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### ORIGINAL RESEARCH

# Fraud Claims Filed Involving Practicing Ophthalmologists from 1985 Through 2020

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**Introduction:** Like all United States physicians, ophthalmologists may be implicated in lawsuits claiming fraudulent medical practice. In order to educate, raise awareness, and mitigate fraudulent practice, we reviewed a legal database and analyzed fraud claims in ophthalmology lawsuits.

**Methods:** A retrospective legal literature review was performed on jury verdicts and settlements from the online legal database LexisNexis Academic from 1985 through 2020 that were filed by or against an ophthalmologist, involved a fraud claim, and included a final decision or settlement. Cases were evaluated for factors including demographics of plaintiffs and defendants, type of fraud claim, ophthalmologist party status (plaintiff or defendant), decision outcome, and amount awarded (when applicable).

**Results:** Of the 27 cases analyzed, all ophthalmologist defendants involved were male and the most common sub-specialty for an ophthalmologist defendant was refractive surgery. The most common fraud type was a fraud claim involving a malpractice lawsuit (12 of 27), followed by contract fraud and billing fraud. While the ophthalmologists in malpractice-related fraud cases experienced more rulings in favor of the defendant on the fraud claims (8 of 12), ophthalmologists in billing fraud cases experienced fewer rulings in their favor (0 of 5).

**Discussion:** Ophthalmology lawsuits involving fraud claims occurred in various settings, including malpractice lawsuits, contract cases, and Medicare and Medicaid billing. Defendants were all male and most commonly refractive surgeons.

Keywords: ophthalmology fraud, legal ophthalmology, fraud, medical fraud, medicolegal issues, legal medicine

# Introduction

Like all United States physicians, ophthalmologists may be implicated in lawsuits claiming fraudulent medical practice. Fraud, the practice of making a false or misrepresented claim, is an issue contributing to inefficiencies, high healthcare costs, and waste in the practice of medicine.<sup>1,2</sup> Fraudulent activity contributes to 3–10% of total health spending and more than \$100 billion annually.<sup>2</sup> The fight against fraud is costly as well — from 2011 to 2020, the federal government allotted \$350 million to fighting Medicare fraud.<sup>3</sup> While physicians may not intentionally commit fraud, studies show nearly all physicians will contribute to improper payments at some point in their careers.<sup>4</sup> Thus, it is important to increase physician education and awareness on how to avoid fraudulent activity, such as improper billing, in order to reduce an individual physician's risk of being implicated in a fraud lawsuit and to decrease systemic cost burden.

Chen et al previously examined the characteristics of physicians from all specialties who were excluded from US Medicare and state public programs for fraud, health crimes, or unlawful prescribing of controlled substances.<sup>5</sup> Excluded physicians tended to be older, male, and/or osteopathic physicians. The most common specialties were family medicine, psychiatry, internal medicine, anesthesiology, surgery, and obstetrics/gynecology. However, little information regarding ophthalmology has been reported. Further analysis of fraud litigation in ophthalmology can allow for education, awareness, and mitigation of fraudulent practice.

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# Methods

The research adhered to the tenets of the Declaration of Helsinki, and the University of Miami Institutional Review Board approval was waived, as all data was publicly available. The LexisNexis Academic legal database was accessed using an institutional subscription to review state and federal case records from across the US. This database only contains cases filed at the state and federal level. Cases that were handled by a third-party arbitration or appealed at the district level were not included.<sup>6</sup> On August 26, 2021 the database for US cases that were filed from January 1, 1985 to December 31, 2020 at the federal and state levels was queried using the following Boolean search term logic: (ophthalm\* AND (fraud\* OR extortion OR deceit)). The results were further filtered to only include those cases which had jury verdicts or settlements. Cases that were filed by or against an ophthalmologist, involved a claim involving fraud, and included a final decision or settlement were included in the analysis.

The included cases were evaluated for plaintiff gender, defendant gender, subspecialty of the ophthalmologist, age of the ophthalmologist at time of case (calculated using current age and year of the case), whether the ophthalmologist was the plaintiff or the defendant, US state involved in the claim, decision outcome, the amount won (if applicable), and the type of fraud. If demographic information could not be obtained on LexisNexis, a Google search was performed to attempt to find missing data. Type of fraud was categorized as follows: a fraud claim included in an ophthalmology malpractice case ("malpractice fraud"), a fraud claim regarding a contract with a company ("contract fraud"), a Medicare or Medicaid fraud claim ("billing fraud"), a fraud claim included in an employment harassment or wrongful termination case ("employment harassment and fraud"), a fraud claim among members of the same business or practice ("business fraud"), deception and fraud that occurred during an ophthalmology-related trial ("fraud during trial"), and fraud that occurred as a result of a company performing bribery ("kickback scheme fraud").

Descriptive analyses were performed in order to evaluate factors including demographics of plaintiffs and defendants, type of fraud claim, ophthalmologist party status (plaintiff or defendant), decision outcome, and amount awarded (when applicable).

### Results

A total of 100 cases were returned by the initial search query. Of these 100 cases, 49 were excluded because neither party was an ophthalmologist, 13 were repeated cases, 6 involved no fraud claim, and 5 did not provide enough information. As such, a total of 27 cases were included in the analysis (Table 1). Thirteen of the cases were ruled in favor of the plaintiff, five cases reached a settlement, and nine of the cases were ruled in favor of the defendant.

