APPENDIX A

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 17-11455

D.C. Docket No. 3:14-cr-00075-BJD-PDB-1

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

DAVID MING PON,

Defendant-Appellant.

Appeal from the United States District Court
for the Middle District of Florida

(June 29, 2020)

Before ED CARNES, MARTIN, and ROGERS,* Circuit Judges.

ED CARNES, Circuit Judge: A jury found David Pon guilty of twenty counts of health care fraud, in

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* Honorable John M. Rogers, United States Circuit Judge for the Sixth Circuit, sitting by designation.

violation of 18 U.S.C. § 1347, and the district court entered a judgment of conviction on the verdict. After finding that Pon's fraud scheme resulted in a loss of nearly $7 million, the court sentenced him to 121 months in prison. He appeals his convictions and sentence.

A jury found David Pon guilty of twenty counts of health care fraud, in violation of 18 U.S.C. § 1347, and the district court entered a judgment of conviction on the verdict. After finding that Pon's fraud scheme resulted in a loss of nearly $7 million, the court sentenced him to 121 months in prison. He appeals his convictions and sentence.

I. FACTS

Pon was an ophthalmologist.[1] As a sole practitioner, he established his practice with a main office in Leesburg, Florida, and a satellite office in Orlando. Many of his patients were elderly. He diagnosed hundreds of them with, and lasered their eyes to purportedly treat, a debilitating and uncurable eye disease known as wet age-related macular degeneration (WMD).

Here is how his scheme worked. Pon would run diagnostic tests on a patient. After diagnosing the patient with WMD, he would move on to the "treatment" phase, which involved lasering one or both of the patient's eyes. Pon would laser his patients' eyes with the laser set on the lowest power setting and in

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[1] Pon was once a licensed doctor but we do not refer to him as one because Florida's Board of Medicine revoked his license in August 2016 as a result of the jury's guilty verdict.

micropulse mode.[2] He would then submit a claim to Medicare for the diagnostic tests and the laser session. As a result, he would receive from Medicare around $1,200 total for each set of diagnostic tests and lasering.

Pon would bill his micropulse laser sessions under Medicare code 67220, the code for "laser photocoagulation for [WMD], for a choroidal neovascular membrane," or in other words, "burning an area of abnormal leaking blood vessels with a laser." Laser photocoagulation is a treatment for WMD that creates a scar in the eye by "cooking" shut the abnormal blood vessels (feeder vessels) that are characteristic of WMD. But the extremely low power settings that Pon set his laser to before each session were not high enough to achieve coagulation, so his purported treatments left no scars and did not fit under code 67220. One expert testified that Pon's settings were "way too low" for coagulation purposes, and that his method was tantamount to "jump-start[ing] [a car] off a flashlight. It's so little energy."

And Pon agreed. He described his purported treatment technique — which he referred to as "the micropulse laser technique for treatment of feeder vessels"—as treating WMD while leaving "no or minimal

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[2] The laser that Pon used has several different user-selectable modes of operation. When micropulse mode is selected, the laser is on for only a predetermined percentage of the exposure time. For example, a 15 percent duty cycle means that the laser is on for only 15 percent of the exposure time and is off for the remaining 85 percent of the exposure time. Pon would set his laser to micropulse mode with a 15 percent duty cycle before lasering his patients' eyes.

scarring." According to Pon, "the whole concept" behind his purported treatment was to use the laser to heat up the WMD feeder vessels "without causing a burn." His intention was "to get the effect from the laser without causing a burn, coagulation." In fact, according to Pon, he would "virtually never get a scar or a burn" if he did his "technique properly." But Pon continued to bill Medicare for his laser "treatments" under code 67220 for laser photocoagulation—or laser scarring.

And Pon became a top Medicare biller of WMD laser scarring treatment, billing Medicare for his micropulse laser (which is intended not to create a scar), under code 67220 for laser photocoagulation (which is intended to create a scar). The percentage of his patients whom he diagnosed with WMD and billed Medicare under code 67220 for laser photocoagulation treatment substantially increased over the years. Around 2006, drug injections had supplanted laser photocoagulation as the typically favored WMD treatment method, so other ophthalmologists' laser treatments and billing amounts for laser photocoagulation went down. Pon's, by contrast, went up dramatically.

Pon's practice produced puzzlement and sowed suspicion. Other doctors who also treated Pon's patients were puzzled about his WMD diagnoses and laser "treatments." In the fall of 2008, for example, Virginia-based doctor Robert Vogel was treating his longtime patient, D.M., and noticed that the 83-year-old had several left-eye maladies, but not WMD. Because D.M. would be in Florida for the winter months, Dr. Vogel told him to check in with an eye doctor after he got there. D.M. chose Pon, who diagnosed him with WMD and micropulse lasered his eyes. When D.M. returned to Virginia a few months later, Dr. Vogel was

"shocked" when D.M. told him that Pon had lasered both of his eyes. Dr. Vogel examined both eyes, did not see WMD in either of them, and could not understand why either one would have been lasered. Nor did Dr. Vogel see a scar in either eye that would indicate Pon had used a laser at settings that would have treated WMD if D.M. had actually suffered from it. This "unusual" situation prompted Dr. Vogel to tell D.M. to find a doctor other than Pon the next time he went to Florida.

Other experts observed similar anomalies involving Pon's practice and patients. Optometrist Sam Williams referred some of his own patients to Pon, who diagnosed every one of them with WMD. Dr. Williams, who has more than forty-five years of experience as an optometrist, became concerned when some of those patients told him that Pon had lasered their eyes on multiple occasions. As a result, Dr. Williams sent them to other ophthalmologists for second opinions about the medical necessity of the suspicious laser treatments. "[O]n every occasion" the ophthalmologists found that there was no sign Pon had lasered those patients' eyes in a way that would actually treat WMD or that the patients needed any laser treatment for any eye disease. Dr. Williams stopped referring his patients to Pon.

Ophthalmologist and retinal specialist Elias Mavrofrides discovered much the same thing. He examined at least thirty of Pon's patients and determined that, although many reported having undergone repeated laser treatment by Pon for WMD, their eyes showed no signs of the disease. Many of Pon's patients told Dr. Mavrofrides that they were not sure why Pon was lasering their eyes, but "were told that they would lose vision without treatment." Dr.

Mavrofrides thought that Pon's reported use of lasers on his patients "over and over and over [was] extremely atypical or unusual." In 2008 an optometrist referred to Dr. Mavrofrides a patient Pon had diagnosed with WMD and lasered eight months in a row. After examining the patient, Dr. Mavrofrides wrote a letter to the optometrist stating that he "honestly d[id] not see any necessity for the [laser] treatments [the patient] has had."

Sometime before the fall of 2011 the government discovered Pon's scheme. It happened when Special Agent Christian Jurs conducted a data analysis to determine whether any doctors were billing Medicare under codes associated with what he was told were outdated WMD treatment methods, including laser photocoagulation.[3] That analysis revealed that Pon was a "significant outlier" with respect to the Medicare claims he submitted under 67220, the billing code for laser photocoagulation. In 2010, for example, Pon had submitted claims under that code for approximately 93 percent of his Medicare patients, while his ophthalmologist peers had submitted claims under that code for an average of only seven-hundredths of one percent of their patients. That is a disparity of about 132-to-1. The disparity prompted Agent Jurs to run Pon's name through a complaint database, which showed that an unidentified person had lodged a complaint about

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[3] Special Agent Jurs is a Medicare fraud investigator who became an agent with the United States Department of Health and Human Services after having worked as a naval intelligence officer and as an agent for the Naval Criminal Investigative Service. He has worked with Medicare data on numerous occasions since he became a HHS special agent nearly two decades ago.

Pon's WMD treatment. And that, in turn, prompted him to interview approximately thirty doctors who had seen patients whom Pon had diagnosed with WMD and micropulse lasered. After Agent Jurs conducted some of those interviews, the government obtained a warrant to search Pon's offices.

In September 2011 federal law enforcement officers executed the search warrant and seized Pon's patient files along with thousands of photographs and videos of his patients' eyes. The next month the Centers for Medicare and Medicaid Services sent Pon a letter notifying him that it had suspended his Medicare payments based on what it identified as "credible allegations of [health care] fraud." The suspension letter stated that between 2004 and 2011 Pon had submitted Medicare claims under codes associated with laser photocoagulation treatment and a type of WMD diagnostic test "that were disproportionate to claims submitted by other ophthalmologists for these codes," and "that many of [Pon's] patients did not have the underlying medical conditions that would support the procedures represented by these codes."

Sometime after Pon's Medicare payments were suspended, Agent Jurs retained an expert, Dr. Thomas Friberg, to review the photos and videos of the eyes of about 500 patients whom Pon had diagnosed with WMD. Dr. Friberg was asked to review whether Pon's patients did, in fact, have WMD. Dr. Friberg had obtained his medical degree from the University of Minnesota, completed an ophthalmology residency at Stanford University Medical Center, and held fellowships at the Harvard Medical School and the Duke University Eye Center. He is a professor of ophthalmology and a professor of bioengineering at the University of Pittsburgh, has authored or co-authored

more than 175 articles in peer-reviewed publications, and has, over the course of his four-decade career, received more than $7 million in grants to study age-related eye diseases, including WMD.

Dr. Friberg's review of the more than 10,000 images of the eyes of patients whom Pon had diagnosed with WMD and "treated" took him about a year to complete. He found what he saw "shocking." He realized that he "was looking at hundreds of images of patients that had nothing wrong with their eye[s]." According to Dr. Friberg, maybe "five to ten"—only one or two percent—of the 500 patients whom Pon had diagnosed with WMD actually had any form of macular degeneration. Dr. Friberg concluded that Pon had shown a "reckless disregard for his patients."

II. PROCEDURAL HISTORY

In April 2014 a federal grand jury returned a twenty-count indictment against Pon. Each count charged him with health care fraud, in violation of 18 U.S.C. § 1347.[4] The indictment alleged that he committed health care fraud by falsely diagnosing eleven of his patients with WMD and using those false diagnoses as a basis for submitting a total of twenty Medicare reimbursement claims (a different one described in each count) for performing both additional WMD

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[4] Section 1347 makes it a crime to "'knowingly and willfully' engage in a scheme (1) 'to defraud any health care benefit program' or (2) to use false pretenses to obtain money from 'any health care benefit program,' 'in connection with the delivery of or payment for health care benefits, items, or services.'" *United States v. Bergman*, 852 F.3d 1046, 1065 (11th Cir. 2017) (quoting 18 U.S.C. § 1347).

testing that he knew was medically unnecessary and laser sessions that could not actually treat the disease even if the patients had been suffering from it, which they had not.[5] Pon faced a statutory maximum of ten years per count. 18 U.S.C. § 1347(a). He went to trial.

A. The Daubert Hearing

Before trial Pon notified the government that he intended to offer the expert testimony of Giorgio Dorin, a former director of development at the company that manufactured the laser Pon used. Dorin's proposed testimony boiled down to two main points. First, he would testify about the general concepts of lasers and their application to eye diseases. Second, he would testify about a "newer method" of treating WMD that Pon said he had used on his patients: "subthreshold micropulse laser photostimulation." Dorin would opine that the newer method could be used to close feeder vessels in a way that, unlike laser photocoagulation, would not leave a scar. Dorin chose to use the term "photostimulation" because the term "photocoagulation" suggests that the treatment necessarily produces a visible scar. The object of Dorin's testimony would be to show that the low-power laser sessions Pon had subjected his patients to could actually treat WMD and could do so without leaving a telltale scar.

The government moved to exclude Dorin's proposed testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), after its medical and laser experts advised it that "Dorin's assertion

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[5] To protect their privacy, the indictment does not refer to the patients by name, and we will follow that lead by referring to them as the eleven patients, or individually as Patient One, Patient Two, and so on.

regarding subthreshold micropulsed laser 'photostimulation' is not a medically accepted standard of care for the treatment of [WMD]." The government stated in its motion "that the term now used by the defense, laser 'photostimulation[,]' is apparently an attempt to somehow legitimatize the fact that there is no scarification in the retinas of [Pon's] victims."

The district court held a three-day *Daubert* hearing. Dorin was the only witness for the defense. The government put on two witnesses—Dr. Friberg and David Buzawa, the co-founder of the company that manufactured Pon's laser. All three of the witnesses testified about whether subthreshold micropulse laser photostimulation (which left no scar) could treat WMD.

At the hearing, Dorin testified that the use of subthreshold micropulse laser photostimulation to treat WMD was "[t]heoretical[]." He conceded that he was unaware of any journal article stating that it is possible to use subthreshold micropulse photostimulation with Pon's laser to treat WMD. But he talked about previous research that he said at least supported the idea. He described a study showing that subthreshold micropulse laser treatment was effective for diabetic macular edema, but that is a different medical condition than WMD. Defense counsel then asked Dorin whether he could, as a result of that one study involving diabetic macular edema, infer that subthreshold micropulse laser treatment was effective for WMD. Dorin responded: "I don't see why ... not, but we don't have so many paper[s] published yet. I have not seen the clinical data."

Dorin also discussed a paper he authored that a peer-reviewed ophthalmology journal published in

2004, when Dr. Friberg was the journal's editor-in-chief. In the paper Dorin stated that "laser pulses" could treat WMD by closing feeder vessels and could do so without causing "retinal burns." Dorin's paper concluded, however, that "[i]t does take a 'leap of faith' to accept that a retina with serious disease can be treated with ... sub-visible-threshold protocols and without the use of additional pharmacological agents."

At the *Daubert* hearing, the government called Dr. Friberg. Dr. Friberg testified that Dorin's proposed theory about subthreshold micropulse laser photostimulation had not been tested and had "absolutely not" gained general acceptance in the scientific community. He also testified that Dorin's statement that subthreshold micropulse laser photostimulation can produce the same beneficial effect as laser photocoagulation was "crazy." When asked whether there was even one study showing that the type of laser Pon used has closed a feeder vessel without leaving a scar while in micropulse mode, Dr. Friberg responded: "No." He believed that there was "absolutely no acceptance in the ophthalmological community for Dorin's conjecture."

The government's other witness at the *Daubert* hearing, David Buzawa, held nine patents related to laser technology and had nearly forty years of experience with lasers. He was also the co-founder of the company that manufactured Pon's laser. Buzawa testified that the power settings that Pon said he set his laser to before each laser session were "unusually low for micropulse." Buzawa also stated that he had "never heard of or read a publication of successful feeder vessel closure using micropulse [mode] at [Pon's] settings or any settings." He concluded that feeder vessel treatment always creates a visible scar,

according to "every paper and presentation that [he had] heard or read."

At the end of the *Daubert* hearing, defense counsel admitted that his proffered witness "Dorin [was] drawing conclusions that have not yet been scientifically tested." The district court ruled that Dorin could testify about the general concepts of lasers and their applications. But he could not offer his opinion that subthreshold micropulse laser photostimulation could treat WMD by closing feeder vessels. The court found that Dorin's proposed opinion was "conjecture" and ruled that it did not satisfy either Federal Rule of Evidence 702 or *Daubert*. Then came the jury trial.

B. The Trial

The jury trial began in September of 2015. The government presented nineteen witnesses and introduced more than 700 exhibits during its seven-day case-in-chief.

Dr. Friberg was one of the government's first witnesses. He began with an overview of the science behind WMD and how it is diagnosed and treated. He explained, for example, that laser photocoagulation, which is billed under Medicare code 67220, is a WMD treatment that can be used to "cook" feeder vessels. He testified that laser photocoagulation did not "have much uptake" in the medical community because the laser leaves behind a scar that can itself impair vision. Dr. Friberg also testified that he was "very certain" that if a doctor uses "enough [laser] energy ... to cook the feeder vessel, you're going to leave a [scar]." And he stated that he was "[a] hundred percent" certain that Pon's micropulse laser technique could not close a feeder vessel.

Dr. Friberg also explained the science behind drug injections, another WMD treatment that was introduced after laser photocoagulation. He testified that "there is no [WMD] treatment that we know of that is better than these [drug injections]."

Dr. Friberg then described how Agent Jurs had retained him to review the photos and videos of the eyes of the approximately 500 patients whom Pon had diagnosed with WMD and "treated" with his micropulse laser technique. Dr. Friberg described how his review of those photos and videos revealed that the vast majority of those patients did not actually have WMD. For that reason, what he saw in his review "got [him] kind of mad." According to Dr. Friberg, Pon was unnecessarily lasering the eyes of patients for a disease they did not have.

Dr. Friberg discussed in front of the jury hundreds of images of the eyes of the eleven patients identified in the indictment—patients Pon had diagnosed with WMD and for whom Pon had billed Medicare under code 67220 for laser photocoagulation treatment for that disease. Dr. Friberg testified that based on his review of the images he did not see any indication that any of those eleven patients had WMD or any evidence of the scarring that necessarily results from laser photocoagulation treatment. *See infra* [at 36a–49a].

The government also presented the testimony of other doctors who had personally examined the eleven patients. With each of those doctors the government went patient by patient, eliciting testimony about each patient; the doctors explained to the jury the medical records they had created to document their examinations of the patients. *See id.* None of those doctors concluded that any of the eleven patients had WMD

when Pon diagnosed them with it. Some of those patients did not even have dry age-related macular degeneration, which typically precedes WMD. And several doctors echoed Dr. Friberg's conclusion; they testified that treating WMD by using laser photocoagulation always leaves a scar indicating the use of that treatment method—a scar that the doctors testified they did not see in the eyes of the eleven patients listed in the indictment, even though Pon had billed Medicare under code 67220 for the laser photocoagulation treatment of each patient.

One doctor read from a medical record of his own examination of one of the eleven patients. Pon had billed Medicare more than ten times under code 67220 for the laser photocoagulation of that patient. In his own medical record, the doctor stated that both of the patient's retinas were "completely normal." He testified that he had seen many of Pon's patients for a second opinion, and all of them "had a history of multiple [billed laser photocoagulation] procedures without any visible indication for such procedures or any clinical evidence that such procedures had been performed."

The jury also heard from some of the eleven patients themselves. One of them testified that only after a second doctor confirmed that she did not actually have WMD was she relieved of the shock and fear she felt as a result of her diagnosis. Another testified that Pon never gave her the option of drug injections instead of laser treatments, and she "felt terrible" after another doctor told her that she did not have WMD. Despite the fact that Pon had diagnosed both of those patients with WMD years before the trial, and they had never received any medically recognized treatment for it, each of them testified that they still had the requisite vision to (and did) drive a car.

After the government rested, Pon himself took the stand. He testified that he ran so many diagnostic tests (and billed Medicare for them) because he wanted to be "as comfortable as possible not to miss a diagnosis." He claimed that the reason the patients did not have a scar in their eyes showing that they had undergone the laser photocoagulation treatment he had billed Medicare for was his use of what he termed his "miraculous treatment." As had Dorin at the *Daubert* hearing, Pon testified that his micropulse laser technique could not only treat WMD but could do so without leaving a telltale scar. His technique, Pon explained, was to set his laser to the lowest power settings before each session and then adjust those settings during the session "until [he] s[aw] the reaction that [he] want[ed] to get." He said that he had attended a presentation "in the early 2000s sometime" that discussed this purported treatment, which he described as "the most fantastic news [he had] ever heard," and "a major breakthrough." He did not, however, have any memory of when or where the presentation took place. None.

After hearing the presentation, Pon was "real enthusiastic" that he could use the technique described "to help a lot more patients." Pon said that he believed the technology used to perform the technique described in the presentation was "the greatest thing since sliced bread," so he purchased the necessary equipment. But he later testified that "it all happened about the same time," so he couldn't "recall exactly" whether he bought the new equipment before or after the presentation he claimed had inspired him.

Pon said that once he had the equipment, he began to practice the technique he had heard about in the presentation. He first attempted the technique "on the

patients that [we]re very advanced, so there's really not very much downside risk there." Eventually he "got the procedure to evolve" so that the risk was "almost zero." He did not say whether he had billed Medicare under code 67220 for laser photocoagulation on these early, experimental patients as he had billed Medicare for laser photocoagulation on the patients listed in the indictment.

Pon testified that an important part of his purported treatment was his ability to identify and diagnose WMD in its very early stages. He claimed that by using the new technology he could "visualize, directly visualize, these blood vessels" that caused WMD. But, even with the new technology, "finding the feeder vessel ... is extremely difficult, even for someone" with a lot of experience diagnosing WMD. Pon testified that learning how to accurately interpret the diagnostic images and identify the feeder vessel locations "takes a lot of learning," and "takes years, literally years, to learn how to do."

Pon admitted he did not "know of anybody specifically" who used the same micropulse laser technique to treat WMD. He said that one reason he might be the only one doing so is that the technique has "a steep learning curve." But he was "too busy"—despite taking at least two months of vacation each year—and didn't "feel obligated" to publish anything describing his technique or the treatment results he was achieving.

After Pon's testimony, the defense called thirteen of his patients and the spouse of one deceased patient. Only one of those patients was among the eleven listed in the twenty counts of the indictment. They generally testified that they thought Pon was generous and

trustworthy and that their vision had improved after seeing him. They were not, of course, qualified to testify whether they had ever actually had WMD.

After the government presented some rebuttal testimony, Pon presented some surrebuttal testimony, and the case eventually went to the jury, which found him guilty on all twenty counts.

C. The Sentencing

At Pon's sentence hearing, the district court rejected the probation office's finding and the government's argument that the amount of loss attributable to Pon's fraud scheme was more than $11 million. Instead, the court found that the loss amount was approximately $7 million, which resulted in an 18-level enhancement to the base offense level. The court's application of that and other enhancements yielded an advisory guidelines range of 121 months to 151 months in prison. The court sentenced Pon to 121 months in prison on each count, to run concurrently.

III. THE CONVICTION ISSUES

Pon raises two contentions about his convictions, neither of which questions the sufficiency of the evidence to convict him. First, he contends that under *Daubert* and Federal Rule of Evidence 702, the district court should have allowed his expert to testify about the use of subthreshold micropulse photostimulation as a treatment for WMD. Second, Pon contends that the district court should not have allowed the government to present rebuttal evidence showing that he billed Medicare for performing services on patient J.L.'s blind left eye. In the alternative, he argues that even if that rebuttal evidence was properly admitted, the court should have allowed him to present all of his surrebuttal evidence.

A. The Daubert Issue

It is not easy to persuade a court of appeals to reverse a district court's judgment on *Daubert* grounds. *United States v. Brown*, 415 F.3d 1257, 1264 (11th Cir. 2005). Doing so is tough toil because the "theme that shapes appellate review in this area is the limited nature" of that review. *Id.* We review evidentiary decisions under the abuse of discretion standard. *Id.* at 1264–65 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141 (1997)). And under that standard district courts have a "significant" range of choice, which is to say that we defer to their evidentiary "decisions to a considerable extent." *Id.* at 1265; *accord McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002) ("[O]ur review of evidentiary rulings by trial courts ... is very limited.") (quotation marks omitted).

The deference we show trial courts on evidentiary rulings is especially pronounced in the *Daubert* context, where the abuse of discretion standard places a "heavy thumb"—"really a thumb and a finger or two"—"on the district court's side of the scale." *Brown*, 415 F.3d at 1268. That's done for a number of reasons. The district court occupies the best position to rule on *Daubert* issues given its familiarity "with the procedural and factual details" of the trial, which it presides over and is immersed in. *Id.* at 1266. The rules that control the admission of expert testimony "must be applied in case-specific evidentiary circumstances that often defy generalization." *Id.* And deference maintains the importance of the trial and discourages appeals of rulings about expert witness testimony. *See id.* As a result, "the task of evaluating the reliability of expert testimony is uniquely entrusted to the district court," and we must grant "the district court considerable leeway in the execution of its duty." *Rink v.*

Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005) (citations and quotation marks omitted). We do so mindful, of course, that granting that leeway "is not the same thing as abdicating appellate responsibility." *Brown*, 415 F.3d at 1266.

After holding a three-day *Daubert* hearing, the district court found that Dorin's theory that subthreshold micropulse photostimulation could treat WMD by closing feeder vessels was unreliable. As a result, it allowed Dorin to testify about only the general concepts of lasers and their application to eye diseases. That ruling was not an abuse of discretion.

Federal Rule of Evidence 702 "controls the admission of expert testimony." *United States v. Frazier*, 387 F.3d 1244, 1259 (11th Cir. 2004) (en banc). Under that rule expert witnesses may testify if, among other things, their "testimony is the product of reliable principles and methods." Fed. R. Evid. 702(c). Determining whether expert testimony is the product of "reliable principles and methods" is the province of the *Daubert* test. *See City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998) (stating that courts must determine whether "the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*").

Daubert instructs that a reliability determination involves four main inquiries about the expert's theory or technique: "(1) whether it can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) what its known or potential rate of error is, and whether standards controlling its operation exist; and (4) whether it is generally accepted in

the field." *Brown*, 415 F.3d at 1267 (citing *Daubert*, 509 U.S. at 593–94).

In *Joiner* the Supreme Court added another inquiry to gauge reliability: whether there is "an analytical gap between the data and the opinion proffered." 522 U.S. at 146; *accord McDowell v. Brown*, 392 F.3d 1283, 1300 (11th Cir. 2004) ("[A]n expert opinion is inadmissible when the only connection between the conclusion and the existing data is the expert's own assertions ...."') (citing *Joiner*, 522 U.S. at 146). If the analytical distance between the data and the opinion proffered "is simply too great," a court may conclude that the opinion is unreliable. *Joiner*, 522 U.S. at 146.

Here, three of the four *Daubert* factors weigh against the reliability of Dorin's theory. First, Dorin testified that although his theory could be tested, it has not been. Dr. Friberg agreed. So did defense counsel, who conceded that "Dorin [was] drawing conclusions that have not yet been scientifically tested." And like Pon, Dorin acknowledged that he did not "know of anybody doing it." Second, Pon failed to provide evidence about the theory's known or potential rate of error and whether any standards exist to control for error. Dorin himself acknowledged that he "ha[d] not seen ... clinical data" about it. And third, the record shows that Dorin's theory is not generally accepted in the ophthalmology field. Dr. Friberg testified that the theory has "[a]bsolutely not" gained that acceptance. Buzawa's testimony that "[f]eeder vessel treatment has always been superthreshold," instead of subthreshold, according to "every paper and presentation that [he had] heard or read" confirmed the point.

That leaves only one factor that weighs—ever so slightly—in favor of reliability: Dorin's peer-reviewed

paper mentioning the theory. But just as "[p]ublication ... is not a *sine qua non* of admissibility," *Daubert*, 509 U.S. at 593, publication alone is not enough to conclude that a district court abused its discretion in not admitting expert testimony, *see Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1313 (11th Cir. 1999).

A further indication that Dorin's theory was unreliable is the analytical gap between it and the research that Dorin said supports it. *See Joiner*, 522 U.S. at 146. At the hearing, Dorin suggested that because a study showed subthreshold micropulse laser treatment can treat diabetic macular edema, his theory that it could treat WMD is sound. That is a "leap[ ] from an accepted scientific premise to an unsupported one." *Allison*, 184 F.3d at 1314. Diabetic macular edema is a different condition than WMD. Between the premise that subthreshold micropulse laser treatment can treat the first condition and Dorin's theory that it can treat the second one, there is an analytical gap.

Instead of properly bridging that gap, Dorin tried to *ipse dixit* over it; but a bald assertion cannot carry the *Daubert* burden. *See Williams v. Mosaic Fertilizer, LLC*, 889 F.3d 1239, 1249 (11th Cir. 2018) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.") (quoting *Joiner*, 522 U.S. at 146). The district court concluded that "there [was] simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. That was not an abuse of discretion but a proper exercise of the

"considerable leeway" the court had. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).[6]

B. The Rebuttal Issue

Pon also contends that his convictions must be reversed because the district court erred in two of the evidentiary rulings it made during his fourteen-day trial: (1) allowing the government to present rebuttal evidence showing that he billed Medicare for performing certain medical services on J.L., who was one of his patients, and (2) partially limiting the scope of his surrebuttal evidence about J.L. We review both of those evidentiary rulings only for an abuse of discretion. *See Frazier*, 387 F.3d at 1270; *United States v. Haimowitz*, 706 F.2d 1549, 1560 (11th Cir. 1983). And an abuse of discretion does "not warrant reversal where the resulting error was harmless." *United States v. Barton*, 909 F.3d 1323, 1330 (11th Cir. 2018).

One of the fourteen defense witnesses (not counting Pon) was J.L., who took the stand on the eleventh day of the trial. Like some of Pon's other patients who appeared as defense witnesses, J.L. testified about his history as Pon's patient and described him as generous and trustworthy. He also told the jury that in 1994 both of his retinas had detached because of a complication from diabetes and Pon had performed surgery that year on each eye—the left eye in July and the

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[6] Pon also argues that the district court violated his Sixth Amendment right to put on a meaningful defense because it "mechanistically" applied the *Daubert* factors. We disagree. The district court gave ample reasons why three of those factors weighed against the reliability of Dorin's theory and outweighed the fourth factor.

right eye in August. Pon knew J.L. was unemployed and uninsured at the time and performed the surgeries without any guarantee he would be paid. The 1994 surgery on J.L.'s right eye was successful, but the one on his left eye was not; he lost all of his sight in it soon after that surgery.

Defense counsel also put into evidence excerpts of Pon's treatment records for J.L. Those records included logs in which Pon documented procedures he had performed on J.L.'s right eye between 2004 and 2015. They also indicated that Pon had diagnosed J.L. with WMD in 2009 and had micropulse lasered J.L.'s right eye several times. The excerpts from Pon's records of treating J.L. did not list any tests or procedures that Pon had performed on J.L.'s blind left eye.

During cross-examination, the prosecutor asked J.L. when Pon had last performed any procedure on his left eye, the one in which he had been completely blind for more than twenty years. J.L. said it had "been a couple years"; he said Pon did a "regular eye check on it," which involved an exam with "the eye charts," an "ultrasound," and "pictures," but that Pon had done no "major procedures" on his left eye. The prosecutor then asked J.L. whether Pon had ever done "any kind of an injection" or any "dye tests" in J.L.'s left eye. J.L. responded: "No. I've never had anything done in my left eye." On redirect, J.L. reiterated that Pon had not done "any tests on [his] left eye," including fluorescein angiograms, but Pon had examined that eye "a couple times" by looking at it "through a lens" to see if he could improve the vision in it. J.L.'s firm testimony that Pon had never done any fluorescein angiograms on his left eye was significant because it contradicted the bills Pon submitted to Medicare on at least a half dozen occasions—bills for performing

fluorescein angiogram tests on J.L.'s totally blind left eye. *See infra* [at 26a–29a].

In light of J.L.'s testimony and the medical records Pon's attorney had put into evidence, the government sought to introduce through one of its agents rebuttal evidence in the form of a spreadsheet and related testimony. Agent Jurs had created the spreadsheet after J.L. testified by looking through Pon's Medicare claims history for billings related to J.L.'s left eye after 1994, when he had lost all of his sight in it. The billing records for the decade between 1994 and 2004 were not available,[7] but the records from 2004 until the trial in 2015 were.

