0 1 2 3 4 5 6 7 United States District Court 8 9 Central District of California 10 UNITED STATES OF AMERICA, et al., Case № 2:17-cv-01903-ODW (SSx) 11 ex rel. DR. KUO CHAO, 12 ORDER DENYING DEFENDANTS' 13 Plaintiffs, **MOTION TO DISMISS [106]** v. 14 15 MEDTRONIC PLC, et al., 16 Defendants. 17 18 I. **INTRODUCTION** 19 This is a case brought under the federal False Claims Act, 31 U.S.C. §§ 3729-20 Defendants Medtronic PLC; Medtronic Vascular, Inc.; Covidien LP, and 21 Covidien Sales LLC (collectively, "Medtronic") move to dismiss Plaintiff-Relator Dr. 22 Kuo Chao's Third Amended Complaint. (Mot., ECF No. 106; Third Am. Compl. 23 ("TAC"), ECF No. 102.) The Motion is fully briefed. (Opp'n, ECF No. 109; Reply, 24

ECF No. 111.) After carefully considering the papers filed in connection with the

Motion, the Court deemed the matter appropriate for decision without oral argument.

Fed. R. Civ. P. 78; C.D. Cal. L.R. 7-15. For the following reasons, the Court **DENIES**

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Medtronic's Motion.

II. FACTUAL BACKGROUND

For purposes of this Rule 12(b)(6) motion, the Court accepts Dr. Chao's well-pleaded allegations as true. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001).

Medtronic is the manufacturer of a medical device called the Pipeline, a flexible cylinder-shaped medical device that is surgically inserted at the site of a brain aneurysm to help treat the aneurysm and its associated symptoms. (TAC ¶¶ 29–40.) Doctors order Pipeline devices for their patients; Medtronic provides the devices to the hospitals where the doctors work; and the hospitals seek reimbursement for the Pipeline device from Medicare, Medicaid, and other government health care programs. (*See* TAC ¶¶ 45–46.) Dr. Chao alleges that these reimbursements are tainted with fraud because they are the result of a multifaceted kickback scheme in which Medtronic compensates doctors to induce them to order a greater number of Pipeline devices for their patients. (*See* TAC ¶ 9.)

The kickbacks Dr. Chao alleges take four forms. First, Dr. Chao alleges that Medtronic maintains a proctoring program through which it regularly overpays doctors for professional services. Through the proctoring program, Medtronic hires doctors with experience inserting Pipelines as proctors to teach other doctors how to perform the Pipeline procedure, in part by being present for and supervising the procedure when performed by the trainee doctor. These proctors are themselves doctors with their own practices, and the gravamen of Dr. Chao's accusation is that Medtronic systematically and habitually overpays its proctors for their proctoring services, which functions as a disguised kickback meant to incentivize the doctors to order more Pipelines for their own practices. (TAC ¶ 107–130.) As an example, Dr. Chao sets forth allegations regarding one Dr. Woodward, who took excessive payments for both himself and his companies in exchange not only for his proctoring and medical data analysis services but also as a disguised kickback for continuing to use a high volume of Pipeline devices in his own practice. (TAC ¶ 248–257.)

Second, Dr. Chao alleges that Medtronic acquired, at an inflated rate, companies in which doctors with a high volume of Pipeline usage held ownership interests. The result of these acquisitions was that the doctors received a substantial windfall which significantly exceeded the fair market value of their ownership interests. These windfalls, Dr. Chao argues, constitute a kickback that improperly induced these doctors to perform more Pipeline procedures. (TAC ¶¶ 204–240.)

Third, Dr. Chao alleges that Medtronic maintained two data collection registries, IntrePED and ASPIRe, that it also used to disguise kickback payments to its Pipelineusing doctors. Medtronic asked doctors who performed Pipeline procedures to upload a small amount of patient- and procedure-related data to these registries in exchange for a substantial payment. This data was very easy for doctors to gather, and Medtronic paid the doctors for this data in excess of both the fair market value of the data and the value of the doctors' collection efforts. This excess, Dr. Chao alleges, constitutes a kickback. (TAC ¶¶ 170–203.)

Fourth, Dr. Chao alleges that Medtronic distributed illegal kickbacks to doctors and hospitals disguised as fellowships, grants, and research funds. Medtronic distributed these funds based in part on the doctors' or hospitals' volume of Pipeline usage. Thus, Dr. Chao alleges, these fellowships, grants, and research funds functioned as improper direct compensation for using more Pipeline devices—the very definition of a kickback. (TAC ¶¶ 241–262.)