Case demographics are shown in Table 2. Among all 27 cases, there were 31 ophthalmologists involved. Ten ophthalmologists were plaintiffs with a median age of 48.5 years (IQR 42.5–56.5) during time of the case and 2 ages unknown. Twenty-one ophthalmologists were defendants with a median age of 53 years (IQR 44-58) and 8 unknown ages. All ophthalmologist defendants were male, and the most common specialty for an ophthalmologist defendant was refractive surgery.

Litigation outcomes were collected (Table 3). The median payout for cases that were ruled in favor of the plaintiff was \$2,652,285 (IQR \$313,644-\$5,729,091). Three of these cases noted prison sentences of 21 months, 60 months, and 10 years. The median settlement payout was \$320,000 (IQR \$100,000-\$6,720,000) with no prison sentences.

Of the 13 cases ruled in favor of the plaintiff, 3 were malpractice fraud, 3 were contract fraud, 4 were billing fraud, 2 were employment harassment and fraud, and 1 was business fraud (Table 4). Of the 5 cases that reached a settlement, 3 were malpractice fraud, 1 was billing fraud, and 1 was kickback scheme fraud. Of the 9 cases ruled in favor of the defendant, 6 were malpractice fraud, 2 were contract fraud, and 1 was fraud during a trial.

## Discussion

There is a literature gap regarding fraud in ophthalmology. While there is no standard on how to classify fraud, a 2015 study on fraud in medicine identified 18 fraud types, including providing unnecessary care and phantom billing (a process in which a physician bills for services not performed)<sup>1,7</sup> The examples of fraud seen in this study show the broad

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Table I Case Descriptions of Fraud in Ophthalmology Legal Cases 1985 through 2020

State	Year of Case	Plaintiff Award	Fraud Classification	Ophthalmologist Party Status	Ophthalmologist Sub-Specialty	Allegations	Case Summary	Case Reference*	Fraud Statute Involved
Outcom	Outcome: In Favor of Plaintiff								
CA	2003	\$31,676,301	Contract fraud	Plaintiff		Insurance bad faith and breach of contract	Plaintiff began experiencing anxiety attacks while performing surgery. Sued insurance company for insurance bad faith and breach of contract.	2003 Jury Verdicts LEXIS 51748	Not available
FL	2009	\$9,704,500	Business fraud	Plaintiff and Defendant		Breach of fiduciary duties, business fraud, financial mismanagement, and spying on the plaintiffs and patients	Defendant committed fraudulent misrepresentation and security fraud during sale of stocks in the Surgicenter, and invasion of privacy against the plaintiff physicians by installing surveillance cameras in their private offices.	2008 Jury Verdicts LEXIS 28139	F.S.A. § 517.301, F.S.A. § 934.03
FL	2015	\$7,100,000	Billing fraud	Defendant		Medicare fraud	Defendant falsely diagnosed Medicare beneficiaries with wet age-related macular degeneration and billed Medicare for medical services that were not medically necessary or were never performed.	2015 FL Jury Verdicts Rptr. LEXIS 602	Not available
NY	1996	\$4,358,182	Employment harassment and fraud	Defendant		Wrongful termination for not helping to commit fraud	Plaintiff refused to participate in Medicaid and Medicare fraud. Was terminated from his job.	1996 Jury Verdicts LEXIS 61300	Not available
FL	2005	\$3,891,848	Billing fraud	Defendant		Medicaid fraud	Outpatient clinics at a university health system double-billed Medicaid.	2005 Jury Verdicts LEXIS 44079	False Claims Act
AL	1997	\$3,400,000	Malpractice fraud	Defendant		Fraud, negligent care, outrageous conduct	Defendant performed surgery on wrong eye, implanted experimental lens without informed consent, and did not provide proper follow-up care.	What's It Worth? §10.04 (1997 ed.)	Not available

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Table I (Continued).

State	Year of Case	Plaintiff Award	Fraud Classification	Ophthalmologist Party Status	Ophthalmologist Sub-Specialty	Allegations	Case Summary	Case Reference*	Fraud Statute Involved
CA	2001	\$1,904,569	Contract fraud	Plaintiff		Fraudulent breach of contract	Management company entered a contract with ophthalmology practice. Company originally sued seeking declaratory relief that the agreement did not prohibit them from operating another facility in the area. Plaintiff countersued for intentional interference in contractual relations.	2001 Mealey's Jury Verdicts & Settlements 404	Not available
CA	2001	\$464,653	Billing fraud	Defendant		Medicare fraud	Fraudulent billing of laser eye surgeries to the Medicare program.	2001 Jury Verdicts LEXIS 6332	18 U.S.C. § 1341, 18 U.S.C. § 1347
тх	2001	\$327,288.93	Malpractice fraud	Defendant		Fraudulent lack of informed consent, medical negligence, battery	Plaintiff claimed defendant failed to obtained consent during eye lift procedure for performance of 2nd erbium laser procedure for scarring under eyes. Procedure caused scattered white scarring and discoloration.	2001 Jury Verdicts LEXIS 37784	Not available
FL	1988	\$300,000	Malpractice fraud	Defendant		Fraudulent lack of informed consent, medical negligence	Plaintiff claimed defendant failed to meet the standards of care for plaintiff's radial keratotomy. Defendant failed to advise plaintiff of risks, dangers, and side effects.	1988 FL Jury Verdicts Rptr. LEXIS 1978	Not available
NY	2008	\$170,000	Billing fraud	Defendant		Medicare fraud	Defendant ophthalmologist charged by government for committing Medicare fraud.	2009 Jury Verdicts LEXIS 21563	Not available
ОК	2012	\$75,000	Employment harassment and fraud	Defendant		Employment harassment for not helping to commit fraud	An ophthalmology technician alleged her ophthalmologist employer sexually harassed her and then retaliated against her when she refused to engage in improper Medicaid billing.	2012 OK Jury Verdicts & Sett. LEXIS 107	Not available
IL	2006	Not available	Contract fraud	Plaintiff		Fraudulent breach of contract, copyright infringement, unfair competition, and deceptive trade and business practices	Defendant agreed to remove plaintiff's visual acuity testing systems from all documents circulated by defendant. Defendant continued to distribute documents with referencing plaintiff's devices after agreement.	2011 Jury Verdicts LEXIS 194052	Illinois Consumer Fraud and Deceptive business Practices Act, 815 ILCS 505/2 et seq., Copyright Act of 1976, 17 U.S.C. S. § 101 et seq, Trademark Act of 1946, 15 U.S.C.S. § 1051, Illinois Deceptive Trade Practices Act, 815 ILCS 510/2 et seq.

