in South Carolina, was billed \$212.50 for 42,500 SkyMiles for his flight to Minneapolis and \$185.73

for a private flight to South Dakota. Dr. L. was also billed \$185.73 for the private flight. The invoiced amounts are well below FMV.

140. A PL executive advised a PL physician customer in 2011 that PL's practice for many years was to charge physicians a fraction of the cost of the White Lake hunting trips while the company paid for the remainder of the trip cost.

4. Frequent Flyer Miles

141. As referenced in some of the examples above, PL has used frequent flyer miles as inducements for various physicians. The miles were used both for trips that the physicians took with PL and Ehlen and for other personal travel for the physicians and their friends and family.

142. PL recognized in internal documents that the frequent flyer miles were very valuable. The company indicated in May of 2012 that Ehlen was selling the miles to customers for 0.5 cents per mile, and resolved that it would monitor those transactions closely to make sure the sale of the miles to the customers were generating sufficient value for the company.

143. Reichert has indicated by way of a verified court filing that the miles PL and Ehlen were selling had a market value of approximately 1 cent/mile. Even accepting that modest value, the company charged physicians much less than that.

144. The PL customers to whom PL sold the miles were almost always ophthalmologists that PL wanted to induce to start, or continue, generating business for PL.

145. For example, Dr. Vance T. was a frequent recipient of these discounted SkyMiles. In 2012, he purchased SkyMiles for several trips taken by him and his family: 50,000 for a trip taken by his wife to New York City; 200,000 for a honeymoon trip to Jamaica for his child; and 440,000 for his own trip to China.

146. The last invoice indicated that the SkyMiles came from Ehlen's personal account. The invoice included a notation that it was "Payable in sheep, wine or whatever is appropriate!" It appears that a wine company owned by Dr. T ultimately paid the invoice.

147. PL sold the frequent flyer miles to physicians at a rate below FMV, and below what it sold them to others. These sales often allowed the physicians to fly at heavily discounted rates compared with what they would have paid for the flights on the open market.

148. For instance, at around the same time that PL was providing frequent flyer miles to Dr. Vance T, it also sold miles to a PL consultant at higher rates. In 2012, the same year Dr. Vance T. received miles from PL for three trips at the rate of 0.5 cents per mile, PL sold miles to a PL consultant at the rate of 1.0 cent per mile plus the Delta service fee associated with redeeming the miles. When PL provided miles to physicians, it did not ask them to pay the associated service fee.

149. Physicians who generated business for PL used the PL frequent flyer miles to procure flights for less money than the doctors could purchase them for in cash.

150. Dr. Vance T. used the miles to obtain flights at a discount to what they could be purchased on the open market. In some instances, for example, he used miles when the

actual market values of the flights were especially high because the tickets were being purchased at the last minute.

151. In late 2013, Norling was checking into flights so that a PL physician customer could use them for a ski trip with Ehlen. Norling advised in an email that the price PL would charge the physician for SkyMiles, .625 per mile at that point, would yield a considerably cheaper flight than if the physician purchased the flight directly. Ehlen was copied on the email.

152. In 2013, Dr. Richard L.'s assistant asked whether Dr. L. could purchase 70,000 miles from PL because regular flight prices had become exorbitant.

153. Reichert and Norling concluded that selling miles to Dr. Richard D. to allow him to purchase six flights for a Montana vacation in 2013 would save him over \$3,000.

154. In January 2014, PL and Ehlen provided 50,000 miles to Dr. Aaron A. in order to fly from Montana to Minnesota. Norling notified Dr. A. that PL would charge him 1 cent per mile, but that the doctor would still be saving over \$300 because the flight would have cost \$831 if purchased in cash.

155. During that same trip, PL and Ehlen flew Dr. A. round trip from Minnesota to South Dakota on a private plane. Its records do not indicate an invoice for this flight.

156. A few months after this trip, in July 2014, Dr. A. wrote a letter asking a clinic where he performed surgery to do business with Precision Eye Services, a company Ehlen formed to compete with Sightpath after the relationship between PL and Sightpath became adversarial.