The spreadsheet showing the billings and Agent Jurs' testimony established that Pon had billed Medicare for performing services on J.L.'s left eye—in which he had been blind since 1994—52 times between 2004 and 2015. Those 52 billings totaled approximately $19,500 and, aside from three billings for a January 2009 surgery on the blind eye (which Pon would later testify were merely the result of clerical errors), all of the billings were for ophthalmic ultrasounds, fluorescein angiograms, and fundus photography, which are diagnostic tests.

Pon billed Medicare all of those times and for all of that money claiming that he had done procedures on J.L.'s blind left eye, including fluorescein angiograms,

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[7] Agent Jurs testified that he wasn't certain why he had not been able to access Pon's Medicare billing records before 2004. He thought the most likely explanation was that the Medicare system did not give records that "go back, you know, to when the earth cooled. They usually go [back] a five- or ten-year time frame."

even though his own witness, J.L., testified that Pon never performed a fluorescein angiogram or any test involving the injection of dye on his left eye. All Pon had ever done on that eye, J.L. insisted, was perform a "regular eye check on it," and examine it by looking through a lens "a couple of times." His testimony evidenced, at the very least, that Pon's six billings for fluorescein angiograms, which involve the injection of dye, on J.L.'s left eye were fraudulent.

Defense counsel moved to exclude the spreadsheet and Agent Jurs' testimony about it, arguing that the evidence was not proper rebuttal. The district court allowed the government to present the rebuttal evidence because the court recalled (incorrectly, it turned out) that the defense, during J.L.'s testimony, had been the first to bring up the fact that Pon had treated J.L.'s blind left eye. Pon asserts that ruling was reversible error. It wasn't.

Rule 611(a) vests district courts with authority to "exercise reasonable control over the mode and order of examining witnesses and presenting evidence." Fed. R. Evid. 611(a). District courts have "broad discretion" in exercising that authority and will not be reversed except for abuse of that discretion. *United States v. Hill*, 643 F.3d 807, 845 (11th Cir. 2011); *accord Haimowitz*, 706 F.2d at 1560. Pon presented J.L.'s testimony as an example of how he had treated a patient out of the goodness of his heart and not for a profit motive. In light of that, the district court did not abuse its discretion in admitting billings Pon had generated for services he claimed to have rendered on that patient's blind eye.

C. The Surrebuttal Issue

1. The Procedural Facts

Pon alternatively asked the district court, if it was not going to keep out the government's rebuttal evidence, to let Pon retake the stand and present as surrebuttal evidence his explanation for billing Medicare for services on J.L.'s blind left eye. The court reserved a ruling on that alternative request until after the government presented its rebuttal evidence.

After the government did so, Pon renewed his request to present surrebuttal testimony, arguing that he had not had an "opportunity to respond" to the "impression" the government created that Pon improperly conducted and billed for treatments on a blind eye. The district court characterized the government's rebuttal evidence as "very damning" and stated that it had "this idea of fairness tug[ging]" at it, but its "inclination" was to deny the defense's request that Pon be allowed to testify again. The court also asked "the further question of whether, in deference to ... Dr. Pon's Sixth Amendment right ... he should be given an opportunity to offer an explanation" about the billed procedures for J.L.'s blind left eye. The court gave the attorneys the weekend to research the surrebuttal issue and indicated it would do the same.

On Monday, the court heard argument from both sides about whether it had erred by allowing the government's rebuttal testimony and, if so, how any error should be remedied. Neither side mentioned the Sixth Amendment or any other constitutional right that Pon might have to present surrebuttal testimony. Before ruling, the court allowed Pon to proffer the testimony he wished to present in response to the government's rebuttal evidence. He took the stand in a testimonial

proffer, stating that he had performed services on J.L.'s blind left eye to determine whether it had a problem that could lead to complications that might result in a complete loss of vision in the right eye.

Pon testified that ophthalmic ultrasounds, which made up 41 of the 52 billings in the spreadsheet, are used to look for abnormalities in the eye. And in J.L.'s case, "it's very important to examine his left eye and continue to examine his left eye" to make sure he was not developing sympathetic ophthalmia—a condition that can lead to blindness in both eyes. For that reason, Pon said that it was necessary to examine J.L.'s left eye "periodically." But Pon didn't explain what "periodically" meant, and he didn't explain why he needed to examine J.L.'s left eye as frequently as he billed Medicare for doing. The records proved that Pon sometimes billed Medicare for performing ophthalmic ultrasounds on J.L.'s left eye multiple times in one month and, on at least four occasions, twice on the same day.

When asked about the six fluorescein angiograms he had billed Medicare for conducting on J.L.'s blind left eye, Pon said they are "a very useful test to help diagnose sympathetic ophthalmia." Of course, J.L. himself had emphatically testified that Pon never performed a fluorescein angiogram on his left eye. Pon didn't offer any explanation for that contradiction.

Finally, Pon also proffered that the January 2009 surgery was done on J.L.'s right eye, not his left as Pon had billed Medicare. He said that billing for surgery on the left eye resulted from a "clerical error."

After the proffer, defense counsel argued that it would be "incorrect" and "misleading" to prevent Pon from testifying about the clerical error in the billing of

the January 2009 surgery. The district court agreed and decided to let Pon testify that he billed for surgery on the wrong eye as a result of a clerical error. The court would not allow Pon to testify about any of the numerous non-surgical services on the blind left eye and why he claimed they were necessary.

After the jury returned, Pon took the stand and testified that the billing for surgery on J.L.'s left eye in 2009 was a clerical error, and that surgery actually had been performed on J.L.'s right eye. On cross-examination, Pon admitted that those three 2009 clerical errors about the surgical services were "just three entries out of two pages of entries," and that the total billing for those three entries was "less than $3,000." The two pages of entries showed that Pon had billed $16,441 for the 49 non-surgical services on J.L.'s blind left eye—billings that Pon never claimed were the result of clerical error.

During closing arguments to the jury, the government spent its time and aimed its arguments at the evidence involving the fraudulent billings for treatments Pon claimed to have rendered to the eleven patients listed in the indictment—evidence it had presented through nineteen witnesses and nearly 760 exhibits over seven days of the fourteen-day trial. It mentioned J.L. (who had testified for less than one hour of the trial), but just barely. It described him only as someone Pon had incorrectly diagnosed with WMD. It said nothing at all about any services that Pon had billed for J.L.'s blind left eye. Not one word.

Defense counsel, by contrast, discussed J.L. at length in his closing argument. Referring to the surgery Pon had performed on J.L. in 1994, for which Pon did not know if he would get paid, counsel asked the

jury: "Is that, ladies and gentlemen, what a fraudster would do?" And addressing the rebuttal evidence that Pon billed for services on J.L.'s blind left eye, counsel argued:

> I submit to you that the diagnostic tests and examinations that Dr. Pon did, whether it's on the right eye, which still was viable, or the left eye, which he was legally blind in, are still tests that are appropriate for a doctor to do, and there's absolutely nothing wrong with doing those tests and billing Medicare for it.

However, he did not offer the jury any explanation for why J.L., the witness he called who would have been the subject of those tests—including tests involving dye injections—would testify under oath that at least some of them had never been performed.

After closing arguments, the court instructed the jury, among other things, that Pon was "on trial only for the specific crimes charged in the indictment," and the jury's task was to determine whether Pon was "guilty or not guilty of those specific crimes." The jury found him guilty of all twenty counts of health care fraud, none of which mentioned J.L.

We review rulings about whether to allow surrebuttal evidence only for an abuse of discretion. *See Frazier*, 387 F.3d at 1270; *Haimowitz*, 706 F.2d at 1560. The district court's ruling partially granted and partially denied Pon's request to present surrebuttal evidence. The court granted his request to re-take the stand and testify that the three billings for surgery on J.L.'s left eye were clerical errors, and he had actually performed the surgery on J.L.'s functioning right eye. But the court denied Pon's request to testify that the reason he billed for so many diagnostic tests on J.L.'s

blind left eye was to determine if there was a problem with it that could lead to complications that might result in a loss of vision in the right eye.

2. The Preservation Issue

Pon contends the court's refusal to let him testify to that was both trial error and constitutional error. The constitutional error he claims is a violation of his Sixth Amendment right "to defend against the government's evidence" and denial of a fair opportunity to respond to the government's rebuttal testimony. Pon clearly preserved the trial error issue in the district court, but it is far from clear that he preserved the constitutional issue.

"No procedural principle is more familiar ... than that a constitutional right may be forfeited in criminal as well as civil cases by the failure to make timely assertion of the right before a tribunal having jurisdiction to determine it." *Yakus v. United States*, 321 U.S. 414, 444 (1944). To preserve an error in a criminal trial, a party must "inform[ ] the court—when the court ruling or order is made or sought—of the action the party wishes the court to take, or the party's objection to the court's action and the grounds for that objection." Fed. R. Crim. P. 51(b). Failing to contemporaneously object "ordinarily precludes the raising on appeal of the unpreserved claim of trial error." *Puckett v. United States*, 556 U.S. 129, 135 (2009).

Although a contemporaneous objection preserves an issue for appellate review, "not every objection is a constitutional objection." *United States v. Candelario*, 240 F.3d 1300, 1304 (11th Cir. 2001). We have held over and over again that to preserve an issue, a litigant must "first clearly present it to the district court, that is, in such a way as to afford the district court an

opportunity to recognize and rule on it." *See, e.g.*, *Juris v. Inamed Corp.*, 685 F.3d 1294, 1325 (11th Cir. 2012) (quotation marks omitted).

While Pon did preserve through objection and argument the issue of whether the district court's partial limitation on his surrebuttal evidence violated the rules governing the presentation of rebuttal and surrebuttal evidence, he never once mentioned the Sixth Amendment or argued to the district court that the limitation violated that or any other constitutional provision. Our precedent indicates that an objection on nonconstitutional grounds is not enough to preserve a constitutional issue. For example, in *United States v. Chau*, 426 F.3d 1318 (11th Cir. 2005), we held that the defendant's hearsay objection in the district court did not preserve the Confrontation Clause issue he pressed on appeal. *Id.* at 1321–22 ("[A] hearsay objection does not preserve the [Confrontation Clause] issue...."). In *United States v. Hawkins*, 934 F.3d 1251 (11th Cir. 2019), we concluded that the "tepid objections made by defense counsel" and the "rumblings of concern about the phrasing of questions" did not preserve the argument the defendants made on appeal that the trial court had admitted improper opinion testimony. *Id.* at 1264. And in *United States v. Elbeblawy*, 899 F.3d 925 (11th Cir. 2018), we held that a defendant had not preserved an argument when he only "mentioned it, in passing, in a post-trial reply motion" because the "post-trial remark was neither timely nor sufficiently developed" to preserve the issue. *Id.* at 938. Pon did not even mention in passing to the district court the constitutional issue he wants to pursue before us.

It is true that at one point the district court—not Pon—stated: "[T]here's the further question of

whether, in deference to ... Dr. Pon's Sixth Amendment right ... he should be given an opportunity to offer an explanation at that point." That probably is not enough to preserve the Sixth Amendment issue for appeal, even under the view of the treatise that the dissent relies on to reach the contrary conclusion. *See* Dissent at [72a].

The relevant part of that treatise states:

> [I]f the record reveals that the parties and the court were aware of the claim or issue *and litigated it*, then whether or not it served as the basis for determination the claim or issue was raised and is reviewable on appeal. Moreover, *if the district court* sua sponte raised an issue of law and *explicitly resolved the issue on the merits*, that ruling is fully reviewable on appeal even though no party raised it below.

19 James Wm. Moore et al., *Moore's Federal Practice* § 205.05(1) (3d ed. 2019) (emphases added) (footnotes omitted). Like our precedent, the treatise states that the mere mention of an issue does not preserve it. Instead, the issue must have been "decide[d]," "litigated," and "explicitly resolved ... on the merits" to be preserved. *Id.*

As our discussion of the surrebuttal argument in the district court has shown, the Sixth Amendment issue was not decided, litigated, or explicitly resolved on the merits there. Defense counsel did not even mention it; the government did not mention it; and the district court mentioned it only in passing in a single sentence. Even after the district court referred to it, defense counsel did not argue that Pon had a Sixth Amendment right to present surrebuttal evidence in these circumstances. The failure to do so is all the

more significant because counsel objected on Sixth Amendment grounds to five other rulings against Pon on evidentiary issues during the trial.[8] But he did not assert or even mention the Sixth Amendment in connection with the partial limitation on surrebuttal evidence. On this record, the author of the treatise might well say that the Sixth Amendment issue does not "fairly appear[ ] in the record as having been raised or decided." Moore's § 205.05(1).

But we don't have to decide if that Sixth Amendment issue was presented to the district court. We can assume that it was. We can make that assumption because even if partially limiting Pon's surrebuttal did

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[8] For example, in objecting to the district court's ruling that he could not admit exhibits during cross-examination, counsel argued that "the restriction impinge[d] Dr. Pon's Sixth Amendment constitutional right to cross-examination"; he moved for a mistrial after information came out about what a nontestifying doctor said, invoking the Sixth Amendment and arguing that Pon was "deprived of [his] right to confrontation"; in offering an exhibit that the government sought to have excluded, he argued that Pon's "Sixth Amendment constitutional right to present evidence" entitled him to have the exhibit accepted; he sought the court's permission for Pon to confer with counsel during breaks in his testimony, arguing that Pon was entitled to do so because of "the right to counsel under the Sixth Amendment"; and he again argued that one of Pon's exhibits should have been admitted because the district court's "exclusion of [the proffered exhibit was] a denial of Dr. Pon's Sixth Amendment right to present evidence."

violate his Sixth Amendment rights, that error was harmless beyond a reasonable doubt, which necessarily means that any nonconstitutional error from that limitation was harmless as well.

3. The Harmless Error Standard

We review preserved assertions of error—both constitutional and nonconstitutional error—for harmlessness. *See* Fed. R. Crim. P. 52(a) ("Any error, defect, irregularity, or variance that does not affect substantial rights must be disregarded."); *United States v. Olano*, 507 U.S. 725, 734 (1993) ("When the defendant has made a timely objection to an error and Rule 52(a) applies, a court of appeals normally engages in a specific analysis of the district court record—a so-called 'harmless error' inquiry—to determine whether the error was prejudicial.").

As this Court sitting en banc has recognized, the Supreme Court has repeatedly held that "the vast majority of constitutional errors that occur at a criminal trial, including Sixth Amendment violations, should be examined for prejudicial effect and those errors do not require reversal if they are harmless." *United States v. Roy*, 855 F.3d 1133, 1167 (11th Cir. 2017) (en banc). The harmless error doctrine is important because it "promotes public respect for the criminal process by focusing on the underlying fairness of the trial." *Neder v. United States*, 527 U.S. 1, 18 (1999) (quotation marks omitted). Review for harmlessness "is also essential to avoid a 'sporting theory of justice' and a regime of gotcha review." *Roy*, 855 F.3d at 1142 (quoting *United States v. Agurs*, 427 U.S. 97, 108 (1976)).

A constitutional error is harmless if the government proves "beyond a reasonable doubt that the error complained of did not contribute to the verdict

obtained." *Chapman v. California*, 386 U.S. 18, 22 (1967). And "[t]o say that an error did not contribute to the verdict is ... to find that error unimportant in relation to everything else the jury considered on the issue in question, as revealed in the record." *Yates v. Evatt*, 500 U.S. 391, 403 (1991); *accord Cape v. Francis*, 741 F.2d 1287, 1294–95 (11th Cir. 1984) ("If, upon its reading of the trial record, the appellate court is firmly convinced that the evidence of guilt was so overwhelming that the trier of fact would have reached the same result without the tainted evidence, then there is insufficient prejudice to mandate the invalidation of the conviction.").

A nonconstitutional error, on the other hand, is harmless unless it "resulted 'in actual prejudice because it had substantial and injurious effect or influence in determining the jury's verdict.' " *United States v. Guzman*, 167 F.3d 1350, 1353 (11th Cir. 1999) (quoting *United States v. Lane*, 474 U.S. 438, 449 (1986)). If a reviewing court "can say with fair assurance ... that the judgment was not substantially swayed by the [nonconstitutional] error," the court must affirm even if the district court erred. *United States v. Hornaday*, 392 F.3d 1306, 1315–16 (11th Cir. 2004).

Under both harmless error standards, the reviewing court examines the trial record in its entirety to make its prejudice determination. *See Neder*, 527 U.S. at 19 (constitutional standard); *United States v. Sweat*, 555 F.3d 1364, 1367 (11th Cir. 2009) (nonconstitutional standard). The government bears the burden of showing harmlessness in both situations when the issue was properly preserved by timely objection. *See, e.g.*, *United States v. Vonn*, 535 U.S. 55, 62 (2002) (noting that it is the government's "burden of showing that any error was harmless" under harmless-error

review). As may be apparent, the constitutional harmless error hurdle is the higher of the two for the government to clear. *See generally United States v. Mathenia*, 409 F.3d 1289, 1291 (11th Cir. 2005) (noting "the less demanding [harmless error] test that is applicable to non-constitutional errors"); *United States v. Robles*, 408 F.3d 1324, 1327 (11th Cir. 2005) (noting that "[w]hen the error is of the constitutional variety, a higher standard is applied" than when the error is nonconstitutional). For that reason, a holding that a constitutional error is harmless necessarily means that it is also harmless if it happens to be nonconstitutional error.

4. The Harmlessness of the Assumed Error

We are persuaded that, even if the district court erred in partially limiting Pon's surrebuttal evidence, and that error violated the Sixth Amendment, it was harmless beyond a reasonable doubt. *See United States v. Willner*, 795 F.3d 1297, 1322 (11th Cir. 2015) ("One circumstance in which courts find constitutional errors harmless beyond a reasonable doubt is when the evidence of the defendant's guilt is 'so overwhelming.' ") (quoting *Harrington v. California*, 395 U.S. 250, 254 (1969)). Here's why.

a. *The Eleven Patients Listed in the Indictment*

First, the government presented a slew of compelling evidence that not a single patient out of the eleven identified in the indictment had WMD, yet Pon had diagnosed every one of them with that degenerative eye disease anyway. And those patients' eyes showed no signs at all of having undergone laser photocoagulation treatment for WMD, though Pon had billed Medicare under code 67220 for laser photocoagulation treatment for each patient. The government

presented the testimony of not one, but a dozen doctors about the patients listed in the indictment. Dr. Friberg and eleven other doctors who had examined the eleven patients identified in the indictment testified against Pon. All told, the twelve of them collectively had more than 330 years of experience.[9] None of those doctors could find any evidence that any of the eleven patients identified in the indictment had WMD when Pon diagnosed them with it, and they all concluded that the patients did not have the telltale scars associated with the laser photocoagulation treatment that Pon had billed Medicare for performing on each patient. Because the overwhelming amount of the evidence is important, we recount in detail the doctors' testimony about each of the eleven patients.

(1) Patient One

About Patient One, the jury heard testimony from three ophthalmologists: Dr. Friberg and two others. Dr. Friberg testified that before trial he reviewed images of both of Patient One's eyes, each of which Pon had diagnosed with WMD and for each of which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment. The images of the patient's left eye (the basis for Count One) were taken both on and after the "treatment" date, and the images of the patient's right eye (the basis for Count Two) were taken before, on, and after the

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[9] Dr. Friberg: 32 years; Dr. Williams: 45 years; Dr. Berger: 31 years; Dr. Magruder: 26 years; Dr. Gills: 47 years; Dr. Pennachio: 30 years; Dr. Wehrly: 21 years; Dr. Mavrofrides: 11 years; Dr. Schwenk: 31 years; Dr. Beneke: 24 years; Dr. Vogel: 21 years; Dr. Kraut: 19 years.

"treatment" date. Dr. Friberg told the jury about his review of those images and explained that he did not see any indication at all that the patient had WMD in either of her eyes or a scar showing she had actually received laser photocoagulation treatment in either eye.

The second ophthalmologist testified about five examinations he had conducted on Patient One after Pon's diagnosis and purported treatment. He was "confident that [the patient] was not" suffering from WMD when he examined her, and he said she did not have the disease when Pon billed Medicare for laser photocoagulation treatment on her eyes.

Patient One went to the third testifying ophthalmologist to get a second opinion about whether she had WMD. That ophthalmologist had examined Patient One on three separate occasions after Pon's diagnosis and purported laser treatment of her eyes. He discussed with the jury the medical records of his examinations of Patient One. Based on those three examinations, he testified that she did not have WMD when Pon billed Medicare for laser photocoagulation treatment of her eyes nor did she have a laser-related scar in her eyes afterwards. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient One.

(2) Patient Two

About Patient Two, the jury heard from Dr. Friberg and two other ophthalmologists. Before trial, Dr. Friberg reviewed images of this patient's left eye, which Pon had diagnosed with WMD and for which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment on two separate occasions. The images Dr. Friberg

reviewed were taken before, on, and after the first "treatment" date (the basis for Count Three), and before and on the second "treatment" date (the basis for Count Four). Dr. Friberg testified that based on his review there was "a high degree of medical certainty" that the patient had not had WMD. He also testified that he did not see any indication that the patient had a scar in her eye showing she had actually undergone laser photocoagulation treatment.

The second ophthalmologist testified about six examinations he had conducted on Patient Two's eye after Pon's diagnosis and supposed treatment. After reviewing for the jury the medical records of his examinations, he testified that this patient did not have WMD when Pon billed Medicare for laser photocoagulation treatment of her eye.

The third ophthalmologist testified that he had examined Patient Two on two separate occasions just months before Pon diagnosed her with WMD. He had not seen any evidence that the patient had WMD, and he testified that the chance of her developing the disease in the brief period between the time he examined her and the time Pon billed Medicare for laser photocoagulation of her eye was "very unlikely." None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Two.

(3) Patient Three

Patient Three was also the subject of testimony from Dr. Friberg and two other ophthalmologists. Before trial, Dr. Friberg reviewed images of both of this patient's eyes, each of which Pon had diagnosed with WMD and for each of which he had billed Medicare under code 67220 as though he had performed laser

photocoagulation treatment. The images of the patient's left eye (the basis for Count Five) were taken on and after the "treatment" date, and the images of the patient's right eye (the basis for Count Six) were taken before, on, and after that date. Dr. Friberg testified that based on his review he did not see any indication that on any of those dates the patient had WMD or a scar indicating he had actually undergone laser photocoagulation treatment.

The second ophthalmologist explained to the jury the medical records documenting some of Patient Three's visits with him. He testified to his "shock[ ]" of learning that the patient had purportedly undergone laser photocoagulation treatment at Pon's office just months after he himself had concluded that the patient did not have WMD. He also stated that he had examined the patient after Pon did and had concluded that the patient did not have WMD or any laser photocoagulation scars in his eyes.

The third ophthalmologist testified that he examined this patient on three separate occasions more than four years after Pon's diagnosis and purported treatment and, on each occasion, he saw no indication that the patient had WMD. He also testified that he did not see any laser photocoagulation scars in the patient's eyes. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Three.

(4) Patient Four

The jury heard from Dr. Friberg and another ophthalmologist about Patient Four. Before trial, Dr. Friberg reviewed images of this patient's right eye, which Pon had diagnosed with WMD and for which he had billed Medicare under code 67220 as though he

had performed laser photocoagulation treatment on two separate occasions. The images Dr. Friberg reviewed were taken before, on, and after the two "treatment" dates (the basis for Counts Seven and Eight). Dr. Friberg testified that based on his review he did not see any indication that the patient had WMD or a scar in her eyes showing that she had actually received laser photocoagulation treatment for that disease. Instead, the patient's eye that Pon said suffered from WMD "look[ed] pristine" and there was "[n]o medical reason" to laser it.

The other ophthalmologist testified about his examination of Patient Four several years after Pon had diagnosed her with WMD and supposedly treated her. He stated that she did not have WMD when Pon diagnosed her with it and billed Medicare for laser photocoagulation of it, that he did not see any scarring in her right eye that would indicate she had undergone that treatment, and that she still did not have WMD at the time he had examined her eyes. He added that the patient's eyesight was "[v]ery good" for her age. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Four.

(5) Patient Five

The jury heard from Dr. Friberg and another ophthalmologist about Patient Five. Before trial, Dr. Friberg reviewed images of the patient's right eye, which Pon had diagnosed with WMD and for which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment. The images Dr. Friberg reviewed were taken on and after the purported treatment date (the basis for Count Nine). Dr. Friberg testified that he was "[v]ery

certain" the patient did not have WMD. He added that her blood vessels looked "[e]xcellent." And although Pon had billed Medicare for laser photocoagulation of this patient's right eye six times, Dr. Friberg saw no scars indicating she had ever received any laser photocoagulation in that eye.

The second ophthalmologist testified about seven examinations he conducted on Patient Five after her optometrist referred her to him for a macular degeneration evaluation. All seven of the examinations were after Pon had diagnosed Patient Five with WMD and purportedly treated her. Based on his examinations, this ophthalmologist testified that there was no way that Patient Five had WMD when Pon diagnosed her with the disease. And he testified that he saw no scarring in her right eye that would indicate she had received laser photocoagulation treatment for WMD. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Five.

(6) Patient Six

The jury heard about Patient Six from Dr. Friberg and two other ophthalmologists. Before trial, Dr. Friberg reviewed images of both of the patient's eyes, each of which Pon had diagnosed with WMD and for which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment. The images Dr. Friberg reviewed were taken before and after the "treatment" date for this patient's right eye (the basis for Count Ten) and before, on, and after the "treatment" date for this patient's left eye (the basis for Count Eleven). Dr. Friberg testified that based on his review the patient had not had WMD in either eye. And he testified that the patient's eyes had

no scars indicating that she had ever received any laser photocoagulation treatment.

The second ophthalmologist testified about his treatment of Patient Six over a nine-year period that overlapped with the time Pon had treated her. This ophthalmologist reviewed for the jury his medical records from twelve examinations of the patient and testified that she had never showed signs of WMD.

The third ophthalmologist testified about examinations he had conducted on Patient Six after Pon's diagnosis and purported treatment. He stated that she did not have WMD and did not have any scarring from laser photocoagulation treatments. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Six.

(7) Patient Seven

The jury heard from Dr. Friberg and two other ophthalmologists about Patient Seven. Before trial, Dr. Friberg reviewed images of both of the patient's eyes, each of which Pon had diagnosed with WMD and for each of which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment. The images Dr. Friberg reviewed were taken before, on, and after the "treatment" date for this patient's left eye (the basis for Count Twelve) and on the "treatment" date for this patient's right eye (the basis for Count Thirteen). Dr. Friberg testified that based on his review the patient never had WMD in either eye and did not have a laser scar indicating that he ever received laser photocoagulation treatment in either eye.

The second ophthalmologist examined Patient Seven after Pon had billed Medicare numerous times

for laser photocoagulation treatment of his right eye. This ophthalmologist testified that he found "no evidence whatsoever of any previous laser treatment." He was "[a] hundred percent" certain that the patient did not have WMD or any scars indicating laser treatment.

The third ophthalmologist examined Patient Seven after the patient was referred to him for a cataract evaluation. He went over for the jury the five examinations he had conducted on Patient Seven after Pon's diagnosis and purported treatment. None of the evaluations showed any sign of WMD. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Seven.

(8) Patient Eight

The jury heard about Patient Eight from Dr. Friberg, two other ophthalmologists, and an optometrist with 45 years of experience. Before trial, Dr. Friberg reviewed images of both of the patient's eyes, each of which Pon had diagnosed with WMD and for each of which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment. Those images were taken before, on, and after the "treatment" date for this patient's left eye (the basis for Count Fourteen) and before and on the "treatment" date for this patient's right eye (the basis for Count Fifteen). Dr. Friberg testified that based on his review the patient did not have WMD in his left eye and did not have a scar indicating he had ever received laser photocoagulation treatment in either eye. Dr. Friberg also testified that there was no WMD in the area of the patient's right eye that Pon had marked

for treatment. That area, Dr. Friberg added, was "quite pristine."

The second ophthalmologist testified about five examinations conducted on Patient Eight—one before and four after Pon's diagnosis and purported laser photocoagulation treatment of the patient's eyes. He testified that none of the examinations showed any indication of WMD or scarring from laser photocoagulation treatment.

The third ophthalmologist performed cataract surgery on Patient Eight after Pon had diagnosed the patient with WMD and billed Medicare for laser photocoagulation treatment of both eyes. This ophthalmologist discussed his pre-and post-operation examinations of the patient's eyes and testified that he never saw any evidence of WMD.

The optometrist was another witness who testified about his examinations of Patient Eight's eyes after Pon had diagnosed them with WMD and purportedly treated them. He testified that he saw no evidence of the scarring that would accompany laser photocoagulation treatment, and no evidence of WMD in the patient's eyes. And he explained that because the patient did not have WMD when he examined him after Pon had diagnosed and supposedly treated his eyes, there was no way the patient had WMD when Pon diagnosed him with it. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Eight.

(9) Patient Nine

The jury heard from Dr. Friberg and another ophthalmologist about Patient Nine. Before trial, Dr. Friberg reviewed images of both of this patient's eyes, each of which Pon had diagnosed with WMD and for

each of which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment. The images Dr. Friberg reviewed were taken on and after the "treatment" date for this patient's left eye (the basis for Count Sixteen) and before, on, and after the "treatment" date for this patient's right eye (the basis for Count Seventeen). Dr. Friberg testified that based on his review the patient did not have WMD in either eye at the time Pon diagnosed her with that disease, and she did not have scarring from laser photocoagulation treatment in either eye.

The other ophthalmologist examined Patient Nine after Pon had diagnosed her with WMD and purportedly treated her eyes. This ophthalmologist testified that he was "[a] hundred percent" certain that she had not had WMD or any scarring from laser photocoagulation treatment for that disease. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Nine.

(10) Patient Ten

The jury heard about Patient Ten from Dr. Friberg, from another ophthalmologist, and also from an optometrist with 45 years of experience. Before trial, Dr. Friberg reviewed images of the patient's left eye, which Pon had diagnosed with WMD and for which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment. The images Dr. Friberg reviewed were taken on the "treatment" date for this patient's left eye (the basis for Count Eighteen). He testified that based on his review the patient did not have WMD at the time Pon diagnosed her with that disease, nor did she have a scar

indicating that she had ever received laser photocoagulation treatment for the disease.

The other ophthalmologist testified about his treatment of Patient Ten after Pon had diagnosed her with WMD and purportedly treated her. Patient Ten had come to him for a second opinion about whether she had macular degeneration. He testified that he was "[a] hundred percent certain" that she did not have WMD or any scars from laser treatment for that disease.

The optometrist told the jury about four examinations he had conducted on Patient Ten after Pon's diagnosis and purported laser treatment. He testified that he never saw any indication that she had WMD and he had never seen any scarring from laser photocoagulation treatment for that disease. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Ten.

(11) Patient Eleven

The jury heard about Patient Eleven from Dr. Friberg, from another ophthalmologist, and from the optometrist with 45 years of experience. Before trial, Dr. Friberg reviewed images of this patient's right eye that Pon had diagnosed with WMD and for which he had billed Medicare under code 67220 as though he had performed laser photocoagulation treatment on two separate occasions. The images he reviewed were taken before, on, and after the first "treatment" date (the basis for Count Nineteen) and on and after the second "treatment" date (the basis for Count Twenty). Dr. Friberg testified that based on his review, he was "[c]ertain" that the patient did not have WMD when Pon diagnosed her with that disease, and that she did

not have a scar indicating she had received laser photocoagulation treatment for the disease.