Outcor	ne: Settlem	nent						
PA	2017	\$13,000,000	Kickback scheme fraud	Plaintiff	Fraudulent brib of physicians	Plaintiff claimed biopharmaceutical company committed fraud by providing free business advisory services to ophthalmologists who prescribed company's products.		Federal Civil False Claims Act, 3 U.S.C. § 3729 et. seq.
СО	2001	\$440,000	Malpractice fraud	Defendant	Medical neglige common-law fr violation of Consumer Protection laws	aud, surgery performed by defendant Prescription for the left eye was entered incorrectly and plaintiff	LEXIS 201686	Consumer Protection Laws
CA	2000	\$200,000	Malpractice fraud	Defendant	Medical neglige fraud, battery, a intentional infliction of emotional distr	surgery would improve plaintiff's vision. Plaintiff experienced worse vision after the surgery.	2000 Jury Verdicts LEXIS 59725	Not available
TX	2004	\$0	Malpractice fraud	Defendant	Fraudulent misrepresentati medical neglige		2004 Jury Verdicts LEXIS 43942	Not available
IL	2011	Not available	Billing fraud	Defendant	Medicare fraud	Defendant charged with submitting false claims for reimbursements of services rendered to Medicare patients.	2010 Jury Verdicts LEXIS 3286	False Claims Act, 31 U.S.C.S. Section 3729 et seq.
Outcor	ne: In favor	of Defendant			<u>'</u>		•	
CA	2003	None	Malpractice fraud	Defendant	Fraudulent misrepresentati medical malpractice	Plaintiff claimed defendant misrepresented defendant's experience before performing plaintiff's LASIK surgery.	2003 Jury Verdicts LEXIS 51306	Not available
CA	2003	None	Malpractice fraud	Defendant	Fraudulent lack informed conse medical malpractice, battery		2003 Jury Verdicts LEXIS 50170	Not available
CA	1995	None	Contract fraud	Plaintiff and defendant	Fraudulent brea of contract	Breach of contract and fraud in purchase of ophthalmology surgery practice.	1995 Jury Verdicts LEXIS 56666	Not available

Table I (Continued).

State	Year of Case	Plaintiff Award	Fraud Classification	Ophthalmologist Party Status	Ophthalmologist Sub-Specialty	Allegations	Case Summary	Case Reference*	Fraud Statute Involved
PA	2016	None	Contract fraud	Plaintiff		Fraudulent breach of contract	Ophthalmologist claimed biotechnology firm profited from his research on the treatment of macular degeneration without paying plaintiff royalties or giving plaintiff professional recognition.	2006 Jury Verdicts LEXIS 48301	Not available
CA	2003	None	Malpractice fraud	Defendant		Fraudulent lack of informed consent, medical malpractice, battery	Plaintiff suffered vision impairment following refractive surgery and claimed defendant failed to inform that plaintiff's keratoconus was a contraindication to surgery.	2003 Jury Verdicts LEXIS 50168	Not available
KY	2011	None	Fraud during trial	Defendant		Deceit during a deposition	Plaintiff filed a medical malpractice case against defendant. Defendant repeatedly lied in the case's deposition about information he provided patient.	2011 KY Trial Ct. Rev. LEXIS 133	Not available
CA	2002	None	Malpractice fraud	Defendant		Fraudulent misrepresentation, medical negligence	Plaintiff claims that defendant fraudulently induced him to have the procedure because he wanted to collect his 20% comanagement fee.	2002 Jury Verdicts LEXIS 54761	Not available
TX	1988	None	Malpractice fraud	Defendant		Fraudulent lack of informed consent, medical malpractice	Fraud with failure to receive informed consent after surgery left plaintiff with vision loss.	1988 Jury Verdicts LEXIS 23845	Not available
CA	2001	None	Malpractice fraud	Defendant		Fraudulent lack of informed consent, medical malpractice	Plaintiff was deceived into thinking plaintiff's eye biopsy performed by defendant was an emergency. Plaintiff experienced worsened vision after the procedure.	2001 Jury Verdicts LEXIS 49488	Not available

Note: \*Case references are searchable on LexisNexis.

