AO 91 (Rev. 11/82)		CRIMINAL C	COMPLAINT	OLEDIK I	FILED
UNITED STATES DISTRICT COURT			CENTRAL DISTRICT OF CALIFORNIA		
UNITED STATES OF AMERICA v.			DOCKET NO.	CENTRAL D	STRICT COMPANY
RANDALL J. JETT, also known as Randy Jett			MAGISTRATE'S CASE NO.	6)	
			SA16-3	32 M	
Complaint for violation o			_		
NAME OF MAGISTRATE JUDGE				LOC	ATION
HONORABLE KAREN E. S		UNITED STATES MAGISTRATE JUDGE		nta Ana, California	
DATE OF OFFENSE	PLACE OF C	PFFENSE	ADDRESS OF ACCUSED (IF K		
On or about August 28, 2014	Orange (County			
On of about August 2 RANDALEJ. JEPT, also kn money, to Dr. M.R., DPM, to the furnishing, of any item of care program, namely Tricare	8, 2014, in own as Ran o refer an increase for	Orange County, dy Jett, knowing dividual, namel	y, P.P., to a person for	ed to pay r	emuneration, that is,
BASIS OF COMPLAINANT'S CHARGE AGAINST THE ACCUSED: (See attached Affidavit which is incorporated herein by this reference as part of this Complaint)					
(See attached Affiday	it which is	incorporated he	rein by this reference a	is part of th	is Complaint)
MATERIAL WITNESSES IN RELATION T	O THIS CHARGE	: N/A			
Poing duly gworn I declare	hat the	SIGNATURE OF COMPLAINANT			
Being duly sworn, I declare that the foregoing is true and correct to the best of my knowledge.		MONICA PANDIS S			
		OFFICIAL TITLE Special Agent – Federal Bureau of Investigation			
Sworn to before me and subscribed in my presence,					
SIGNATURE OF MAGISTRATE JUDGE ⁽¹⁾					DATE
ISI	KAREN E. SCOTT	Ī		June Z9 2016	

AFFIDAVIT

I, MONICA PANDIS, being duly sworn, declare and state as follows

I. AFFIANT'S BACKGROUND

1. I am a Special Agent ("SA") of the Federal Bureau of Investigation ("FBI"). I have been so employed since approximately June 2002. I am currently assigned to the white collar crime squad of the Orange County Resident Agency of the Los Angeles FBI Field Division, which investigates allegations of Public Corruption and Health Care Fraud. Over that past 14 years I have been assigned to investigate Health Care Fraud. As an FBI SA, I have investigated over 50 health care fraud and other white-collar cases including cases involving the payment of illegal kickbacks affecting federal health care programs. Before becoming an FBI SA, I was a medical social worker assigned to hospice and pediatric HIV patients. I have a Master's Degree in Social Work, a Bachelor's Degree in Behavioral Science and a Minor in Criminal Justice and Corrections.

II. PURPOSE OF AFFIDAVIT

- 2. This affidavit is made in support of a complaint and request for the issuance of an arrest warrant charging Randall J. Jett, aka Randy Jett, with Illegal Remunerations for Health Care Referrals, in violation of 42 U.S.C. § 1320a-7b(b)(2)(A).
- 3. The facts set forth in this affidavit are based upon my personal observations, my training and experience, documents obtained from various sources including financial institutions,

information obtained from various law enforcement personnel, and from witnesses. This affidavit is intended to show only that there is probable cause to support the referenced complaint and request for issuance of an arrest warrant for JETT. It does not purport to set forth all of my knowledge of or investigation into this matter, nor is it intended to provide all of the information obtained in connection with the investigation. Also, unless specifically indicated otherwise, all conversations and statements described in this affidavit are related in substance and in part only, and are not verbatim.

III. SUMMARY OF PROBABLE CAUSE

4. Based upon the evidence and information stated herein, I have probable cause to believe that JETT offered to pay illegal remuneration, namely, a kickback, to a podiatrist to prescribe medication. JETT's offer occurred at the time of an enormous uptick in claims, many of them fraudulent, made by pharmacies for Tricare reimbursements for filling compounded medications prescriptions. Those pharmacies had agreed to pay referral fees to so-called marketers in exchange for steering those prescriptions to the pharmacies. I have probable cause to believe those referral fees were also illegal kickbacks.