5. Other Inducements

157. PL has also provided various additional forms of remuneration to physicians in violation of the AKS.

158. PL owned a water taxi that it permitted physicians to use. The physicians were at most charged for the cost of fuel and an hourly charge for the captain.

159. After deciding to spend \$20,000 for repairs to the boat in 2012, PL indicated that it should be used more for customers the following year.

160. PL also provided physicians with tickets to sporting events, either for free or at a discounted rate. For example, in mid-to-late 2011, Precision Lens provided Dr. Darrell W. with tickets to a Vikings game. PL's records indicate that Dr. W. did not pay for the tickets. In September 2010, PL provided Minnesota Twins tickets to Dr. Harold R. and his family. PL's records indicate that Dr. Harold R. did not pay for the tickets. In 2009, Ehlen took Dr. David W. to a Green Bay Packers game via private plane.

161. PL and Ehlen took physicians out for various expensive meals, notwithstanding knowledge that this practice was improper. For example, in October 2014, Ehlen took three physicians out to a dinner at one of the most upscale restaurants in Chicago. The bill came to just under \$2,000 for dinner for six. In January 2014, PL spent approximately \$2,500 for a steak dinner for 10. Various additional examples were listed in the preceding sections.

6. PL and Ehlen Intended the Trips and Other Inducements to Persuade Physicians to Work With PL and Recommend that their Facilities Work with PL. They Were Often Successful.

162. In selecting the physicians to remunerate via lavish trips, PL prioritized selecting those who could generate the most business for PL.

163. In discussing the trips internally, PL executives indicated that PL curried favor with physicians by asking them to go on the trips. In a summary of a June 2008 meeting, PL's CFO wrote about Sutton Bay, one of the private clubs where PL regularly took physicians: "this [venue] is expensive so make sure you have your trips planned well, and if you have don't have docs lined up or they drop out, then cancel your trip. Part of the benefit is just in the asking."

164. Relator Mr. Fesenmaier was involved in planning meetings that were used to select physicians for trips to Big Narrows in 2004 and 2005. He recalls Ehlen being present at those meetings. Fesenmaier recalls that the focus of the discussion was on selecting high-volume PL customers that PL wanted to maintain, and potential customers with whom PL hoped to increase its market share. Fesenmaier recalls that one of the selection meetings began with a list of approximately 30 physicians, which was reduced during the meeting based on current volume and the likelihood of increased future volume.

165. Fesenmaier also recalled a similar discussion regarding ski trips several years earlier.

166. Fesenmaier's understanding was that the process of selecting physicians for the trips was supposed to be kept secret.

167. When Ehlen and PL flew Dr. J.S. and Dr. Samuel. S. to Sutton Bay on a private plane in November 2008 for a weekend of upscale lodging, food and hunting, PL's contemporaneous notes regarding the trip indicate that it hoped to persuade Dr. J.S. to convert to implanting a cataract lens that would benefit PL financially.

168. When PL discussed its initial plan to eliminate taking physicians on trips in light of the AdvaMed Code in 2009, PL discussed at an executive meeting that the company should use this change to reduce expenses and monitor to see whether the change would have an impact on sales. PL ultimately decided not to stop the trips.

169. In an email following the 2011 Masters trip, an independent sales representative, Brendan Sheil, asked Ehlen for more money in commissions for the accounts of two of the doctors that PL had taken to the Masters (with Sheil). Sheil indicated that PL's sales efforts had persuaded two of those physicians to begin ordering premium IOLs from PL, which they had not done in the past. Sheil indicated that PL had succeeded in converting the physicians to premium IOLs supplied by PL after considerable effort.

170. Dr. Kurt W. was one of the four physicians on the Masters trip. As indicated in the chart in an earlier section, PL records indicate that in 2008 and 2009, PL provided Dr. Kurt W. with no deluxe IOLs, but those numbers increased to 41 in 2010 and 422 in 2011.