Table 2 Characteristics of Cases

Total Cases   27 (100%)		r
Cases in favor of plaintiff         3 (60.0%)           Cases that reached a settlement         1 (20.0%)           Cases in favor of defendant         1 (20.0%)           Cases with ophthalmologist as defendant         20 (74.0%)           Cases in favor of plaintiff         10 (50.0%)           Cases in favor of defendant         7 (35.0%)           Cases in favor of defendant         7 (35.0%)           Cases in favor of plaintiff         1 (50%)           Cases in favor of defendant         1 (50%)           Plaintiff Gender         1 (50%)           Total Plaintiffs         37 (100%)           Male         17 (45.9%)           Female         14 (37.8%)           Not Applicable         6 (8.1%)           Ophthalmologist Plaintiffs         10 (27.0%)           Male ophthalmologist         4 (40.0%)           Female ophthalmologist         28 (100%)           Male         28 (100%)           Female ophthalmologist         28 (100%)           Male         20 (71.4%)           Female         1 (3.6%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         1 (3.6	Total Cases	27 (100%)
Cases that reached a settlement	Cases with ophthalmologist as a plaintiff	5 (18.5%)
Cases in favor of defendant	Cases in favor of plaintiff	3 (60.0%)
Cases with ophthalmologist as defendant	Cases that reached a settlement	I (20.0%)
Cases in favor of plaintiff         10 (50.0%)           Cases that reached a settlement         3 (15.0%)           Cases in favor of defendant         7 (35.0%)           Cases in favor of plaintiff         1 (50%)           Cases in favor of defendant         1 (50%)           Cases in favor of defendant         1 (50%)           Plaintiff Gender         1 (50%)           Total Plaintiffs         37 (100%)           Male         17 (45.9%)           Female         14 (37.8%)           Not Applicable         6 (8.1%)           Ophthalmologist Plaintiffs         10 (27.0%)           Male ophthalmologist         6 (60.0%)           Female ophthalmologist         28 (100%)           Male ophthalmologist         28 (100%)           Female         0 (0.0%)           Group (ie US government or a company)         7 (25.0%)           Unspecified         0 (0.0%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         0 (0.0%)           Ophthalmologist Sub-Specialty           Total Ophthalmologists Involved         31 (100%)           Ophthalmologist Sub-Specialty <tr< td=""><td>Cases in favor of defendant</td><td>I (20.0%)</td></tr<>	Cases in favor of defendant	I (20.0%)
Cases that reached a settlement         3 (15.0%)           Cases in favor of defendant         7 (35.0%)           Cases with ophthalmologists as both plaintiffs and defendants         2 (7.41%)           Cases in favor of plaintiff         1 (50%)           Cases in favor of defendant         1 (50%)           Plaintiff Gender           Total Plaintiffs         37 (100%)           Male         17 (45.9%)           Female         14 (37.8%)           Not Applicable         6 (8.1%)           Ophthalmologist Plaintiffs         10 (27.0%)           Male ophthalmologist         4 (40.0%)           Female ophthalmologist         28 (100%)           Female ophthalmologist         28 (100%)           Group (ie US government or a company)         7 (25.0%)           Unspecified         1 (3.6%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         1 (3.6%)           Ophthalmologist Sub-Specialty         1           Total Ophthalmologists Involved         31 (100%)           Ophthalmologist is Plaintiff         10 (32.3%)           General         5 (50.0%)           Refra	Cases with ophthalmologist as defendant	20 (74.0%)
Cases with ophthalmologists as both plaintiffs and defendants         7 (35.0%)           Cases with ophthalmologists as both plaintiffs and defendants         2 (7.41%)           Cases in favor of defendant         1 (50%)           Plaintiff Gender           Total Plaintiffs         37 (100%)           Male         17 (45.9%)           Female         14 (37.8%)           Not Applicable         6 (8.1%)           Ophthalmologist Plaintiffs         10 (27.0%)           Male ophthalmologist         6 (60.0%)           Female ophthalmologist         4 (40.0%)           Defendant Gender           Total Defendants         28 (100%)           Male         20 (71.4%)           Female         0 (0.0%)           Group (ie US government or a company)         7 (25.0%)           Unspecified         1 (3.6%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         1 (4.8%)           Ophthalmologist Sub-Specialty         1 (4.8%)           Total Ophthalmologists Involved         31 (100%)           Ophthalmologist si Plaintiff         10 (32.3%)           General         <	Cases in favor of plaintiff	10 (50.0%)
Cases with ophthalmologists as both plaintiffs and defendants         2 (7.41%)           Cases in favor of plaintiff         1 (50%)           Cases in favor of defendant         1 (50%)           Plaintiff Gender           Total Plaintiffs         37 (100%)           Male         17 (45.9%)           Female         14 (37.8%)           Not Applicable         6 (8.1%)           Ophthalmologist Plaintiffs         10 (27.0%)           Male ophthalmologist         6 (60.0%)           Female ophthalmologist         4 (40.0%)           Defendant Gender           Total Defendants         28 (100%)           Male         20 (71.4%)           Female         0 (0.0%)           Group (ie US government or a company)         7 (25.0%)           Unspecified         1 (3.6%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         1 (4.8%)           Ophthalmologist Sub-Specialty           Total Ophthalmologists Involved         31 (100%)           Ophthalmologists in Plaintiff         10 (32.3%)           General         5 (50.0%)           Refractive </td <td>Cases that reached a settlement</td> <td>3 (15.0%)</td>	Cases that reached a settlement	3 (15.0%)
Cases in favor of plaintiff         I (50%)           Cases in favor of defendant         I (50%)           Plaintiff Gender         37 (100%)           Total Plaintiffs         37 (100%)           Male         I7 (45.9%)           Female         I4 (37.8%)           Not Applicable         6 (8.1%)           Ophthalmologist Plaintiffs         I0 (27.0%)           Male ophthalmologist         6 (60.0%)           Female ophthalmologist         4 (40.0%)           Defendant Gender         28 (100%)           Total Defendants         28 (100%)           Male         20 (71.4%)           Female         0 (0.0%)           Group (ie US government or a company)         7 (25.0%)           Unspecified         I (3.6%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         I (4.8%)           Ophthalmologist Sub-Specialty           Total Ophthalmologists Involved         31 (100%)           Ophthalmologist is Plaintiff         10 (32.3%)           General         5 (50.0%)           Refractive         I (10.0%)           Cataract         I (10.0%	Cases in favor of defendant	7 (35.0%)