IV. STATEMENT OF PROBABLE CAUSE

A. BACKGROUND

TRICARE1

"In 1994, Tricare replaced CHAMPUS as the health care program for active-duty military personnel, retirees, and their families. See http://www.Tricare.mil/faqs/question . . . ," U.S. ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 318, note 5 (D. Mass. 2011), as a "comprehensive managed health care program for the delivery and financing of health care services in the Military Health System," see 32 C.F.R. § 199.17(a). Tricare is applicable to all of the uniformed services. 32 C.F.R. § 199.17(a)(3). "[A]11 CHAMPUS-eligible beneficiaries who are not Medicare eligible on the basis of age are eligible to enroll in" a Tricare program. 32 C.F.R. § 199.17(c). Tricare is a "health care benefit program" as defined by 18 U.S.C. § 24(b), that affects commerce, see Taylor v. United States, 89 F.Supp.3d 766, n. 1 (E.D.N.C. 2014), and as that term is used in 18 U.S.C. § 1347. Tricare is administered by the Defense Health Agency ("DHA").

Compounded Medications

6. During the course of this investigation, I have learned from reviewing documents, witness interviews, and

 $^{^{1}}$ Statutory and case citations and legal analysis have been prepared by the Assistant U.S. Attorney with whom I am working on this investigation. I have relied upon those citations and that analysis in support of this affidavit.

speaking with other investigators involved in the investigation, that:

- a. In general, "compounding" is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug or multiple drugs to create a drug tailored to the needs of an individual patient.
- b. Compounded drugs are not FDA-approved, that is, the FDA does not verify the safety, potency, effectiveness, or manufacturing quality of compounded drugs. The California Board of Pharmacy regulates the practice of compounding in the State of California.
- c. Compounded drugs may be prescribed when an FDAapproved drug does not meet the health needs of a particular
 patient. For example, if a patient is allergic to a specific
 ingredient in an FDA-approved medication, such as a dye or a
 preservative, a compounded drug can be prepared excluding the
 substance that triggers the allergic reaction. Compounded drugs
 may also be prescribed when a patient cannot consume a
 medication by traditional means, such as an elderly patient or
 child who cannot swallow an FDA-approved pill and needs the drug
 in a liquid form that is not otherwise available.
- d. The compounded medication prescriptions in this case were ostensibly prescribed for the treatment of pain, scarring, stretch marks, erectile dysfunction, or for "general wellness." The prescriptions were based on substantially

similar 8 1/2" x 11" forms with check-the-box sections that described the chemical compounds for each of these conditions. Although it may be possible, I have reviewed hundreds of these forms, and discussed well over a thousand of these forms with other agents involved in this and related investigations, and I am not aware of any instances in which a prescribing physician altered the pre-formulated prescriptions to suit the individual needs of any patient.

Anti-Kickback Statute

- 7. The federal health care anti-kickback statute, at 42 U.S.C. § 1320a-7(b)(2)(A), ("AKS") prohibits the offer or payment of any remuneration (including any kickback, bribe, or rebate) for referrals in connection with federal health care programs such as Tricare. To prove a violation of the AKS statute, the government must prove each of the following elements beyond a reasonable doubt:
- (1) The defendant knowingly and willfully offered or paid remuneration, directly or indirectly, overtly or covertly;
- (2) Referred an individual to a person for the furnishing or arranging for the furnishing of any item or service; and
- (3) Payment was or would be made in whole or in part under a federal health care program.
- See, e.g., United States v. Patel, 17 F.Supp.3d 823, 824
 (N.D.Ill. 2014).
- 8. The government need not prove that a defendant had actual knowledge of the AKS or a specific intent to violate it.

42 U.S.C. § 1320a-7(b)(h); United States v. St. Junius, 739 F.3d 193, 210 (5th Cir. 2013) ("Section 1320a-7b(h) clarifies that the Government is not required to prove actual knowledge of the Anti-Kickback Statute or specific intent to violate it. Instead, the Government must prove that the defendant willfully committed an act that violated the Anti-Kickback Statute."). "The [AKS] is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct. Rather, the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal." United States v. Vernon, 723 F.3d. 1234, 1259 (11th Cir. 2013), citing United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998). The AKS may be violated even where the referral payment has multiple purposes, so long as at least one purpose was to induce referrals (as opposed, for example, to compensate for advertising expense). United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000); United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989). Evidence that an individual engaged in illegal kickbacks may include that the kickback payor deliberately mischaracterized a kickback as a seemingly legitimate expense. See, e.g., United States v. Moran, 778 F.3d 942, 953 (11th Cir. 2015) (kickback payor "initiated the plan to have the patient recruiters [kickback payees] sign fraudulent 'case manager' contracts' to create appearance of legitimacy for kickbacks).