171. When the expenses associated with the trips increased at one point, PL executives advised at a company meeting that when choosing physicians to take on the trips, they should focus on choosing physicians that could provide real value to the company. PL referred to the trips as large entertainment expenses.

172. PL meeting minutes indicate that PL viewed hunting trips as a strong tool in cementing relationships. At a PL executive meeting in 2007, PL discussed a new AMO executive who had recently been promoted, and with whom PL wanted to maintain a good relationship. The meeting minutes indicated that Ehlen planned to take him pheasant hunting.

173. Individuals involved in choosing doctors for the trips have indicated that PL chose at least some of the doctors for the trips based on the potential revenue the physicians could bring to PL.

174. In discussing PL's strengths and weaknesses in 2007, PL referenced the "PL Mystique" as a strength, and indicated that the PL plane was part of the PL mystique.

C. PL's Knowledge of Wrongdoing

175. PL and Ehlen recognized that it was improper to provide remuneration to physicians in the form of trips and the various forms of entertainment.

176. Defendants knew that compliance with the AKS was a condition of payment and a material requirement for receiving Medicare and Medicaid reimbursement.

177. Reichert, PL's CFO, maintained in his files an overview of the AKS from 2000. The document indicated that the AKS applies broadly, and subjects violators to felony criminal charges and civil damages and penalties.

178. In 2004, Ehlen stated that the AKS prohibited PL from providing inducements to ophthalmologists.

179. During an executive meeting in January 2007, PL discussed a recent settlement for kickbacks related to entertainment practices and consulting contracts. PL's

contemporaneous meeting notes indicated that the company at issue had paid a significant amount of money to settle kickback allegations, and PL indicated that it should proceed with caution in this area.

180. At an October 2007 executive meeting, PL sought to understand how one of its main competitors “gets away with paying for customer trips,” and PL CFO Reichert agreed to look into the question.

181. In 2009, Advanced Medical Technology Association, an industry trade group, published an updated AdvaMed Code of Ethics on Interactions with Health Care Professionals (“AdvaMed code”). The AdvaMed code provides guidelines for how companies should interact with health care professionals, and sets out a number of practices that companies should avoid in order to remain compliant.

182. The 2009 version of the AdvaMed code updated an earlier version.

183. AMO, one of PL’s primary suppliers, required PL to sign agreements in 2009 indicating that PL would comply with the AdvaMed code. PL did so, and required many of its owners and employees to individually sign documents indicating that they would comply with the AdvaMed code.

184. On behalf of PL, Ehlen agreed that PL had received a copy of the AdvaMed code and agreed that PL would comply with it.

185. The 2009 version of the AdvaMed code provides a number of specific limitations on how companies are permitted to deal with medical professionals. For example, Section VII indicates that “a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care

Professional. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips.” AdvaMed further clarified that remuneration for these events should not be provided regardless of their value, whether the company has engaged the medical professional to speak or consult, or whether the entertainment value of the event or activity is secondary to an educational purpose.

186. The AdvaMed code also clarifies that charitable donations may not be made as an unlawful inducement, and provides steps that companies should follow to ensure that the donations are being made appropriately.

187. Reichert retained notes from a January 2009 presentation about the changes to the AdvaMed code. The presentation referenced a number of kickback cases that helped give rise to the need for an updated AdvaMed code. The presentation referenced the code’s prohibition on providing entertainment or recreation to any health care professional.

188. When PL received notice of the 2009 version of AdvaMed, it held a series of meetings. PL indicated at an initial meeting that “we will adhere to the restrictions on marketing contained in AdvaMed, including no:

- Trips—will cancel hunting, fishing, etc.
- Golf, sports tickets”

189. The prohibition on these activities is clear, as is PL’s knowledge of the prohibition.

190. In subsequent meetings, however, PL indicated that it might not cancel these activities.

191. Various other PL meeting minutes indicate that PL executives discussed the AdvaMed code. The meeting minutes as a whole indicate that PL was aware of the restrictions placed on it by the AKS, and further clarified by the AdvaMed code updated in 2009. Ehlen participated in these meetings.