The other ophthalmologist told the jury that Patient Eleven had been referred to him for a second opinion about whether Pon's frequent lasering of her eye was necessary. He testified that he examined the patient twice and both examinations showed no evidence of WMD and no scar indicating she had received laser photocoagulation treatment for that disease.

The optometrist testified about his treatment of Patient Eleven over a period of six years, some of which overlapped with Pon's treatment of her. He testified that none of his examinations revealed any sign of WMD. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with Patient Eleven.

(12) Summary

In regard to the eleven patients whose cases were the basis for all of the counts in the indictment, the jury heard from twelve different doctors, each of whom testified that Pon had diagnosed patients with WMD when those patients clearly had never had it. Those doctors also testified that none of those patients had the telltale scarring that necessarily results from the laser photocoagulation treatment that Pon billed Medicare for performing on them. Other than himself, Pon presented no ophthalmologist or optometrist to testify that any one of the eleven patients actually had WMD at the time he purportedly treated them for it or had the scarring that would necessarily have resulted from the laser photocoagulation treatment he billed Medicare for performing. Not only that, but Pon billed Medicare for laser photocoagulation treatment of the eleven patients, which necessarily causes a scar, even

though he himself conceded that his treatment did not cause any scarring. And nobody (other than Pon) testified to support his claim that WMD could be laser-treated without scarring. None of Pon's excluded surrebuttal evidence, which is the assumed error we are talking about, had anything to do with any of the eleven patients listed in the indictment or the bills he submitted to Medicare for the laser photocoagulation treatment that he never administered to those patients.

b. *The Hundreds of Other Patients*

The overwhelming proof of Pon's guilt did not stop there. There was also strong evidence—uninfluenced and unaffected by the partial limitation on Pon's surrebuttal evidence (the assumed error we are talking about)—that Pon incorrectly diagnosed and improperly "treated" not just the eleven patients listed in the indictment but also hundreds of other patients.

As discussed, Dr. Friberg testified that almost none of the 500 patients whom Pon had diagnosed with WMD actually had the disease. He recounted how, during his close review of the files of approximately 500 of Pon's patients, it was "rare" for him to see any indication that any patient had any form of macular degeneration—either dry or wet. Only a "very minimal minority"—one or two percent—of the 500 patients whose charts he reviewed had any sort of macular degeneration. Other eye doctors corroborated Dr. Friberg's diagnoses for dozens of Pon's patients not named in the indictment.

Only Pon testified that his WMD diagnoses were correct, and that he believed the treatments he administered were helpful and medically necessary. But Pon had strong motivation to say that—a substantial

interest in the outcome of the trial. He acknowledged that most of his patients were Medicare beneficiaries and that the vast majority of the money he made was from Medicare. If convicted, he would lose his medical license and livelihood. And, of course, he faced a prison sentence—ten years as it turned out.

The jury was entitled to take Pon's interest into account in evaluating his testimony, as it undoubtedly did. We have even held that because a jury is free to infer from a testifying defendant's demeanor that he is not telling the truth, "a statement by a defendant, if disbelieved by the jury, may be considered as substantive evidence of the defendant's guilt" when combined with other evidence. *United States v. Brown*, 53 F.3d 312, 314 (11th Cir. 1995); *accord United States v. McCarrick*, 294 F.3d 1286, 1293 (11th Cir. 2002) ("In *Brown*, we held that, *in combination* with other evidence, the jury's disbelief of a defendant's testimony may be used to help establish his guilt."); *see also United States v. Hough*, 803 F.3d 1181, 1188 (11th Cir. 2015) ("Having seen and heard [the defendant's] testimony, the jury was free to discredit her explanation, to infer that the opposite of what she said was true, and to consider that inference as substantive evidence of her guilt."). This is especially true in regard to "highly subjective elements" such as "the defendant's intent or knowledge." *Brown*, 53 F.3d at 315. The jury observed Pon for more than three days on the witness stand and had ample time to evaluate his demeanor and credibility. *See United States v. Deverso*, 518 F.3d 1250, 1258 (11th Cir. 2008) ("Given the opportunity to evaluate [the defendant's] demeanor and credibility, the jury was entitled not only to disbelieve his testimony but, in fact, to find that the opposite of his testimony was true.").

The government also offered overwhelming evidence—again, completely separate from the assumed error about limiting Pon's surrebuttal evidence — that Pon knew the patients he diagnosed with WMD did not have that disease and knew that his micropulse laser technique did not treat that disease. Almost every doctor who testified—even Pon himself—said that a person with untreated WMD would suffer a substantial decline in the quality of his vision. And yet, the evidence at trial showed that Pon abruptly stopped all WMD treatments on at least four patients he had diagnosed with WMD and on whom he had been using his micropulse laser technique. But Pon continued to treat these patients for other eye conditions, so he would have known that the WMD he had diagnosed in them did not progress even though they were not receiving any treatment for it, which had to mean there was no WMD to begin with and Pon knew it.

c. *Different Treatment for Patients Who Actually Had WMD*

The evidence also showed that Pon used very different WMD treatment methods for different patients. Recall the testimony that at the time of Pon's trial, injecting drugs directly into the eye had become the most widely used, accepted treatment for WMD. *See supra* [at 2a–6a, 10a–12a]. But evidence at trial showed that Pon used those drug injections as a WMD treatment for only some of the patients he diagnosed with WMD, at least of those he called as witnesses at trial. Significantly, the evidence showed that he used drug injections to treat WMD largely, if not only, for those patients whose WMD diagnoses were corroborated by another doctor. In other words, he used drug treatments for the rare patients of his who actually had WMD. For other patients, ones for whom there was no

evidence of WMD but he billed as if there were, Pon didn't use drug injections as a WMD treatment or he used it only rarely.

For example, four of the thirteen patients who testified on Pon's behalf had a WMD diagnosis that had been confirmed by another doctor. Pon gave all four of these patients drug injections. For two of these patients, Pon used the accepted drug injection treatment as well as his micropulse laser "treatment," all in the same eye. For the other two of these four, he administered injections often and consistently, and he never discontinued the injections for either of them. The sum of it is that for the few patients whose WMD was confirmed by other doctors, Pon treated with the accepted drug injections, as well as his micropulse laser technique, and billed for both.

At least seven of the patients who testified on Pon's behalf had WMD diagnoses from Pon that Dr. Friberg rejected. For these patients, Pon either did not use injections to treat what only he had diagnosed as WMD, or he used injections only occasionally. And, as we discussed, for four of these patients, Pon stopped administering any WMD treatment—laser or injections—but continued to treat them for other eye diseases. That, of course, is evidence that Pon knew those patients did not actually have WMD, but he nonetheless diagnosed them with it and administered his micropulse laser "treatment," while billing Medicare under code 67220 for laser photocoagulation treatment.

d. *The Ineffectiveness of Pon's Micropulse Laser "Treatment"*

The government also offered testimony from other doctors—uninfluenced by Pon's excluded surrebuttal evidence—that Pon's micropulse laser technique could

not treat WMD and could not coagulate a feeder vessel. One ophthalmologist testified that he was "certain far beyond a reasonable medical ... certainty" that Pon's micropulse laser technique would not close a feeder vessel. Another testified that he was not aware of any way that Pon's micropulse laser technique could coagulate a feeder vessel, which was necessary to treat WMD, and was what Pon billed Medicare for doing. And yet another ophthalmologist testified that there was no way to achieve "subthreshold coagulation" of a feeder vessel, as Pon claimed, because those two "terms are mutually exclusive." And so it went.

Numerous doctors testified that WMD could not be treated with a laser without leaving a scar. Dr. Friberg was "very certain" that using a laser at a power high enough to "cook the feeder vessel," which is how WMD is treated with a laser, would leave a mark in the eye. He testified that even if the scars did not show up in the eye immediately, "you could see them down the road." His certainty about this came from his experience directing a clinical trial in which the doctors "used very minimal laser" and thought they "didn't leave any marks." But in "[a] month or two," the patients' eyes showed signs of scarring.

Another ophthalmologist had participated in a clinical trial in which the doctors attempted to treat dry macular degeneration—which usually precedes WMD—using "very, very light laser treatment." But the trial was stopped early because the patients being treated were developing WMD more quickly than their counterparts who were receiving no treatment at all. This ophthalmologist testified that laser photocoagulating leaking blood vessels, the treatment Pon was billing Medicare for, would "by definition, pretty much create a full-thickness burn" and leave a scar in the

eye. He testified that laser treatment for WMD leaves scars that don't ever completely heal, "and that's the point actually," because that is how WMD is treated with a laser.

Other doctors agreed. Another ophthalmologist testified that if a feeder vessel had been closed with a laser, "you would see a scar." And another testified that laser treatment for WMD that has "any kind of effect on the underlying blood vessels" would cause "some kind of scar." And another testified that "the purpose of" laser treatment for WMD is to "cook[ ]" the tissue in the eye, which stops the blood vessels from leaking and necessarily results in a visible scar in the eye. And another testified that laser treatment for WMD results in "tiny focal laser scars" that are generally visible with a standard eye exam and that would always show up on a fluorescein angiogram. And yet another testified that "there's no description of [its] being possible" to close a feeder vessel without scarring, and "there's a lot of theoretical and scientific reasons why that would seem extremely unlikely to be possible." Nonetheless, as we discussed, every single doctor who examined the eyes of a patient listed in the indictment testified that the patient's eyes showed no indication of the scarring that necessarily accompanies laser photocoagulation—the WMD treatment that Pon billed Medicare for administering. *See supra* [at 36a–49a].

e. *Filling Out Charts in Advance*

The record also shows that Pon filled out portions of some patients' charts with WMD diagnoses and planned diagnostic tests before he had even seen the patients. The government admitted patient notes for three of Pon's patients who had not shown up for a

scheduled appointment. Even though Pon didn't examine the patients on the date listed in their charts, parts of their charts were filled out as though he had seen them, including diagnoses and treatment plans. For each of the three patients, the prefilled patient notes diagnosed the patient with WMD and indicated that fluorescein angiogram and ICG tests (the tests Pon used in making his WMD diagnoses) would be performed in both of the patient's eyes.

Pon testified that the patient notes were filled out ahead of time likely because his technicians were "trying to save time." He stated that "if anything needed to be corrected" after he actually examined the patient, he "would have crossed it off" to "make sure everything was consistent with [his] examination." And he identified seven patients whose prefilled notes he had modified to replace the diagnosis or treatment plan with one he thought was more appropriate.

But the government had a response to that. Agent Jurs testified about three patients whose prefilled charts Pon had changed to indicate that fluorescein angiogram and ICG tests would be done only on one eye (instead of on both eyes, as the prefilled charts had originally indicated). For each of those three patients, the government introduced an exhibit listing the procedures that Pon had billed Medicare for. Those exhibits showed that Pon had billed Medicare for fluorescein angiograms and ICGs on *both* eyes for each of the patients. In other words, although Pon had modified the three patients' prefilled charts to show that those tests were done on only one eye, he still billed Medicare as though he had done the tests on both eyes.

f. *The Sound of Silence*

Finally, the record shows that Pon was professionally silent about his purported treatment. He acknowledged that he didn't know of any other doctor anywhere who used subthreshold micropulse laser to treat WMD. Yet even though he claimed to have discovered a "miraculous treatment" for WMD, he did absolutely nothing to present, publish, or even talk with other doctors about what he thought of as a cure for the leading cause of irreversible blindness in older people. His silence spoke volumes.

g. *Summary*

All of this great volume of evidence we have just recounted was presented before and was completely unrelated to and uninfluenced by the exclusion of any of Pon's proposed surrebuttal evidence. And it was that great volume of evidence that the government discussed in its closing, not anything about Pon billing Medicare for testing he did on J.L.'s blind left eye. In view of the totality of the evidence presented, what the jury heard about billing for testing on J.L.'s left eye was miniscule. J.L. as one of 34 witnesses who testified at trial, one of fifteen who testified for Pon. J.L.'s testimony about the procedures done on his blind left eye took up only fifteen pages of transcript. And Agent Jurs' rebuttal testimony concerning that subject, which is what Pon wanted to present surrebuttal testimony about, took up only eleven pages. That's eleven out of more than 2,000 pages, or about one half of one percent, of the testimony that was presented during the trial.

And it bears repeating that J.L. was not one of the patients listed in the crimes charged in the indictment. As we noted, the district court instructed the jury that

Pon was "on trial only for the specific crimes charged in the indictment," and that it had to determine whether Pon was "guilty or not guilty of those specific crimes." "[T]he Supreme Court has repeatedly held that we must presume that juries follow their instructions," and this Court has "obediently followed" that direction. *Roy*, 855 F.3d at 1186–87 (collecting cases). Following that direction, we presume that the jury's guilty verdict was based on its determination that Pon *was* guilty as charged of fraudulently billing Medicare for laser photocoagulation for the eleven patients listed in the indictment, not for fraudulently billing Medicare for procedures on J.L.'s blind left eye.

For all these reasons, we have no doubt, much less a reasonable doubt, that if the district court had not partially limited Pon's surrebuttal evidence about J.L., the jury would still have found Pon guilty as charged. The ruling we are assuming was an error did not contribute to the jury's guilty verdict. *See Chapman*, 386 U.S. at 22. Any error was harmless beyond a reasonable doubt.

5. Our Application of the Harmless Error Rule is Faithful to Precedent

Our conclusion that the partial limitation on Pon's surrebuttal testimony was harmless beyond a reasonable doubt is in keeping with the Supreme Court's understanding, expressed in *Neder*, that "[a] reviewing court making th[e] harmless-error inquiry does not, as Justice Traynor put it, become in effect a second jury to determine whether the defendant is guilty." 527 U.S. at 19 (quotation marks omitted). And it is consistent with the Court's description of the harmless-error determination as a task done in "typical appellate-court fashion." *Id.* Of course harmless error

inquiries are typical: "We are, after all, talking about 'the harmless error *rule*,' not 'the harmless error exception.' Because errorless trials are not expected, much less required, harmless error analysis is the rule, not the exception." *Roy*, 855 F.3d at 1143.

And for good reason. "The harmless error rule serves vital interests, chief of which is conserving scarce judicial resources by avoiding pointless retrials." *Id.* at 1142. And, as we have mentioned, the rule "is also essential to avoid a 'sporting theory of justice' and a regime of gotcha review." *Id.* (quoting *Agurs*, 427 U.S. at 108). The Supreme Court has recognized and relied on these important considerations in holding—over and over again—that the harmless error rule applies in a wide variety of circumstances. The Court has explained that the harmless error rule "promotes public respect for the criminal process by focusing on the underlying fairness of the trial." *Neder*, 527 U.S. at 18 (quotation marks omitted). It has directed that when "the record developed at trial establishes guilt beyond a reasonable doubt, the interest in fairness has been satisfied and the judgment should be affirmed." *Rose v. Clark*, 478 U.S. 570, 579 (1986). And it has noted that "[r]eversal for error, regardless of its effect on the judgment, encourages litigants to abuse the judicial process and bestirs the public to ridicule it." *Delaware v. Van Arsdall*, 475 U.S. 673, 681 (1986) (quoting R. Traynor, *The Riddle of Harmless Error* 50 (1970)).

The Supreme Court has instructed us that "if the defendant had counsel and was tried by an impartial adjudicator, there is a *strong presumption* that any other errors that may have occurred are subject to harmless-error analysis." *Rose*, 478 U.S. at 579 (emphasis added). The Court has "consistently made clear

that it is the *duty* of a reviewing court to consider the trial record as a whole and to ignore errors that are harmless, including most constitutional violations."[10] *United States v. Hasting*, 461 U.S. 499, 509 (1983) (emphasis added); *accord Neder*, 527 U.S. at 8 (noting that "most constitutional errors can be harmless" and only "a very limited class of cases" evade harmless error review) (quotation marks omitted); *Arizona v. Fulminante*, 499 U.S. 279, 306 (1991) (noting that "the Court has applied harmless-error analysis to a wide range of errors and has recognized that most constitutional errors can be harmless"); *Van Arsdall*, 475 U.S. at 681 ("[W]e have repeatedly reaffirmed the principle that an otherwise valid conviction should not be set aside if the reviewing court may confidently say, on the whole record, that the [error was harmless]."). The *Fulminante* decision is the paramount example of the breadth of the harmless error rule because it held that even where the error was the admission of an unconstitutionally coerced confession, courts must still assess the totality of the evidence and determine if it was

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[10] As the Court's use of the word "duty" indicates, when the Supreme Court applies harmless error analysis to a certain kind of error, it does not merely suggest that we do the same—it dictates that we are bound to do so. *See, e.g.*, *Mathis v. United States*, —— U.S. ——, 136 S. Ct. 2243, 2254 (2016) ("[A] good rule of thumb for reading [Supreme Court] decisions is that what they say and what they mean are one and the same ...."); *United States v. Johnson*, 921 F.3d 991, 1001 (11th Cir. 2019) ("[W]e must apply Supreme Court precedent neither narrowly nor liberally—only faithfully."); *Prison Legal News v. Sec'y, Fla. Dep't of Corr.*, 890 F.3d 954, 966 (11th Cir. 2018) ("The only Court that can properly cut back on Supreme Court decisions is the Supreme Court itself.").

harmless beyond a reasonable doubt. *See* 499 U.S. at 310 ("When reviewing the erroneous admission of an involuntary confession, the appellate court, as it does with the admission of other forms of improperly admitted evidence, simply reviews the remainder of the evidence against the defendant to determine whether the admission of the confession was harmless beyond a reasonable doubt.").

The Supreme Court has also strictly limited the power of federal courts to circumvent a harmless-error inquiry and has rebuked courts who shirk their harmless-error review duties. *See, e.g.*, *Bank of Nova Scotia v. United States*, 487 U.S. 250, 254 (1988) ("[A] federal court may not invoke supervisory power to circumvent the harmless-error inquiry prescribed by Federal Rule of Criminal Procedure 52(a)."); *Hasting*, 461 U.S. at 507 (stating that the harmless-error doctrine "cannot be so lightly and casually ignored in order to chastise what the court view[s] as prosecutorial overreaching").

We are not saying, of course, that courts shouldn't be careful with the harmless error rule. Courts should be careful in the application of all rules. Carelessness is not desirable in any field. But it is not careless to rely on overwhelming evidence of guilt to find an error harmless. The Supreme Court itself has done it. *See, e.g.*, *Neder*, 527 U.S. at 17 ("In this situation, where a reviewing court concludes beyond a reasonable doubt that the omitted element was uncontested and *supported by overwhelming evidence*, such that the jury verdict would have been the same absent the error, the erroneous instruction is properly found to be harmless.") (emphasis added); *cf. Yates*, 500 U.S. at 405 (describing the *Chapman* harmless-error inquiry as requiring a court to "ask[ ] whether the force of the evidence presumably considered by the jury in accordance

with the instructions is *so overwhelming* as to leave it beyond a reasonable doubt that the verdict resting on that evidence would have been the same") (emphasis added). And in doing so, the Supreme Court has found errors harmless based on overwhelming evidence without displaying special wariness.

Our own precedent is thick with decisions finding errors, even serious errors, harmless, oftentimes because of overwhelming evidence of guilt. *See United States v. Esquenazi*, 752 F.3d 912, 931 (11th Cir. 2014), *superseded by statute in non-relevant part*, 18 U.S.C. §§ 1956, 1957 (finding an error in the trial court's jury instructions harmless "[b]ecause overwhelming evidence support[ed] the jury's finding" of guilt); *United States v. Jones*, 601 F.3d 1247, 1264 (11th Cir. 2010) (finding the constitutional error the district court allegedly committed harmless because even without the error "the government's case against [the defendant] was strong"); *United States v. Phaknikone*, 605 F.3d 1099, 1109 (11th Cir. 2010) (affirming, in spite of an error, the conviction "in the light of the overwhelming evidence of [the defendant's] guilt").

We do that here.

IV. THE SENTENCE ISSUES

Pon challenges the procedural reasonableness of his sentence, arguing that the district court improperly calculated his guidelines range by erroneously applying an 18-level enhancement to his base offense level. The primary issue at sentencing was the amount of loss that resulted from Pon's health care fraud scheme. The government said the loss amount was $11.5 million, which would have resulted in a 20-level enhancement. *See* U.S.S.G. § 2B1.1(b)(1)(K) (Nov. 2010) (providing for a 20-level enhancement

when the total loss amount is more than $7 million but not more than $20 million). The district court, however, rejected the government's number and instead estimated the loss amount at $6.97 million, which resulted in an 18-level enhancement. *See id.* § 2B1.1(b)(1)(J) (providing for an 18-level enhancement when the total loss amount is more than $2.5 million but not more than $7 million). The guidelines range those calculations produced was 121 to 151 months.

Pon contends that the district court did not base the loss amount on reliable and specific evidence. We review the district court's loss determination only for clear error. *United States v. Cobb*, 842 F.3d 1213, 1218 (11th Cir. 2016). For that determination to be clearly erroneous, "we must have a definite and firm conviction that a mistake has been made." *United States v. Ford*, 784 F.3d 1386, 1396 (11th Cir. 2015).

Under the Guidelines, "loss is the greater of actual loss or intended loss." U.S.S.G. § 2B1.1, cmt. n.3(A). Although the district court "may not speculate about the existence of facts and must base its estimate on reliable and specific evidence, [it] is required only to make a reasonable estimate of the loss." *Ford*, 784 F.3d at 1396. That is "because often the amount of loss caused by fraud is difficult to determine accurately." *United States v. Medina*, 485 F.3d 1291, 1304 (11th Cir. 2007) (quotation marks omitted). And the district court "is in a unique position to assess the evidence and estimate the loss based upon that evidence," so its "loss determination is entitled to appropriate deference." *United States v. Campbell*, 765 F.3d 1291, 1301 (11th Cir. 2014) (quoting U.S.S.G. § 2B1.1 cmt. n.3(C)).

Contrary to what Pon says, the district court did base its loss estimate on reliable and specific evidence.

It considered a spreadsheet that Agent Jurs prepared for the sentence hearing, which shows the total amount of money that Medicare paid Pon for the thousands of claims he billed on behalf of the patients Dr. Friberg determined did not have WMD. The spreadsheet lists each patient's name, the notes that Dr. Friberg took when he reviewed the photos and videos of the patient's eyes, and the number of Medicare claims that Pon had submitted for that patient.

The district court also heard extensive testimony from Agent Jurs, who at the time had nearly seventeen years of experience working with Medicare data. He testified that the spreadsheet's total loss amount was accurate because it was calculated on a patient-by-patient basis. He also explained that for each of the patients Dr. Friberg determined did not have WMD, he "went into the Medicare records, pulled the claims that were specific to that [patient], went into the diagnosis code section of the claims history, pulled the [WMD] diagnosis code that [HHS] knew to be fraudulent and incorrect, and then totaled up only those claims, the numbers amount billed and the amount paid for only those claims." Agent Jurs also testified that the amount billed, the amount paid, and the number of actual claims came directly from Medicare's database.

That evidence is reliable and it is specific. And based on it, the district court made a reasonable estimate of the loss. *See Cobb*, 842 F.3d at 1218–19. There was no error in calculating the loss amount.[11]

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[11] Relying on out-of-circuit decisions, Pon also argues that due process required the district court to use the beyond a reasonable doubt standard instead of the preponderance of the evidence standard in

There is one other sentence issue. Pon has not raised it, but the government has. The district court imposed concurrent 121-month terms of imprisonment on each of Pon's twenty counts of conviction. The government concedes that this was error because the statutory maximum penalty for each count is only 120 months. *See* 18 U.S.C. § 1347(a). We agree, and we commend the government for bringing the error to our attention.

Section 5G1.2(d) of the Guidelines provides that where, as here, there are multiple counts of conviction,

> [i]f the sentence imposed on the count carrying the highest statutory maximum is less than the total punishment, then the sentence imposed on one or more of the other counts shall run consecutively, but only to the extent necessary to produce a combined sentence equal to the total punishment. In all other respects, sentences on all counts shall run concurrently, except to the extent otherwise required by law.

U.S.S.G. § 5G1.2(d). We have interpreted § 5G1.2(d) to require "multiple sentences to be served consecutively if the sentence specified by the guidelines is longer than the sentence authorized for any individual count of conviction." *United States v. Pressley*, 345 F.3d 1205, 1213 (11th Cir. 2003); *accord United States v. Sarras*, 575 F.3d 1191, 1209 n.22 (11th Cir. 2009)

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determining the loss amount. But "it is the settled law of this circuit that at sentencing, a federal defendant's due process rights are ... satisfied by the preponderance of the evidence standard." *United States v. Patti*, 337 F.3d 1317, 1323 n.9 (11th Cir. 2003) (quoting *United States v. Jackson*, 57 F.3d 1012, 1019 (11th Cir. 1995)).

(concluding that § 5G1.2(d) remains binding even "[ ]though the guidelines are now advisory"). Those multiple sentences must, of course, run consecutively "to the extent necessary to reach the defendant's guidelines range." *United States v. Johnson*, 451 F.3d 1239, 1243 (11th Cir. 2006).

The district court erred in imposing concurrent 121-month terms on each of Pon's twenty counts. While the Guidelines specify a sentence of 121 to 151 months in prison, the statutory maximum for the count with the highest maximum (of any of the twenty counts) is 120 months in prison. Because the statutory maximum is one month less than the 121-month bottom of the guidelines range, § 5G1.2(d) called for at least some of the sentences to run consecutively "to the extent necessary to reach [Pon's] guidelines range" of 121 to 151 months in prison. *Id.* The sentence structure must be modified to reach that range.

We vacate Pon's sentences on each count and remand the case to the district court for the limited purpose of letting it modify Pon's sentence structure to bring it in line with § 5G1.2(d). We leave to the court's discretion how it will do so.[12] Because we do not set aside Pon's "entire sentencing package" or the time he will remain in prison, the modification does not require a resentencing hearing at which Pon must be present. *See United States v. Tamayo*, 80 F.3d 1514, 1518, 1519 & n.7 (11th Cir. 1996).

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[12] The government has argued on appeal that one of Pon's twenty 120-month sentences should be made to run consecutive to the other nineteen by one month. Pon has not addressed that issue. But in any event it's an issue for the district court to decide.

V. CONCLUSION

We **AFFIRM** Pon's convictions but **VACATE** his sentences on Counts One through Twenty and **REMAND** the case for resentencing.

MARTIN, Circuit Judge, concurring in part and dissenting in part:

Like the majority, I see no abuse of discretion in the District Court's exclusion of David Pon's expert witness at trial. Nor do I see clear error in the District Court's loss amount calculation. I agree, too, that this Court's precedent forecloses Mr. Pon's due process challenge to the loss amount calculation. But I part ways with the conclusion reached in the majority opinion that any error in denying Mr. Pon a surrebuttal was harmless. I believe the denial of a surrebuttal violated Mr. Pon's constitutional right to present a complete defense. And I do not believe this error was harmless. Rather than affirm his conviction, I would give Mr. Pon a new jury trial. I therefore dissent from the majority opinion's ruling on the harmlessness of any surrebuttal error.

I.

"[T]he Constitution guarantees criminal defendants a meaningful opportunity to present a complete defense." *Holmes v. South Carolina*, 547 U.S. 319, 324 (2006) (quotation marks omitted). Whether this right springs from the fundamentals of due process or from the Sixth Amendment, *see Crane v. Kentucky*, 476 U.S. 683, 690 (1986), it encompasses "the right to present the defendant's version of the facts as well as the prosecution's to the jury so it may decide where the truth lies." *Washington v. Texas*, 388 U.S. 14, 19 (1967).

This right is not boundless. If it were, trials might be never-ending. District courts wield broad discretion to control the mode and order of presenting evidence, both to preserve the trial's truth-seeking function and to avoid wasting time. *See* Fed. R. Evid. 611; *United States v. Jeri*, 869 F.3d 1247, 1262 (11th Cir. 2017). But this "discretion does not ... extend to the exclusion of crucial relevant evidence necessary to establish a valid defense." *United States v. Kelly*, 888 F.2d 732, 743 (11th Cir. 1989) (quotation marks omitted).

When the government presents rebuttal evidence in a criminal case, the right to present a defense sometimes requires district courts to allow criminal defendants a surrebuttal. *See, e.g.*, *United States v. Murray*, 736 F.3d 652, 656–59 (2d Cir. 2013); *United States v. Barnette*, 211 F.3d 803, 821–24 (4th Cir. 2000); *United States v. Moody*, 903 F.2d 321, 330–31 (5th Cir. 1990). "The purpose of rebuttal evidence is to explain, repel, counteract, or disprove the evidence of the adverse party." *United States v. Frazier*, 387 F.3d 1244, 1269 (11th Cir. 2004) (en banc) (quotation marks and alteration omitted). The same is true of a surrebuttal, except that its function is to explain, repel, counteract, or disprove evidence presented in a rebuttal. Though narrower in scope than a defense to the government's case-in-chief, surrebuttal nonetheless serves an important purpose. It allows criminal defendants to present their version of any new issues that arise in the course of the government's rebuttal. Juries sometimes cannot "decide where the truth lies" if they hear only the government's side of a rebuttal issue. *Washington*, 388 U.S. at 19.

I say Mr. Pon was entitled to a surrebuttal. The rule in this Circuit, as in others, is that a "surrebuttal is merited where (1) the government's rebuttal

testimony raises a new issue, which broadens the scope of the government's case, and (2) the defense's proffered surrebuttal testimony is not tangential, but capable of discrediting the essence of the government's rebuttal testimony." *Moody*, 903 F.2d at 331; *see also United States v. Durnin*, 632 F.2d 1297, 1301 n.8 (5th Cir. Unit A 1980).[1] Under this standard, this Court's sister circuits have ruled that the Constitution requires a surrebuttal where the government's rebuttal raised new, uncharged allegations of fraud in a fraud case, *Moody*, 903 F.2d at 330–31, advanced a new mental health diagnosis as evidence of future dangerousness to support a death sentence, *Barnette*, 211 F.3d at 821–24, and introduced new evidence placing a defendant more frequently in the vicinity of the crime, *Murray*, 736 F.3d at 658–59. Rightly so. Without a surrebuttal, the government could use rebuttal in those cases both to meet the defense case and to make a new, unchallenged case of, respectively, fraud, future dangerousness, and frequent presence at the scene of the crime. That result would eviscerate the right to present a defense.

Both conditions for a surrebuttal were plainly met here. The government's rebuttal certainly introduced a new issue about the treatment of J.L.'s left eye for conditions wholly unrelated to wet macular degeneration.[2] Mr. Pon's proffered surrebuttal testimony about

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[1] In *Bonner v. City of Prichard*, 661 F.2d 1206 (11th Cir. 1981) (en banc), this Court adopted as binding precedent all decisions of the former Fifth Circuit handed down before October 1, 1981. *Id.* at 1209.

[2] Mr. Pon contends the District Court abused its discretion in allowing a rebuttal. Not so. The District

that treatment would have discredited the essence of the government's rebuttal case. Mr. Pon's right to present his defense required the District Court to allow him to testify to his reasons for treating J.L.'s left eye.

