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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,  
*et al., ex rel. DR. KUO CHAO,*

Plaintiffs,

v.

MEDTRONIC PLC, MEDTRONIC  
VASCULAR, INC., MEDTRONIC  
USA, INC., COVIDIEN LP, AND  
COVIDIEN SALES LLC,

Defendants.

Case No. 2:17-cv-01903-MCS-SS

**ORDER GRANTING IN PART AND  
DENYING IN PART MOTION TO  
DISMISS [67]**

Defendants Medtronic PLC, Medtronic Vascular, Inc., Medtronic USA, Inc., Covidien LP, and Covidien Sales LLC move to dismiss Plaintiff Relator Dr. Kuo Chao's First Amended Complaint (FAC, ECF No. 59). (Mot., ECF No. 67.) The matter is fully briefed. (Opp'n, ECF No. 75, Reply ECF No. 77.) The Court deems this matter appropriate for decision without oral argument. *See* Fed. R. Civ. P. 78; C.D. Cal. L.R. 7-15. For the following reasons, the motion is granted in part and denied in part.

## 1 I. BACKGROUND

2 On March 9, 2017, Plaintiff Relator Dr. Kuo Chao (“Relator”), standing in the  
3 shoes of the United States of America, the District of Columbia, and several States<sup>1</sup>  
4 (collectively, the “Government”), filed a *qui tam* action against Defendants Medtronic  
5 PLC, Medtronic Vascular, Inc., Covidien LP, Covidien Sales LLC, EV3, Inc., and  
6 Micro Therapeutics, Inc. (Compl., ECF No. 1.) The Government declined to intervene  
7 on May 28, 2020. (Election, ECF No. 41.) By stipulation of the parties, on December  
8 4, 2020, Relator filed the operative First Amended Complaint (“FAC”). (FAC, ECF No.  
9 59.) The FAC asserts a claim for violation of the federal False Claims Act (“FCA”), 31  
10 U.S.C. § 3729 *et seq.*, as well as analogous state claims, against Medtronic PLC,  
11 Medtronic Vascular, Inc., Medtronic USA, Inc., Covidien LP, and Covidien Sales LLC  
12 (collectively, “Defendants”). (*Id.*) Specifically, Relator alleges that Defendants  
13 promoted a medical device with an aggressive sales program that utilized illegal  
14 kickbacks and simultaneously caused to be submitted false claims for reimbursement  
15 from Medicaid, Medicare, or other federal and state health care programs.

### 16 A. The Parties

17 Dr. Kuo Chao is a physician specializing in neuroradiology and has experience  
18 with the treatment of aneurysms. (FAC ¶ 17.) Through his work, Relator learned the  
19 facts that form the basis of this action. (*Id.* ¶ 18.) Defendants Covidien LP and Covidien  
20 Sales LLC are organized under the laws of Delaware with principal place of business  
21 in Massachusetts. (*Id.* ¶¶ 19–20.) Both entities were subsidiaries of Covidien PLC until  
22 January 2015, at which time all Covidien entities were purchased by Medtronic PLC.

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23  
24 <sup>1</sup> The States are as follows: State of California, State of Colorado, State of  
25 Connecticut, State of Delaware, State of Florida, State of Georgia, State of Hawaii,  
26 State of Illinois, State of Indiana, State of Iowa, State of Louisiana, State of Maryland,  
27 Commonwealth of Massachusetts, State of Michigan, State of Minnesota, State of  
28 Montana, State of Nevada, State of New Jersey, State of New Mexico, State of New  
York, State of North Carolina, State of Oklahoma, State of Rhode Island, State of  
Tennessee, State of Texas, State of Vermont, Commonwealth of Virginia, and State of  
Washington.

1 (*Id.*) Defendant Medtronic PLC is a company organized under the laws of Ireland, with  
2 principal place of business in Dublin, Ireland, and a United States headquarters in  
3 Minnesota. (*Id.* ¶ 21.) Defendant Medtronic Vascular, Inc. is a corporation organized  
4 under the laws of Delaware, with principal place of business in Santa Rosa, California,  
5 and is a subsidiary of Medtronic PLC. (*Id.* ¶ 22.) Defendant Medtronic USA, Inc. is a  
6 corporation organized under the laws of Minnesota, with its principal place of business  
7 in Minneapolis, Minnesota, and is also a subsidiary of Medtronic PLC. (*Id.* ¶ 23.)

### 8 **B. Relevant Medical Information**

9 The backdrop of this action concerns aneurysms and one FDA approved method  
10 for their treatment, the “Pipeline.” “An aneurysm is a blood-filled bulge in the wall of  
11 a blood vessel” and “result[s] when the pressure of blood within the blood vessel causes  
12 a weak area of the vessel wall to expand and fill with blood.” (*Id.* ¶ 29.) “A Pipeline is  
13 a flexible mesh cylinder that expands to take on and reinforce the shape of the blood  
14 vessel in which it is placed,” which reduces risk of rupture and also decreases aneurysm  
15 size over time. (*Id.* ¶¶ 33, 36.) The FDA approved the first version of Pipelines promoted  
16 by Defendants in 2011, then approved an updated version in 2015. (*Id.* ¶ 38.)