192. A consultant cautioned Reichert about the criminal, civil and administrative penalties associated with the AKS in a 2010 letter.

193. PL discussed at a 2011 executive meeting that if PL paid certain fees on behalf of PL customers, it could create a problem under AdvaMed and the AKS.

194. In a 2012 email including Reichert, Ehlen and other PL executives, Reichert and Ehlen discussed AKS and AdvaMed prohibitions. A customer had asked about PL providing money to support a customer's efforts to expand its cataract business. Ehlen informed the customer that the request could be a problem, because AdvaMed does not permit the provision of items of material value that could appear to be an inducement. Reichert echoed Ehlen's concerns, indicating that the AKS and the AdvaMed code prevented PL from providing marketing funds to the customer. He indicated that AKS violations create criminal and civil liability.

195. In 2013, Reichert and Ehlen discussed over email a kickback case filed against a large healthcare company involving lavish meals and trips.

D. Claims Examples

196. As a condition of payment, Medicare providers such as physicians and surgical facilities must certify compliance with the AKS. The United States relied upon

these health care providers' compliance with federal health care laws, including the certifications of compliance submitted or caused to be submitted.

197. These false certifications are material. For decades, compliance with the AKS has been material to the United States' decision to pay Medicare claims. The United States has continuously brought suit and pronounced publicly that it will not use taxpayer money to reimburse services arranged for through the use of unlawful inducements.

198. Compliance with the AKS was a condition of payment and a material requirement for receiving Medicare reimbursement during the RTP.

199. It is CMS' policy not to pay claims that are tainted by kickbacks.

200. The following paragraphs contain a number of examples of claims that were tainted by the defendants' kickbacks, along with a sense of the magnitude of claims at issue.

201. On January 10, 2012, Dr. Richard D. performed the following cataract surgeries at Bay Microsurgical Center in Georgetown, SC:

¹ Patient initials	Procedure Code	Medicare paid physician	Medicare paid facility
P.B.	66984	\$ 561.80	\$ 671.91
S.C.	66984	\$ 449.80	\$ 704.61
T.C.	66984	\$ 449.80	\$ 704.61
A.E.	66984	\$ 561.80	\$ 671.91
J.E.	66984	\$ 561.80	\$ 676.77
K.F.	66984	\$ 449.80	\$ 704.61
S.G.	66984	\$ 561.80	\$ 671.91
F.H.	66984	\$ 561.80	\$ 675.14
L.H.	66984	\$ 449.80	\$ 704.61
M.M.	66984	\$ 449.80	\$ 704.61
J.M.	66984	\$ 484.35	\$ 704.61

¹The United States will provide the parties with additional information about these claims, including full patient names.

B.Q.	66984	\$ 532.34	\$ 704.61
J.W.	66984	\$ 561.80	\$ 675.14

202. On March 3, 2009, Dr. Richard D. performed the following cataract surgeries at Bay Microsurgical Center in Georgetown, SC:

Patient initials	Procedure Code	Medicare paid physician	Medicare paid facility
M.S.	66984	388.70	715.34
W.M.	66984	388.70	715.34
L.J.	66984	485.88	715.34
P.W.	66984	485.88	715.34
H.J.	66984	388.70	715.34
U.T.	66984	388.70	715.34
T.C.	69984	485.88	715.34
A.C.	66984	388.70	715.34
R.B.	66984	388.70	715.34
K.D.	66984	485.88	715.34
E.R.	69984	485.88	715.34
M.K.	66984	485.88	715.34
S.T.	66984	485.88	715.34
A.A.	66984	388.70	715.34
R.H.	66984	485.88	715.34
M.G.	66984	485.88	715.34

203. On September 10, 2014, Dr. Richard D. performed the following cataract surgeries at Bay Microsurgical Center in Georgetown, SC:

Patient initials	Procedure Code	Medicare paid physician	Medicare paid facility
C.C.	66984	491.51	700.95
J.E.	66984	491.51	700.95
A.F.	66984	491.51	700.95
M.F.	66984	491.51	700.95
A.H.	66984	393.21	700.95
J.L.	66984	491.51	700.95
C.L.	66984	491.51	700.95
D.M.	66984	393.21	700.95
D.W.	66984	491.51	700.95

204. IOLs supplied by PL were used in all of the surgeries referenced in the preceding three paragraphs. The conduct of PL and Ehlen violated the AKS, and caused these claims to be false.