I discern no real dispute about whether the government's rebuttal evidence introduced a new issue. The rebuttal evidence concerned treatment of J.L., a patient who testified during the defense case. The substance of J.L.'s testimony was that Mr. Pon treated J.L. for detached retinas even knowing J.L. did not have insurance, that Pon restored vision in J.L.'s right eye but not his left, and that Pon later diagnosed J.L. with wet macular degeneration and treated him with the laser method. On cross examination, the government asked J.L. whether Mr. Pon had performed any tests on his left eye. J.L. said he had not. J.L. reiterated on redirect examination that Mr. Pon hadn't treated his left eye. After the defense rested, the District Court allowed the government to put on rebuttal,[3]

Court had discretion to allow the government to rebut the impression J.L.'s testimony created of Mr. Pon's altruism and to clarify J.L.'s treatment history.

[3] The District Court's decision to allow rebuttal seemed to rest in part on the government telling the District Court that it was Mr. Pon who first put the matter in issue by asking about J.L.'s left eye on redirect. The District Court sided with the government, believing the defense first asked about treatments on J.L.'s left eye on redirect. The government's representation and the District Court's belief in this regard is contradicted by the record. It was the government who first introduced the issue of J.L.'s left eye by inquiring about it on cross-examination.

including a spreadsheet made by the government's investigator showing Mr. Pon billed Medicare for treating J.L.'s left eye on more than fifty occasions between 2004 and 2015. All told, the services added up to $19,350 worth of Medicare charges over eleven years.

Up to the point the government put the spreadsheet into evidence, nothing would have indicated to Mr. Pon that he had to defend his reasons for treating J.L.'s left eye. For that matter, he would have had no reason to prove that those treatments even happened. The government's case-in-chief revolved around Mr. Pon's false diagnosis and treatment of wet macular degeneration, *see* Maj. Op. at [12a–17a], while the defense case depended on showing Mr. Pon lacked the necessary intent to defraud Medicare. With the spreadsheet, the government injected an entirely new, unrelated, and uncharged fraud. The clear implication of the rebuttal evidence was that Mr. Pon fraudulently billed Medicare not only for diagnosing and treating nonexistent wet macular degeneration, but for other procedures as well. This broadened the scope of the government's case. *See Moody*, 903 F.2d at 331 (holding the government broadened its fraud case when it brought up new, uncharged frauds in rebuttal).

Nor is there any real disputing that Mr. Pon's proffered surrebuttal testimony would have gone right to the heart of the government's rebuttal. In his proffer, he explained that he did in fact treat J.L.'s left eye and that he had a medical reason for doing so—namely, preventing blindness in J.L.'s right eye. This evidence, if believed, would squarely rebut the government's contentions that Mr. Pon never treated J.L.'s left eye but billed for it anyway. The limitation of surrebuttal on this record violated Mr. Pon's right to present a defense.

The government stresses that the District Court limited rather than outright denied Mr. Pon's surrebuttal. And the District Court did allow Mr. Pon to testify in surrebuttal that three of the more than fifty entries were the result of a clerical error. However, limiting Mr. Pon to this explanation may have exacerbated the problem. By allowing Mr. Pon to explain only three of the over fifty treatments, the jury may have been left with the impression that Pon had no explanations for the remaining treatments. Indeed, the government's cross-examination of Mr. Pon played up the fact that Mr. Pon only had an explanation for "just three entries out of two pages of entries." I question the propriety of this argument by the government when it knew Mr. Pon had an explanation for the other entries the court forbade him from testifying about. Mr. Pon's full explanation (treating the left eye helped prevent issues in the right eye) would have rebutted a key contention of the government's rebuttal case. The exclusion of this testimony violated the right to present a defense just as surely as a complete denial of surrebuttal would have. The limited surrebuttal allowed the government to exploit the District Court's ruling, creating the impression that Mr. Pon had no explanation at all for more than forty treatments. In fact he did.

The short of it is that the District Court allowed the government to inject a whole new allegation of fraud into the trial, then hobbled Mr. Pon's ability to respond to it. Mr. Pon had no chance to defend himself against allegations that he billed Medicare for treatment he never provided on an eye that couldn't see. Rather than decline to decide the issue, *see* Maj. Op. at [33a–34a], I would hold the District Court violated Mr. Pon's constitutional right to present a defense.

II.

Not all errors require reversal. This one does.

Under the harmless error doctrine, this Court will not reverse a district court's constitutional trial error if it is "clear beyond a reasonable doubt that a rational jury would have found the defendant guilty" regardless of the error. *Neder v. United States*, 527 U.S. 1, 18 (1999); *see Chapman v. California*, 386 U.S. 18, 24 (1967).[4] Following the Supreme Court's lead, this Court has identified cases in which "the evidence of the defendant's guilt is 'so overwhelming' " as "[o]ne circumstance in which courts find constitutional errors harmless beyond a reasonable doubt." *United States v. Willner*, 795 F.3d 1297, 1322 (11th Cir. 2015) (quoting *Harrington v. California*, 395 U.S. 250, 254 (1969)).

But the Supreme Court has equally cautioned us to be careful with the harmless error doctrine. Take, for example, *Neder*. It raised the question of whether the harmless error doctrine applies in cases where a district court omits an element of the offense from the

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[4] As the majority recognizes, the parties dispute which harmless error standard applies. *See* Maj. Op. at [32a–34a]. The government says Mr. Pon did not preserve his constitutional error because he did not object on constitutional grounds below. I think the issue was sufficiently preserved. The District Court specifically raised Mr. Pon's Sixth Amendment right to offer an explanation when considering whether to grant a surrebuttal. The issue seems to me to "fairly appear[ ] in the record as having been raised or decided" and thus is before the Court. 19 James Wm. Moore et al., *Moore's Federal Practice* § 205.05(1) (3d ed. 2019).

jury instructions. *Neder*, 527 U.S. at 8. The Court held the error "is subject to harmless-error analysis." *Id.* at 15. But it warned that courts "should not find [an] error harmless" where the defendant contested the omitted element and "raised evidence sufficient to support a contrary finding." *Id.* at 19. Those circumstances would, the Court said, preclude the reviewing court from "conclud[ing] beyond a reasonable doubt that the jury verdict would have been the same absent the error." *Id.*

It is important to remember that harmless error review is no substitute for a jury trial. The Sixth Amendment demands no less. U.S. Const. amend. VI ("In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury."). A reviewing court treads on the right to a jury trial when it uses harmless error review to "'become in effect a second jury to determine whether the defendant is guilty.'" *Neder*, 527 U.S. at 19 (quoting Roger J. Traynor, *The Riddle of Harmless Error* 21 (Ohio State Univ. Press 1970)). And there are practical consequences, too. Whenever we invoke harmless error, "the deterrent force of a reversal remains unfelt by those who caused the error." Harry T. Edwards, *To Err Is Human, But Not Always Harmless: When Should Legal Error Be Tolerated?*, 70 N.Y.U. L. Rev. 1167, 1170 (1995).

We should be particularly wary of invoking "overwhelming evidence" to hold an error harmless. "[T]he Constitution does not trust judges to make determinations of criminal guilt." *Neder*, 527 U.S. at 32 (Scalia, J., concurring in part and dissenting in part) (emphasis omitted). The right to a jury trial forbids us from doing so. This is why a federal judge may direct a judgment of acquittal but never a judgment of guilt. *See*

Rose v. Clark, 478 U.S. 570, 578 (1986); Fed. R. Crim. P. 29. We owe it to defendants who come before us to ask ourselves always whether a rational jury could acquit, and never whether we ourselves think the defendant guilty.

Taking up this task, I believe a rational jury might have voted to acquit Dr. Pon. The majority opinion concludes the government's evidence against Mr. Pon proved beyond a reasonable doubt that "Pon had diagnosed patients with [wet macular degeneration] when those patients clearly had never had it" and that Pon "billed Medicare for laser photocoagulation treatment of the[se] ... patients." Maj. Op. at [56a–57a]. But the government had to prove more than misdiagnosis and unnecessary treatment to win a conviction. To win, it had to show Mr. Pon intended to defraud Medicare by submitting claims he knew "were, in fact, false." *United States v. Crabtree*, 878 F.3d 1274, 1285 (11th Cir. 2018) (quotation marks omitted); *see also* Pattern Crim. Jury Instr. 11th Cir. O53 (2019). The focus on whether there was any doubt that the patients named in the indictment had wet macular degeneration or needed laser treatment elides this point.

Of course, I do not contend the evidence the government presented about Mr. Pon's diagnoses and treatments lacked probative value. The evidence of misdiagnosis and unnecessary treatment supplied circumstantial evidence of Mr. Pon's intent, and enough of it to support a conviction. *See United States v. Clay*, 832 F.3d 1259, 1309 (11th Cir. 2016); *United States v. Bradley*, 644 F.3d 1213, 1239 (11th Cir. 2011). But Mr. Pon also met the government's case with enough evidence to support an acquittal, had the jury so decided.

Mr. Pon spent more than three days on the stand. At the outset, he testified he "absolutely [did] not" intend to defraud Medicare. He spent the next several days explaining in granular detail how he diagnosed and treated patients. He said he got the idea for his diagnostic method from a talk given by Dr. Robert Murphy, a leading ophthalmologist. Dr. Murphy proposed using an emerging technology to visualize "occult neovascularization"—essentially, new, difficult-to-see blood vessels forming in the eye. Mr. Pon said he thought the technique was "the greatest thing since sliced bread, because this technology was going to allow direct visualization of those tiny, tiny little blood vessels." Mr. Pon said he believed based on Dr. Murphy's presentation that he could detect wet macular degeneration in its earliest stages using a cutting-edge technique.

As for treatment, Mr. Pon said he got some ideas about that from Dr. Murphy's presentation, too. Dr. Murphy reported using a laser to create a "thermal gradient"—a heat differential—in the eye to close the feeder vessels that caused wet macular degeneration. This technique did not cause scarring, as do traditional laser techniques for treating wet macular degeneration. Dr. Pon also thought this was "the greatest thing since sliced bread."

Mr. Pon bought the equipment he believed he needed to put Dr. Murphy's diagnostic and treatment techniques into practice. He later upgraded the equipment with a purchase he explained he would not have made if his intent had been to defraud. Mr. Pon began treating patients with it and said he found lower power settings provided better results than Dr. Murphy's thermal-gradient method.

And the jury didn't have to take Mr. Pon's word for it. Mr. Pon called twelve of his patients and the spouse of another to testify that the lasers improved their (or her spouse's) vision. One witness, who has advanced public health degrees and background as a nurse, testified she learned from Mr. Pon to identify feeder vessels on a diagnostic monitor during Pon's treatment of her husband, who Pon diagnosed with wet macular degeneration. Another, a laser nurse, likewise testified she could see the problem areas Mr. Pon identified and that her vision improved with laser treatments. The government agreed some of these thirteen patients actually had wet macular degeneration. It disagreed as to others. But for all the patients who testified for Mr. Pon, their testimony was uniform that Mr. Pon's laser treatment helped.

With this evidence before it, a rational jury could acquit Mr. Pon. This hypothetical acquitting jury could do so without any belief that: (1) Mr. Pon indeed diagnosed his patients with wet macular degeneration no one else could see or (2) treated it using miraculous new technologies in ways no other doctor could. Yet these are the two issues the majority opinion focuses on. To acquit, a jury would have to conclude only that Mr. Pon believed in good faith he could do these things. His own testimony and that of his patients, some of whom even the government admits had wet macular degeneration, would suffice for a rational jury to believe Mr. Pon acted in good faith. If a patient who couldn't read a menu before says he can after a doctor gave him a laser treatment, reasonable people could agree the doctor believed the treatment worked. I do not dispute that reasonable jurors could also convict Mr. Pon. But the government's evidence of intent, as distinct from the evidence that Mr. Pon misdiagnosed

and unnecessarily treated his patients, is not so overwhelming that this Court should affirm the judgment of guilt.

The case for acquittal would have been even stronger if Mr. Pon had the chance to give his full surrebuttal. The government's rebuttal evidence was highly prejudicial, or "very damning," as the District Court saw it. In a case all about Mr. Pon's intent, the government's rebuttal certainly created the impression that Mr. Pon either 1) billed Medicare for treatments he never provided, or 2) billed Medicare for dozens of useless treatments on a blind eye. And then the government nailed Mr. Pon during his surrebuttal, emphasizing how limited an explanation he gave, just three entries, in the face of a spreadsheet showing years of treatments. The government implied Mr. Pon had nothing to say about the other entries, when of course it knew he had an explanation. The jury may well have taken this as essentially a confession to an unrelated fraud. A "defendant's own confession is probably the most probative and damaging evidence that can be admitted against him." *Arizona v. Fulminante*, 499 U.S. 279, 296 (1991) (quotation marks omitted).

Between the spreadsheet and the limited surrebuttal, so far as the jury knew Mr. Pon had no explanation at all for treating a blind eye. And so far as we know, the jury went back to their deliberations thinking Mr. Pon was a crook because of it. A rational jury allowed to hear the case *with* Mr. Pon's explanation could render a different verdict than this one did. That being the case, I must say this error was harmful. I believe Mr. Pon should get a new trial.

III.

I believe a second jury should have decided Mr. Pon's guilt or innocence. For this reason, I dissent from the majority opinion's holding that any error in Mr. Pon's case was harmless.

APPENDIX B

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 17-11455

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

DAVID MING PON,

Defendant-Appellant.

Appeal from the United States District Court for the Middle District of Florida

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ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

BEFORE: MARTIN, ED CARNES, and ROGERS,* Circuit Judges.

PER CURIAM:

The Petition for Rehearing En Banc is DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petition for Panel Rehearing is also denied. (FRAP 40)

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* Honorable John M. Rogers, United States Circuit Judge for the Sixth Circuit, sitting by designation.

APPENDIX C

EXCERPTS FROM THE TRIAL TRANSCRIPT OF TESTIMONY FROM DEFENDANT'S FOURTEEN WITNESSES (Dkts. 215, 231, 232, 233)

CURTIS VICTOR ARMSTRONG, DEFENDANT'S WITNESS, SWORN DIRECT EXAMINATION

Q. All right. Would you describe to the ladies and gentlemen of the jury the experience of going to Dr. Pon's office and how that went, if there's such a thing as a typical day?

A. I've been a lot, and there's a pattern. I get there fairly early in the morning. I try to get an appointment at 9 o'clock, 10 o'clock.

They will log you in, and soon after that, they will take you back and check your vision to see how well you see, how the Es are on the—the letters and all on the board. They will also check your pressure.

I have a family history of glaucoma, and so they check your pressures to see how they are. And then they put some drops in your eyes that basically dilate your eyes. It opens up your eye so you can see in there. And then I have to go back into the waiting room and wait on all of that to take effect.

And then after that, there are two tests that are conducted, I think, every time that look inside your eyeball.

And one of them, I think you see the eyeball from the front, and then there's a way—and I'm not sure how it does it—that it can see it from the side. And one of those tests, they put a dye in so they can—so that it shows up better.

And then after that, there's some time that you'll wait because usually there are a lot of people in that waiting room. And I would say the average time that I spend with Dr. Pon is four to five hours. If I get in there at 9 o'clock in the morning, I'll get out at, like, 3:00 in the afternoon.

Q. All right. Now, you mentioned—let me interrupt you. You mentioned these tests that Dr. Pon performed. This is with some equipment that he had there in his office?

A. Yes.

Q. Now, did you—after these tests were run, did you have occasion to sit down with Dr. Pon and look at screenshots or pictures of what he had developed from this testing?

A. Yes. Absolutely every time.

Q. Every time.

A. Absolutely every time.

Q. And he showed—at that point is when he told you that he—that he believed that you had evidence of wet macular degeneration.

A. Yes.

Q. All right. And he treated you with a laser on January the 5th, 2009?

A. May I say something?

Q. Yeah.

A. I think he did it on both eyes. One eye didn't have it; one did.

Q. I was going to point that out. Looking at the chart, apparently only the right eye—

A. Yes.

Q.—had the problem and not the left eye.

A. Yes.

Q. And he never diagnosed anything wrong with your left eye in the way of at least wet macular degeneration, did he?

A. Not macular degeneration.

Q. You had some other problems, but—

A. Yeah. But you have to know—I wanted him looking in that left eye to see if that retina was going to detach. I didn't want to do chapter 2 of this.

Q. All right. And he continued to treat you on—looks like May the 4th was the next time with the laser, but then there was an injection of Avastin.

A. Yes, sir.

Q. You remember that?

A. Yes, sir.

Q. And that was an injection in your eye.

A. I was scared about that. They used Avastin on my wife to treat breast cancer, and it was like, "You're going to put some Avastin in me?"

And so we had to talk about that before we did that, but it worked.

Q. But he gave you the option of what treatment modality you wanted to employ, did he not?

A. Absolutely.

* * *

Q. All right. Well, the question is, you already kind of jumped ahead and you've already told us that your

vision right now—you don't wear glasses of any kind, do you?

A. That's right.

Q. And that's the first time in your life that's ever been true.

A. It's the first time in my life, yes.

Q. All right. But can you relate—how can you tell us that this was related to your wet macular degeneration? How can you tell that?

Did you see that yourself with evidence from these screenshots from the testing?

A. Yes. We—there was a lot of talking that went on with us reviewing the results of the tests. He has an incredible amount of equipment.

And I've had people say, "Well, why don't you go to somebody in Athens?" There's a guy that comes to Athens two hours on Thursday. He couldn't haul the stuff over there that Dr. Pon has to talk to me.

So I go down to Dr. Pon, and we—we go through this every time. And there is a discussion of, I don't know, 15 or 20 minutes that we look at where we came from, and he shows me the stages. So I feel like I'm up to date all the time on this.

Q. So you were able to actually look at the screen and see the progress that was being made? I mean, could you see it yourself?

A. Yes.

Q. All right. And ultimately it related—it resulted in where you are now, with seemingly perfect vision?

A. That's right.

Q. What's the drive time between Athens, Georgia, and Dr. Pon's office?

A. Seven hours.

Q. And you have been a patient of Dr. Pon's ever since November the 28th of 2008?

A. You bet.

* * *

JACK CARTWRIGHT, DEFENDANT'S WITNESS, SWORN DIRECT EXAMINATION

* * *

Q. And then with regard to when you're going in for treatment and we're talking about whether we're going to treat the wet macular degeneration with the laser or we're going to treat it with an injection, how was it decided, which one to use?

A. Well, quite honestly, we'd discuss it. Dr. Pon and I would discuss it, and my answer was always, "I trust you very much, Dr. Pon. You tell me which is best for me at this time."

Q. So is it a fair statement that sometimes he recommended the injection with the Avastin, and sometimes the recommendation was the laser?

A. Yes. That is very true.

Q. Okay. And let me ask you this question. Did it help your eyesight?

A. Absolutely.

Q. I mean, can you give us any concrete examples of how it helped your eyesight?

A. The laser?

Q. The laser.

A. When I would go in to him, a good many times my vision had gotten much worse, and after the laser treatments, it improved considerably. The much worse was that it looked like a cloud in front of my eyes that was getting closer and closer to me when I went in. Also, the distance I could see got less and less.

And after the laser treatments, the cloudy – the cloud moved away—never totally went away but it moved away—and my vision got longer in the ability to see.

Q. And so just in fairness, you're legally blind in one of your eyes.

A. I am legally blind in one of my eyes, yes.

Q. Okay. Did the laser still help?

A. The laser still helped.

Q. When you would come in and treat with Dr. Pon, would you tell him about how the laser affected your eyesight?

A. Oh, yes. Absolutely. He always asked that question, and we would discuss how it affected my eyesight. Sometimes it was better than other times, but all times it was improvement.

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JEROME LEWIS, DEFENDANT'S WITNESS,
SWORN DIRECT EXAMINATION

* **

Q. Okay. When he did the laser, what impact did that have on your vision?

A. After the lasers were done, my vision usually cleared up for—it would—it would last a couple days, maybe a week or so, and steadily go back to what it was before.

Q. According to these records, he did a laser surgery for macular degeneration for the first time on July 10 of 2009, then he did another one November 13 of 2009.

A. Uh-huh.

Q. In 2009 were you living in Orlando or—

A. No.

Q.—West Palm Beach?

A. West Palm Beach.

Q. Okay. So if the laser only lasts for a very short time, did you call Dr. Pon, or did you—had you already made another appointment—

A. Yes.

Q.—to come back a few months later?

A. Another appointment was made, yeah, for follow-up.

Q. And you went back, then, in November and had another laser treatment?

A. Uh-huh.

Q. And the same procedure in terms of how he diagnosed you looking at the screens and everything?

A. Everything.

Q. And then what impact, if any, did the—did that laser treatment have on your vision?

A. The same improvements.

Q. But they didn't last long?

A. Yeah. They—I mean, it would—it would last maybe a little bit longer, but, you know, it always comes back to what it was before.

* * *

SHIRLEY RAMIREZ-ZAPATA, DEFENDANT'S WITNESS, SWORNDIRECT EXAMINATION

* * *

Q. Ms. Ramirez, where do you live?

A. (In English:) San Francisco, California.

Q. I think that we understood. We're on a roll here. Ms. Ramirez, have you lived most of your life in San Francisco?

A. Only ten years.

Q. Okay. Is that the last ten years?

A. Yes, sir.

Q. When you—was there a point in time when you were diagnosed, in San Francisco, by a doctor with macular degeneration?

A. Yes, sir.

Q. Did you receive treatment for macular degeneration from the doctor in San Francisco?

A. Yes, sir.

Q. What kind of treatment did you receive?

A. An injection, Avastin.

Q. Avastin?

A. Yes.

Q. Okay. Did the injections help you?

A. An improvement that I could notice, no.

Q. Were you concerned about your vision?

A. Yes, sir.

Q. What were your concerns?

A. I had distortion. It's a problem I have in my left eye. I was unable to have a real vision with that eye.

Q. Were you told that your—you could lose your vision or go blind with the macular degeneration?

A. Basically what they said, that there was no way of healing and that probably I could lose a frame of vision with time.

Q. Did you and your husband do research and did he do research on the Internet to try to find another doctor to treat your eyes?

A. Yes. Both of us were worried because we noticed that my quality of life was suffering a great change.

Q. Through that research did you learn of Dr. David Pon?

A. Yes. My husband was investigating and speaking also about this with many people. He found this doctor.

Q. Did your husband call Dr. Pon and talk with him about your problems with your eyes?

A. Yes, sir. They were in communication.

Q. And did Dr. Pon agree to review records if those records would be sent to Dr. Pon?

A. Yes, sir. He requested them, and they were sent to him.

Q. After Dr. Pon reviewed the records, did he then have another conversation by telephone with your husband?

A. Yes, of course he did.

Q. After that phone call, did you and your husband arrange to come to Florida for Dr. Pon to examine you?

A. Yes, sir.

* * *

Q. What effect did the laser have on your vision in your left eye?

A. It was incredible for me because I was able to see my husband's face again without any distortion.

Q. For how long had you not been able to see your husband's face without distortion?

A. Two or three years. It was long time for me.

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DENNIS THACKER, DEFENDANT'S WITNESS, SWORN DIRECT EXAMINATION

* * *

Q. Mr. Thacker, after you were initially diagnosed with dry macular degeneration in 2003, did there come a time when you received the bad news that you, in fact, had progressed to wet macular degeneration?

A. Yes, sir. It was in September of 2013.

Q. 2013?

A. Yes.

Q. And that was not—that diagnosis was not made by Dr. Pon, was it?

A. No, it was not.

Q. It was made by your doctor in Columbia, South Carolina.

A. Yes, a retinal specialist in Columbia.

Q. All right. Had this been the same physician that had been treating you since your original diagnosis of dry macular?

A. No. He was referred to me by the physician that was monitoring me.

Q. Okay. And so did you—were you tested, as far as you were concerned, thoroughly enough that you could accept that diagnosis and knew that that's exactly what you had?

A. Yes.

Q. And particularly so with your family history.

A. Yes.

Q. All right. As a result of that, did your physician in Columbia undertake any kind of treatment regimen with you to treat that wet macular degeneration?

A. Yes, he did. We went to an Avastin injection monthly to five-week basis.

Q. I'm sorry. I didn't hear that last part.

A. I had monthly injections—

Q. Of Avastin?

A.—between every four to five weeks.

Q. Of Avastin?

A. Of the Avastin.

Q. All right. And how long did you continue with that treatment?

A. I went through that treatment for 16 months.

Q. All right. I meant to ask you, how did you—before the diagnosis was made in Columbia, did you recognize that something was going not well with your eye?

A. Yes, sir. I was watching a football game on television, and I noticed blurred vision in the right eye and some color distortions when looking at the TV.

Q. All right. And this was all in the right eye?

A. Yes.

Q. And was that what prompted you to go to the physician and in turn get the referral to the retinal specialist?

A. Yes, it did.

Q. All right. And to get back to where we were, apparently the physician that you saw there that made that diagnosis started you on the standard of care, the Avastin.

A. Yes, he did.

Q. Once a month or every five weeks or so.

A. Yes.

Q. And how long, again, did you continue with that?

A. I had 16 treatments.

Q. And what was the result of those treatments?

A. At that point in time I had noticed a decrease in my vision.

Q. I mean, something that you could recognize?

A. Yes.

Q. I mean, you could tell that things weren't going well?

A. During the eye chart exam in his office, I could tell it was changing.

Q. All right. And so what did you do at that point?

A. At that point I was—took early retirement and made an appointment to come down and see Dr. Pon.

Q. All right. What kind of symptoms were you experiencing? Do you recall? Was it just generally bad vision, or was it blurry, or what was it?

A. It's blurry vision. There's a slight loss of light recognition between the right and left eye.

Q. All right. And you could tell a difference from one eye to the other?

A. Yes, I can.

Q. All right. And you came down to see Dr. Pon, if our record is accurate, on May the 21st, 2015. Does that square with your memory?

A. Yes. That's correct, sir.

Q. And at that time did Dr. Pon undertake and do an examination of you that was something like your physician in South Carolina?

A. Yes. He did a very thorough exam, which I actually felt was more in-depth than the physician had given me in Columbia.

* * *

Q. All right. What treatment did Dr. Pon offer you at that time, sir?

A. We reviewed a couple different treatments, including—anything from laser to continuing the Avastin.

Q. What did you think about continuing the Avastin after 16 months?

A. It had helped in keeping it stable for most of that 16 months. We discussed and decided to go with a combination program.

Q. Combination of laser and Avastin.

A. Yes.

Q. And did you do the laser that very day, that very day that you first went in on May the 21st?

A. I believe I did.

Q. Well, we're looking at the record. The record would seem to suggest that it was done on May the 21st, and then the Avastin was given the following day—

A. Yes.

Q.—on May the 22nd.

A. Yes.

Q. Does that square with your memory?

A. That squares with my memory.

Q. All right. When you did that, when you—the laser treatment that you described, could you—was there sensation to that? In other words, were you aware that it was going on when it was going on?

A. Other than the light and the pressure from the optical devices he was using, I had no sensation of the laser.

Q. So there was no pain.

A. No.

Q. All right. And the—when you left that night and when you woke up the next morning, did you feel and—did you see any difference in your eyesight within the next 24 hours or so?

A. Yes. I noticed a significant improvement in vision in the right eye.

Q. And was that with—after the Avastin or even before the Avastin was—

A. Even before the Avastin.

Q. And did that—did that phenomenon, that effect, did it increase even more with the Avastin, or was it just the laser that seemed to do it?

A. It appeared more that the laser had the effect on the eye.

Q. But to be clear, I mean, were you been able to see things that you had not been able to see before, after the—

A. Yes, I was.

Q. And were you—I mean, specific things like road signs and, you know, fine print and things of that sort?

A. I was able to read fine print and could actually identify separate leaves on the trees and read road signs at a further distance.

Q. And how long had it been since you'd had vision of that quality?

A. It had been at least 18 months.

Q. I'm sorry?

A. 18 months, before I started the treatments with the other doctor.

* * *

Q. Did you get any additional help from this second laser that you experienced on June the 26th?

A. Yes, I did. I feel it prolonged the effect that I had from the first laser treatment.

Q. I don't even know the answer to this. Have you seen Dr. Pon since that time?

A. I've had a total of three treatments with Dr. Pon, and I have not seen him since then.

Q. All right. And what has been the result of those three treatments with Dr. Pon and the laser or laser as accompanied by a shot of Avastin?

A. I showed signs of clearer vision, able to read documents and small print better.

* * *

ZILLIAH JANE GOULD, DEFENDANT'S WITNESS, SWORN DIRECT EXAMINATION

* * *

Q. Let me ask you more specifically, from August of 2006 through the present, have you been a patient of Dr. Pon's and been treated for and diagnosed for wet macular degeneration?

A. Yes, I have.

Q. And related to that diagnosis and treatment for wet macular degeneration, have you gotten laser treatment for that?

A. Excuse me?

Q. Related to the wet macular degeneration, have you gotten laser treatment for that?

A. Oh, absolutely.

* * *

Q. Okay. Now, let me focus in first on the laser treatment. When you received the laser treatment, did it have any effect on your eyesight?

A. The laser treatments seemed to help my eyes much better than the injections that I had with Avastin, and I'm sure that I told Mr. Pon or Dr. Pon that if I had the choice, I would prefer the laser rather than the injection.

Q. And why is that?

A. Because with the injection, I had a sort of a reaction. It took me several days to get over the—the injection. Whereas, with the laser immediately I could feel some improvement in my eyes.

Q. Can you give us any sort of concrete example as far as how your eyesight improved with the laser?

A. Well, with the laser, watching television, my vision was clearer, and also with my reading, it was clearer. It wasn't as fuzzy.

Q. All right. And then I want to see—you're still a patient of Dr. Pon's today. Is that right?

A. Yes, I am.

Q. And so you obviously received a large number of laser treatments over the time since 2006?

A. Oh, absolutely.

Q. And also—

A. And—

Q. I'm sorry. Go ahead.

A. Well, I said I firmly believe that Dr. Pon has helped to keep my vision as good as it is, and I credit—credit him with my vision.

I still work every day. I work with children every day. I do clerical work, filing papers and grading papers and this, that, and the other. And I really attribute it to the special care that I've had with Dr. Pon.

CATHERINE BOXBERGER, DEFENDANT'S WITNESS, SWORN DIRECT EXAMINATION

* * *

Q. Now, Ms. Boxberger, Dr. Pon wasn't the first doctor to actually diagnose you with wet macular degeneration.

A. (Shakes head from side to side.)

Q. Tell us how you ended up going to see Dr. Pon.

A. Well, my first doctor told me I had macular a long time ago, and when it got worse, he told me there's nothing he could do. So he sent me to an ophthalmologist, a Dr. Campbell, and when I went to see him, my vision was 0/80, and he said nothing he could do.

But there was a new doctor in Orlando of his realm and would I like to—if I wanted to go to see him, so I said I did, and I went to see Dr. Pon.

And he worked and worked on my macular until I had 20/20 vision again and was able to drive for—until 2009.

Q. Till 2009?

A. Uh-huh.

Q. All right. Now, I asked you this before so you said I could ask you this question. How old are you today?

A. 94.

Q. And so you were able to drive, with Dr. Pon's help, until 2009?

A. Uh-huh, till I was almost 90, uh-huh.

Q. All right. So I know that you also, in addition to being treated with the laser, that you also got injections of Avastin—

A. I did.

Q.—into your eye.