B. CRIMINAL INVESTIGATION

Tricare Beneficiary Complaints

- 9. Based upon my discussion with agents of the Defense Criminal Investigation Service ("DCIS"), I learned the following:
- a. In 2015, DHA made a criminal referral to the DCIS based, in part, on complaints that DHA had received from Tricare beneficiaries. Among other things, beneficiaries had complained about prescriptions for compounded medications. For example, on or about April 14, 2015, Tricare beneficiary M.H. complained to DHA that M.H. had received an "Explanation of Benefits" form from Tricare stating that M.H. received a prescription for compounded medications for which the dispensing pharmacy had charged Tricare \$59,362.33; that the beneficiary had never received the medication; that the beneficiary did not know the prescribing physician; and that the beneficiary had received no phone calls about the medication. Tricare paid the dispensing pharmacy \$46,981.59 on that claim.³
- b. At least twenty Tricare beneficiaries made similar complaints to DHA around this same period of time.

JETT's Kickback Offer to M.R., DPM

10. On May 11, 2016, I interviewed JETT who told me the following:

³ I reviewed Tricare claims data and noticed that it was not uncommon for Tricare to reimburse for less than the amount of a claim.

- a. He had worked in medical sales for 30 years and had extensive contacts in the medical community that he believed proved to be a valuable commodity. He often did marketing for start-up companies. He was currently part-time employed and owned a "marketing" company called RJM.
- In 2014, JETT was a marketing representative for Products for Doctors ("PFD") based in San Diego. PFD offered compounded medications in the form of creams that were delivered directly to patients' homes. PFD operated as an intermediary between doctors and pharmacies. PFD would route prescriptions to different pharmacies and, in exchange, pharmacies paid PFD and PFD, in turn, paid JETT a 30% commission on the amount that the pharmacies paid to PFD. JETT earned \$2,000 to \$6,000 per month from PFD, all based on commissions. (Based on my investigation that included reviewing documents, including contracts between so-called "marketers" and pharmacies, and interviewing witnesses, including pharmacy owners, I have learned that this arrangement was consistent with that of other entities or individuals that had agreements with pharmacies involved in this investigation. Those agreements called for the payment of large fees, sometimes up to 65% of the amount a pharmacy would receive from Tricare reimbursements, in exchange for referring to the pharmacy a huge stream of compounded medications prescriptions. The bulk of the prescriptions were generated through telemedicine or other means where patients had little, if any, doctor-patient contact. The prescriptions were routinely delivered electronically to the pharmacies by the so-

called marketers or telemedicine site operators, rather than walked-in by the patients.)

- c. JETT "had heard rumors" regarding a scheme involving compounded cream medications, but he did not know much about the scheme. He knew that Tricare was like Medicare for the military but claimed that he did not solicit prescriptions knowing that reimbursement would be sought from Tricare. Most of the patients for whom compounded medications prescriptions were written, on which he earned a commission, were Medicare patients with secondary private insurance.
- d. In 2014, JETT asked M.R., a Doctor of Podiatric Medicine ("DPM"), if she would prescribe compounded medications. Although JETT denied that he offered to pay M.R. for writing compounded medications prescriptions, M.R. told him that such compensation was considered an illegal kickback. JETT then told M.R. that, if M.R. signed up for a "pain study" that PFD was conducting, M.R. could be paid a percentage of the value of the compounded medications prescriptions that M.R. wrote. JETT told M.R. that "we've got to do it this way or the doctors can't be paid." JETT told M.R. that, as long as doctors signed a form stating that they were participating in a pain study, payments to them for writing such prescriptions would not be considered a kickback.
- e. M.R. refused to sign the pain study "form" and, therefore, M.R. was not paid any incentives for writing such prescriptions.