205. From 2007 through April 2009, Dr. Richard D. billed Medicare for at least 1,091 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. D. \$595,416.37 for these claims and related services, and paid \$778,725.23 in corresponding facility fees.

206. From October 2011 through 2015, Dr. Richard D. billed Medicare for at least 3,369 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. D. \$1,561,231.55 for these claims and related services, and paid \$2,333,977.90 in corresponding facility fees.

207. Bay Microsurgical Center (“Bay”), which is owned in part by Dr. Richard D., was a customer of Precision Lens during the RTP. Bay purchased IOLs from Precision Lens for use in cataract surgeries. The number of IOLs purchased from PL and the amounts paid to PL by Bay for the RTP are as follows:

Year	Amount Paid	IOLs
2007	\$ 254,158 ²	unknown
2008	\$ 359,081	2482
2009	\$ 76,699	530
2010	0	0
2011	\$ 117,617	1090
2012	\$ 376,211	3512
2013	\$ 458,793	3814

² The dollar figures listed in the amounts paid column for each physician or entity may include some figures for products in addition to IOLs and viscoelastics.

2014 (lens #s through Sept.) ³	\$ 485,209	2845
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208. From 2007 through 2015, Dr. Kurt W. billed Medicare for at least 10,054 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. W. \$4,858,875.07 on these claims and related services, and paid \$9,136,004.97 in corresponding facility fees.

209. Dr. Kurt W. practiced at Southwest Eye Clinic and additional locations in Oklahoma (“W. Entities”). The W. Entities purchased IOLs and other items from Precision Lens for surgeries at these locations. The annual numbers of IOLs and viscoelastics purchased from PL and the amounts paid to PL by the W. Entities by year are as follows:

Year	Amount Paid	Standard IOLs	Deluxe IOLs	Visco
2007	\$ 137,654	unknown	unknown	Unknown
2008	\$ 211,258	1113	0	744
2009	\$ 229,601	1309	0	864
2010	\$ 300,345	1430	41	1050
2011	\$ 684,703	1581	422	1828
2012	\$ 806,701	1552	562	2077
2013	\$ 995,781	1586	778	2268
2014 (lens #s through Sept.)	\$ 1,177,228	1306	663	1880

210. From 2006 through 2015, Dr. Elizabeth D. billed Medicare for at least 3,344 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. D.

³ Precision Lens has produced unit sales data through September 2014.

\$1,754,848.03 on these claims and related services, and paid \$ 2,672,927.40 in corresponding facility fees.

211. From 2009 through 2015, Dr. Richard L. billed Medicare for at least 687 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. L. \$337,387.94 on these claims and related services, and paid at least \$896,684.77 in corresponding facility fees.

212. MEC, where Dr. Elizabeth D. and Dr. Richard L. are partners, purchased lenses and supplies from Precision Lens for its various locations. The numbers of IOLs and viscoelastics purchased from PL and the amounts paid to PL by Minnesota Eye Consultants by year are as follows (these numbers include surgeries performed by several other physicians):

Year	Amount Paid	IOLs	Visco
2007	\$ 611,856.14	unknown	unknown
2008	\$ 739,179.11	3077	3231
2009	\$ 862,384.88	3628	3917
2010	\$ 1,003,737.45	3933	3886
2011	\$ 1,026,933.60	4686	4589
2012	\$ 1,058,300.75	5111	5390
2013	\$ 1,169,117.35	5528	5923
2014 (lens #s through Sept.)	\$ 1,189,469.71	4229	4641

213. From 2008 through 2011, Dr. Christopher W. billed Medicare for at least 1,348 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. W. \$600,491.31 on these claims and related services, and paid corresponding facility fees of \$1,674,575.12.