A. Uh-huh.

Q. And could you tell the difference as far as whether it was the Avastin or the laser treatment that helped you?

A. In its own way because it—it is like time release. It doesn't help you immediately, but it keeps you seeing longer.

Q. And what about with the laser?

A. The laser is immediate, and it helps a lot. And he's working on this eye and he's got—I can see light through it where it used to be black, and we're still working on this eye.

Hopefully I'll be able to see something out of it someday.

Q. Okay. Would you discuss with Dr. Pon whether or not the laser was beneficial to your eyesight?

A. The laser?

Q. Yeah.

A. Absolutely. That's what saved my sight.

Q. And what would you tell him?

A. Uh-huh.

Q. What would you tell him about the laser treatment?

A. Well, I think it's wonderful. It's one of the best, and it does help you heal. And it takes a long time to take care of macular, but we've been working on it for years and it's working.

* * *

RUBY ANN BRITT, DEFENDANT'S WITNESS, SWORN DIRECT EXAMINATION

* * *

Q. Now, Ms. Britt, did I understand that you—that Dr. Pon would recommend that you would come back periodically every few months?

A. If he treated my eye for whatever reason, whether it was a retina detachment or blood behind the eye or whatever, and he treated it, he would want me to come back maybe for three months just to see how I was doing.

Q. Right. Did you do that, or did you set your own schedule?

A. No, I didn't always do that. If I wasn't having problems with my eye, if my vision had not changed, I usually wouldn't go back for a year.

Q. With specific reference to this treatment of wet macular degeneration that we've just described, did

you kind of set your own pace of when you got a laser treatment?

A. Well, I can't really say that exactly.

Q. All right.

A. We kind of cooperated with each other.

Q. What—

A. You know, every time I went—I didn't get the laser every time I went.

Q. Right.

A. He treated my eyes for different things.

Q. Correct.

A. As a matter of fact, he did surgery on my right eye.

Q. What was the surgery?

A. The surgery was to replace an intraocular lens that had slipped off my eye.

Q. And was that successful?

A. Pardon?

Q. Was that successful?

A. Very successful.

Q. All right.

A. And he also treated my husband with surgery because of the vitreous in his eyes. He literally restored his vision for him.

Q. Your husband referred to him—A. And after that he called him his hero.

Q. His hero.

A. Yes.

Q. That's what he called him, wasn't it?

A. Yes. Dr. Pon's our hero, that's for sure. He also treated my sister.

Q. Did you—

A. She was having trouble in one of her eyes, and he did surgery on her, and her surgery was very successful.

Q. With specific reference to the treatment with this laser, this treatment of wet macular degeneration by laser, did you notice any improvement in your vision?

A. Every time he did laser in my eye, my vision improved.

Q. Without exception.

A. Without exception, right. Otherwise, I would not have him laser it because we would agree on the laser. You know, he'd say, "Are you sure this is going to help you? Now, if it's not going to help you, I don't want to do it. If it's going to help you, I want to do it."

I said, "I'm positive it helps me. Please, do it."

Q. So you would—

A. Yes.

Q. You would—

A. Every time it would help me.

Q. He would ask you every time, "Are you sure that this is helping you?"

A. Yes. He didn't want to do it unless he was sure it was helping me.

Q. And you told him each and every time, "Yes, this is helping."

A. He never lasered my eye that it did not help improve my vision. This was the left eye most of the time.

* * *

MARION GRAY, DEFENDANT'S WITNESS,
SWORN DIRECT EXAMINATION

* * *

Q. Did he indicate that he thought that you needed laser treatment for your vision?

A. He said he'd like to try it, and I agreed.

Q. Okay. And how did—

A. He wanted to see if it would improve, and it improved.

Q. Did it improve your vision?

A. Yes.

* * *

Q. Okay. And then that looks like the last time that he did, back in January 6th of '11, the laser for your macular degeneration.

Did your eyesight improve every time after you had the laser treatments?

A. Yes.

Q. And can you give us an indication of how it improved? What changed in your vision?

A. I could read better. I could do my crossword puzzles and be happy.

Q. Could you read them and do your crossword puzzles—

A. Yes.

Q.—before the laser? How about before the laser?

A. I had to wear magnifying glasses.

Q. Okay. Did you have to wear magnifying glasses after the laser?

A. No.

* * *

SHARON KELLEY, DEFENDANT'S WITNESS,
SWORN DIRECT EXAMINATION

* * *

Q. Okay. So there are a lot of times over the years that you

and your husband came down to see Dr. Pon, correct?

A. Correct.

Q. Where were you living at the time?

A. Springfield, Illinois.

Bud always—because I had been a nurse, he always asked me to go with him and be with him. And whether it was his open-heart surgery in Indianapolis or whatever, I was sort of the spokesman for him.

Q. I'm not very familiar with Springfield, Illinois, but are there ophthalmologists in Springfield?

A. Yes.

Q. How far is Springfield from Chicago?

A. It's about a three-and-a-half-hour drive.

Dr. Pon offered to refer us to a—early on when we were seeing him to a doctor in Chicago, but my

husband said that Dr. Pon saved his eyesight the first time, and he would just as soon choose.

Now, we did see every one that was in Springfield, and we saw one after he had his open-heart surgery and his eye was bleeding in Indianapolis. And then St. Louis Retinal Associates, and I can't remember what year that was.

But none of them at the time would have—well, they would tell us there was nothing they could do.

Q. So why did you then make the decision—there are obviously ophthalmologists and retina specialists in Chicago.

Why did you and Bud, all these times, come down to Florida to see Dr. Pon?

A. Because Bud kept getting better. He would be able to see. Bud was still working, and he was a lobbyist for about 40 years in Illinois as well as congress.

And he had a lot of reading he had to do, and his vision, when we started really getting lots of treatments, had decreased. He couldn't see to read. He couldn't read menus.

He couldn't read the newspaper. He couldn't read the bills that were sent to him from the legislature. But we would get a treatment and—and the laser treatment, within hours, Bud was—we'd go out that evening and he'd read the menu.

I would bring him down. We drove a lot of the times. Bud couldn't read any of the signs. He couldn't even read the big interstate signs. And we brought another lady every time with us from Springfield as well, and neither one of them could, and they both got the same treatments.

But we'd go out to dinner and they could read menus after the laser treatment. Bud was reading the newspaper, and in two or three days, we would head home, and I'd be driving and they drove me nuts. They were the worst backseat drivers you've ever seen telling me, "You're at Colonial Drive. You've got to slow down," or, "You're here," or, "You're there." I mean, Bud got better and—

Q. So Dr. Pon did, according to his treatment records, a treatment of your husband for diabetes, as well as treatment for macular degeneration.

Let's talk a little bit about just the macular degeneration treatment.

A. I understand.

Q. Were you always in the examining room and the treatment room when Dr. Pon was examining or treating your husband, Bud?

A. From the minute they called Bud back, I probably drove his staff crazy because whether it was getting his—his pictures taken or just having his eyes tested or dilated or whatever, I was with Bud.

And, yes, every time for the full time that Bud would get treatments with Dr. Pon, I was in the room.

Q. And you were a nurse, registered nurse, for 18 years. You've indicated you worked in a lot of different places. I assume you've seen a lot of different doctors examine patients?

A. Yes, I have.

Q. How would you compare Dr. Pon's examination of your husband with his—with the examinations that you've observed other physicians do?

A. Dr. Pon took the time. He took whatever time necessary.

When we would go to these other physicians or these other retinal specialists, if they looked in Bud's eye, you know, five minutes, that's pushing it.

They would examine the eye a very short period of time. They would look at the records and whatever, but we were in and out in 15 minutes at most—most of these specialists' offices.

With Dr. Pon, I could plan on spending two to three hours there. At the time you had your—you took your turn to get your pictures. When he would come and examine the eye, he would go look at the pictures, and he would let me go with him to look at those pictures.

He would make a determination on what treatment he needed to do. The treatment itself took a long time. The laser treatment took a long time.

Q. And were you present for those laser treatments?

A. Yes.

Q. Let's—before we get to the treatment, let's back up a little bit for the diagnosis.

So when Dr. Pon did his diagnosis, were you present when Bud—well, was Bud injected with dye for tests that the jury has heard about with fluorescein angiography and indocyanine-green, or ICG?

A. ICGs. That's what I—

Q. Are you familiar with those terms?

A. Yes.

Q. Are you familiar with those tests?

A. Yes.

Q. And did your husband, Bud, receive those tests in Dr. Pon's office?

A. Always received them, it seemed like.

And sometimes Dr. Pon would send him back. If—if the person taking the picture didn't just capture it as well, if they blinked or if it was blurred, he would go back—you know, send him back to have pictures taken again, and I was there with Bud, yes.

Q. Okay. And then did Dr. Pon discuss what he saw in those images with you and Bud?

A. With me. Bud was there in the room, but I was the one that would get up and go over to the computer where he would have these displays of the pictures from that day or—then he would show me pictures from the months before or the treatment before. I was the one that was really looking at them, yes.

Q. Okay. Are you familiar with the term feeder vessel?

A. Yes.

Q. And what does that mean to you?

A. That's where—you know, they find this bleeding in the eye, and the source of that comes from the vessels. They—sometimes they talk about the vessels are leaking or bleeding, but it's like the source. If he could find the feeder vessel, if he could identify it and treat it, then you didn't have that bleeding.

That's not to say some others might not develop, but it was the spot. And it was not easy to see. First, when he would point them out, it took me a while to learn. I would say, "Is that it?" or something, and it would be some other artifact or something on the

picture. But eventually, yeah, I—then I could see what he was talking about and—

Q. Is that—

A.—it was the spot that he wanted to get to, that he wanted to seal off.

Q. And is that pretty much true every time you went in and there was a—either a fluorescein angiography or an ICG test done, that you—ICG test done, that you would talk with Dr. Pon, with your husband there, about what it was that Dr. Pon saw?

A. Yes.

Q. And—

A. And, you know, over the years, he had—he didn't have that machine at first that took some of these pictures, and he kept saying, "If I can see it, I can fix it."

And we waited and kept going back until he got his first machine, and that's when I really started looking at the pictures, because when we first started, he didn't have that type of equipment that I remember. I refer to it, I think, for the ICGs and the Heidelberg machine and things like that.

But he always explained to me the process of lasering because I was very concerned about scarring.

* * *

Q. The treatments that Dr. Pon did of Bud for wet macular degeneration—

A. Yes, sir.

Q.—did Bud have improved vision every time?

A. Every time. And it was—you know, I wondered – I questioned Bud because he would have such poor vision, and it would be within hours. He usually liked to go back to the motel and lay down for a couple hours, and—maybe three, and then we'd go out to dinner.

And by the time we'd got out to dinner, he was reading the menu, and I just couldn't hardly believe that his vision could improve that much. It was within hours.

Q. Could he have read the menu before the laser treatment?

A. No, sir. He could not read any menus.

And the problem was we didn't always get here as often as we would like, whether Bud was having another major health problem or his business or my business. So sometimes his—we didn't get to stay on a protocol of so many weeks that we'd like to.

And his vision would be very poor, and he would say to me, "We have just got to go. I can't drive. I can't read. I can't see." You know, and we would come down here and get a treatment, and he would be better in hours.

Q. And how long would that—how long would that improved vision normally last?

A. Normally his—for Bud, it would last 8 weeks to 12 weeks, and after 12 weeks, it would start—he would start complaining.

Sometimes it would be a little before that he would start complaining, but there were times—Bud had to have a graft to his leg because of the diabetes. He needed to have a vein transplant or an arterial

transplant to get blood to his foot because he had a sore, and we had to not come down for three or four months.

And Bud could not function. He really couldn't function. I would have—he would hold onto my arm, and I'd have to get him out of the doctor's office or to wherever we were going because of his decreased vision.

Q. On each of the occasions when you came back down after the laser treatments, or even, I guess, on those occasions when you went back the very next day and Bud would get an Avastin injection, if that happened, would you or Bud tell Dr. Pon about the improved vision and what you've just told us?

A. Absolutely. And, you know, the thing was that they would always do an eye test on Bud when he came in, and—and not just the pictures but they'd have him read, you know, the big old eye chart.

And they—Bud, whether they offered him an eye chart afterwards, after laser treatment, or not, he was always going—they had it hanging at the end of the hall there in Leesburg. And he would always go and see what he could read on the chart and which line he could read on the chart. And every time his vision improved, every time.

But Dr. Pon also did testing, and he knew that Bud's vision had improved. Sometimes he would act a little surprised in the beginning that it would happen so quickly, Dr. Pon did.

He'd say, "Really? You can see that? You can do that?" But eventually, I think he got tired of asking us because we kept telling him, and, you know, he didn't seem quite so surprised after that.

* * *

Q. Did you and Bud have occasion to recommend Dr. Pon to other people?

A. People would call Bud. People who knew Bud, some of his clients, some of, you know, our friends or whatever, they knew that his eyes were getting better. He could come to Florida and his eyes would get better.

We brought at least 10 to 12—we brought them with us over those years, 10 to 12 people at the minimum to see Dr. Pon. And I know we referred two or three others who traveled on their own down here to see Dr. Pon.

And every one of them would call us and tell us that Dr. Pon helped them, every one. We had a sign made up and put on the side of our van because we were hauling people to Dr. Pon's office. Bud had it made up.

It was a magnetic sign that said "Dr. Pon's Illinois Patients," and he made Dr. Pon come out and see the van one time, and we took pictures because people couldn't get that help anywhere. They would be told, "There's nothing can be done."

And I sat in that waiting room and I talked to people from all over this country. I talked to a lady from South America. I talked to a lady from California, I mean, up in Michigan and Wisconsin individuals. Every one of them had the same story: "We went to our doctor. We went to our retinal doctor, and they told us nothing could be done." And that's why they would travel there.

That's why we traveled there.

Q. And did they all seem to get improvement from Dr. Pon?

A. Everybody got improvement, and that's why they kept coming back.

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JAMES THOMPSON, DEFENDANT'S WITNESS, SWORN DIRECT EXAMINATION

* * *

Q. Okay. With respect to the diagnosis of macular degeneration and the other, how long after this surgery, approximately, do you recall that that diagnosis was made? Do you have any feel for that interval at all?

A. Within a year—

Q. Okay.

A.—the first one.

Q. All right. And did Dr. Pon, at the time that he made those diagnoses, both of them, did he tell you whether or not either of these diseases were truly curable?

A. Oh, he said neither one of them were curable, but he felt that he could retard the progress or stop the progress or slow it down a little bit. And what he said to me was, "We're going to shoot for a 50 percent improvement in your eye." So I'm looking at probably 90/20 at the time. This is what my left eye was going to be.

I'll jump ahead of everything to my last visit a month ago. The vision in my left eye to this day is 25 over 20. I can shut my good eye and see almost as well as I can out of—with my bad eye, the left eye, as I can with my right eye.

Q. So, in other words, when you first started treating with Dr. Pon, your vision was somewhere, you say, in the range of 20/90, and it currently is 20/25.

A. It was probably—it was—I was hoping it would come to 90/20. Probably it was closer to 180. It was so bad that I couldn't—I had trouble reading the fourth line from the bottom on the eye chart.

If you've all had eye examinations, you know that there's—I don't know how many lines there are, but the fourth line from the bottom, not really small. It's kind of easily readable. I had trouble with that.

And the last time I went, I read the bottom line with the exception of maybe one.

* * *

Q. Did you—did you experience—when you started with the laser treatment for your macular degeneration, did you recognize or experience any improvement in your eyesight?

A. Virtually immediately.

Q. Virtually immediately?

A. Yeah.

Q. And that continued during the course of the treatment with this focal—

A. As I said, my eye was almost unusable, and now it's 25/20, so yes.

Q. All right. Now, it looks like this chart—I mean, there was an interruption because frankly the government came in and took the charts in—somewhere in 2011.

I want to flip back to what seems to be a continuation and partial overlap. That X is mine, by the way,

beside 4/29/11 because I marked one that didn't belong in this list.

But, again, we're seeing then—towards the bottom we see a number of procedures involving laser. But down here towards the bottom we see that—I think it's October the 18th, as I'm reading it, and this now is in 2013, that there were several times—more than several. There were five times there, extending into 2014, when Dr. Pon administered Avastin.

Do you recall that?

A. Yes.

Q. And Avastin, we have learned, is administered by a shot in the eye.

A. Yes.

Q. Tell us about that.

A. It's unpleasant. I mean, I don't know of anybody that likes to get stuck in the eye. I personally don't react well to deadening agents. It started back when I would go to the dentist. He would take four or five Novocain shots to dull the pain.

When I would have these shots in the eye, it took drop after drop after drop to deaden it, and I could still feel the pain. And, you know, the doc would say, "You just feel the pressure."

And I'd say, "No, I feel the pain." I mean, I just—he couldn't deaden it.

I literally begged him and argued with him to give me laser treatments after I found out what—that they weren't going to create—

Q. Did he—

A.—scar tissue.

Q. Did he explain why he wanted to try this to you – try this treatment, this alternative treatment, this Avastin at that time?

A. Oh, he probably did. I mean, he explained everything he did whenever he did it. I don't really remember. All I know is when he said—as soon as he said shot, I started shaking. And I'm not trying to be funny.

Q. That discussion with Dr. Pon continued for a period of time, did it not—

A. Yeah—

Q.—until—

A.—all the time. Every time I would go and he says, "We're going to give you a shot," I'm ready to go, get up and leave, unless I see a bottle of bourbon or something. Now that is trying to be funny, but—

Q. What about the effect of the Avastin? Can you compare the effect of the Avastin on your eyesight with the effect that you've experienced from the focal laser, the laser that he has treated that same eye?

A. I personally think there was more success with the laser. I mean, literally the day after I would get a laser treatment, I actually saw better, and I cannot honestly remember a time when it did not improve my vision.

Q. And did that continue with—every time that you had that laser throughout the entire—

A. Like I say, I don't remember a time when it did not improve it. So the answer would be yes, every time I had a laser treatment, it improved my vision.

Q. Well, this thing shows—

A. 25/20.

Q. I'm sorry. This chart, at least, seems to cut off on June the 30th, 2015. Have there been shots—listen to me, shots. Have there been other laser treatments since June of '15, do you believe?

A. No. The last time I saw him, I tested the 25/20, and he said, "You don't need anything. You're perfect. You know, as near as you could get. Way better than what we ever expected."

And he would always compliment me on doing well, and quite frankly, I didn't do well at all. You know, he did it, you know. And if—if you ever need an eye doctor, a man to work on your eyes, he's your man.

* * *

GLORIA MOULTON, DEFENDANT'S WITNESS,
SWORN DIRECT EXAMINATION

* * *

Q. Okay. So let me ask you about the laser treatment itself. When you were treated—first of all, can you differentiate—do you have in your mind the difference for when you were treated with the laser for wet macular degeneration and when you were treated with the laser for some other—whatever diagnosis you were dealing with?

A. Right, yes. With the laser for the macular degeneration, I did feel this funny sensation up in my nose area. And he said that's common.

Made me feel very comfortable about having it done. And I was not a bit concerned, only that I wanted to see better and that was my whole objective.

I have family. I want to see better. I don't want to go to blind. I have no intentions of going blind if I can help it.

Q. Well, a good follow-up to that would be after you had the laser for the wet macular degeneration, did it help your eyesight?

A. Definitely. And it has helped me considerably.

Q. Can you give me, like, any examples as far as—

A. I'm not wearing my prescription glasses. I'm reading with over-the-counter.

Q. That's a good example.

A. Just the fine print gets to me. But other than that, I can see pretty good. I can see way back there. I can see off sides.

Q. With regard to the treatment that you received for the laser—and I'm specifically talking about the wet macular degeneration.

A. Okay.

Q. And you've already told us that it assisted you or helped your eyesight. Did you discuss that with Dr. Pon?

A. Considerably. We did talk about it, because I was concerned about it. Like I said, my ex-husband had it. I did not want to be in that—in that category of never being treated. I wanted whatever treatment that Dr. Pon felt that was good for me.

What he did with his other patients, that was between him and his other patients. But what he did with me, we discussed, definitely.

Q. What did you tell him? What did you tell him as far as whether it helped—

A. He said that this laser treatment should help my eyes. He was going to keep track of it. And each time, I could see—as the months went by, I could see a difference in my eyes.

Q. And you shared that with him?

A. Yes, I did. And I've even shared that it's – at nighttime, I don't need my glasses either, so...

* * *

MAXINE BLAIS, DEFENDANT'S WITNESS,
SWORN DIRECT EXAMINATION

* * *

Q. All right. Now, before we get into other problems that you may have had that he treated, did you have any kind of a reaction in your eyesight? Did you have any improvement in your eyesight as a result of these initial treatments with the laser?

A. Absolutely.

Q. I mean, was it something that you noticed that you really and truly could tell?

A. Well, you know if you have a bleed in your eye because you can't see. It gets very blurry. And you know something's going on. So when he uses the laser afterwards, that clears up.

Q. And it's kind of, again, getting ahead of the story, but has that been consistently true throughout the time that you treated with Dr. Pon?

A. Absolutely.

Q. That every time he used the laser to treat wet macular degeneration—

A. Every time he used it, it improved my vision.

* * *

Q. Okay. Now, again, up until the time that you had the retinal detachment in January 2010, and, in fact, right before that, you had some other kind of treatment January 29th where there may or may not have been a different laser.

Were you continuing to experience improvement in your vision as a result of these laser treatments that Dr. Pon was performing?

A. Yes.

Q. And, Ms. Blais, again, I want to—was this just kind of some subjective thing that you felt a little better or were you able to see things clearly that you couldn't see before?

A. Absolutely.

Q. I mean, like reading newspapers and—

A. It's like going—one demonstration was this last bleed that I had, I told him that when I looked at the—it was in my right eye. When I looked at the TV screen, I could see the left part of the TV screen was like there was a curtain. I couldn't hardly see it at all.

And then he corrected the bleed, and almost immediately when I went home, I could see the full screen

* * *

DORIS SHOWERS, DEFENDANT'S WITNESS,
SWORN DIRECT EXAMINATION

* * *

Q. And what was your husband's name?

A. Harry C. Showers.

Q. And do you know about when he began seeing Dr. Pon?

A. I believe it was back in '08.

Q. Okay. And what was his eye condition at that time?

A. He mad macular degeneration and very bad glaucoma.

Q. Okay. Did he have other health problems going on around that time, too?

A. Yes. He was very ill and in poor health.

Q. Okay. Did you go with him when he went to see Dr. Pon? Or did he go by himself?

A. Oh, no, I—I would go with him. Sometimes he would drive. Sometimes I would at that time.

Q. Do you know what kind of treatment that he had from Dr. Pon?

A. He had laser treatment and also some kind of drops they use for the glaucoma pressure.

Q. Before he went to see Dr. Pon, what kind of eyesight problems did he have?

A. Pretty much what you would just call failing eyesight. And he was under heavy medication for the glaucoma to try to keep the pressure down.

Q. Before he went to Dr. Pon, did he have magnifying glasses that he needed to use for reading at home?

A. Oh, yes. Uh-huh (affirmative).

Q. Did you keep several of them around, or did he?

A. Yes.

Q. And what did he need the magnifying glasses to read?

A. To read the TV schedule or his sporting magazines that he liked to read.

Q. And after he had laser treatment for macular degeneration by Dr. Pon, how did that affect—how did the laser affect his eyesight? Could he see better, about the same, or worse?

A. Gradually it—it improved, that—I would see him pick up the magazine or the schedule and be able to—to tell what program he wanted to watch.

Q. Without the magnifying glass?

A. Without—he had different strengths of them, different sizes. And only he knew which one was the better one.

Q. Okay. So did the laser seem to help his vision?

A. Yes, it did.

Q. And did he have several times that he went to Dr. Pon for laser treatment?

A. Oh, yes.

Q. Did the laser seem to help every time that he went?

A. Yes. Uh-huh (affirmative).

* * *

Q. Did he do laser treatments on both of your eyes?

A. Yes.

Q. And how did—how did they affect your vision? Did they work?

A. Yes.

Q. Can you give us an example of—of what kind of a change there was after he did laser treatment on you?

A. It was like looking at a—at a glass that—a drinking glass that had film—a film on it from washing it in soap.

And after the treatments, it would—it was kind of like the fog had disappeared off the glass and it was like somebody had washed the windows when you looked at something.

Everything was clearer.

Q. And was that true each of the times that he did laser treatment on your eyes?

A. It was more of a—of a gradual improvement. Maybe a little bit each month when you—

Q. Each time—it got better each time he did the laser?

A. Yeah. Uh-huh (affirmative).

* * *

Q. Let me ask you about your experience generally in going to see Dr. Pon. Approximately what time would you normally arrive? And how long would you be there?

A. I believe we would have got the 1 o'clock appointment.

Q. And then how long—how long would it be before you would normally end and leave his office?

A. Oh, sometimes it would be 5:00, 5:30. He took his time and explained everything as he went.

Q. Did you find him to be thorough?

A. Oh, yes.

Q. And did he answer your questions along the way, if you had questions?

A. Yes.

Q. Was his waiting room generally pretty full of other patients?

A. Not what we would call overfull, but a group—I mean, he did not load his office with patients.

Q. Okay. Were there patients from all over the—the state or elsewhere?

A. Oh, yes. Uh-huh (affirmative). And someone would say, I drove up from Key West, or, I drove up from Marathon, or something like that. And then, I drove down from Georgia, or someplace like that.

Q. Did most patients seem to have to wait quite a while before they got in to see Dr. Pon?

A. Oh, yes. Uh-huh (affirmative). Uh-huh (affirmative).

Q. And you and your husband or other patients, did some of them even take coolers?

A. Oh, yeah.

Q. And why did they take coolers?

A. Well, you were in there for quite some time. And most of us were elderly. And you just needed some snacks along the way.

Q. So how does that compare to other doctors you've been to? Do you normally have to wait nearly as long for other doctors?

A. No.

Q. So why did you keep going to Dr. Pon, you and your husband?

A. Because we knew he was helping us.

Q. Okay. So it was worth the wait?

A. Oh, absolutely.

APPENDIX D

EXCERPTS FROM THE TRIAL TRANSCRIPT CONCERNING THE GOVERNMENT'S REBUTTAL TESTIMONY AND DEFENDANT'S MOTION FOR SURREBUTTAL (Dkt. 215)

MR. KIEFER: We want to make an oral motion in limine with respect to part of what we understand the government intends to offer in evidence in rebuttal.

Our understanding is that with respect to patient Jerome Lewis, the government intends to introduce evidence that Dr. Pon billed Medicare something on the order of $28,000 for examination of Jerome Lewis' left eye, which he was legally blind in.

I don't know what that is in rebuttal to. There was testimony from Jerome Lewis and Dr. Pon that Dr. Pon did surgery on both eyes, that he was unable to save his left eye, that it was legally blind.

I think Jerome Lewis testified that he was still wanting Dr. Pon to examine his left eye because of—there was a reference to stem cells, and he was hoping that at some point Dr. Pon would be successful in being able to find some way to give him some vision back in his left eye.

The government cross-examined Dr. Pon about each patient, including Jerome Lewis. And I don't know what the relevance would be—or not just relevance, but how it is rebuttal of any defense case-in-chief evidence that Dr. Pon did periodic examinations of Jerome Lewis' left eye and billed Medicare for it.

My understanding is—I mean, there's no evidence that he treated the left eye or billed Medicare for

treating the left eye. There's no evidence that he did fluorescein angiogram or ICG or OCT of the left eye. My understanding is he did an ultrasound on the left eye. And that would be appropriate.

If the government is permitted to introduce that evidence, we're going to ask the court to allow us to put Dr. Pon back on the stand to testify as to what procedures he did or what tests he did on Jerome Lewis' eye and why he did it.

The government could have asked those questions on cross-examination of Dr. Pon and they did not do so. And it would create, I think, an improper inference to the jury if the government is permitted to introduce that evidence on rebuttal without any opportunity for Dr. Pon to explain why he did the tests that he did and what the medical necessity was.

THE COURT: Mr. Devereaux?

MR. DEVEREAUX: If I could just have a moment, Your Honor.

THE COURT: Certainly.

(Counsel confers with agent.)

MR. DEVEREAUX: Your Honor, it's the government's recollection, and from reviewing my notes that I was taking when Mr. Lewis testified—and to orient the court, the defense was asking specifically—it was near the end of his testimony, so on the redirect by Mr. Kiefer.

And it had to do with whether or not they ever took photographs of his eye. And he said, Oh, no, because I – I only put my eye up to the one, like, camera lens.

And I specifically keyed on that. I never had a reason to know that to cross-examine Dr. Pon on that issue.

And so the defense has put Mr. Lewis on the stand in connection—he was being treated, he did have wet macular degeneration in one eye. The indictment ends up talking about the fact that he's billing for both eyes on this.

And he had—Mr. Lewis, unfortunately, had been blind since approximately 1994. It was April of '94 that he had unfortunately lost his eyesight in that eye.

And we ended up having the fact that there was great testimony from Mr. Lewis. It was emotional testimony of a young man, and that they couldn't save his eye, that Dr. Pon had—on the left eye, surgery for ten hours, and that he was semiconscious during the surgery, and he was trying to reattach the left eye retina with stitches.

The surgery was not successful and he lost complete vision on the left eye in August of '94. And then the—he talked about surgery on the right eye.

The government's evidence is that since—from 2004 through 2015, Dr. Pon has continued to bill for treatments on the blind eye, specifically the left eye, to include fluorescein angiograms, fundus photography, the pictures.

And these are the ones that would be specifically contrary to that, that Mr. Allen had testified—and I'm not saying—or Mr. Lewis. I apologize.

I'm not saying that Mr. Lewis testified falsely or made any kind of false statement. The evidence that we have is that Dr. Pon billed under the beneficiary number for Mr. Jerome Lewis. And he ended up—for

fluorescein angiograms, for cornea work, et cetera, two pages of billings for that.

And we believe it is relevant based upon the fact that this is the conduct that the defendant is on trial for, and that is billing for services not rendered in connection with the patient that he is treating for wet macular degeneration.

And the United States feels strongly—the defense is the one that brought this out. It was extremely emotional testimony, both from—I think Mr. Lewis—and then their last witness, the widow, when she testified about her husband's, you know, extreme difficulties, we'll have rebuttal on that as well.

But just on Mr. Lewis, the evidence that the government would be putting on is that he billed for an eye that would never need any testing, because it was basically, unfortunately, dead.

THE COURT: In rebuttal of what evidence offered by the defense?

MR. DEVEREAUX: The defense offered the testimony of Mr. Lewis. And Mr. Lewis said they did not take any – do anything to my left eye, and—to include the pictures.

Because I remember specifically saying—I watched him where he said he only put his eye up to the one.

THE COURT: No. I do recall that particular testimony as well.

MR. DEVEREAUX: Yes, sir. And that's why the government—we didn't have that until yesterday. And we worked on it last night. And I provided it—the spreadsheet to Mr. Kiefer this morning before our lunch hour.

THE COURT: All right. Thank you, Mr. Devereaux.

I'm going to overrule the motion in limine and deny the request for placing Dr. Pon back on the stand, in connection with that particular issue.

MR. KIEFER: All right. Well, Judge, I guess my—the issue I think we have is, the government could have cross-examined Dr. Pon about Jerome Lewis. He testified about Jerome Lewis. And they didn't do so.