III. PROCEDURAL BACKGROUND

Dr. Chao is a medical doctor with experience in the treatment of aneurysms and is currently affiliated with the Kaiser Permanente Los Angeles Medical Center. (TAC ¶ 17.) He became aware of Medtronic's business practices through his personal experience as a doctor interacting with Medtronic personnel and proctors. (TAC ¶ 18.) On March 9, 2017, believing Medtronic's business activity to constitute a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the associated government health care program reimbursements to therefore constitute a fraud on the government, Dr.

Chao, as Plaintiff-Relator, filed a False Claims Act Complaint against Medtronic. (Compl., ECF No. 1.) According to Dr. Chao, Medtronic charges the government twelve to fifteen thousand dollars per Pipeline device and, as a result of Medtronic's kickback scheme, millions of dollars in government health care claims have been tainted with fraud. (TAC ¶¶ 7–9.) He sets forth a claim under the federal False Claims Act, 31 U.S.C. § 3729, and twenty-eight analogous state-law claims arising from various state versions of the False Claims Act.

The case remained sealed for some time, and on May 28, 2020, the United States provided notice that it and all state plaintiffs declined to intervene.¹ (Notice, ECF No. 41.) On May 29, 2020, the Court entered an Order unsealing the case. (Order re: Election, ECF No. 42.)

Shortly thereafter, the case was transferred to Judge Scarsi. On December 4, 2020, Dr. Chao filed a First Amended Complaint. (First Am. Compl. ("FAC"), ECF No. 59.) Medtronic moved to dismiss, and on April 12, 2021, Judge Scarsi dismissed all Dr. Chao's claims and provided leave to amend. (Order Mot. Dismiss FAC, ECF No. 80.) Dr. Chao proceeded to file his Second Amended Complaint, (ECF No. 81), and on May 21, 2021, the case was transferred to this Court, (ECF No. 91). On June 29, 2021, pursuant to the Court's order granting leave, Dr. Chao filed the now-operative Third Amended Complaint.

On August 2, 2021, Medtronic moved to dismiss the TAC pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6), on the grounds that Dr. Chao failed to correct the deficiencies that supported dismissal of the FAC and that he otherwise continues to fail to state a claim. (Mot. 1–3.) At the same time Dr. Chao opposed, the United States filed a Statement of Interest arguing that Dr. Chao states a claim for False Claims Act violations and urging the Court to deny Medtronic's Motion. (Statement of Interest, ECF No. 108.) After Medtronic replied and the Court took the matter under submission,

¹ Pursuant to the Maryland False Claims Act, the effect of this Notice was to require dismissal of the Maryland False Claims Act claim. Md. Code Ann., Health-Gen. § 2-604(a)(7); (see Order re: Election, ECF No. 42 (dismissing Maryland False Claims Act claim without prejudice)).

Dr. Chao filed a Notice of Supplemental Authority. (ECF No. 113.) The Court invited Medtronic's response, (Min. Order, ECF No. 115), which Medtronic provided on October 27, 2021, (Resp., ECF No. 117).

IV. LEGAL STANDARD

A court may dismiss a complaint under Rule 12(b)(6) for lack of a cognizable legal theory or insufficient facts pleaded to support an otherwise cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). A complaint need only satisfy the minimal notice pleading requirements of Rule 8(a)(2)—a short and plain statement of the claim—to survive a dismissal motion. *Porter v. Jones*, 319 F.3d 483, 494 (9th Cir. 2003). The factual "allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding that a claim must be "plausible on its face" to avoid dismissal).

The determination of whether a complaint satisfies the plausibility standard is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. A court is generally limited to the pleadings and must construe all "factual allegations set forth in the complaint . . . as true and . . . in the light most favorable" to the plaintiff. *Lee*, 250 F.3d at 679. However, a court need not blindly accept conclusory allegations, unwarranted deductions of fact, and unreasonable inferences. *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). Ultimately, there must be sufficient factual allegations "to give fair notice and to enable the opposing party to defend itself effectively," and the "allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011).

V. DISCUSSION

As a preliminary matter, the government's decision not to intervene has no relevance to the resolution of this Motion. This is because "[i]n any given case, the

government may have a host of reasons for not pursuing a claim." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006). While the government did not intervene, it also did not seek to have this case dismissed, as it had the right to do. *See* 31 U.S.C. § 3730(c)(2)(A). "[T]he simple fact that the government did not intervene has no probative value and is not relevant," *United States ex rel. El-Amin v George Washington Univ.*, 533 F. Supp. 2d 12, 21 (D.D.C. 2008), including at the pleading stage, and the Court should not and will not consider the government's election in determining whether Dr. Chao states a claim.