214. From 2008 through 2011, Dr. Michael M. billed Medicare for at least 1,176 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. M.

\$563,499.91 on these claims and related services, and paid corresponding facility fees of \$1,071,969.67.

215. Regional Eye Surgery Center in Hutchinson, MN, owned in part by Dr. W. and Dr. M. and where they perform cataract procedures, purchased IOLs and other supplies from Precision Lens. The numbers of IOLs and viscoelastics purchased from PL and the amounts paid to PL by Regional Eye Surgery Center for a portion of the RTP are as follows:

Year	Amount Paid	IOLs	Visco
2007	\$124,745.17	unknown	unknown
2008	\$266,102.57	957	1877
2009	\$254,419.52	981	1969
2010	\$223,599.12	885	1545
2011	\$173,689.28	843	1655

216. From 2009 through 2015, Dr. Vance T. billed Medicare for at least 3,544 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. T. \$1,493,822.89 on these claims and related services, and paid \$3,324,610.48 in corresponding facility fees.

217. Vance Thompson Vision, the ASC started in late 2012 by Dr. Vance T. in Sioux Falls, SD, and where Dr. T. performs cataract surgeries, purchased IOLs and supplies from Precision Lens. Sanford USD Medical Center, where Dr T. performed surgeries before the creation of the ASC, also purchased IOLs and supplies from Precision Lens. The amounts paid to PL and the number of IOLs and viscoelastics purchased from PL by these entities by year were:

Year	Amount Paid	Standard IOLs	Deluxe IOLs	Visco
2007	\$267,663.59	unknown	unknown	unknown
2008	\$367,458.41	551	120	816
2009	\$430,509.98	637	192	1140
2010	\$707,646.41	1318	289	2196
2011	\$832,041.81	1692	348	2604
2012	\$881,613.89	1977	341	3517
2013	\$917,992.88	2131	474	3128
2014 (lens #s through Sept.)	\$881,953.45	1895	419	282

218. From 2007 through 2009, Dr. Samuel S. billed Medicare for at least 2,755 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. S. \$1,553,061 on these claims and related services, and paid corresponding facility fees of at least \$1,939,649.70.

219. Dr. Samuel S. practiced at Florence Surgery & Laser Center (“Florence Surgery”) and other locations in South Carolina during the RTP. Florence Surgery purchased IOLs and other items from PL for surgeries performed by Dr. S. (The other locations where Dr. S. performs surgeries purchased IOLs and supplies through Sightpath.) In 2008, Florence Surgery & Laser Center paid PL \$542,078, which represented an increase of more than \$100,000 from 2007. That number decreased to \$213,877 in 2009 and declined further from there.

220. From 2007 through 2013, Dr. Douglas E. billed Medicare for at least 2498 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. E. \$1,213,034.61 on these surgeries and related services, and paid \$2,341,707.57 in corresponding facility fees.

221. From 2007 through 2013, Dr. Matthew H. billed Medicare for at least 933 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. H. \$529,987.85 on these surgeries and related services, and paid \$ 907,356.87 in corresponding facility fees.

222. From 2007 through 2013, Dr. Kevin F. billed Medicare for at least 1,176 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. F. \$669,481.28 on these surgeries and related services, and paid \$1,291,101.42 in corresponding facility fees.