And I don't think they are permitted to wait until rebuttal, and then we don't have an opportunity to put Dr. Pon on the stand to explain why he did the tests that they never asked him about on cross-examination. That puts us at a tremendous prejudice.

THE COURT: Well, based upon your decision to ask Mr. Lewis questions that Dr. Pon had not been asked about—I think you introduced the issue of his treatment to his left eye. So I don't know that you—it is their rebuttal.

And there are rare occasions in which surrebuttal is permitted. I'll consider – I'll consider it. But at this juncture, my decision is to not permit—to not preclude the testimony, certainly, and to preclude any surrebuttal, is basically what you're asking for—

MR. KIEFER: Yes.

THE COURT:—from Dr. Pon.

(Counsel confer.)

MR. KIEFER: I understand, Your Honor.

THE COURT: All right. Thank you.

Mr. Devereaux, are you ready to proceed?

* * *

SPECIAL AGENT CHRISTIAN TANNER JURS,
GOVERNMENT'S WITNESS,

SWORN DIRECT EXAMINATION

BY MR. DEVEREAUX:

Q. Agent Jurs, I'm going to place two documents in front of you. The first is Government's Exhibit No. 806. The next is 807. Directing your attention to both of those exhibits, can you identify those exhibits?

A. Yes.

Q. First 806. Can you tell me what that is?

A. 806 is a Department of Labor certification that was filled out related to Mr. Jerome Lewis and signed by Dr. Pon on or about July 26th, 2007.

Q. And did you obtain this during the execution of the federal search warrant on Dr. Pon's offices 15 September 2011?

A. Yes.

Q. Directing your attention to Government's Exhibit 807, did you create that document?

A. Yes. This is a spreadsheet of claims from – from Medicare that were filed by Dr. Pon under—for Mr. Jerome Lewis, related to services in his left eye—

Q. All right.

A.—spanning the time frame 2004 through 2015.

Q. Based on the fact that this time frame for the government's presentation is rebuttal, this is specifically in connection with the third patient called yesterday by the defense, Thursday morning—that would be yesterday morning—a soft-spoken individual that is living in West Palm Beach, a Mr. Jerome Lewis, that

unfortunately had lost sight in his eye—one of his eyes completely, and has wet macular degeneration as well. Do you recall his testimony?

A. Yes.

Q. Do you recall what eye he lost his testimony – his testimony, his—which eye he lost his sight in?

A. He lost his sight in his left eye as a result of an operation that didn't work in 1994, I believe.

Q. And at that—that operation, is that the one he talked—talked about, said—took until about—it was a total of a ten-hour surgery in that left eye, and unfortunately it was unsuccessful and he lost complete vision in that eye?

A. That's correct.

Q. And, again, what year was that?

A. I believe it was 1994.

MR. DEVEREAUX: Okay. At this time, Your Honor, the United States would offer what has been identified by the witness as Government's Exhibit No. 806.

MR. KIEFER: Just offering 806, we have no objection.

THE COURT: That will be marked and admitted.

(Government's Exhibit No. 806 was received into evidence.)

BY MR. DEVEREAUX: Q. Would it be fair to say that Government's 806 is a document that was submitted to the Department of Labor on behalf of Jerome Lewis? And it does specifically mention the fact that he was blind in his left eye, correct?

A. Yes.

Q. And this was signed by Dr. Pon?

A. Yes.

Q. And submitted to the United States Department of Labor?

A. Apparently so.

* * *

Q. The document that is marked as Government's Exhibit No. 807, can you attest to the accuracy of the information on that document?

A. Yes.

Q. How can you do that?

A. Because as—these are Medicare claims. They came directly from—from Medicare, and appear—they have all of the information that are consistent with the claims for the same individual, on time frames before, time frames after.

The diagnoses are consistent—and always—they seem consistent with all the other claims that I obtained at the same time from the Medicare records.

Q. After Mr. Jerome Lewis testified yesterday—or, in fact, during his testimony, were you able to access Medicare's records?

A. I had—I was accessing a claims history from Medicare that I had previously downloaded and had on one of my computers.

Q. And last night, after the trial had ended for the evening, did you, in fact, prepare a spreadsheet regarding certain billings by Dr. Pon regarding Mr. Jerome Lewis?

A. Yes.

Q. And did you confine your search and what appears on Government's Exhibit 807 to a specific parameter of information?

A. Yes. In every claim that's filed with the Medicare system, there's an opportunity for the provider to put on modifiers. And the modifiers can be a wide variety of different things.

In ophthalmology, it's very common to use modifiers for either—either LT or RT, so left or right, to give specificity as to which eye the service is being rendered onto.

In this case I only took services related to Mr. Lewis for his—that were rendered to his left eye, the blind eye.

Q. And would it be fair to say that—you indicated that he testified that he was blind in his left eye since '94, 1994?

A. That's correct.

Q. So would it be fair that you jumped to 2004 to see if there were any bills submitted by Dr. Pon for treating that blind eye?

A. That's correct. I—or that that's just when the claim history had cut off. I don't a hundred percent know why I have only from 2004.

When you download spreadsheets from the Medicare system, or request spreadsheets, they don't go back, you know, to when the earth cooled. They usually go and get a five-or ten-year time frame.

MR. DEVEREAUX: At this time, Your Honor, the United States would offer Government's Exhibit No.

807, claims being submitted by Dr. Pon, regarding treatment to the left eye of Jerome Lewis.

* * *

Q. All right. Now, we have a number of—you don't say specifically what these are. But if we just go here—so we know all of them are left, correct?

A. Yes, sir.

Q. And then we have the CPT code 76512. What are those two?

A. That's an ophthalmic ultrasound, also generally referred to as a B-scan.

Q. All right. And then we have 92235?

A. That is a fluorescein angiogram.

Q. And that's like the fluorescein angiograms we—angiograms we've seen here?

A. Yes.

Q. How about 76512?

A. That's also ophthalmic ultrasound.

Q. Jump down to 92—92250.

A. Fundus photography.

Q. That's like what I've been calling the moon, the big moon?

A. The big orange moon pictures that we've seen a whole lot of.

Q. And we keep going down. We have the 76512?

A. Yes. The majority of the spreadsheet is made up of 76512, sir.

Q. And those are the ultrasounds?

A. Yes, sir.

Q. And then, again, above that, 92235, that's the fluorescein angiogram?

A. That's right.

Q. So throughout these we end up having, like—being billed on various days, between $351, the lowest $140, then we have up to $1200. What's the $1200 one?

A. Those three codes, the 65400, 65436, and 65450, are related to some manner of surgery and cryotherapy—the cornea that was done on—apparently all on July 14, 2009.

Q. And this continues on to the next page with similar codes, correct?

A. That's correct.

Q. And you have some excision of the corneal lesion, correct?

A. Correct.

Q. Some removal of the corneal epithelium?

A. Correct.

Q. And others are destruction of—or lesion of cornea by cryotherapy?

A. Or photocoagulation or thermocoagulation, I believe it is.

Q. And if we go down to the bottom—if we were to add all these up, approximately, what do we get?

A. Approximately 19-and-a-half thousand dollars.

Q. And that was all billed by Dr. Pon between—not 2004—ten years after Mr. Lewis is unfortunately blinded in his left eye?

A. That's correct. And I reviewed Mr. Lewis' file as well. And under the left eye for—you know, over a long period of time, it just usually either has a line through it to delineate nothing or NLP, for no late perception.

So he was consistently, according to Dr. Pon's own records, completely blind in this eye during this entire period.

Q. As recently as June 5th of this year?

A. Yes, sir.

Q. And we look down—it's '04, '05, '06—the only time—we're missing '07s, correct?

A. That's correct.

Q. Then we have '08, '09, '10, '11, '12, '13, 2014, and 2015. He billed numerous times, correct?

A. Yes.

* * *

MR. DEVEREAUX: Thank you very much. No further questions.

MR. KIEFER: May I have a few minutes, Judge?

THE COURT: Yes, sir.

(Counsel confers with defendant.)

MR. KIEFER: Judge, may we come to the bench?

THE COURT: You may.

(Sidebar conference.)

MR. KIEFER: Judge, I would request a recess before cross for the purpose of looking at the billing records on Jerome Lewis that Agent Jurs said he had on his computer for the right eye.

I would like to know whether or not on the same dates that are covered on—whatever the government exhibit is, that spreadsheet, if there were billings on the—on the right eye, but on the left eye.

I think that's relevant to my cross. And I—these have not been produced before. I understand he just did that. I'm not objecting to the lateness of it.

THE COURT: I understand.

MR. KIEFER: I don't think it—I don't think it will take but five or ten minutes, would be my guess. But if I could have a brief recess for us to look at it, I'd appreciate it.

MR. DEVEREAUX: We can make it happen, sir.

THE COURT: Yeah. I'm just wondering where we—where we're going after this. How long is your cross?

MR. KIEFER: Oh, very brief.

THE COURT: Okay. It's going to be brief?

MR. KIEFER: Yeah.

THE COURT: Do you have anything further?

MR. DEVEREAUX: No. I'm not going to—I don't think I'll redirect.

THE COURT: I still have under advisement the motion for surrebuttal. And is it—you're objecting to surrebuttal, Dr. Pon being given an opportunity to explain this?

MR. DEVEREAUX: I am.

THE COURT: I'm thinking through the presentation of evidence. Dr. Pon testified first; is that right—well, before—

MR. KIEFER: For the defense, yes.

THE COURT: And before Mr.—what's his name?

MR. DEVEREAUX: Jerome Lewis, yes.

MR. KIEFER: Jerome Lewis.

THE COURT: So it was on your cross-examination, was it not, that the issue of the left eye not being treated came out?

MR. DEVEREAUX: No. It was—it had to do with—it was the redirect by Mr. Kiefer. And that's when—well, that's when he talked about looking at the eye—that it was only his left eye. That's when we got pinged on that.

THE COURT: I remember him saying that he only looked at his left eye. But my recollection was that it was in response to a question that you put to him.

MR. DEVEREAUX: No, it wasn't. Because I have it written down. I can't do it twice. I can't be asking it and taking notes.

MR. KIEFER: I know that I asked him on redirect, but I would have only asked on redirect based on something that was asked on cross. I don't remember right now what it was.

MR. HEAVENER: Mr. Kiefer asked the question on redirect whether they looked in both eyes. And Mr. Lewis testified that they only put the camera on his—I guess it was his right eye, the good eye. He was very—

THE COURT: Well, I guess the—the point I'm—the issue that I'm struggling—this is the first time that I think Dr. Pon has heard this testimony; would you agree?

MR. DEVEREAUX: From Agent Jurs?

THE COURT: Correct.

MR. DEVEREAUX: Yes.

THE COURT: And you don't believe he should have a right to address it—

MR. DEVEREAUX: No, sir. It's rebuttal.

THE COURT: —because it's rebuttal?

MR. DEVEREAUX: It's rebuttal. But they decided to put their case on—I have to say it's—usually the defendant goes on last.

But they decided how they wanted to put their case on. I had no idea—they gave us a list of 60 people they were going to call, although some of them were—and they did call Doris Showers. But they gave us 60 people. And it was even longer than the government's exhibit list.

THE COURT: Okay. I'm going to take a brief recess to allow you to look at the exhibit. And as soon as you're done, let us know.

* * *

MR. DEVEREAUX: Nothing further. The United States rests its rebuttal case, sir.

MR. KIEFER: May we approach, Judge?

(Sidebar conference.)

MR. KIEFER: We looked—we did determine that—with two exceptions, there were billings for both eyes for Jerome Lewis.

We'd request permission at this point, as we have earlier, to present a very limited surrebuttal for the purpose of calling Dr. Pon, to explain why, in his opinion—why he did the tests that he did on the left eye, and why, even though he was—Jerome Lewis was blind in the left eye, what—what his medical necessity was, and justification for doing those tests. I think that is a ten-minute, probably, surrebuttal.

But right now the government has created an impression that there was no medical necessity and improper to bill for it because he was blind. And Dr. Pon disagrees with that. There's been no opportunity for him to respond to questions on that issue.

THE COURT: Mr. Devereaux?

MR. DEVEREAUX: The United States opposes any kind of surrebuttal. The defense elected to put these witnesses on in the fashion that they did.

It was the defense that elicited the specific testimony regarding the left eye, which caused me then to look into that over the evening hours. And that should not give the defense an opportunity to come up with some rebuttal—surrebuttal opportunity.

MR. KIEFER: Judge, this issue of billing Medicare for services performed on the left eye came up for the first time in the government's rebuttal. And we've had no opportunity to respond to that.

MR. DEVEREAUX: The rebuttal was rebutting the defense's contention that was left with us—with the jury that he only billed on the right eye, and—when, in fact, he billed on the left eye.

So it was the defense's position, their testimony, their witness that brought it up, not—not that they first heard it from—from this rebuttal.

MR. KIEFER: Judge, I don't believe we had any testimony in our case about whether or not Dr. Pon ever billed for the left eye.

THE COURT: Except to the extent that Mr.—what's his name again?

MR. DEVEREAUX: Lewis.

THE COURT:—Lewis was presented first in your case.

MR. DEVEREAUX: And, also—

MR. KIEFER: He—he—yeah. Well, he—he—there was nothing about the billing.

MR. DEVEREAUX: Well, no.

MR. KIEFER: There was—may I finish?

MR. DEVEREAUX: If I can interject, the defense—the defense brought up—very, very passionately to try to prove that the doctor is doing all this work for free, and brought in the fact that he never billed for the services because Mr. Lewis was not in a position to do that, and he didn't bill him at all for it.

MR. KIEFER: That's not—no. That was for the—Judge, that was for the surgery that he performed in 1994. It had nothing to do with the time period covered by the government's evidence, which is 2004 through, I think, '12.

THE COURT: Okay. I'm going to need to look at the testimony. I can't recall the exact chronology. And, in fairness, I think I need to be certain about the necessity of the rebuttal.

And then there's the further question of whether, in deference to Mr.—or Dr. Pon's Sixth Amendment right—and this is—it's very damning evidence—whether or not it should be—at least from the court's perspective, he should be given an opportunity to offer an explanation at that point.

I'm going to give you-all an opportunity to research the question over the weekend. And I will make a decision and announce it on Monday morning as to whether Dr. Pon will be permitted to testify at all.

My inclination is to deny the request, but I am still tug—having this idea of fairness tug at me. And I just need to make sure my decision comports with the law.

I'll be looking for some argument on it—

MR. DEVEREAUX: Monday.

THE COURT:—on Monday morning, to start with that. That may push our schedule back a little bit. But I think it's an important-enough issue we should do that—

MR. KIEFER: Judge, if you—

THE COURT:—consider it.

MR. KIEFER: If you deny our request, we will request leave out of the presence of the jury to put Dr. Pon on the witness stand—

THE COURT: For a proffer?

MR. KIEFER:—to make a proffer, because I can't possibly summarize it myself.

THE COURT: That's understandable.

APPENDIX E

EXCERPTS FROM THE TRIAL TRANSCRIPT CONCERNING DISTRICT COURT'S RULING ON DEFENDANT'S MOTION FOR SURREBUTTAL, DEFENDANT'S PROFFER, AND DEFENDANT'S LIMITED SURREBUTTAL TESTIMONY (Dkt. 234)

THE COURT: All right. I'll take a moment to look at *Pantone* a little more closely. The fact that it involves a defendant's testimony, I think, probably injects some additional considerations that are not before the Court.

And the pivotal issue, as I understand it, is whether or not new evidence has been introduced by the—one of the parties that, in fairness, should be permitted to be addressed, essentially.

I am familiar with the *Haimowitz* case and had located it, along with the *Sadler* case, which raises the other issue as to whether or not, by failing to object to object to a cross-examination that touched on issues outside of the direct, you've waived your right in that regard.

But surprisingly to me, Mr. Willis, your comment this morning that you had an opportunity to look at the record and that you'd come to a conclusion about the case, the conclusion being that there had not been any evidence introduced by the defense, was surprising to me. I thought you were about to concede that Exhibit 193 directly places into evidence the treatment of Mr. Lewis.

And you all need to correct me about my recollection of the record if it's wrong. In the government's

case in chief, Mr. Lewis was not a party named in the indictment, was he?

MR. DEVEREAUX: No, sir.

THE COURT: I thought that was the case.

Nor was there any evidence offered by the government with respect to Mr. Lewis's treatment.

MR. DEVEREAUX: No, sir.

THE COURT: So Mr. Lewis, as a witness and anything he had to say, was first introduced by the defense. His testimony regarding his treatment and a record regarding his treatment of his left eye is first introduced by the defense.

So I don't agree with your characterization of the record that somehow this issue of the treatment of his left eye is the responsibility or should be attributable to the government.

That being the case—and what further testimony was elicited on cross-examination that went to the treatment of his left eye was not objected to by the defense. So to the extent that you want to argue that the government brought that issue into the case, despite the fact that Mr. Lewis was first offered by the defense, his records of treatment were first offered by the defense, I think, could fairly be found as a complaint that has been waived.

And then on redirect of Mr. Lewis, Mr. Kiefer further explored the left eye issue, to the point that the testimony that stood out most in my mind was Mr. Lewis's direct testimony with regard to how it was he had concluded that only his right eye had been treated, that he actually had to look through an instrument that Dr. Pon had. That was brought out by Mr. Kiefer.

So I don't—I'm not prepared to accept your characterization of who's first responsible for the introduction of evidence. I'm not prepared to find that it is a new issue that now requires the production of surrebuttal evidence.

So your motion for a mistrial will be denied, and I do believe that it's proper for the record to be protected for you to offer on proffer what Dr. Pon would have to say in surrebuttal, so that will be permitted.

Are you ready to do that now?

* * *

DR. DAVID MING PON, DEFENDANT'S WITNESS, SWORN PROFFER

BY MR. WILLIS:

Q. Dr. Pon, you've been present in the courtroom, so of course you know we're discussing the matter of your treatment of Jerome Lewis, correct?

A. Yes.

Q. The government is—I'm not sure we made it clear. I want to make clear. You first treated Mr. Jerome Lewis back in '94/'95 when you did surgery on him. Is that correct?

A. Yes. To the best of my recollection, yes.

Q. And you did surgery on one eye and then came back and did surgery on the other eye.

A. Correct.

Q. And did you get paid for doing that?

A. No.

Q. All right. Have you ever been paid for doing that?

A. No. As far as I can recollect, no.

Q. All right. Now, the government offered into evidence the other day Exhibit No. 807, which purports to be a readout from the Medicare people.

COURTROOM DEPUTY: Press the green button.

BY MR. WILLIS:

Q. This is Government's 807. Do you recall that exhibit?

A. Yes.

Q. And that—if I recall correctly, I understood that to be a printout of Jerome Lewis's billing for anything to do with his left eye.

Do you remember that?

A. Yes.

Q. And that column that we're looking at, just for openers, that billing amount that is there that I think counsel totaled up to be 19-and-a-half million dollars -

MR. DEVEREAUX: No, thousand.

MR. KIEFER: Thousand.

MR. WILLIS: I'm sorry. What did I say, million?

MR. DEVEREAUX: Yeah.

MR. WILLIS: Yeah, it wasn't quite that.

BY MR. WILLIS:

Q. It was 19-and-a-half thousand dollars. That was the amount you billed. How much do you actually get paid as opposed to how much you bill?

A. A small fraction of that, usually.

Q. Okay. We don't have a column for that anywhere, do we?

A. No. It's usually a very small fraction of that, maybe—

Q. And to look at the period of time that's covered by this, it starts April the 16th, 2004. Is that the first time that you got any payment from—for billing to Medicare?

A. I don't know when—the first time I received payment from Medicare.

Q. Okay. Do you do your own billing, Doctor, by the way?

A. My office does. I don't personally do it.

Q. You don't do any of that, do you?

A. No.

Q. All right. If you can, the spreadsheet that's proffered and that totals 19-and-a-half thousand dollars billed, that began in April of 2004, continues down to the bottom of the page to 2010 and carries over to the following page of a date all the way into and including June of 2015, right?

A. Yes.

Q. So that's a span of somewhere—roughly speaking, somewhere around, what, 11 years that it covers?

A. Yes, approximately.

Q. Now, examining that document, 807, it would appear that the majority of that—that billing, at least by numbers, has to do with code 76512. Is that true?

A. Yes. I believe so. I can't see it right here on the screen.

Q. All right. Let me move it over here so that—

A. Yes.

Q. Okay. And you see that over and over. That's every few months. Sometimes it varies. I think that's from April to August, and then from August of '04 to February of '05. Not again until—I'm sorry.

From April to August and then from August to July of the following year and then again in August of the following year, 2005, but then not again till November of 2005 and so on.

A. Yes.

Q. What is that billing code, sir?

A. That's for what they call a B-scan ultrasound.

Q. An ultrasound?

A. Yes.

Q. Explain to us, if you would, what an ultrasound is and why you would employ it in somebody like this gentleman.

A. Ultrasound is a device to—using sound waves, to determine—to look for different areas of—different things that may be abnormal in the eye. And in his particular case, it's—it's very useful in cases where you cannot see very clearly the back of the eye.

So it could determine or it can help you identify areas of the retina that are—or of the sclera or the choroid that are abnormal.

Q. All right. And what would have prompted your concern that you would examine both this eye and perhaps the right eye as well of this gentleman, starting in 2004, using an ultrasound?

A. Well, in his case it's very important to examine his left eye and continue to examine his left eye because there's a condition called sympathetic ophthalmia which, if untreated, can lead to complete and total—it can relentlessly progress and lead to complete and total blindness in both eyes.

And the inciting factor is thought to be the eye that has been injured or damaged somehow, in some way. And the theory or the thought is that—the current thought is that the body creates some type of immunological or autoimmune reaction to the eye or the proteins or something in the eye, and it attacks both eyes. And as a result you can go completely blind in both eyes.

So in his particular case, it is—he's a very complicated patient, and he only has one good seeing eye. So the problem in his particular case is he has—he had intermittent episodes of inflammation that we were—that was coming up in his examination of his right eye with what we call uveitis, which is an inflammation.

And then—that is a clue that that could be developing. So the only way to know for sure is to see if – I mean, a B-scan is a way to know or at least a way to find out more information about the other eye, to see if something is going on there and causing the—which may lead to sympathetic ophthalmia in the right eye.

You may remember a gentleman named Braille, who invented Braille. Louis Braille, I believe, his name was. He had injury to one eye when he was a child, and then unfortunately he developed this condition called sympathetic ophthalmia, which we believe it was sympathetic ophthalmia, and he went blind in both eyes. The eye that wasn't injured, he went

completely blind, and then he went on to develop Braille for blind people. So this—

Q. This left eye that we're talking about, Dr. Pon, his left eye, it's been described by counsel as dead.

Was this eye dead?

A. No. This eye is never dead. It's just like a—that was never dead. It has a blood supply, and it's a normal eye and it's—a normal eye in that it receives a blood supply and it's still there. It hasn't been removed.

So it could get infection. It could have hemorrhage.

It could get inflammation. There could be a corneal perforation. There could be a number of different things going on in this left eye.

So those things are things that could lead to problems in that eye itself, but more importantly is the concern that it would lead to problems in the right eye, the remaining good right eye.

And he only had that one good remaining right eye, so it's really important to take every precaution to find out—I mean, to discover, at the earliest possible opportunity, whether or not there is some inciting factor or something going on in the left eye that may precipitate the sympathetic ophthalmia and then lead to complete loss of vision in both eyes. So the earlier you catch that, the better.

So periodically you need to have examinations of the left eye, diagnostic examinations of the left eye, to make sure that's not going to be the case.

Q. Okay. Now, Doctor, this sympathetic ophthalmia, does the idea that one eye can develop a condition and then, in fact, attack the other eye, it would spread

to the other eye or induce disease in the other eye, is that oversimplification or is that a fair statement?

A. I guess that would be a fair statement. It's a lay way to say it, but it's a fair statement.

Q. All right. Doctor, is that a recognized condition?

A. Yes.

MR. WILLIS: Your Honor, may I—

THE WITNESS: Absolutely.

MR. WILLIS: Your Honor, may I approach the witness?

THE COURT: You may.

BY MR. WILLIS:

Q. Dr. Pon, I'm putting before you the entire volume, whereas I have selected excerpts that we would intend to offer in evidence.

There are two volumes that we have before you, one of which is Exhibit 220 and the other of which, as I recall, is Exhibit 221. And Exhibit 220, what is that, sir?

A. I'm not sure which one you're referring to.

Q. The full volume, the Wills Eye Manual.

A. Yes. The Wills Eye Manual, yes.

Q. Do you have that before you?

A. Yes.

Q. If you would, Doctor, turn in that manual—I think you've got it marked—to page 392. Chapter 12, 392—

A. Okay.

Q.—all right?

And explain to us, if you will—read that to us, that first—the symptoms and the signs and so on, and then explain what that's telling us.

A. You want me to read the entire thing?

Q. Sure.

A. Okay. "Sympathetic ophthalmia." This is page 192, Chapter 12: "Symptoms: bilateral eye pain, photophobia, decreased vision, near vision is often affected before distance vision, red eye, a history of penetrating trauma or intraocular surgery, most commonly vitreoretinal surgery."

Q. Let me stop you there. Is that word which I'm having trouble pronouncing, vitreoretinal surgery, is that what you did on this man?

A. Yes. Specifically, I performed vitreoretinal surgery on his left eye.

Q. So that is, in fact, a risk factor for the development of this condition.

A. Yes. Apparently, it's the most common surgery that causes sympathetic ophthalmia.

Q. All right. Continue on.

A. So " … most commonly vitreoretinal surgery to one eye, usually four to eight weeks before but the range is between"—I mean, I'm sorry, "the range is from five days to 66 years, with 90 percent occurring within one year may be elicited."

Q. So in other words, this condition can develop as long as—apparently has been demonstrated as long as 66 years after this vitreoretinal surgery.

A. Yes. It's—it can develop many, many years later. And like in Louis Braille's case, it had happened several years, I believe, after he had his initial injury, and unfortunately he went blind as a result of it.

So you need to be vigilant, always vigilant, in a patient with one eye who has had some type of an issue in the other eye, that this could develop and cause blindness in the one remaining good eye. I mean, they'll go completely blind if you do not catch this early enough.

And then here—do you want me to go on with signs?

Q. Go ahead.

A. Under "Signs: Critical: Suspect any inflammation in the uninvolved eye after unilateral ocular trauma. Bilateral severe anterior chamber reaction with large mutton-fat KP may be"—I'm sorry—"may have asymmetric involvement, with typically more reaction in the sympathetic eye.

"Posterior segment findings include small deepening of nodules at the level of the retinal pigment epithelium (Dalen-Fuchs nodules) and thickening of the uveal tract. Signs of injury or surgery in one eye are usually present."

Q. Doctor, let me stop you there.

Each of these eyes, each of these eyes, you had performed vitreoretinal surgery on, correct?

A. Correct.

Q. So you had to be concerned with each of these eyes and something developing in each of these eyes that would affect the other. Is that the idea?

A. Yeah. Of course, you've got to be concerned that either one of these eyes could demonstrate signs of this, I mean, condition.

Q. Do you think that's good medicine, to check that periodically?

A. Of course. It's—you have to check for it, especially in a case like him because you only have one remaining good eye. You need to be always vigilant.

It could occur 66 years later. It's been documented as long as 66 years later. So periodic checks of the left eye are, I would say, considered mandatory if you're going to be watching carefully because he already has had—he already has had signs of inflammation in the other eye, in the good eye, in the good eye.

And like it says right here, "Suspect"—in the first line—sentence it says, "Suspect any inflammation in the uninvolved eye after unilateral ocular trauma."

So you consider the left eye having a detachment and all these other things, consider it—you consider that as an inciting factor and, in particular, the vitreoretinal surgery.

Vitreoretinal surgery apparently is the most common cause or precipitating type of surgery for sympathetic ophthalmia.

Q. All right. Let's move on to the second code that we need to be concerned with, second and third really, the 92235, which occurs much less frequently but does occur. It looks like it was billed in November of 2005, if I'm reading it correctly, for the first time, unless I'm missing one—I'm sorry. Billed originally in February of 2005 and then in November of 2005, and apparently in concert with 92250, which is the fundus photography. Is that your understanding as well?

A. Yeah, but the fundus photography is usually not bilateral; it's unilateral, so they usually don't have a left or right. It's just one code for that, so it should not actually have a left or right because it's just—it's the same code for both.

Q. So you don't—

A. So if you do one eye, it's the same as both eyes or whatever, so I don't believe it has a left or right modifier for that one.

Q. All right. What about the—what about 92235, the fluorescein angiogram?

A. Yeah. Well, that's a very useful test to help diagnose sympathetic ophthalmia. You see under workup on page 393, of the Wills Eye Manual—

Q. Right.

A.—you see on the workup for sympathetic ophthalmia, item No. 5, it says IVFA, which stands for intravenous fluorescein angiogram, or B-scan ultrasound, US—it says US but it means ultrasound—or both to help confirm the diagnosis under the Wills Eye Manual.

Q. So that is a—so the combination of those two is something that is recommended by the Wills Eye Manual.

A. That is correct.

Q. Doctor, then we move—and, again, those show up somewhat irregularly but two or three times at least. But the biggest item, I suppose, on the page is right in the middle, January the 14th, 2009. Do you see that?

A. I'm sorry. It's off the screen. I can't see it.

Q. Oh, can you—let me see if I can find it for you. It's January the 14th, 2009.

A. Yes, I see it.

Q. We've got code 65400, $919; 65436, $1200; and 65450, $790. Do you see that?

A. Yes.

Q. Again, that's what you billed. That's not what you get paid, correct?

A. That's correct.

Q. All right. Now, Doctor, what—those are surgical—those are surgical types of coding, are they not?

A. Yes.

Q. Doctor, are you trying to tell us that you found some medical necessity to perform surgery on the left eye of a blind man? Is that the idea?

A. No, sir. That's absolutely incorrect.

Q. What is correct, Doctor?

A. This surgery was performed on the right eye, if you'll check the records. This was performed at the hospital, and it was performed on the right eye.

MR. WILLIS: A moment, Your Honor?

Pardon me. You caught me unawares, but I wanted to go farther on the proffer. And it's right here, just where it's always been.

Your Honor, may I approach the witness?

THE COURT: You may.

BY MR. WILLIS:

Q. Dr. Pon, I'm going to show you something that's been marked as Defendant's Exhibit 219 and ask you if you recognize that.

A. Yes.

Q. Tell the Court what that is, sir.

A. This appears to be a Bates-stamped operative report from Florida Hospital, it looks like, on Jerome Lewis.

Q. On Jerome Lewis.

And the date of that—that's an operative report/procedure, and the date on that is January the 14th, 2009?

A. Yes. That is correct.

Q. And at the bottom of that page, Dr. Pon, does that help us in understanding where we got this document?

A. Well, it has a Bates stamp on it. It says—

Q. From the government.

A. Box 104—

Q. From the government?

A. Yes. It apparently is from the government, yes.

Q. Dr. Pon, looking down that document under the section on preoperative diagnosis, item 4, does that read, "Corneal neovascularization inferiorly in the right eye"?

A. Yes. That's what it reads.

Q. And the postoperative diagnosis, item 4 is exactly the same.

A. Yes.

Q. Second page, top of the one, two, three, fourth paragraph when you're describing what surgery was performed, does that read, "The patient's right eye was then sterilely prepped and draped"?