Substantively, the parties do not dispute the basic legal framework supporting Dr. Chao's claims. As is relevant to this case, the federal Anti-Kickback Statute provides civil liability for those who "knowingly and willfully solicit[], receive[], offer[], or pay[] any remuneration (including any kickback, bribe, or rebate) . . . in return for purchasing . . . or arranging for or recommending purchasing" a medical device subject to reimbursement under a federal health care program such as Medicare or Medicaid. 42 U.S.C. § 1320a-7b(b)(1). A payor violates the Anti-Kickback Statute whenever one purpose of the remuneration was to induce future referrals or orders, "even if the payments were also intended to compensate for professional services." *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1053 (C.D. Cal. 2016) (quoting *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989)). The False Claims Act, in turn and in relevant part, makes it unlawful for any person to (1) "knowingly . . . cause[] to be presented[] a false or fraudulent claim for payment or approval"; (2) knowingly cause a false statement to be made or used in such a claim; or (3) conspire to accomplish (1) or (2). 31 U.S.C. § 3729(a)(1)(A)–(C).

When the procurement of medical supplies is tainted by a knowing violation of the Anti-Kickback Statute and the violator knows those supplies are subject to reimbursement by a federal health care program, the submission to the government of a reimbursement claim for those supplies turns the Anti-Kickback Statute violator into a False Claims Act violator as well. 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes

items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the federal False Claims Act]."); *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96 (3d Cir. 2018) (confirming that the purpose of this amendment to the False Claims Act is to "strengthen[] whistleblower actions based on medical care kickbacks" and "to ensure that *all* claims resulting from illegal kickbacks are considered false claims" (quoting 155 Cong. Rec. S10852–54 (daily ed. Oct. 28, 2009) (statement of Rep. Kaufman))). Kickbacks taint medical judgment, which is material to the government's decision to pay a particular claim. *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53, 54 (D. Mass. 2011) (collecting cases). To submit a claim tainted by a kickback "is in effect to ask the government to fund criminality retroactively, a result specifically proscribed by the Anti–Kickback Statute." *Id.* at 55.

The parties also agree that Rule 9(b)'s requirement that fraud be pleaded "with particularity" applies to False Claims Act claims. (See Mot. 7; Opp'n 6–7); see Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1054 (9th Cir. 2011). "This means the plaintiff must allege the who, what, when, where, and how of the misconduct charged, including what is false or misleading about a statement, and why it is false. Knowledge, however, may be pled generally." United States v. United Healthcare Ins. Co., 848 F.3d 1161, 1180 (9th Cir. 2016) (cleaned up²); see also United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., 953 F.3d 1108, 1122 (9th Cir. 2020) ("A complaint needs only to allege facts supporting a plausible inference of scienter.").

The False Claims Act "does not require absolute particularity or a recital of the evidence," and "a complaint need not allege a precise time frame, describe in detail a

² This Order uses (cleaned up) to indicate that internal quotation marks, alterations, and citations have been omitted from quotations. *See, e.g., Mo. State Conference of the Nat'l Assn. for the Advancement of Colored People v. Ferguson-Florissant Sch. Dist.*, 894 F.3d 924, 930 (8th Cir. 2018); *United States v. Reyes*, 866 F.3d 316, 321 (5th Cir. 2017); *Guevara v. Chaffey Joint Union High Sch. Dist.*, No. ED CV 20-1929 FMO (SPx), 2021 WL 4439230, at *4 (C.D. Cal. Aug. 10, 2021).

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single specific transaction[,] or identify the precise method used to carry out the fraud." *Id.* Similarly, a relator is not required to recite the details of "representative examples of false claims"; it is enough to allege the details of the scheme itself "paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.*

Beyond these basic agreements, though, Dr. Chao and Medtronic largely argue past one another. Medtronic argues that Dr. Chao fails to address the deficiencies the Court described in its Order dismissing Dr. Chao's FAC. (Mot. 2–3.) And while Dr. Chao argues that his new allegations address the previously described deficiencies, he nevertheless maintains that the legal standards previously applied were too stringent or otherwise erroneous. (*See* Opp'n 8, 21.)

This Court finds it appropriate to conduct an analysis of the TAC from the ground up, unbound by any prior legal determinations made in connection with a now-inoperative pleading. *See Balla v. Idaho State Bd. of Corr.*, 869 F.2d 461, 465 (9th Cir. 1989) (confirming courts have inherent power to modify interlocutory orders before entering a final judgment); *see also United States v. Desert Gold Mining Co.*, 433 F.2d 713, 715 (9th Cir. 1970) (affirming second judge's vacating of first judge's summary judgment order, where second judge had taken over case after first judge's passing). In so doing, this Court finds that Dr. Chao states a claim for a health care kickback and reimbursement scheme that is "plausible on its face." *Iqbal*, 556 U.S. at 678.