- f. JETT's supervisor at PFD was Steve Schur. Schur instructed JETT about how to sign-up doctors for the pain study. Schur told JETT that PFD had a legal opinion that paying doctors for writing prescriptions based on the pain study was acceptable.
- g. JETT did not know whether there was actually a pain study.
- 11. After I admonished JETT against making false statements to federal agents (I had earlier identified myself to JETT as a federal agent), JETT then admitted that he knew that there was no pain study. (I know from my investigation that similar purported studies served as ruses for kickback payments. For example, two so-called marketers were indicted in Texas for kickbacks that were in part disguised as payments for a "study" by a purported pain foundation. United States v. Cesario, et al., CR. 3-16CR-060-M, filed February 18, 2016, Dkt. 3.)

M.R.'s Rejection of JETT's Kickback Offer

- 12. On May 10, 2016, a DCIS agent and I interviewed M.R., DPM (the same M.R. to whom JETT had referred during his interview, above), who told us the following:
- a. M.R. is a Doctor of Podiatric Medicine. Her office is located in Placentia, California.
- b. M.R. knows JETT. In 2014, JETT, a representative of RJ Medical USA of Lake Forest, California, approached M.R. at her office to solicit business for prescription compounded creams.

- c. JETT was "very pushy" and his main sales pitch was that the pharmacies that dispensed the creams would deliver the creams to patients' homes.
- d. JETT left M.R. a prescription order form that contained a pre-formulated list of compounds that M.R. could prescribe.
- e. JETT offered to pay M.R. a fee or percentage from each prescription that M.R. wrote in conjunction with using JETT's services. M.R. told JETT, "that would be a kickback and I cannot accept kickbacks." JETT responded by saying, "no, it's not and we could do it a certain way where it would not be a kickback."
- f. M.R. never received any money from JETT for writing prescriptions.
- g. M.R. did prescribe a few of the compounded creams that JETT had pitched, including to patient P.P. (discussed below). M.R. filled-out the prescription forms and gave the forms to JETT at M.R.'s office. JETT then delivered the forms to PFD.
- h. At some point thereafter, P.P. showed M.R. a copy of P.P.'s "Explanation of Benefits" form that showed that her Tricare insurance had paid \$3,000 for the compounded creams that M.R. had prescribed. M.R. then contacted JETT to inquire about why the charge was so high. JETT told M.R. that P.P.'s insurance carrier had been billed for a year's supply of the medication. M.R. told JETT that she (M.R.) had not authorized

- any refills. M.R. thereafter did not write any compounded medications prescriptions through JETT.
- 13. On May 9, 2016, I interviewed, P.P. (mentioned above), who told me the following:
 - a. She is a patient of Dr. M.R.
- b. In or about October 2014, while at M.R.'s office, M.R. told P.P. that there was a sales rep in M.R.'s office who had information about compound cream for pain.
- c. P.P. then spoke to the sales rep, whose name she could not recall. P.P. described the sales rep as an older, big, Caucasion male. (Having seen JETT, I believe that JETT matched the description given by P.P.)
- d. P.P. did not recall whether M.R. prescribed compounded creams for P.P.
- e. After that visit to M.R.'s office, in or about October 2014, P.P. received compounded cream from Professional Compounding Pharmacy ("PCP"). The package arrived at her residence; she did not visit PCP. P.P. did not pay a co-payment to PCP. P.P. did not feel that the medication was helpful.
- f. Approximately one month later, P.P. received yet another package at her residence containing the same medication, also from PCP. P.P. mailed the package back to PCP. P.P. at that same time called PCP. She did not recall the name of the person at PCP with whom she spoke, but P.P. recalled telling that person that P.P. was returning the second package and did not want any more. The person told P.P. that PCP was at that

time in the process of sending P.P. yet a third package of the same medication.

- g. P.P. received a questionnaire in the mail from the sales rep that she had met at M.R.'s office. She recalled completing the questionnaire by stating that the medication was not effective. She mailed the questionnaire to the sales rep.
- h. In late 2014, P.P. received a statement from Tricare regarding the cost of the compounded cream medication. She was angry to see the high charge. She took the statement to M.R. who was also angry and stated that she (M.R.) was going to call the sales rep.
- 14. I checked the Tricare claims data for compounded medications prescriptions dispensed by PCP and learned the following:
 - a. PCP was located in La Habra, California.
- b. For calendar year 2013, PCP submitted approximately 62 Tricare claims for filling compounded medications prescriptions, for approximately \$60,343.83. Tricare paid approximately \$58,003.96 on those claims.
- c. For calendar year 2014, PCP submitted approximately 1,344 Tricare claims for filling compounded medications prescriptions, for approximately \$5,126,604.47. Tricare paid approximately \$4,412,824.86 on those claims.
- d. For calendar year 2015, PCP submitted approximately 2,727 Tricare claims for filling compounded medications prescriptions, for approximately \$17,495,016.03.