A. That's correct.

Q. Two pages over, the kind of a sheet of information on the patient himself and things of that sort, but all the way down to the bottom, do we have your somewhat unmistakable handwriting beside D/C?

What's D/C mean? What's that for?

A. I don't see where that is.

Q. You don't see it right in the left-hand column right below the word "nonsmoker"?

A. Oh, that's OD, right eye. Oculus dexter, right eye. That's the abbreviation for it.

Q. And the final document in this grouping, again, two pages over, history at the top, physical exam at the top, other information as you go down the page, and at the bottom something that says impression in the right margin?

A. Yes.

Q. Left margin, rather.

A. Yes.

Q. And finally and once again, does that say OD, right eye?

A. It says OD and then it says right eye right after that.

Q. All right. Once again, Doctor, did you do surgery on the left eye on Jerome Lewis on the date of January the 14th, 2009?

A. No, I did not.

Q. Did you do surgery on the right eye of Jerome Lewis on that date?

A. Yes.

Q. And the documents which demonstrate that conclusively we received from the government.

A. Yes.

MR. WILLIS: That's all we have.

* * *

THE COURT: Very good. Any further argument?

MR. DEVEREAUX: The argument from the United States, Your Honor, is the fluorescein angiograms—I mean, this witness—no question, he's saying he did fluorescein angiograms on the person's left eye when the witness that was called, Mr. Lewis, said he specifically recalled no. And that was to Mr. Kiefer's own questions.

Mr. Kiefer asked him, "Are you sure there was no treatment on your left eye?" and he said absolute—no because he remembered and actually physically almost acted like he was sitting in the chair. I think the Court recalled that as well, with his showing that he only put his right eye up to the camera.

And so clearly this was fair rebuttal to that.

THE COURT: Mr. Willis?

MR. WILLIS: Please the Court, I would first want to remind the Court that we're dealing with events that are—as we stand here today, are approximately six years ago, and so I don't know that Mr. Lewis's recollection of what was and was not done is particularly noteworthy.

What I do think is noteworthy, however, is counsel did not address this January 14th, 2009, which is the largest expenditure of all, where it's very clear, I think, from the record that we introduced that Dr. Pon did surgery on the right eye. It's simply a clerical error, whether it's by CNS or whether it's his office.

And the government had those records at the time that they prepared, created, and entered this resume of services to the left eye. And nonetheless, they put it before the jury that he charged for surgery to the left eye, and it's the most expensive item on the page.

And clearly that's—I think anybody can agree that's just incorrect. That's misleading. But we have an entitlement, we believe, to correct that misleading impression.

THE COURT: All right.

MR. DEVEREAUX: But, Your Honor, the defense had that record, had that information, and had, in fact, the benefit of the defendant sitting right next to it. And Mr. Kiefer specifically elected not to cross-examine Mr. Jurs on anything.

He merely made an oral stipulation that we had agreed to and didn't cross-examine him at all and chose not to do that.

And so he could have cross-examined him on that and he elected not to, and he already had those records on – in his file. He had possession of those records.

THE COURT: Is that correct? You made reference to the government having the evidence that established the clerical error. The question is whether or not—for my purposes, whether or not the defense had that record as well.

MR. WILLIS: Did we have that together with literally hundreds of thousands of documents? Yes, we did. We were handed that spreadsheet over the noon hour right before the examination took place, and we were granted about a five-minute recess to look at it.

I think it strains credulity for us to be expected to find that, generate that record, and be in a position to recognize the significance of it.

Dr. Pon, I don't expect him to have a recollection going back that far until he had time to consider it.

THE COURT: All right. Thank you, gentlemen. I'm going to allow Dr. Pon to testify as to the clerical error, which is evident in the entry on Government's 807 that pertains to—what is the date, January—

MR. WILLIS: January 14th, 2009.

THE COURT:—14th, 2009. That will be the only testimony he'll be allowed to offer in rebuttal, surrebuttal.

* * *

DR. DAVID MING PON, DEFENDANT'S SURREBUTTAL WITNESS, SWORN

DIRECT EXAMINATION

BY MR. WILLIS:

Q. Dr. Pon, in accordance with the Court's direction, I'm going to focus your attention very narrowly on a portion of Government's Exhibit 807 that was introduced at the tail end of Friday's proceedings. Do you recall that exhibit?

A. Yes.

Q. And it was a printout, really a prepared sort of resume of billings to Medicare by your office regarding patient Jerome Lewis. Do you remember that?

A. Yes.

Q. Just as a preliminary matter, Dr. Pon, do you do your own billing, or is that done by somebody on your staff?

A. Somebody on my staff.

Q. Okay. What we're going to focus specifically on—rather than go through all of this, we are going to focus right in the middle of that page, and we'll see several entries for the date of January the 14th, 2009. Do you see that?

A. Yes.

Q. Right here where my pen is. Do you see that?

A. Yes.

Q. And so that's code 65400, that's code 65436, and that's 65450, correct?

A. Correct.

Q. And the import of that document and that listing was to show that you billed for services to the left eye of Jerome Lewis that we've already discussed that he'd been blind for quite some time, correct?

A. Correct.

MR. WILLIS: If I may approach the witness, Your Honor?

THE COURT: You may.

BY MR. WILLIS:

Q. Dr. Pon, before getting into that, as such, this document that we do have up on the overhead right now, this has a column that is entitled Billings.

Do you recall that, these various dollar figures beside it?

A. Yes.

Q. Is that the amount that your office—

MR. DEVEREAUX: Objection, Your Honor.

THE COURT: Sustained.

BY MR. WILLIS:

Q. All right. Confining myself to January the 14th, 2009, is that the amount that you billed Medicare in connection with these three codes on January the 14th, 2009?

A. That is the amount that is billed.

Q. Is that in any way close to what you actually receive?

MR. DEVEREAUX: Objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: Normally we only receive a small—a fraction of that.

BY MR. WILLIS:

Q. All right. All right. But, Dr. Pon, I've put in front of you for your consideration a document in evidence as Defendant's 219. And, again, reminding everyone that the date that we're dealing with is limited to January the 14th, 2009. And I have a copy of that same document before me. Does that look like the first—does that look like the first page of that several-document exhibit that we just put in front of you?

A. Yes.

Q. All right. And that—at the top of that document it says operative report/procedure, and over to the side, patient: Jerome Lewis, correct?

A. Correct.

Q. And that document relates to an operation performed by you on January the 14th, 2009, on Jerome Lewis.

A. Correct.

Q. Now, that document we received from the government in discovery, correct?

A. Correct.

Q. All right. And that document, does that reflect – does that accurately reflect the surgery that you performed on Jerome Lewis on January the 14th, 2009?

A. Yes.

Q. All right. If we can look down the page—one moment. Looking down the page under preoperative diagnosis, do you see item No. 4?

A. Yes.

Q. And would you read that for the jury?

A. Corneal neovascularization inferiorly in the right eye.

Q. And to be reminded again, the left eye was the eye that was blind in Jerome Lewis, correct?

A. Yes.

Q. And a little further, the postoperative diagnosis, in other words, the diagnosis that was formulated

after the surgery was performed, item No. 4 again, what was that?

A. Corneal neovascularization inferiorly in the right eye.

Q. In the right eye. And down at the bottom under the description, the partial description that appears there under the section entitled Operation, that last phrase, removal. Pick it up.

A. "Removal of feeding superficial corneal neovascularization, right eye."

Q. All right. And at the bottom, of course, this is the government's Bates stamp, they call it, that keeps track of their documents.

On the second page of that document, the second paragraph up from the bottom, I've highlighted the first sentence of that paragraph, and, again, does that paragraph make reference to the patient's right eye?

A. Yes.

Q. And what does it say?

A. "The patient's right eye was then sterilely prepped and draped."

Q. And three pages over, we've got sort of a—I'm not sure what you would call that but an information page on this same patient, same date, January the 14th, 2009, and at the bottom there is a section where you put your remarks on your diagnosis and treatment.

And what is that sign in the left-hand side under the—I think it says nonsmoker, immediately beneath that?

A. That says OD, underlined, and it refers to right eye. That's the abbreviation we commonly use for right eye.

Q. And a similar document later in the same package two pages over, where it's called—at the top it's got history and physical exam of the same patient on the same date.

And directing your attention to the bottom of that page under the—beside the section entitled Impression, I've highlighted it. Can you see? It appears to say OD, right eye.

Is that what it says?

A. Yes.

Q. So you did surgery on the right eye of this gentleman on January the 14th, 2009.

A. That is correct.

Q. You did not do surgery on the left eye of this gentleman on January the 14th, 2009, did you?

A. That is correct. I did not do surgery on the left eye—

Q. All right.

A.—on that date, yes.

MR. WILLIS: Your Honor, that's all we have but for the—I'm not sure if we need to readmit or admit this before the jury, but we had admitted it previously, and I wanted to make sure the record was complete.

THE COURT: For the record, you want to admit which exhibit?

MR. WILLIS: 219.

THE COURT: It will be marked and admitted.

(Defendant's Exhibit 219 was received in evidence.)

MR. WILLIS: Thank you, sir. That's all we have.

THE COURT: Cross-examination?

CROSS-EXAMINATION

BY MR. DEVEREAUX:

Q. Mr. Willis asked you questions regarding Defense Exhibit 219 saying this was a government report or a government document and it was—here there was a Bates stamp. He mentioned that.

Do you recall?

A. Yes.

Q. In fact, these are documents that were seized from your office. I mean, these are actually your records, not the government's records. The government got these records after they searched your office, correct?

A. I don't know when they got them, but they—these are—apparently these are from the government, how the defense team got it. That's my understanding.

Q. But these records are records of your treatment of your patient Mr. Lewis, correct?

A. Yes.

Q. Okay. And so these are not government records. These were your records that the government took custody of, correct?

A. Yes.

Q. So you've had these records since they were made somewhere around January 14th of '09, correct?

A. Yes, approximately then.

Q. Now, on Government Exhibit No. 807, the listing, what we're talking about here is just three entries out of two pages of entries, correct?

A. Yes.

MR. WILLIS: Your Honor, we would object, and we'd like a sidebar on that if we can.

THE COURT: All right. Let me see counsel at sidebar.

(At sidebar, out of the hearing of the jury:)

MR. WILLIS: Your Honor, counsel is exploiting the Court's ruling to our detriment.

THE COURT: Well, I don't know because he hadn't asked the question yet, but in fairness, I do want Mr. Devereaux to stay within the bounds of the direct examination, which did not include references to any treatments or billings outside of the January date.

MR. DEVEREAUX: Yes, sir.

THE COURT: But I don't know that he was doing that.

MR. DEVEREAUX: I'm going to add up just those three.

THE COURT: Okay. Very good. Thank you.

(End of discussion at sidebar.)

BY MR. DEVEREAUX:

Q. These three on January 14th of 2009, if we add up 919, 1,200, and 790, we get approximately $2,909.

Would that be fair?

A. Yes.

Q. So is it your contention that these three are billing errors, this less than $3,000?

A. Yes. It appears to be a clerical error.

Q. Okay.

MR. DEVEREAUX: Thank you.

THE COURT: Thank you, Dr. Pon. You may step down, sir. Please watch your step.

Ladies and gentlemen, you have now heard all of the evidence you are going to hear in connection with this matter.

APPENDIX F

TRIAL EXHIBIT 131

Transcription of Dr. Murphy's presentation on feeder vessel treatment (Jacksonville, FL – January 6th, 2001)

One of the more rewarding things for me in this field is collaborating with a number of people and especially with industry. My relationship with IRIS goes back many years. I was at Hopkins when Eduardo came in with a box no larger than a shoebox and said it was a laser. It turns out that that little box is used a lot. We have a busy practice. I would say we do about 99% of our laser procedures with that laser. Things have come a long way.

The Macular Photocoagulation Study was a pretty interesting study because the presumption was that macular degeneration was pretty well defined. All you had to do was cauterize it with a visible wavelength. It was very interesting to me at the reading center. The angiograms we saw at the reading center were horrible with shades of gray and white. It was months before we saw a well-defined vessel. What we saw was a whole field of occult neovascularization. It was lucky that the MPS had any results at all because the treatment only benefited the well-defined vessels. It was years afterwards that we discovered what occult neovascularization was and the classification of occult neovascularization became available. It became perfectly obvious then that if you were going to treat macular degeneration you were going to have to treat fibrovascular proliferation or occult neovascularization. This was not addressed in the MPS. Interestingly, this is not addressed by the verteporfin study. The vast

majority of the neovascularization in macular degeneration is fibrovascular proliferation.

When I was at Hopkins I worked many years with Bob Flower, who attempted to image the choroidal circulation. If we could image the blood vessels of the choroid we could learn about these diseases. After all, CNV is fibrovascular tissue. Neovascularization is just an ingrowth of blood vessels and scar tissue. Nothing else. We don't know why it happens or how it happens exactly but that is what it is.

The choroidal circulation is about fifty times what you need for the metabolic functions of the retina. So it is excessive circulation. The pigment epithelium plays a key role in retinal function by supporting the rods and cones. The rods and cones need a blood supply, which derives oxygen and nutrients from the choroid to the RPE to bath the retina. In macular degeneration something goes wrong with that process. It probably has a lot to do with Bruch's membrane hardening and thickening. With localized thickening you start to see the visible drusen. Then if things really go badly for reasons we don't understand at all, blood vessels begin to grow in from the choroid into Bruch's. Then they grow underneath the RPE, eventually through the RPE, and then between the RPE and the rods and cones. When the neovascularization is at the level of Bruch's, which is the early and most common form of CNV, it shows a fluorescein pattern of smudgy poorly defined leaks. That is occult neovascularization. If the CNV gets through the RPE, it is referred to as classic disease. The problem is that FA, as a standard diagnostic tool one cannot image very well underneath the RPE. So if the vessels grow through the RPE and lie on top of the RPE then you can see the vascular detail and the membrane very well. That is

classic CNV. But in the early stages of macular degeneration it is occult to FA because the vessels are hidden by the RPE. Occult neovascularization is a smudgy appearance caused by leakage from the vessels that have penetrated Bruch's membrane. So for occult CNV, usually FA shows some subretinal fluid under the retina. You do the FA and all you see is a smudgy spot because the vessels are underneath the RPE and cannot be visualized very well.

Well ICG angiography uses an infrared system that makes the RPE partially transparent. With ICG you can start to see details under the RPE very clearly. Over ten years ago, Larry Yanuzzi showed the first ICG angiogram. At least with static late frame study images, usually 20 minutes after injection, just showing where the ICG dye had collected. He could show what we call a plaque or a circular area of fluorescence. This is probably a monolayer of bloodvessels with a connective tissue that has grown into Bruch's membrane. Often this first stage of neovascular in-growth may not even be leaking yet and shows up as a big fluorescence spot on the ICG. But still it was very helpful because eventually there was histopathologic correlation showing indeed that it was the growing in from blood vessels into Bruch's membrane. But it still did not help us to treat that because most people with plaque were not symptomatic. Even if we begin to think that these vessels were going to go badly we could not treat. Treating a big plaque right in the center of the macula with a 20/20 eye one could burn all the rods and cones.

As we see this information develop we can see the picture of neovascularization developing. But we still could not image the individual choroidal vessels under the RPE. The first breakthrough came about five

years ago. Bob Flower was able to image in an animal model, under perfect conditions, the small blood vessels of the choriocapillaris. The breakthrough came with more sensitive digitized video cameras in the infrared range. With that breakthrough came our ability now to image the small blood vessels of the choriocapillaris. These are exactly the blood vessels that are responsible for CNV. We worked with Bob Flower and at the same time we discovered that the Heidelberg Company in Germany had a SLO (scanning laser ophthalmoscope) system. This system was ideal for imaging blood vessels. What you need to do the diagnosis of the vessels causing the neovascularization is to have a high-resolution high speed imaging system. The reason is you are looking at the filling of the individual choroidal vessels, which takes place in a fraction of a second. The studies that we use to diagnose the vascular structure are about two or three seconds long. We are capturing images mostly at 6 to 12 frames per second during the choroidal filling phase. We expected to find these vessels in the choroid coming right up into the CNV from below. The first thing we discovered was that most of the neovascular membrane complex had developed a blood supply not at the capillary level but deeper to the capillary level called Sattler's layer of the choroid. This surprised us. Also, the blood vessels supplying blood flow to the neovascularization were long tangential vessels that came into the CNV from the edge of the complex (racket type). Only a few were directly from below (umbrella type).

About the same time investigators from Italy started to demonstrate the same results. Staurenghi was the first to define FV as racket or umbrella types: he called the feeder vessels coming in from the side a racket pattern (a stem feeding the CNV from the edge

of the complex). He also defined the umbrella pattern when the stem was feeding the CNV complex directly from below.

So now after twenty years of only having cautery to treat neovascularization we have wonderful diagnostic system that allows us to actually see the internal circulation of the neovascularization. We can see through the RPE. Vessels that were occult on FA now have a very clear vascular pattern. This was a major breakthrough.

Obviously we want to treat these vessels. Since most of our experience was with the visible wavelength at that time we started using visible wavelength lasers to treat. The diagnostic part is a simple elegant procedure and is cost effective. Also, it doesn't take very long. In the patient where we see a neovascularization we take them to the Heidelberg camera. We immediately switch over to the FA. I like the Topcon unit that has high resolution. Bert likes to use the Heidelberg FA. We use a T system for injection so we do not have to do multiple injections. Within ten minutes you have two images: you have static FA, a standard sort of picture, but you also have a digitized video angiogram of the capillary filling of the choriocapillaris. This is what it looks like. This is a still frame from the movie image but it shows very clearly the retinal vessels. It is large enough to show the retinal vessels but it also shows the normal choroidal filling. By studying that little movie, the filling patterns of the neovascularization, we can identify the feeder vessels in over 90% of the cases. It turns out that, for occult CNVM, the filling rate is typically a little bit slower (about 1.5 second slower than the filling of normal choroidal vessels) while the emptying rate is quicker than in surrounding normal vasculature. This differential

filling/emptying rate helps us in the identification of the feeder vessels.

You are obviously going to want to treat these vessels. You have to figure out a way. I went back to our experiences at the Wilmer Reading Center. We started making little drawings off of the Heidelberg unit because we would have the retinal vessels. We would then draw them as the landmark, then draw in the feeder vessel. You end up with a little map with the normal retinal blood vessels along with the feeder vessel. Then you can transpose that image to the black and white digitized image of the fundus. I like to take them with the Topcon camera. Then you draw in the feeder vessel. These are very accurate and can be done in about 20 seconds. If we have a good FA and the ICG on the same unit we could do that electronically. Then we could immediately treat the patients.

We began treating the patients with the laser we had the most experience with: a visible green laser. The green laser depends on the pigment of the eye to change that laser energy into burns. If you are using visible wavelength laser energy like green, the first layer of pigment the laser finds is the pigment in the RPE. You then start to generate a spherical thermal burn base primarily on the absorption of the pigment in the RPE. If you make a big enough burn you can get that thermal energy deep enough to close the feeder vessel. You end up with pretty big burns. But because the feeder vessel is coming in from the edge of the macula it did not really matter if you had a 500-micron to 1-millimeter burn at the edge of the macula. It was visually insignificant as long as you closed the feeder vessel. The problem was we were getting a lot of destruction treating too close to the center. With this type of burn you were burning the rods and cones.

The challenge was to get this laser energy past the pigment epithelium without having the pigment epithelium turn into a burn. We thought about pulsing the laser. Micropulsing was inappropriate because the micropulsing put the energy preferentially at the level of the RPE. What we came up with was taking the 810-diode laser and pulse it. We pulsed the laser one tenth of a second on and one tenth of a second off. This would allow you to create a thermal gradient deep. However, the 50% duty cycle allows the choriocapillaris, which is right under the pigment epithelium, to cool the pigment epithelium preferentially while you maintain a thermal gradient deeper. It turns out to be a very elegant way to generate a thermal differential deep. Certainly you are developing a thermal gradient at the level of the RPE but you are well below coagulation threshold. The bottom line is that it works. The idea is to use the 810-diode laser in the pulse mode a tenth on and a tenth off. Just by trial and error we discovered that by treating for about two minutes allows you to close a vast majority of the visible feeder vessels. The problem was still that you got this visible whitening before the treatment was quite as much as you wanted. So then we decided to treat with a lower power about 200 milliwatts. We put in 15 to 20 to 30 seconds in the lower power range then gradually increased the power. By starting low and gradually increasing the power you could get up to powers of 500, 700 or 800 milliwatts still incredibly without getting any visible thermal effect. We typically use a 75, 125 or a 200- micron spot size. We start low about 200 to 250 milliwatts, a tenth on and a tenth off, gradually increasing the power. We put in about 300 applications. Then you start to increase the power as high as 600, 700, and 800 milliwatts. Most of the time you will not get a visible burn. If on the other hand you put in

one spot at 600 or 700 milliwatts on untreated retina you immediately get a blanch. These burns are not so bad. First of all they are very tiny and are away from the center. Certainly they are minimal burns. We have never once gotten a choroidal rupture. This is very safe. We weren't really so much concerned about the burns whitening the retina. We were more concerned about not getting a visible burn so we could get more energy deep as whitened retina blocks the laser.

This works so that now most of the time we just work by the numbers. We don't wait to get a visible effect. We put into two to three minutes getting up the power to 600 or 800 milliwatts. With this power level you can be pretty sure the vessel is going to be closed. So if I show you how we actually do it will be a little clearer.

In macular degeneration the typical membrane we see is mostly occult. There can be an epicenter of plaque of neovascularization. Most of these are occult membranes. This is the FA that shows the brighter area of well-defined plaque neovascularization. You end up with this big smudgy spot of hyperfluorescence that tells you yes there is leakage but we already knew there was leakage. So the FA really doesn't help you very much. Visudyne is totally ineffective for this common variety of case because it only closes the classic component. It is totally ineffective in closing the occult. A vast majority of cases have a significant amount of occult neovascularization. By doing an infrared angiogram it is like turning back the curtain. All of a sudden you can still see the retinal vessels very clearly but now all of a sudden you see this choroidal circulation in great detail. This case, which was primarily occult, was really not approachable by treating with verteporfin. It was much too large for macular

surgery or translocation and much too large for conventional ablative therapy. But when you do the ICG angiogram you can see the internal vasculature. It turns out that this lesion has one main feeder vessel that provides circulation to the entire vascular complex. So it's a no brainer to go 1500 to 1000 microns away from the center of the fovea and with one tiny spot 200 microns here, close the feeder vessel and therefore close the whole thing. It is effective immediately. You can repeat the ICG angiogram and you can see that the entire abnormal vasculature is completely closed. You get a dark spot. The same sort of dark spot on the FA that you would see with PDT. But you have done it much more quickly. There are fewer personnel, lower cost, and an immediate result.

Let me show you exactly how we do it. This is the image you actually see. It is a digitized infrared angiogram that allows us to see the entire filling process. You end up with a two or three second video loop digitized image on your computer. You can play it in the office over and over again. You can put it on automatic play. It will show the filling of the normal choroid, the retinal vessels, and you can see the feeder vessel I showed you before. After a second or so we are already in the venous phase. This is beyond the point of interest. So the angiogram is very fast. We are not talking about a twenty or thirty minute angiogram. Then you can play it manually, fast or slow. When you play it manually you start to see the normal early filling of the choroidal vessels. These vessels you are just starting to see now are on the arteriole filling side. A tenth of a second further on you can see the normal choroidal vessels. They go away from the macula and branch. All these down here are normal choroidal vessels. At the same time you see this more linear straight vessel

that appears just after the normal choroidal vessels. It is heading right for the CNV. In fact in this case it branches and goes into the neovascularization itself. As I said the neovascularization fills slightly more slowly than the normal choroid. Now we are already in the venous phase. We really haven't got capillary filling in the membrane. You can clearly see the pattern of neovascularization. Now we are in the venous phase and within a half second the arteriole of the feeder vessel of the neovascular complex is patent. The dye has already gone through. Now we have filling of the vein that drains the neovascular complex. So we have a way of separating the afferent from the efferent circulation of the neovascular complex, the so-called arteriole side from the venous side.

You don't want to treat the vein. You could close the neovascularization but you would have a much higher risk of hemorrhage by treating the vein that drains the neovascularization without closing the input side. Not a very good strategy. Twenty-five years ago a number of investigators were trying to use fluorescein angiography to define the feeder vessels. They had some limited success but the problem was they were getting static images of one or two per second. They were not imaging the feeder vessel. They were imaging primarily the veins. It was very dangerous to do it that way.

It is very common in the body for the artery and the veins to be close together. But it doesn't matter to me. This is a mile away. This one you could treat with a 100 micron spot size which is ten spot sizes away from the vein. This is just a very elegant way to treat with a very tiny spot in a very tiny area. Usually there is not visible effect at all. All angiography depends on contrast of the dye in the vessels with less dye

elsewhere. Here the feeder vessel shows up in stark relief because it fills with the ICG dye and the membrane it is going to fill hasn't filled yet. It is a very nice contrast. We were able to get these images in video form on the computer right before the AAO last year. We are not using static images; we are using dynamic images, which makes things very clear very fast. The time it takes now to analyze a single tape is less than a minute. We know exactly what to look for now. Where the vessels are likely to be, what they look like, and when during the sequence they will show up. We can separate the arteries from the veins. The normal from the abnormal. Within a few seconds you either have it or you don't. You don't spend hours analyzing it.

The other nice thing is that the effect is immediate. Remember we cannot see the feeder vessel but when you get the angiograms it is either closed or it is not. You either got it or you didn't. This is unlike other procedures like TTT where the patients continue to improve after one or two months or more. I think that is more reliable as I don't trust the mapping. So here is a post treatment angiogram. You have immediate confirmation. If you did not close this vessel, if I was a little off, I could take them right back to the laser and treat them again. I close the vessels at least 50% of the time but I don't view it as a contest. I view it as a process in which you are using a minimal amount of thermal damage. If that works, great; if not ratchet it up. It just takes a few more minutes.

We can close 55% within two weeks and another 25% after two weeks. The results when treating classic membranes are much better than PDT. This is a case of a PED. The vision is 20/70. This is a typical fluorescein pattern of the filling of this blister of fluid

on the retina. Some of these PEDs, I don't know how many but it is less than half, have this giant ropy tortuous feeder vessel shunting the flow to the PED. It is very dramatic to treat the big feeder vessels. We rarely close the feeder vessels but significantly diminished flow. Post op FA shows complete flattening of the PED. VA improved to 20/50. Our pilot study of PEDs with 6 months follow-up decreased leakage in 6 of the 8.

Here is a series I am interested in. These cases are disciform scars. End stage mac degen with fibrotic scar. The group we tackled had subretinal fluid with hemorrhage. Here is the FA, which gives you some hint that it's got a nicely defined vascular pattern. The late FA shows a whole lot of leakage from that vascular lesion. But the ICG shows you the arteriole side of the neovascularization. Here is the feeder vessel. We treated and closed it immediately. This eye improved from 3/200 to 20/300 in two months. Clinically, you can see the blood is gone. The fluid is all gone. You still have the fibrosis but you have stopped the leakage. That allows visual recovery. Low vision aids could now help this patient. Here is another pre-op showing diffuse leakage with fibrosis. Post-op shows staining of the fibrous tissue but the leakage is totally gone. In the pilot study we have achieved resolution of the SRF in 7/8 cases. We reduced leakage in 7/8 by treating one to three modulating vessels. It took two to five treatments to close but these patients had a mean visual improvement of almost four lines. Remember this is end-stage disease that is supposedly not treatable. In the pilot study you get a range of VA from most dramatically 20/400 to 20/80. Again, this is with very little risk to the patient.

In conclusion, our work is based on two breakthroughs: one is the improved imaging with high-resolution transit choroidal angiography using the SLO. We have developed little mini-angiograms of choroidal filling patterns of lots of different types of neovascularization. Classic, mixed classic, occult, PEDs, and even fibrovascular scars by identifying the vascular pattern of the lesion. We have developed a way using a high repetition diode laser to effectively allow us to close those vessels. When we close those vessels we stop the circulation inside the lesion. Without the leakage the eye will resorb the subretinal fluid that is there. Usually there is an associated visual improvement. The classic cases, the vast majority of cases which were stabilized to prevent further visual loss unlike PDT. We can also attack a much broader part of the macular degeneration spectrum. We can achieve a much better visual improvement than we possibly could before.

In our clinic this is our first approach. We also do TTT and we also do PDT. In the future we believe this will be the first approach to identify the feeder vessels. Then we incorporate PDT or TTT. In our practice only about two or three percent of the eyes are eligible for PDT. We use feeder vessel approach initially then use the PDT. The same with TTT. If we get to the point where we cannot see the feeder vessels anymore and we can't do any feeder vessel treatment we do TTT or PDT. TTT changes the biology of the CNV enough to stop the leakage totally or it allows us to treat the feeder vessels. Right now this is a very exciting technique for us. It allows us to treat CNV in a way that we could not do before by being able to image the vascular pattern and to control the vascular pattern. Presently the best way to do that is by millipulsing the 810 diode laser. Very safe, very elegant, minimal to no

retinal damage and visual results are quite impressive. The first problem is the learning curve. Then there is the cost of the Heidelberg equipment. The younger doctors are going to be more receptive to this technique. They will be willing to put in the time and effort.

There is a clinic outside of Paris. They were not doing things as well as they could be doing. They weren't getting the best images with the Heidelberg unit. They had problems with image output, enhancement, and how to transfer the images quickly and effectively. Two problems are identifying the feeder vessel and treating the right spot. We have tried everyway possible and pretty much have those problems resolved. If you are working with a crummy image or if you don't have a reliable way of mapping out the vessels you will not be successful. They were trying to map out the vessels and trying to use the infrared picture. I could not begin to do it the way they were doing it. But by using the black and white red free image and mapping like I showed you we solved the problems with mapping. It begins with localization. I showed them very quickly, that by using their existing computer, they could get a much better result. By getting simultaneous FA and ICGs you get a degraded ICG image. It's the subtle things that make all the difference.

One of the complaints that I hear from physicians is the cost of the equipment. I think this is the greatest thing since sliced bread. To be able to offer patients something for their macular degeneration. We can now treat it very elegantly and successfully. I thought our biggest problem would have been the stampede of retina specialists to our office. It did not happen. All we got was a stone wall. However, now with long term

follow up and being able to show these images we will get more interest. They are much more powerful than showing static images. And the other people who are buying it are having a lot of success. The cost of the equipment is covered by the reimbursement for the angiography. So in terms of the Heidelberg unit, the Heidelberg unit pays for itself. Because you get reimbursed for the FAs and the ICGs. We can do four or six studies per hour. A single photographer can perform sixty-to-eighty images per day. We have turned photography from a loss center to a profit center. Three studies per day will pay for the lease on the Heidelberg unit. Cost is a non-issue.

We have no proprietary interest in Heidelberg. We did work with them to improve the imaging.