17 Under Medicare, reimbursement is available after hospitals submit claims for  
18 services delivered to beneficiaries on two forms, Form CMS-1450 and Form CMS-  
19 2552, and after doctors submit claims through Form CMS-1500. (*Id.* ¶ 44.) Medicare  
20 provides that “‘no payment may be made’ for a device that is not ‘reasonable and  
21 necessary’ for . . . treatment.” (*Id.* ¶ 49 (citing 42 U.S.C. § 1395y(a)(1)(A)).) Other  
22 health programs, such as Medicaid, TRICARE, and CHAMPVA similarly provide for  
23 reimbursement of medical expenses. (*Id.* ¶¶ 51–55.) Part and parcel to these  
24 reimbursements are an agreement to abide by all relevant legal strictures, including the  
25 Anti-Kickback Statute (“AKS”). (*Id.* ¶¶ 66–73.)

### 26 **C. Defendants’ Alleged Misconduct**

27 From sometime in 2011 through the filing of the FAC, Defendants allegedly gave  
28 kickbacks to doctors and induced the filing of false claims for “tens of millions of

1 dollars.” (*Id.* ¶¶ 92–93.) These alleged kickbacks include proctoring fees, mini-  
2 vacations at lavish resorts, paid travel expenses without travel, investments in side  
3 businesses, excessive payments for data collection, funding awards to hospitals and  
4 doctors in the form of grants and fellowships, prominent research roles, and hiring  
5 doctor-owned companies to work on Defendants’ studies. (*Id.* ¶ 93.)

6 1. The Kickback Schema

7 a. Proctoring Program

8 Relator alleges Defendants disguised kickbacks to doctors as compensation for  
9 their provision of proctoring services, such as overseeing Pipeline procedures or  
10 performing Pipeline research. (*Id.* ¶ 94.) The proctor program began in 2011 and  
11 approximately fifty-five doctors participated. (*Id.* ¶ 95.) To become a proctor, doctors  
12 had to perform at least ten operations using the Pipeline (resulting in approximately  
13 \$224,000 worth of Pipeline sales for Defendants). (*Id.* ¶ 103.) Relator describes various  
14 payment structures, such as \$4,000 to \$5,000 per proctored operation, (*id.* ¶ 104), and  
15 \$400 to \$500 for every hour worked, (*Id.* ¶ 107). Relator alleges that “Defendants . . .  
16 habitually and systematically overpa[id] doctors for a full, eight-hour day of work  
17 regardless of how little time the proctor worked.” (*Id.* ¶ 108.) Defendants also paid  
18 proctors a travel stipend, up to \$1,400, which Relator alleges was paid “even when the  
19 doctor worked at his or her home hospital and did not travel.” (*Id.* ¶ 109.)

20 As a result, “Defendants routinely paid their proctors \$4,600 per day . . . for work  
21 and travel – even when the doctor worked as little as one or two hours and did not travel  
22 at all.” (*Id.* ¶ 110.) To support that allegation, Relator points out that (according to public  
23 data) Defendants, between 2013 and 2015, had 266 exact payments for \$4,600 out of a  
24 possible 8,484 payments and was “by far the most common dollar amount for payments  
25 from the Defendants to physicians” so long as one ignores “numerous payments  
26 reported as \$10, apparently made for incidental expenses incurred while working or  
27 travelling.” (*Id.*) Relator further alleges that, in addition to these cash payments,  
28 Defendants also provided proctors “mini-vacations” disguised as trainings in “posh . . .

1 luxury resorts.” (*Id.* ¶¶ 100–01.) “Because of the cash payments, travel, and other  
2 kickbacks . . . physicians had strong incentives to become proctors.” (*Id.* ¶ 102.)

3 b. Purchases of Companies

4 Relator’s second alleged kickback scheme is Defendants’ targeted purchase of  
5 companies in which high-volume Pipeline usage doctors held financial interests. (*Id.* ¶  
6 126.) Relator points to three such acquisitions: Covidien’s purchase of Nfocus  
7 Neuromedical, Inc., in 2013, Medtronic’s purchase of Lazarus Effect in 2015, and  
8 Medtronic’s purchase of RIST Neurovascular in 2020. (*Id.* ¶¶ 127, 129, 131.) Relator  
9 alleges that after the acquisitions of Nfocus Neuromedical, Inc., and Lazarus Effect,  
10 Medtronic “essentially shelved” development of those companies’ products and  
11 technology. (*Id.* ¶¶ 128, 130.) As a result of these purchases, several doctors would have  
12 received payments. (*Id.* ¶ 129.)

13 c. Data Collection Registries

14 Relator’s third alleged kickback scheme is Defendants’ use of data collection  
15 programs to provide payments to participating doctors. (*Id.* ¶ 132.) Defendants would  
16 ask for “only a small amount of data” which “did not take a significant amount of a  
17 physician’s time” to gather and paid between \$1,000 to \$1,500 for such data. (*Id.* ¶¶  
18 132–33.) Relator alleges all the gathered information from doctors was already in  
19 Defendants’ possession, due to the presence of sales personnel at Pipeline procedures.  
20 (*Id.* ¶¶ 134–35.) These data were ostensibly related to two of Defendants’ studies,  
21 IntrePED and ASPIRe. (*Id.* ¶ 137.) Allegedly, Defendants never conducted preliminary  
22 studies to gauge the efficacy of these two studies. (*Id.* ¶ 139.) As such, they were  
23 “cover” for kickbacks. (*Id.*)

24 d. Fellowships, Grants and Research

25 Relator’s fourth alleged kickback scheme is Defendants’ distribution of funds  
26 through fellowships, grant money, and prominent research roles, based on their Pipeline  
27 usage, which in turn caused doctors to use more Pipelines. (*Id.* ¶ 140.) When awarding  
28 funding, Relator alleges “Defendants’ executives . . . would commonly ask Defendants’

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