223. ASCs and hospitals where Drs. E., H., and F. performed most of their cataract surgeries purchased IOLs and other items from Precision Lens for surgeries at these locations. The numbers of IOLs and viscoelastics purchased from PL and the amounts paid to PL by the two main ASCs for the relevant time period are as follows:

Year	Amount Paid	IOLs	Visco
2007	\$ 238,108.12	unknown	unknown
2008	\$ 363,715.49	1323	1204
2009	\$ 465,801.76	1628	328
2010	\$ 392,413.09	1627	506
2011	\$ 362,608.40	1733	553
2012	\$ 333,751.64	1674	589
2013	\$ 351,771.03	2045	3009

224. From 2007 through 2010, Dr. David W. billed Medicare for at least 1,620 cataract surgeries using procedure codes 66982 and 66984. Medicare paid Dr. W. \$711,342.90 on these claims and related services, and paid corresponding facility fees of \$2,086,447.02.

225. Ophthalmology Ltd. LLC, the ASC owned by Dr. David W. and where he performed many of his cataract surgeries, purchased IOLs and other items from Precision Lens to use in these surgeries during the RTP. The numbers of IOLs and viscoelastics purchased from PL and the amounts paid to PL by the ASC for 2007-2010 are as follows:

Year	Amount Paid	IOLs	Visco
2007	\$ 122,747	unknown	unknown
2008	\$ 168,011	884	1088
2009	\$ 190,108	796	1523
2010	\$ 188,381	845	1324

FIRST CLAIM FOR RELIEF

**Violations of the False Claims Act: Presenting False Claims for Payment
31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A) (2009)**

226. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

227. The United States seeks relief against Defendants under Section 3729(a)(1) of the False Claims Act, 31 U.S.C. § 3729(a)(1), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

228. Defendants' offer and payment of kickbacks violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

229. As a result of Defendants' offer and payment of kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), false and fraudulent claims for payment were made to federal health care programs, including Medicare. Defendants' compliance with the Anti-Kickback Statute was material to the Government's decision to pay the health care claims. Defendants knowingly caused to be presented materially false or fraudulent claims for payment or approval in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

230. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial.

SECOND CLAIM FOR RELIEF

**Violations of the False Claims Act: Use of False Statements
31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B)**

231. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

232. The United States seeks relief against Defendants under Section 3729(a)(2) of the False Claims Act, 31 U.S.C. § 3729(a)(2), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

233. Defendants' offer and payment of kickbacks violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

234. As a result of Defendants' offer and payment of kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), Defendants knowingly caused to be made or used false records or statements that were material to false or fraudulent claims for payment submitted to federal health care programs, including Medicare. Those false records or statements include false certifications of compliance with the Anti-Kickback Statute.

235. The United States, unaware of the falsity of the records and statements made by, used, or caused to be used by Defendants, approved, paid, and participated in payments made by federal health care programs for claims that would otherwise not have been approved and paid.

236. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

THIRD CLAIM FOR RELIEF

Unjust Enrichment

237. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

238. The United States paid claims submitted to Medicare, a federal health care program, in connection with eye surgeries. Those claims violated applicable federal law and regulations, including the False Claims Act and the Anti-Kickback Statute. The circumstances of Defendants' receipt of taxpayer money, whether directly or indirectly, are such that, in equity and good conscience, Defendants should not retain those payments, the amount of which is to be determined at trial.

FOURTH CLAIM FOR RELIEF

Payment by Mistake

239. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

240. By reason of the foregoing, the United States made and/or participated in Medicare payments in reliance on the erroneous belief that Defendants were complying with the Anti-Kickback Statute and the False Claims Act. The erroneous belief was material to the United States decision to make the payments. Consequently, the United States is entitled to recover the amount of the payments in an amount to be determined at trial.

RELIEF REQUESTED

WHEREFORE, the United States respectfully requests judgment against Defendants as follows:

- a) On Claims for Relief One and Two (False Claims Act), treble damages and civil penalties in the maximum amount allowed by law.
- b) On Claims for Relief Three and Four (Common Law), damages to the extent allowed by law;
- c) All costs associated with prosecuting this civil action, as provided by law;
- d) Interest on all amounts owed to the United States; and
- e) For all relief the Court deems just and proper.

Dated: February 8, 2018

Respectfully submitted,

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s/ Chad A. Blumenfield

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