Our approach is to dilate the patients, do the FA, and then do the ICG. The FA tells you what kind it is: whether it is classic or occult. It tells you how big and where. If it is a subfoveal classic perfect for Verteporfin and the ICG shows a nice feeder vessel of course you do the feeder vessel. There is much less damage. Verteporfin, in my opinion, is not so great. Even if we are 100% effective with our treatment there is no ethical issue if you can close the feeder vessel with one tiny little burn. If you don't close it then you can treat with PDT. The same reasoning applies with occult lesions. As long as we can see the feeder vessels then we treat them. If we can no longer find the feeder vessels then we will use TTT. Also, with extra foveal classic membranes we treat the feeder vessel. The MPS treatment closes the membranes; but one must remember recurrence is 50 to 80% and it is always on the foveal side. I have no qualms at all using the feeder vessel technique. The feeder vessels consist of 1 or 2 or 3 roots that make up the branch. The end of

the tree here is the visible part of the neovascularization. MPS treatment uses ablative thermotherapy. We have lots of histology showing a white-hot burn. You get down a little below the RPE but not deep in the choroid so you still leave the taproot. That is why with MPS treatment the recurrence rate is at least 50%. Within a year to a year and a half the vessels recanalizes and you have more growth on the foveal side. With PDT you close the capillaries. That is why you get that dark picture on the FA the next day. However, you have left the entire vascular infrastructure patent. That is why with PDT 90% open up again within a short period of time. It is no surprise because closure is at the capillary level. It is just opposite by going to the taproot first. It is safe, it is controlled, and there is virtually no damage to the retina. But this is as close to minimal damage to the macula that you can get with any treatment. Even with Verteporfin treatment those eyes after two or three treatments show a lot of atrophy at the level of the RPE. There is plenty of other evidence that Verteporfin treatment is not totally benign. You do get a damaging effect at the RPE. There is no question about it. Some of the patients look like they have had subfoveal laser because it is just atrophic. Well you don't get that with feeder vessel treatment. Some of our scars are very hard to find. Look at the options. You can cauterize it or you can stop the leakage at the superficial level with PDT. However, they recur and it is a great expense. Remember, with Verteporfin, 4% to 6% of the eyes develop a severe visual loss. You never see a severe visual loss with feeder vessel treatment.

Whatever we are doing is allowing the development of a thermal gradient deep enough to close the feeder vessel. This may not be at the thermal level. We don't

know how it really works. It is pretty clear to me that one of the components is tissue swelling. I think you do have enough changes in the thermal gradient to form a clot. But you also get some localized tissue swelling that helps to squeeze the vessels closed. It is presumably by cooling the choriocapillaris that prevents the RPE thermal gradient from reaching the point of photocoagulation. Instead of with a blowtorch you are gradually changing the thermal gradient of the tissue. It is a much more controlled and precise technique. You can achieve what you want with a much less adverse effect. We want to get a good two minutes of thermal gradient deep to close the feeder vessel. You don't want to whiten the RPE. By trial and error we pulsed the laser. We started very low with a 200-micron spot, two hundred milliwatts of power, and we pulsed this for 20 or 30 seconds. Then we raise the power to 250 or 300 milliwatts. Do this for another 20 or 30 seconds. Gradually raise the power and pretty soon you reach 600, 700, 800 milliwatts with no visible effects. But if the patient moves just a tiny bit and the laser hits one spot of untreated retina you get an immediate blanch. Clearly there is some conditioning of the retina to a thermal response. Dr. Mainster has postulated there are heat shock proteins that protect the tissue from thermal damage. This may happen by coming in with gradual increases of thermal gradient. This allows a biological effect to occur to help protect the tissue from the thermal gradient. He also thinks that this whitening we get may not be a true burn. It may be some disruption of the neural retina rather than a true burn of the RPE. In many patients the next day that white spot will often subside. But even if it were permanent it is so small and so far from the center it is nothing compared to other modalities. Also the more visible pigment they have, the more sensitive

they are to any laser. With someone who is highly pigmented you ratchet the power way down. Say to 50 milliwatts. Same principle. You start with sub-threshold and you gradually work up. You want to have two minutes of sub-threshold energy to close. So what I do now to increase the closure rate I will go up to three minutes. If I get up to 700 or 800 milliwatts at three minutes and there is no visible effect that's it. If I get a gray blanching I will stop it there. In white scar tissue we will start at 400 to 500 milliwatts and sometimes will go the maximum power, 1400 milliwatts, before we see a graying effect. We seem to be able to get through a lot of pigment with the 810 laser. Something else is at play here. It may be the way we are developing the clot and it may be the swelling of the tissue to keep the vessel taponaded.

APPENDIX G

Bibliography of recent medical literature concerning the diagnosis and treatment of macular degeneration

Bailey, S.T., et al., *Detection of Non-exudative Choroidal Neovascularization and Progression to Exudative Choroidal Neovascularization Using Optical Coherence Tomography Angiography*, 3(8) Ophthalmol. Retina 629–636 (2019) ("Overall, 8 of the 10 eyes with non-exudative CNV developed exudation with a mean time of 8 months and a mean CNV area growth rate of 20%/month (exponential model, p=0.014). * * * Cox proportional hazard analysis showed that having a non-exudative CNV detected was associated with 18.1-fold increase in the rate of subsequently developing exudation (P<0.0001). Conclusions: Non-exudative CNVs are frequently detected by OCTA in the fellow eyes of exudative CNV. These lesions carry a high risk of developing exudation within the first year after detection and could benefit from close monitoring. The high risk of progression may justify prophylactic treatment; further studies are needed.* * *However, given the high rate of exudation in our series, early treatment may prevent vision loss associated with SRF, IRF or hemorrhage.")

Caballero, S, et al., *Bone marrow–derived cell recruitment to the neurosensory retina and retinal pigment epithelial cell layer following subthreshold retinal phototherapy*. 58 Invest. Ophthalmol. Vis. Sci. 5164–5176. 5164, 5171 (2017) ("SRPT induces monocyte recruitment to the RPE followed by hematopoietic progenitor cell homing at 2 weeks. Recruitment occurs in a duty cycle-dependent manner and potentially could contribute to the therapeutic efficacy of SRPT

* * * * Continuous wave (CW) thermal lasers have long been important tools for the treatment of various retinal disorders. Their therapeutic efficacy in the treatment of diabetic macular edema (DME) is well-established but at the expense of potentially serious side effects such as development of scotomata, sub-retinal scarring, and CNV, all resulting from thermal-induced damage to the outer retina, RPE, and Bruch's membrane. However, the precise mechanism of action of CW laser has yet to be fully delineated. Recently developed to minimize photothermal damage to the retina and adjacent structures, micropulse laser induces photochemical injury. In this study, we investigated the migration and microglial nature of BM-derived cells present in the neurosensory retina (NSR) and RPE-choroid at various time points after subthreshold retinal phototherapy (SRPT) using various duty cycles (DCs) * * * * The salient finding of this study is the demonstration, we believe for the first time, that BM-derived cells can be locally recruited to the retina, including the RPE layer, using SRPT")

Chang, D.B., et al., *Comparison of Subthreshold 577 and 810 nm Micropulse Laser Effects on Heat-Shock Protein Activation Kinetics: Implications for Treatment Efficacy and Safety*, 9(5) Transl. Vis. Sci. Technol. 23 (April 2020) ("Defining photocoagulation, and indeed any degree of LIRD, as complications rather than goals of treatment, modern retinal laser therapy seeks to maximize both treatment safety and efficacy and broaden treatment indications by precluding LIRD. The cornerstones of modern retinal laser therapy were established and defined by low-intensity/high-density subthreshold diode (810 nm) micropulse laser (SDM). These include treatments (1) selective to the retinal pigment epithelium (RPE) and

sparing the neurosensory retina; (2) reliably and predictably sublethal to the RPE; and (3) clinically optimized by preservation and normalization of RPE function at the cellular level, with amplification of the cellular response by en masse recruitment of large areas of dysfunctional retina in confluent treatment to maximize therapeutic effects, reverse the disease process, and thereby reduce the risks of visual loss.") (citing Dorin)

Chhablani, J., et al., *Restorative retinal laser therapy: present state and future directions*, 63(3) Survey of Ophthalmol. 307–328. (2018) ("York and colleagues used indocyanine green angiography guided micropulse laser to close choroidal feeder vessels in neovascular age-related macular degeneration (AMD).")

Cohn, A.C., et al., *Subthreshold Nano-Second Laser Treatment and Age-Related Macular Degeneration*, 10(3) J. Clin. Med. 484 (Jan. 2021) ("The evolution in our understanding of AMD, through advances in multimodal imaging and functional testing, as well as ongoing investigation of key pathological mechanisms, have all helped to set the scene for further well-conducted randomised trials to further explore potential utility of the nanosecond and other subthreshold short pulse lasers in AMD. * * * As discussed previously, lasers delivered at subthreshold levels have no visual feedback at the time of application, which can make the titration of laser power for adequate tissue effect extremely difficult.) (citing Dorin)

Dorin, G., *New Laser Technologies in* Samples, John R., Ahmed Iqbal Ike K. eds. *Surgical Innovations in Glaucoma* (October 2014), Springer: New York, pp. 77–84 ("Treatment endpoint of all laser surgeries was always a discernable photothermal, photoacoustic, or

photomechanical tissue effect, such as stretching, blanching, burning, bubbling, popping, perforating, or cutting. Although destructive in nature, the iatrogenic damage and collateral effects associated with these endpoints have been universally accepted as necessary for a useful treatment. Lately, almost by serendipity, it has been found that some procedures result equally effective and more beneficial when performed without destructive endpoint, by eliciting similar mechanisms of action with fewer or no collateral effects * * * * Effective subthreshold laser therapies, with less or no iatrogenic damage, can be administered pro re nata (PRN) and play an important complementary role with emerging microinvasive glaucoma surgeries (MIGS) in the long-term management of glaucoma.")

Guymer, R.H., et al., *Subthreshold Nanosecond Laser Intervention in Age-Related Macular Degeneration The LEAD Randomized Controlled Clinical Trial*. 126 Ophthalmol. 829–838 (2019). ("There is an urgent need for a more effective intervention to slow or prevent progression of age-related macular degeneration (AMD) from its early stages to vision-threatening late complications. Subthreshold nanosecond laser (SNL) treatment has shown promise in preclinical studies and a pilot study in intermediate AMD (iAMD) as a potential treatment. We aimed to evaluate the safety of SNL treatment in iAMD and its efficacy for slowing progression to late AMD * * * * In the last decade, advances in the treatment of the neovascular form of late age-related macular degeneration (AMD) with intraocular injections of anti–vascular endothelial growth factor have reduced vision loss from this complication dramatically. However, delivering this treatment has imposed an enormous financial burden on health systems worldwide because of the need for ongoing

repeated treatment at frequent intervals for an ever-increasing number of patients. Furthermore, long-term visual benefits are not always maintained despite treatment, with vision loss continuing to occur through atrophy or scar formation * * * * Currently, no treatment exists for the other late AMD complication of atrophy, where progressive degeneration and death of the outer retinal cells–the photoreceptors and retinal pigment epithelium (RPE)–occurs. Apart from dietary supplements, such as the Age-Related Eye Disease Study formulations, for subsets of individuals with AMD and general lifestyle modification, there is no specific intervention that prevents or slows progression from earlier, asymptomatic stages of AMD to the visually devastating complications of late AMD. As such, there is an urgent need for an effective intervention to slow or prevent the progression of the disease in its early stages * * * * The effect of a short-pulse, nanosecond laser delivering a speckled-beam profile at subthreshold energy levels has been investigated using the retinal rejuvenation therapy laser device 2RT (Ellex Pty Ltd, Adelaide, Australia). In an in vitro study, this laser induced RPE migration and an increase in matrix metalloproteinases (MMPs) involved in ECM turnover. In an animal model with a thickened BM (ApoE-null mouse), application of this laser treatment resulted in a significant reduction in BM thickness and upregulation of gene expression for a range of genes involved in ECM turnover. In AMD patients, a single application of nanosecond laser resulted in a reduction in drusen load without any evidence of damage to overlying photoreceptors. These preliminary results warranted further investigation, and as such, a randomized controlled clinical trial of subthreshold nanosecond laser (SNL) in iAMD was undertaken to determine if this novel intervention could reduce

progression to late AMD * * * * If the beneficial effect of the SNL treatment in eyes without RPD can be confirmed, it will have major implications for millions of people worldwide with the earliest stages of AMD.")

Gawęcki, M., *Micropulse Laser Treatment of Retinal Diseases*, 8(2) J. Clinical Medicine 242 (Feb. 2019) ("For years, retinal laser treatment involved the destruction of the retinal tissue. * * * Therefore, there has been a constant search for laser treatment of the retina that would deliver the benefits, but not destroy cells. Micropulse and nanopulse lasers give clinicians the opportunity to treat retinal disorders without any visible damage. * * * The idea of subthreshold laser therapy is not to leave any marks on the retina, meaning spots that could be detected by any available diagnostic tools, such as biomicroscopy, fundus autofluorescence (FAF), fundus angiography, or optical coherence tomography. Numerous studies confirm the safety of subthreshold micropulse laser treatment (SMPLT) with no detectable damage to RPE or photoreceptors. Laser power is set at a low level, so that the laser impact does not leave any traces on the retina. In consequence, only a limited thermal impact is exerted on the tissue, without any lethal effect.").

Geneva II, *Photo-biomodulation for the treatment of retinal diseases: a review*, 9(1) Int. J. Ophthalmol. 145–152 (2016) ("Photobiomodulation (PBM), also known as low level laser therapy, [is] a promising new approach to treat a variety of retinal conditions including age-related macular degeneration * * * * The literature supports the conclusion that the low -cost and non - invasive nature of PBM, coupled with the first promising clinical reports and the numerous preclinical-studies in animal models, make PBM well -poised to become an important player in the treatment of a

wide range of retinal disorders. * * * The results from all the studies in animal models of AMD * * * demonstrate the potential of PBM for ameliorating and even *reversing retinal damage* * * * a new US-based clinical trial is currently recruiting participants in order to study the potential benefit, tolerability, and safety of FR/NIR light therapy in adults with wet AMD ('Wet AMD Near Infrared Treatment Trial administered by the New York Eye and Ear Infirmary at Mount Sinai).')")

Heiferman, M.J., et al., *Progression of subclinical choroidal neovascularization in age-related macular degeneration*, 14(6) *PLoS ONE* e0217805 (2019) ("Age-related macular degeneration (AMD) is a leading cause of irreversible vision loss in developed countries. Early and intermediate AMD are defined by the presence of drusen. Late AMD is defined by the presence of choroidal neovascularization or geographic atrophy involving the center of the macula. While most patients with AMD have early or intermediate AMD, severe vision loss is most often related to late AMD. Despite this potential morbidity, the mechanism for progression to late AMD remains unknown. * * * * Histopathologic specimens of eyes with clinically diagnosed dry AMD have shown newly-formed blood vessels [as much as >50%] invading into the subretinal space. These authors proposed the presence of subclinical choroidal neovascularization in a subset of eyes with a clinical diagnosis of dry AMD. Furthermore, they speculated that these new blood vessels are precursors of late AMD. Studies using indocyanine-green angiography (ICG) further supported this hypothesis by demonstrating the presence of focal hyperfluorescence and plaques on ICG in fellow eyes of unilateral exudative AMD. These authors suggested that eyes with

these ICG findings are at higher risk of developing late AMD.")

Ivandic, B.T., et al., *Low-level Laser Therapy Improves Vision in Patients with Age-related Macular Degeneration*, 26 Photomed. Laser Surg. 241–245 (2008) ("LLLT given over 2 wk led to an improvement in visual acuity in most patients with AMD (90%). An increase of three to seven rows of optotypes was observed in 52/182 (28.6%) of eyes with cataracts, and in 59/146 (40.4%) of eyes without cataracts. Unlike other therapeutic approaches, LLLT improved visual acuity in patients with AMD of every stage. The improvement in visual function was maintained for up to 36 mo. The results of this retrospective analysis of a case series are encouraging, especially in light of the fact that if untreated, AMD inevitably leads to irreversible loss of vision. Thus LLLT may, when initiated during the early stages of AMD, help prevent loss of vision. LLLT may also be combined with other therapeutic approaches. Although not investigated in this study, it is likely that synergistic effects may be seen (e.g., improved outcome or shorter treatment duration). In addition to the improvement in visual acuity, other positive effects of LLLT were noted. Eye examinations revealed that LLLT diminished pigment accumulations and cystic drusen. Metamorphopsia, acquired impairments of color vision, and relative scotomas improved as well. Moreover, in patients with wet AMD, edema and bleeding were reduced. * * * In conclusion, this study of a case series shows that LLLT may be a novel therapeutic option for both early and advanced forms of AMD. This simple and highly effective treatment improves visual acuity and may help to prevent loss of vision without adverse side effects.")

Kiire, C., et al., *Subthreshold Micropulse Laser Therapy For Retinal Disorders*, Retina Today 67–70 (Jan./Feb. 2011) ("It has, however, been suggested that full thickness retinal damage may not be needed to obtain beneficial effects from laser. The benefits might be due to the up and down-regulation of angiogenic growth factors (e.g., VEGF) mediated by the biological reaction of RPE cells that have been only sublethally injured. The RPE plays a significant role in repairing the outer and inner blood-retinal barrier, regardless of the type or location of the laser application. Photothermal elevation that does not produce visible intraretinal damage during or after laser treatment may be termed subthreshold laser treatment. Emerging evidence suggests that subthreshold laser treatment may be as effective as conventional laser treatment but with less iatrogenic damage to the tissues surrounding the area of the burn in the RPE.").

Keunen J.E.E., et al., *International Retinal Laser Society Guidelines For Subthreshold Laser Treatment*. 9(9) Transl. Vis. Sci. Technol. 15 (August 2020) ("The recent advent of new laser approaches has revolutionized the laser treatment techniques for retinal diseases. In particular, the goal of modern subthreshold laser (STL) treatment is now retinal preservation and normalization, rather than destruction.") (citing Dorin)

Koev, K., et al., *Five-year Follow-up of Low-level Laser Therapy (LLLT) in patients with age-related macular degeneration (AMD)*, 992 J. Phys.: Conf. Ser. 012061 (2018) ("There was a statistically significant increase in the visual acuity ($p<0.001$, end of study versus baseline) for AMD patients for the period of five years after the treatment. The edema and hemorrhage in the patients with progressive, exudative AMD

significantly decreased. No side effects were observed during the therapy. The prevalence of metamorphopsia, scotoma in AMD group was reduced. In conclusion, this study shows that LLLT may be a novel long-lasting therapeutic option for both forms of AMD. It is a highly-effective treatment that results in a long-term improvement of the visual acuity. * * * The results of this retrospective analysis of a case series are encouraging, as they unambiguously demonstrated the beneficial effect of the LLLT, namely, improvement in the visual acuity in most patients with AMD (93,9%).")

Luttrull, J.K., et al., *Laser Resensitization of Medically Unresponsive Neovascular Age-Related Macular Degeneration*, 35(6) Retina 1184–1194 (June 2015) ("Subthreshold diode micropulse laser treatment restored drug response in drug-tolerant eyes with neovascular age-related macular degeneration. Based on these findings, a theory of subthreshold diode micropulse laser action is proposed, suggesting a wider role for subthreshold diode micropulse laser as retinal reparative/protective therapy.")

Luttrull, J.K., et al, *Low incidence of choroidal neovascularization following subthreshold diode micropulse laser (SDM) in high-risk AMD*, 13(8) PloS one (2018) ("In a review of a large group of eyes with exceptionally high-risk AMD, SDM was followed by a very low incidence of new CNV. If confirmed by further study, SDM would offer a new and highly effective treatment to reduce the risk of vision loss from AMD.")

Luttrull, J.K., et al., *Slowed Progression of Age-Related Geographic Atrophy Following Subthreshold Laser*, 14 Clinical Ophthalmol. 2983–2993 (Oct. 2020) ("The only known effects of SDM, sublethal to the RPE,

are therapeutic. There are no known adverse treatment effects associated with SDM clinically, in vitro or in vivo. This is because therapeutic retinal laser effects arise from living cells affected, but not killed by laser exposure; and adverse retinal laser effects arise from LIRD, which is, at minimum, lethal to the RPE. The effects of thermal laser effects sublethal to the RPE are multivalent, catalytic, reparative, restorative and functionally normalizing to the retina. * * * The response to SDM represents a physiologic "reset" phenomenon.6–15,34–50 This is because the currency of cellular dysfunction, induced by virtually any stressor, including ageing and all chronic progressive retinopathies, is protein misfolding. Because HSP-mediated correction of protein misfolding and consequent normalization of cell function is agnostic to the cause of protein misfolding, SDM acts as a non-specific trigger of disease-specific repair; much like the "reset" function common to electronic devices. * * * Appearing highly effective and without adverse effects, SDM might, if confirmed, contribute significantly to the reduction of visual loss and disability due to AMD.")

Luttrull, J.K., et al., *Prevention of neovascular AMD: Real world efficacy of program of panmacular laser for vision protection*, preprint, available at https://www.researchgate.net/publication/349952308 ("By study conclusion in September 30, 2020, SC+SDM eyes averaged 9 letters better VA than SCA eyes. Confirmed by further study, SDM would set a new standard for prevention of visual loss from AMD with significant public health implications.")

Markowitz, S.N., et al., *A Double-Masked Randomized Sham-Controlled, Single-Center Study With Photobiomodulation For The Treatment of Dry Age-Related Macular Degeneration*, 40(8) Retina 1471–1482

(August 2020) ("Photobiomodulation treatment statistically improved clinical and anatomical outcomes with more robust benefits observed in subjects with earlier stages of dry age-related macular degeneration.")

Merry, G.F., et al., *Photobiomodulation Reduces Drusen Volume And Improves Visual Acuity And Contrast Sensitivity In Dry Age-Related Macular Degeneration*, 95(4) Acta. Opthalmol. e270–e277 (2017) (finding "improvements in functional and anatomical outcomes in dry AMD subjects with PBM therapy" by "stimulat[ing] cellular processes that provide an approach to target the underlying degenerative pathology with disease-modifying potential").

Muste, J.C., et al., *Photobiomodulation Therapy in Age-Related Macular Degeneration*, 32(3) Curr. Opin. Ophthalmol. 225–232 (May 2021) ("PBT might be used in treating nonexudative AMD. Limited evidence suggests that exudative AMD may also benefit from PBT.")

de Oliveira Dias, J.R., et al., *Natural History of Subclinical Neovascularization in Nonexudative Age-Related Macular Degeneration Using Swept-Source OCT Angiography*, 125(2) Ophthalmol. 255–266 (2017) ("After the detection of subclinical MNV, the risk of exudation was 15.2 times (95% confidence interval, 4.2–55.4) greater compared with eyes without subclinical MNV. Conclusions: By 12 months, the risk of exudation was greater for eyes with documented subclinical MNV compared with eyes without detectable MNV.")

Or, C., et al., *Vascularized drusen: a cross-sectional study*, 5 Int. J. Retin. Vitr. 36 (2019) ("Early detection of CNV and early management of exudative AMD have been shown to be associated with better visual acuity

outcomes in patients who convert to clinically significant exudative AMD. Indocyanine green angiography (ICGA) is deemed the gold standard when assessing for the presence of type 1 neovascularization, owing to its improved penetration below the RPE. Studies using ICG videography on patients with non-exudative AMD demonstrated that subclinical neovascularization could occur even in this cohort of patients * * * However, it is still not clear at which point the MNVs arise in the evolution of drusen and pigment epithelial detachments. * * * Recent studies by Roisman et al., de Oliviera Dias et al., and Querques et al. have demonstrated that phenotypic dry AMD consists of two different OCT angiographic subtypes, a high-risk type with non-exudative subclinical MNV and a truly 'dry' type with no MNV. However, it is not clear at what stage the non-exudative MNV develops. This study shows that neovascularization may be present as early as in drusen. * * * The identification of neovascularization in drusenoid lesions presenting with uniform sub-RPE hyperreflectivity suggests that OCT alone is insufficient for its detection. Furthermore, vascularized drusen could not be detected using FA [fluorescein angiography] or CFP [color fundus photography]. Querques et al. suggested that these lesions may be visible on ICG. It remains a limitation of our study that ICGA results were not available to confirm our findings. * * * In all instances, FA failed to identify the presence of the neovascularization.")

Querques, G., et al., *Subthreshold laser treatment for reticular pseudodrusen secondary to age-related macular degeneration*, 11(1) Scientific Reports 2193 (January 2021) ("Subthreshold laser is a safe and effective treatment used in the clinical practice in several retinal disor-ders. Although the exact mechanism

of action of sub-threshold lasers is not completely understood, it has been suggested that it works by targeting, preserving, and "normalizing" the function of the RPE23. Since the dysfunction of the RPE has been suggested as the main driving factor in the pathogenesis of RPD, the subthreshold laser could play a crucial role in the treatment of RPD. However, to date, no prospective studies were designed in order to evaluate the safety and efficacy of this treatment in patients affected by RPD. The aim of the current pilot clinical trial is to evaluate the safety and short-term efficacy of the sub-threshold laser treatment (SLT) in patients affected by RPD secondary to dAMD. * * * "High-density/low-intensity" SLT was first reported in 2005 in the treatment of diabetic macular edema (DME). Subthreshold laser does not cause retinal damage and has no known adverse treatment effects. Indeed, it has been demonstrated that both subthreshold infrared laser and subthreshold yellow laser do not cause clinically visible or invisible scars in the macula, and that SLT can be used transfoveally in eyes with 20/20 visual acuity to reduce the risk of visual loss caused by early fovea-involving DME. Our data have confirmed that SLT is safe also in patients with high BCVA and dAMD. * * * As subthreshold laser seems to play a role in restoring the function of RPE in patients affected by AMD and dysfunction of the RPE has been suggested as the main driving factor in the pathogenesis of RPD, SLT could play a crucial role in the regression of RPD. Our pilot study showed interesting results in the anatomical outcomes of patients treated with subthreshold laser. * * * These results are of fundamental importance because a regression of the stages of RPD due to SLT could reduce the risk of developing an advanced form of AMD, both neovascular or atrophic.")

Roh, M., et al., *Subthreshold Exudative Choroidal Neovascularization Associated With Age-Related Macular Degeneration Identified by Optical Coherence Tomography Angiography*, 4(5) J. Vitreoretinal Diseases 377–385 (2020) ("Fluorescein angiography (FA) has long been the criterion standard for detecting and diagnosing new-onset CNV, with indocyanine green angiography (ICGA) being a useful adjunct for select cases. The introduction of newer, less-invasive imaging modalities, such as optical coherence tomography (OCT) and OCT angiography (OCTA), allows clinicians to more frequently and accurately monitor progression of disease and response to treatment and guide future treatment decisions. Furthermore, multimodal imaging has prompted investigations into subclasses of CNV in AMD, further stratifying exudative AMD patients to allow for personalized therapies and improved predictability of response to treatments.")

Roisman, L., et al., *Optical Coherence Tomography Angiography of Asymptomatic Neovascularization in Intermediate Age-Related Macular Degeneration*, 123(6) Ophthalmology 1309–1317 (2016) ("After all, early detection and treatment of pathological neovascularization is thought to be important in preserving as much vision as possible in these patients who convert to late neovascular AMD * * * * [T]he detection of subclinical MNV required the use of ICGA, which is an invasive procedure associated with the rare but serious risk of an allergic or anaphylactic reaction. Moreover, ICGA is expensive, time consuming, resource intensive, and not routinely performed or reimbursed by insurances when performed on patients with non-exudative AMD. Due to these limitations, angiographic monitoring of eyes with intermediate AMD has never become routine; however, this is about to change with

the availability of OCT angiography. In the three cases presented in this series, asymptomatic eyes with intermediate AMD were imaged with ICGA because the patient was being evaluated for active, symptomatic neovascularization in their fellow eye. When imaged with the ZEISS 1050nm SS-OCT prototype system and the output processed using the OMAG algorithm, type 1 neovascularization was identified and its location corresponded to the central macular plaque seen on ICGA imaging. In our patients, the presence of MNV would have remained unnoticed if the FA and ICGA had not been done and confirmed by OCT angiography.")

Sanislo, S.R., *Non-Damaging Photothermal Therapy of Non-exudative Age Related Macular Degeneration*, Clinicaltrials.gov (last update March 18, 2020), https://clinicaltrials.gov/ct2/show/NCT02569892

Scholz, P., et al., *A Review of Subthreshold Micropulse Laser for Treatment of Macular Disorders*, 34(7) Adv Ther. 1528–1555 (July 2017) ("Traditional laser photocoagulation has been used to treat different retinal diseases for many years. Here, the endpoint is a visible whitening of the retina due to thermal damage of the retinal pigment epithelium (RPE) and the inner retina. However, apart from the favored therapeutic effect, the treatment can lead to undesirable side effects like visual field defects, epiretinal fibrosis, and choroidal neovascularization (CNV) in the area of the laser scar. The mechanisms which are responsible for the therapeutic effect are still poorly understood. Scarring seems not to be necessary to achieve a therapeutic effect. * * * In subthreshold micropulse laser (SML), diffusion of heat to surrounding tissues is minimized and thereby scarring is prevented. The neural retina can be spared by applying the minimum laser

irradiance (watts per square meter) needed to raise the temperature of the RPE, but without exceeding the protein denaturation threshold. * * * The micropulse operating mode and terminology were described by Dorin.") (citing Dorin)

Sivaprasad, S., et al., *Micropulsed diode laser therapy: evolution and clinical applications* 55(6) Surv Ophthalmol 516–30, 516 (2010). ("The development of the diode laser with micropulsed emission has allowed subthreshold therapy without a visible burn endpoint. This greatly reduces the risk of structural and functional retinal damage, while retaining the therapeutic efficacy of conventional laser treatment. Studies using subthreshold micropulse laser protocols have reported successful outcomes * * *")

Smith, R.T., *Sub-threshold nanosecond laser (SNL) treatment in intermediate AMD (IAMD)*, 4 Annals of Eye Science 1, 4 (2019) ("Subthreshold treatment herein reasonably explores the lower end of the dose-response curve to seek safety while still maintaining a therapeutic response. * * * A startlingly good outcome has now been shown in one study for treatment with sub-threshold nanosecond laser for the non-RPD/SDD phenotype of iAMD, and is contrasted with an apparently poor outcome for the RPD/SDD phenotype.")

Stuart, A., *Clinical Update: OCT-A: A Path to Earlier Diagnosis of AMD*, EyeNet (April 2018) ("[OCT-A] has allowed retina specialists to identify a whole new category of AMD—nonexudative neovascular AMD, [Dr. Philip J. Rosenfeld] said.").

Su, D., et al., *A Review of Subthreshold Micropulse Laser and Recent Advances in Retinal Laser Technology*, 6(1) Ophthalmol. Ther. 1–6 (2017) ("The role of retinal photocoagulation as a first line therapy for

various retinal pathologies has decreased with the introduction of anti-vascular endothelial growth factor therapy. However, retinal laser therapy remains an important treatment modality, especially with the emergence of micropulse subthreshold treatment and the integration of newer technology such as augmented reality and semi-automated delivery. * * * Furthermore, subthreshold laser therapy, a term used to describe the deliverance of laser energy below the threshold of causing permanent tissue destruction, has been shown to alter the metabolic activity and gene expression of the RPE, resulting in the release of growth factors and cytokines that regulate angiogenesis and vascular leakage.")