1. Dr. Chao states a plausible, particularized claim for an illegal health care reimbursement kickback scheme and a corresponding False Claims Act violation.

The elements of a False Claims Act claim are "1) a false statement or fraudulent course of conduct, 2) made with scienter, 3) that was material, causing 4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902 (9th Cir. 2017). The disputed elements here are the first and third—whether Medtronic engaged in a materially fraudulent course of conduct. As for the other elements, scienter (that is, knowledge) need not be pleaded

with particularity, and no one disputes that the government actually did pay out money to healthcare providers who submitted claims for Pipeline devices.

The question whether Medtronic engaged in a materially fraudulent course of conduct is no more and no less than the question whether it violated the Anti-Kickback Statute, so the issue is whether Dr. Chao sufficiently alleges Medtronic's violation of the Anti-Kickback Statute. The elements of the Anti-Kickback Statute violation Dr. Chao asserts are as follows: "(1) [the defendant] knowingly and willfully makes a payment (2) as inducement to the payee (3) to purchase or recommend for purchase (4) any good or service that is reimbursable under a federal healthcare program." *Brown*, 226 F. Supp. 3d at 1053 (citing *United States v. Miles*, 360 F.3d 472, 479–80 (5th Cir. 2004)). The parties do not dispute that Rule 9(b) requires parties to plead the Anti-Kickback Statute violations underlying the False Claims Act claim with particularity. (*See* Mot. 7; Opp'n 6–7.) What the parties dispute is exactly how much particularity is required.

Dr. Chao pleads each of the elements of an Anti-Kickback Statute violation sufficiently and with sufficient particularity. He alleges that Medtronic routinely paid doctors who proctored Pipeline procedures a \$3,200 stipend based on eight hours per day at \$400 per hour for a procedure that is known to take less than two hours. (TAC ¶ 133.) It may be, as Medtronic argues, that these proctors indeed worked an eight-hour day or its equivalent providing ancillary services and that these \$3,200 payments therefore represent fair market value for proctor services and not an illegal kickback disguised as a payment for services. However, it is also plausible that these payments were overpayments, and as such, it is equally plausible that Medtronic intended that these overpayments induce their proctors to utilize more Pipeline devices in their own practices.

The Court must stop there; Dr. Chao alleges the kickback scheme in sufficient detail, and no more is required. Rule 12(b)(6) Motions are not for resolving factual disputes, *Arellano v. Santos*, No. 3:18-cv-02391-BTM-WVG, 2020 WL 1275650, at *3

(S.D. Cal. Mar. 16, 2020), nor are they for testing whether the plaintiff will be able to "find evidence to support the pleadings," *Tracy v. United States*, 243 F.R.D. 662, 664 (D. Nev. 2007) (citing *Lee*, 250 F.3d at 688). For these reasons, at this stage the Court declines to enter into an inquiry about specific individual payments to doctors, (*see*, *e.g.*, TAC ¶ 141), or how Dr. Chao first learned about these potential overpayments to proctors, (*see id.* ¶ 137). These are granular evidentiary facts, and whether or not they are included in the TAC means very little in determining whether Dr. Chao alleges a kickback scheme with particularity. Dismissing Dr. Chao's claim based on the insufficiency of these granular facts would signal that the Court was not "accept[ing] the[] allegations as true and draw[ing] all reasonable inferences in [Dr. Chao's] favor," *Lee*, 250 F.3d at 690, and was instead testing the truth of Dr. Chao's allegations by weighing evidence.

2. The personal services safe harbor does not defeat Dr. Chao's claims.

Medtronic nevertheless argues that Dr. Chao fails to plead Medtronic's noncompliance with the Anti-Kickback Statute's personal services safe harbor provision. This argument is based on a provision of the Anti-Kickback Statute that, for purposes of this case, provides³ an exception to liability under the Anti-Kickback Statute when, among other things,

[t]he aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in armslength transactions and is not determined in a manner that takes into account the volume or value of any referrals or business between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

42 C.F.R. § 1001.952(d)(5). This safe harbor also requires that "[t]he aggregate services contracted for do not exceed those which are reasonably necessary to

³ The personal services safe harbor was amended effective January 19, 2021. 85 Fed. Reg. 77,684 (Dec. 2, 2020). The parties do not dispute that the prior version of the personal services safe harbor quoted herein is the one that governs this dispute.

accomplish the commercially reasonable business purpose of the services." 42 C.F.R. § 1001.952(d)(7).