Cases in favor of defendant	Cases with ophthalmologists as both plaintiffs and defendants	2 (7.41%)
Plaintiff Gender   Total Plaintiffs   37 (100%)   Male   17 (45.9%)   Female   14 (37.8%)   Not Applicable   6 (8.1%)   Ophthalmologist Plaintiffs   10 (27.0%)   Male ophthalmologist   6 (60.0%)   Female ophthalmologist   4 (40.0%)   Defendant Gender   Total Defendants   28 (100%)   Male   20 (71.4%)   Female   0 (0.0%)   Group (ie US government or a company)   7 (25.0%)   Unspecified   1 (3.6%)   Ophthalmologist Defendants   21 (75%)   Male   20 (95.2%)   Female   0 (0.0%)   Total Ophthalmologist Sub-Specialty   Total Ophthalmologist Sub-Specialty   Total Ophthalmologists Involved   31 (100%)   Ophthalmologist is Plaintiff   10 (32.3%)   General   5 (50.0%)   Refractive   1 (10.0%)   Glaucoma   1 (10.0%)   Glaucoma   1 (10.0%)   Glaucoma   1 (10.0%)   Glaucoma   1 (10.0%)   General   3 (14.3%)   Refractive   2 (9.52%)   General   3 (14.3%)   Refractive   3 (14.3%)   Refractive   4 (19.0%)   Glaucoma   6 (0.0%)   Refractive   8 (38.1%)   Cataract   4 (19.0%)   Glaucoma   0 (0.0%)   Retina   2 (9.52%)   Pediatric   0 (0.0%)   Retina   2 (9.52%)   Pediatric   0 (0.0%)   Retina   2 (9.52%)   Pediatric   0 (0.0%)   Pediatric   0 (0.0	Cases in favor of plaintiff	I (50%)
Total Plaintiffs         37 (100%)           Male         17 (45.9%)           Female         14 (37.8%)           Not Applicable         6 (8.1%)           Ophthalmologist Plaintiffs         10 (27.0%)           Male ophthalmologist         6 (60.0%)           Female ophthalmologist         4 (40.0%)           Defendant Gender         28 (100%)           Total Defendants         28 (100%)           Male         20 (71.4%)           Female         0 (0.0%)           Group (ie US government or a company)         7 (25.0%)           Unspecified         1 (3.6%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         1 (4.8%)           Ophthalmologist Sub-Specialty         1           Total Ophthalmologists Involved         31 (100%)           Ophthalmologist is Plaintiff         10 (32.3%)           General         5 (50.0%)           Refractive         1 (10.0%)           Cataract         1 (10.0%)           Ophthalmologist is Defendant         21 (67.7%)           General         3 (14.3%)           Refractive         8 (38.1%)	Cases in favor of defendant	I (50%)
Male       17 (45.9%)         Female       14 (37.8%)         Not Applicable       6 (8.1%)         Ophthalmologist Plaintiffs       10 (27.0%)         Male ophthalmologist       6 (60.0%)         Female ophthalmologist       4 (40.0%)         Defendant Gender         Total Defendants       28 (100%)         Male       20 (71.4%)         Female       0 (0.0%)         Group (ie US government or a company)       7 (25.0%)         Unspecified       1 (3.6%)         Ophthalmologist Defendants       21 (75%)         Male       20 (95.2%)         Female       0 (0.0%)         Unspecified       1 (4.8%)         Ophthalmologist Sub-Specialty         Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%	Plaintiff Gender	
Female	Total Plaintiffs	37 (100%)
Not Applicable       6 (8.1%)         Ophthalmologist Plaintiffs       10 (27.0%)         Male ophthalmologist       6 (60.0%)         Female ophthalmologist       4 (40.0%)         Defendant Gender         Total Defendants       28 (100%)         Male       20 (71.4%)         Female       0 (0.0%)         Group (ie US government or a company)       7 (25.0%)         Unspecified       1 (3.6%)         Ophthalmologist Defendants       21 (75%)         Male       20 (95.2%)         Female       0 (0.0%)         Unspecified       0 (0.0%)         Ophthalmologist Sub-Specialty       31 (100%)         Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Refractive       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refr	Male	17 (45.9%)
Ophthalmologist Plaintiffs         10 (27.0%)           Male ophthalmologist         6 (60.0%)           Female ophthalmologist         4 (40.0%)           Defendant Gender         28 (100%)           Total Defendants         28 (100%)           Male         20 (71.4%)           Female         0 (0.0%)           Group (ie US government or a company)         7 (25.0%)           Unspecified         1 (3.6%)           Ophthalmologist Defendants         21 (75%)           Male         20 (95.2%)           Female         0 (0.0%)           Unspecified         1 (4.8%)           Ophthalmologist Sub-Specialty         31 (100%)           Total Ophthalmologists Involved         31 (100%)           Ophthalmologist is Plaintiff         10 (32.3%)           General         5 (50.0%)           Refractive         1 (10.0%)           Cataract         1 (10.0%)           Ophthalmologist is Defendant         21 (67.7%)           General         3 (14.3%)           Refractive         8 (38.1%)           Cataract         4 (19.0%)           Glaucoma         8 (38.1%)           Retina         2 (9.52%)           Pediatric         0 (0.0%) <td>Female</td> <td>14 (37.8%)</td>	Female	14 (37.8%)
Male ophthalmologist       6 (60.0%)         Female ophthalmologist       4 (40.0%)         Defendant Gender       28 (100%)         Total Defendants       28 (100%)         Male       20 (71.4%)         Female       0 (0.0%)         Group (ie US government or a company)       7 (25.0%)         Unspecified       1 (3.6%)         Ophthalmologist Defendants       21 (75%)         Male       20 (95.2%)         Female       0 (0.0%)         Unspecified       1 (4.8%)         Ophthalmologist Sub-Specialty       31 (100%)         Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       8 (38.1%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Not Applicable	6 (8.1%)
Female ophthalmologist   Defendant Gender	Ophthalmologist Plaintiffs	10 (27.0%)