 Tricare paid approximately \$14,722,308.08 on those claims. In

or about early May 2015, Tricare stopped honoring most claims for reimbursement for filling compounded medications prescriptions in part due a CBS News report that an Iowa physician's identity had been stolen and used repeatedly to support prescriptions for compounded medications.

- e. On August 28, 2014, PCP filled a compounded medications prescription for P.P., authorized by M.R., and billed Tricare \$995.00. On September 11, 2014, PCP filled another compounded medications prescription for P.P., authorized by Dr. M.R., and billed Tricare \$995.00. Tricare paid both of those claims at \$983.00 and \$983.00 respectively.
- f. Under Tricare rules, PCP was required for each prescription to either collect a co-payment or first obtain from Tricare a waiver of co-payment collection. Tricare data showed that PCP was required to collect a co-payment for each prescription for P.P.; no data showed that Tricare waived the co-payments. P.P. mentioned that she had not paid a co-payment. (During the course of this investigation, I have found dozens, if not hundreds, of instances in which compounded medications prescriptions were filled by pharmacies that received the prescriptions from cappers like JETT, or other intermediaries, instead of from patients/beneficiaries, and did not collect copayments. Based on that and other information gathered in this investigation, I believe that PCP violated Tricare rules and further shows probable cause to believe that cappers, like JETT, and pharmacies, schemed to defraud Tricare.)

- The AKS has several safe harbors as well as an 15. implied safe harbor that results from either getting or to some extent relying on advisory opinions from the U.S. Department of Health and Human Services ("HHS"). 42 C.F.R. § 1001.952. first safe harbor is a "referral service." A payment to a "referral service" may be exempt from AKS liability if it meets four requirements, set forth in 42 C.F.R. § 1001.952(f), including that payments must be based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated. I know from the evidence gathered in this and related investigations that dispensing pharmacies claimed thousands of dollars per prescription in seeking reimbursement from Tricare and, in turn, paid large amounts of those reimbursements to cappers that had referred the prescriptions to the pharmacies. Based on that evidence, and JETT's statements, described in detail below, that (1) he received compensation tied to a percentage of the value of his referrals, and (2) offered to pay a physician a kickback disquised as a payment to participate in a phony "pain study," I believe that there is probable cause to believe that JETT's activities did not meet the test for the "referral service" exemption described above because the payments to him appeared to be based on the volume and value of the business he generated by his referrals, and were not based on the actual or legitimate cost of operating a bona fide referral service.
- 16. I further believe that JETT cannot claim the employee exemption either, 42 C.F.R. § 1001.952(i), that exempts payments

in a <u>bona fide</u> employment relationship. At least under Medicare AKS case law, "the safe-harbor provision relies on 26 U.S.C. § 3121(d)(2) for the definition that an employee is 'any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee.'" <u>United States v. Robinson</u>, 505 F.App'x. 385, 387 (5th Cir. 2013). JETT admitted to me that he was a "1099 employee" who was an independent contractor who worked entirely on commission. He was not employed by the pharmacies to whom he had referred, or intended to refer, prescriptions for fulfillment in exchange for a fee.

17. Based on my discussions with others involved in this investigation, I have learned that JETT had not sought, nor was he identified as the subject of, an HHS advisory opinion. I therefore believe there is probable cause to believe that JETT's offense conduct, as described herein, would not exempt him from

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criminal liability based upon, or reliance on, an HHS advisory opinion.

IV. CONCLUSION

18. For all of the reasons described above, I believe there is probable cause to believe that RANDY JETT offered to pay an illegal remuneration, in violation of Title 42, United States Code, 1320a-7b(b)(2)(A).

Monica Pandis, Special Agent Federal Bureau of Investigation

Subscribed to and sworn before me this 20 day of June, 2016.

HONORABLE

UNITED STATES MAGIŚTRATE JUDGE

KAREN E. SCOTT