Medtronic argues that the Court must dismiss the TAC because Dr. Chao fails to address the potential applicability of this safe harbor, including principally by failing to allege that the payments Medtronic made to its proctors exceeded the fair market value of the proctors' services. Medtronic's position on this issue, however, is somewhat internally inconsistent. On one hand, Medtronic admits, as the United States urges, that fair market value, or lack thereof, is not an element of an Anti-Kickback Statute claim. (Reply 6 (expressly conceding as much); Statement of Interest 6–8.) On the other hand, Medtronic argues that Dr. Chao fails to "negate the safe harbor" with his allegations, (Mot. 17), suggesting that it is Dr. Chao's burden to plead specific facts negating the safe harbor.

The parties frame this issue as whether the personal services safe harbor is an affirmative defense, but this argument misses the issue's essence. To be sure, by pleading that Medtronic's kickbacks were also payments for the proctors' personal services, Dr. Chao raises the question of whether these personal services qualified for the Anti-Kickback Statute's safe harbor. *Accord U.S. Commodity Futures Trading Comm'n v. Monex Credit Co.*, 931 F.3d 966, 972 (9th Cir. 2019) (explaining that courts may "consider an affirmative defense on a motion to dismiss when there is some obvious bar to securing relief on the face of the complaint" (internal quotation marks removed)), *cert. denied*, 141 S. Ct. 158 (2020). Therefore, regardless of whether this safe harbor is an affirmative defense, Dr. Chao must allege facts that make it plausible that the safe harbor will not defeat his claim. *See id.* ("[D]ismissal based on an affirmative defense is permitted when *the complaint* establishes the defense."). And he must allege these facts with particularity. Fed. R. Civ. P. 9(b). This is not the same as what Medtronic wants the Court to require Dr. Chao to do: set forth the negation of one or more of the elements of the affirmative defense with particularity.

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Here, it is plausible based on Dr. Chao's allegations that the payments and benefits Medtronic provided its proctors exceeded the fair market value of the services the proctors provided. Thus, it is plausible that the personal services safe harbor does not apply. The Court need go no further; the affirmative defense does not, at this stage, defeat the claim.

Moreover, as the United States points out, even some fair-market-value payments will qualify as illegal kickbacks, such as when the payor has considered the volume of reimbursable business between the parties in providing compensation and otherwise intends for the compensation to function as an inducement for more business. (Statement of Interest 7); see United States ex rel. STF LLC v. Vibrant Am. LLC, No. 16cv-2487-JCS, 2020 WL 4818706, at *7 (N.D. Cal. 2020) (noting that remuneration may violate the Anti-Kickback Statute "regardless of whether the payment is fair market value for services rendered"); 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) (explaining that, under the Anti-Kickback Statute, "neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business)."). Here, Dr. Chao alleges that Medtronic's practice of engaging and paying proctors was a "system . . . designed to reward doctors for using Pipelines," perpetuated by an aggressive sales team co-opting purported clinical programs in order to pay highvolume physicians as remuneration for their Pipeline usage. (TAC ¶ 129.) This is a plausible assertion which, if true, would take the payments out of the safe harbor, regardless of whether those payments were made at fair market value. Accord United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.3d 20, 31 (1st Cir. 1989) (observing that the personal services safe harbor exempts "only a small subset" of fair market value transactions).

For these reasons, the Court finds that Dr. Chao states a plausible, particularized claim for Medtronic's violations of the federal False Claims Act. In reaching this conclusion, the Court focused primarily on Dr. Chao's allegations regarding

Medtronic's proctoring program. At this phase, the Court need not and does not determine whether the other alleged aspects of the kickback scheme—purchasing companies at inflated prices, overpaying Pipeline-utilizing doctors for cheap data, and providing fellowships and grants as inducement for Pipeline usage—are validly a part of Dr. Chao's claims.

To complete the analysis, both parties appear to agree, at least for now, that Dr. Chao's twenty-seven remaining state-law analogue claims all rise or fall with his federal claim. (Mot. 25; *see generally* Opp'n.) Accordingly, the entire TAC survives, and Medtronic's Motion to Dismiss is **DENIED** in its entirety.

VI. CONCLUSION

For these reasons, Medtronic's Motion to Dismiss the Third Amended Complaint is **DENIED**. (ECF No. 106.) Medtronic shall answer within **twenty-one (21) days**.

IT IS SO ORDERED.

February 23, 2022

OTIS D. WRIGHT, II UNITED STATES DISTRICT JUDGE