Defendant Gender   Total Defendants   28 (100%)   Male   20 (71.4%)   Female   0 (0.0%)   Group (ie US government or a company)   7 (25.0%)   Unspecified   1 (3.6%)   Ophthalmologist Defendants   21 (75%)   Male   20 (95.2%)   Female   0 (0.0%)   Unspecified   1 (4.8%)   Ophthalmologist Sub-Specialty   Total Ophthalmologists Involved   31 (100%)   Ophthalmologist is Plaintiff   10 (32.3%)   General   5 (50.0%)   Refractive   1 (10.0%)   Cataract   1 (10.0%)   Glaucoma   1 (10.0%)   Retina   1 (10.0%)   Ophthalmologist is Defendant   21 (67.7%)   General   3 (14.3%)   Refractive   8 (38.1%)   Cataract   4 (19.0%)   Glaucoma   Retina   2 (9.52%)   Pediatric   0 (0.0%)	Male ophthalmologist	6 (60.0%)
Total Defendants   28 (100%)   Male   20 (71.4%)   Female   0 (0.0%)   Group (ie US government or a company)   7 (25.0%)   Unspecified   1 (3.6%)   21 (75%)   Male   20 (95.2%)   Female   0 (0.0%)   Unspecified   1 (4.8%)   Ophthalmologist Defendants   1 (4.8%)   Ophthalmologist Sub-Specialty   Total Ophthalmologists Involved   31 (100%)   Ophthalmologist is Plaintiff   10 (32.3%)   General   5 (50.0%)   Refractive   1 (10.0%)   Cataract   1 (10.0%)   Glaucoma   1 (10.0%)   Retina   1 (10.0%)   Ophthalmologist is Defendant   21 (67.7%)   General   3 (14.3%)   Refractive   8 (38.1%)   Cataract   4 (19.0%)   Glaucoma   0 (0.0%)   Refractive   6 (38.1%)   Cataract   4 (19.0%)   Glaucoma   0 (0.0%)   Retina   2 (9.52%)   Pediatric   0 (0.0%)	Female ophthalmologist	4 (40.0%)
Male       20 (71.4%)         Female       0 (0.0%)         Group (ie US government or a company)       7 (25.0%)         Unspecified       1 (3.6%)         Ophthalmologist Defendants       21 (75%)         Male       20 (95.2%)         Female       0 (0.0%)         Unspecified       1 (4.8%)         Ophthalmologist Sub-Specialty       10 (32.3%)         Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Pediatric       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Defendant Gender	
Female	Total Defendants	28 (100%)
Group (ie US government or a company)       7 (25.0%)         Unspecified       1 (3.6%)         Ophthalmologist Defendants       21 (75%)         Male       20 (95.2%)         Female       0 (0.0%)         Unspecified       1 (4.8%)         Ophthalmologist Sub-Specialty       31 (100%)         Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Pediatric       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Male	20 (71.4%)
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Ophthalmologist Defendants       21 (75%)         Male       20 (95.2%)         Female       0 (0.0%)         Unspecified       1 (4.8%)         Ophthalmologist Sub-Specialty       31 (100%)         Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Retina       1 (10.0%)         Pediatric       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Group (ie US government or a company)	7 (25.0%)
Male       20 (95.2%)         Female       0 (0.0%)         Unspecified       1 (4.8%)         Ophthalmologist Sub-Specialty       31 (100%)         Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Retina       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Unspecified	I (3.6%)
Female       0 (0.0%)         Unspecified       I (4.8%)         Ophthalmologist Sub-Specialty         Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       I (10.0%)         Cataract       I (10.0%)         Glaucoma       I (10.0%)         Retina       I (10.0%)         Pediatric       I (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Ophthalmologist Defendants	21 (75%)
Unspecified       I (4.8%)         Ophthalmologist Sub-Specialty       31 (100%)         Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       I (10.0%)         Cataract       I (10.0%)         Glaucoma       I (10.0%)         Retina       I (10.0%)         Pediatric       I (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Male	20 (95.2%)
Ophthalmologist Sub-Specialty         31 (100%)           Ophthalmologists Involved         31 (100%)           Ophthalmologist is Plaintiff         10 (32.3%)           General         5 (50.0%)           Refractive         1 (10.0%)           Cataract         1 (10.0%)           Glaucoma         1 (10.0%)           Retina         1 (10.0%)           Pediatric         1 (10.0%)           Ophthalmologist is Defendant         21 (67.7%)           General         3 (14.3%)           Refractive         8 (38.1%)           Cataract         4 (19.0%)           Glaucoma         0 (0.0%)           Retina         2 (9.52%)           Pediatric         0 (0.0%)	Female	0 (0.0%)
Total Ophthalmologists Involved       31 (100%)         Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Retina       1 (10.0%)         Pediatric       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Unspecified	I (4.8%)
Ophthalmologist is Plaintiff       10 (32.3%)         General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Retina       1 (10.0%)         Pediatric       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Ophthalmologist Sub-Specialty	
General       5 (50.0%)         Refractive       1 (10.0%)         Cataract       1 (10.0%)         Glaucoma       1 (10.0%)         Retina       1 (10.0%)         Pediatric       1 (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Total Ophthalmologists Involved	31 (100%)
Refractive       I (10.0%)         Cataract       I (10.0%)         Glaucoma       I (10.0%)         Retina       I (10.0%)         Pediatric       I (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Ophthalmologist is Plaintiff	10 (32.3%)
Cataract       I (10.0%)         Glaucoma       I (10.0%)         Retina       I (10.0%)         Pediatric       I (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	General	5 (50.0%)
Glaucoma       I (10.0%)         Retina       I (10.0%)         Pediatric       I (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Refractive	I (I0.0%)
Retina       I (10.0%)         Pediatric       I (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Cataract	I (I0.0%)
Retina       I (10.0%)         Pediatric       I (10.0%)         Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Glaucoma	I (10.0%)
Ophthalmologist is Defendant       21 (67.7%)         General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Retina	
General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Pediatric	I (10.0%)
General       3 (14.3%)         Refractive       8 (38.1%)         Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Ophthalmologist is Defendant	
Cataract       4 (19.0%)         Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	·	3 (14.3%)
Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Refractive	8 (38.1%)
Glaucoma       0 (0.0%)         Retina       2 (9.52%)         Pediatric       0 (0.0%)	Cataract	4 (19.0%)
Retina         2 (9.52%)           Pediatric         0 (0.0%)	Glaucoma	
Pediatric 0 (0.0%)	Retina	
	Pediatric	
1 (110%)	Unknown	4 (19.0%)

scope of medical fraud claims that can be made and how ophthalmologists may experience a fraud claim in a variety of settings.

Of the cases analyzed, the most common type of fraud was malpractice fraud. Nevertheless, most of these malpractice fraud claims were not ruled in favor of the plaintiff, with 6 of 12 ruling in favor of the defendant entirely and another 2

Table 3 Litigation Outcomes

Verdict (n, %)	Median Payout (IQR)	Median Prison Sentence
Plaintiff (13, 48.1%)*	\$2,652,284.50 (\$313,644.47-\$5,729,091)	60 months (SD = 40.7)
Settlement (5, 18.5%)**	\$320,000 (\$100,000-\$6,720,000)	N/A
Defense (9, 33.3%)***	\$0	N/A
Total (27, 100%)		

Notes: \*12 awards available, 3 prison sentences, \*\*4 awards available, 0 prison sentences, \*\*\*9 awards available, 0 prison sentences.

Table 4 Fraud Classification

Total Cases	27 (100%)
In favor of Plaintiff	13 (48.1%)
Malpractice fraud	3 (23.1%)
Contract fraud	3 (23.1%)
Billing fraud	4 (30.8%)
Employment harassment and fraud	2 (15.4%)
Business fraud	I (7.69%)
Settlement	5 (18.5%)
Malpractice fraud	3 (60.0%)
Billing fraud	I (20.0%)
Kickback scheme fraud	I (20.0%)
In favor of Defendant	9 (33.3%)
Malpractice fraud	6 (66.7%)
Contract fraud	2 (22.2%)
Fraud during trial	1 (11.1%)

cases ruling in favor of the defendant on the fraud claim but not the malpractice claim. Literature shows that most malpractice lawsuits are unsuccessful, correlating with the finding that most malpractice-related fraud claims were unsuccessful in this study.<sup>8</sup> A possible explanation for this finding may be that the fraud claims in these cases were secondary to malpractice claims, thus warranting less attention. Many of the malpractice-related fraud cases in the current study also did not mention a clear violation of fraud legislation.

Generally, medical fraud cases claim that there is a violation of 1 of 3 statutes: the False Claims Act of 1863, the Anti-Kickback Statute of 1982, or the Stark Law of 1989. The False Claims Act imposes civil liability on any person who submits a false or fraudulent claim to the federal government for payment or approval. The act also allows whistleblowers to act on behalf of the government's behalf to identify fraud and collect compensation. Of all the cases in the current study that mentioned fraud legislation, the False Claims Act was the most cited statute. The Anti-Kickback Statute prohibits anyone from receiving payment for making a referral to a federally reimbursed healthcare program. Kickbacks schemes were not commonly seen in this study, as only one case involved a biopharmaceutical company providing free business advisory services to ophthalmologists who prescribed the company's products. The final law of the three is the Physician Self-Referral (Stark) Law, which prohibits physicians from making referrals to certain designated health services paid for by Medicare of Medicaid if the physician, or an immediate family member, has

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a financial relationship with the entity. None of the malpractice-related fraud lawsuits that were ruled in favor of the ophthalmologist cited a clear violation of a fraud statute; however, it is important to note that this study did not find clear citations of fraud claims in most of the malpractice-related fraud lawsuits included in the study, regardless of final outcome.

While defending ophthalmologists in this study were more likely to succeed on malpractice-related fraud claims, they experienced less success as defendants on billing claims fraud. Some of these billing fraud lawsuits cited the False Claims Act or other related legislation. One case that cited a violation of the False Claims Act involved double-billing of services to Medicaid. Another case cited a violation of the False Claims Act because the defending ophthalmologist made false claims for reimbursements of services rendered to Medicare patients. Both cases were ruled against the defendant ophthalmologist. A possible explanation for why these billing fraud cases were often ruled against the defendant may be the specificity of the False Claims Act against fraudulent actions including double billing or falsified claims. The plaintiff in these cases is also typically the United States government, which may make it harder for the defendant to obtain success with his or her case. Moreover, criminal charges may be included in these cases, as at least 3 of the 5 billing fraud cases included prison sentences.

Although few of the billing fraud cases resulted in prison sentences, the majority of the cases won by plaintiffs included a significant financial award. The case with the largest financial award (\$31,676,301) was a contract fraud case in which the plaintiff sued an insurance company for insurance breach of contract after claiming he was experiencing anxiety attacks from performing surgeries, but the insurance company claimed he was not disabled from performing the surgeries. Other cases with the largest settlements included a kickback scheme, a business fraud case, a billing fraud, and an employment harassment and fraud case, indicating no notable association between fraud type and award amount. Of note, the decision to pursue the case in court or reach a settlement can also impact the amount of the financial award. The median payout for court cases won by the plaintiff was over 8 times greater than the median payout for cases that reached a settlement. Both jail sentences and financial losses can have a significant financial and emotional impact on the parties involved and highlight the importance of physician education on avoiding fraud lawsuits.<sup>8</sup>

While the malpractice-related fraud cases typically included the ophthalmologists as the defendants, ophthalmologists were also seen as plaintiffs in other types of fraud lawsuits, particularly contract fraud cases. These were cases in which the physician posited that there was a breach of contract with a company or other colleagues. Males were more likely to be sued than females, with all defendants being male. This finding coincides with the findings of the 2018 study by Chen et al, which found that physicians who were excluded from Medicare and state public programs due to fraud were commonly male physicians. Moreover, a retrospective, cohort study of 2251 malpractice claims reported to the Ophthalmic Mutual Insurance Company from 1990 to 2008 found that men were sued 54% more often than females over the period studied, indicating a prevalence of claims against men in not only medical fraud, as observed in this study, but also medical malpractice. Moreover, a retrospective of claims against men in not only medical fraud, as observed in this

A future study could investigate whether lawsuits in ophthalmology under the False Claims Act are associated with future reductions in fraudulent activity, such as providing unnecessary procedures or overbilling. A 2020 study by Howard and Desai performed a similar analysis in cardiology by examining cases in which hospitals were investigated under the False Claims Act for billing Medicare for unnecessary percutaneous coronary interventions (PCI) in order to assess the association between these investigations and PCI volumes. The study found that procedure volume declined at the hospitals under investigated by the False Claims Act upon initiation of the investigations, but it also stated that other factors may have been at play in this decline in procedure volume. In order to analyze the association between cases under the False Claims Act and reduction in fraudulent activity in ophthalmology, a more extensive review of cases involving the False Claims Act should be performed, perhaps by using multiple legal databases.

There were several limitations in this study. The number of cases was limited, as many cases queried in the search did not pertain to fraud litigation involving an ophthalmologist. The search strategy was also limited since only one database was used. Further, the database used typically provided summaries of the cases instead of the full text of the case, potentially limiting the amount of information obtained on each case. Since many of the cases were not provided in full text, it was difficult to confirm that the fraud claim did not include a statute or jail sentence, for instance. Additionally, not all plaintiff awards were provided, limiting the analysis of median payouts. Finally, details regarding the ages and

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specialties of the involved ophthalmologists were commonly found via Internet searches, which may limit their reliability.

In conclusion, fraud lawsuits can be seen in all fields of medicine, including ophthalmology, and can have a significant financial and emotional burden on a physician. Even if unintentional, almost all physicians will contribute to improper billing at some point in their careers. This emphasizes the importance of physician education on best practices for submitting appropriate claims, properly documenting information in medical records, and creating and executing contracts.

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Dr Parikh is advisory board for Apellis and reports consulting for Anthem Blue Cross Blue Shield, outside the submitted work. Dr. Sridhar is a consultant for Alcon, Allergan, Apellis, Dorc, Genentech, and Regeneron. The authors report no other conflicts of interest in this work.

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