BENJAMIN B. WAGNER United States Attorney PATRICK R. DELAHUNTY KIRK E. SHERRIFF Assistant United States Attorneys 2500 Tulare Street, Suite 4401 Fresno, CA 93721 Telephone: (559) 497-4000 Facsimile: (559) 497-4099 6 Attorneys for the 7 United States of America 8 9 10 11 12 13 ν. 14

JUL 3 1 2015 DISTRICT COURT CT OF CALIFORNIA

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

CASE NO.

00212 Aw(= 1: 1 5 CR

Plaintiff,

VIOLATION: 18 U.S.C. § 1341 - Mail Fraud, and 18 U.S.C. §§ 981(a)(1)(C), 982(a)(4), 982(a)(7) and 28 U.S.C. § 2461(c) – Criminal Forfeiture

PAUL S. SINGH,

Defendant.

INFORMATION

20 COUNT 1:

[18 U.S.C. § 1341 – Mail Fraud]

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The United States Attorney charges:

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PAUL S. SINGH,

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defendant herein, as follows:

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I.

INTRODUCTION

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At all times relevant to this information:

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1. PAUL S. SINGH, MD, DO, defendant herein, was a licensed medical doctor and resided

in Kern County, in the State and Eastern District of California.

Information

 2. SINGH was the President and Secretary of Paul S. Singh, DO, Inc., located at 276 S. Mill St., Tehachapi, California, within Kern County, in the State and Eastern District of California.

3. SINGH provided obstetric and gynecological services to women, including providing forms of birth control. One form of birth control provided to patients by SINGH was intrauterine devices ("IUDs").

A. <u>ParaGard IUDs</u>

- 4. IUDs are regulated by the Food and Drug Administration ("FDA"), an agency within the United States Department of Health and Human Services. The active ingredient in FDA-approved IUDs is either a hormone (levonorgestrel) or copper. At all relevant times, the only copper IUD approved by the FDA was the ParaGard T-380A ("ParaGard"), which was manufactured by Teva Women's Health (formerly doing business as Duramed Pharmaceuticals). It was approved by the FDA in 1984. At all relevant times, the only authorized ParaGard distributor was ParaGard Direct.
- 5. The insertion of a non-FDA approved copper IUD risks a patient's health and safety. Copper IUDs are implanted into a woman's body for up to a decade, and inferior quality and improper use can result in an increased risk of pelvic inflammatory disease, ectopic pregnancy, hysterectomy, infertility, and other serious complications.
- 6. Warnings against the use of non-FDA approved IUDs were conveyed to obstetrics and gynecology ("OB/GYN") doctors, including SINGH, in the form of bulletins, newsletters, and updates. These warning were issued at times including the period between September 2006 and June 2012. For example, on or about July 2010, the manufacturer of ParaGard IUDs issued a letter to OB/GYN doctors, which Singh received, warning: "The products sold as ParaGard by the online pharmacies are not identical to ParaGard and have not been approved as safe and effective by the ... FDA. There are no generic substitutes for or equivalents to ParaGard approved for use in the United States."
- 7. After receiving complaints that SINGH had inserted non-FDA approved IUDs, FDA agents met with SINGH on or about August 17, 2010. During the course of the meeting, FDA agents warned SINGH that he could not insert non-FDA approved copper IUDs, and SINGH agreed that he would stop doing so. Notwithstanding this warning, SINGH continued to insert non-FDA approved Information 2

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25 27 copper IUDs in his patients and to falsely claim to health care providers and his patients that he was inserting FDA-approved copper IUDs.

Medical Billing of ParaGard IUDs В.

- 8. Many of SINGH's patients had health insurance from health care benefit programs, including: Anthem Blue Cross, Tri-Care, Self-Insured Schools of California, Hawaii Medical Assurance Association, Blue Shield, Robert F. Kennedy Medical Plan, Operating Engineers Health & Welfare Fund, and Bakersfield Family Medical Group. These health care benefit programs provided medical benefits to some of SINGH's patients by covering all or a portion of the costs of their medical care pursuant to the terms of their insurance plan.
- 9. Health care providers use specific codes to seek payment from health care benefit programs for costs associated with particular drugs, devices, or services. At all relevant times, a health care provider billing for a ParaGard IUD was required to use Common Procedural Technology ("CPT") code number J7300. Only ParaGard IUD devices could be billed for reimbursement using CPT code number J7300. At all relevant times, a health care provider billing for the insertion of a ParaGard IUD was required to use Healthcare Common Procedure Coding System ("HCPCS") code number 58300. Only the insertion of an FDA-approved IUD device could be billed for reimbursement using HCPCS code number 58300.
- 10. At all relevant times, SINGH knew that inserting non-FDA approved copper IUDs was prohibited by the FDA and presented health risks to his patients, and he knew that he could not bill either his patients or health care benefit programs for the insertion of non-FDA approved copper IUDs.

II. **SCHEME TO DEFRAUD**

11. Beginning at a time unknown but no later than in or about May 2008, and continuing to at least in or about June 2012, within the State and Eastern District of California and elsewhere, defendant SINGH devised and intended to devise a scheme and artifice to defraud health care benefit programs, patients, and others, of money and property, and obtained money and property from health care benefit programs, patients, and others, by means of materially false and fraudulent pretenses, representations, Information

and promises.

III. MANNER AND MEANS OF THE SCHEME TO DEFRAUD

- 12. At all relevant times, most of the copper IUDs SINGH inserted in his patients were not approved by the FDA. SINGH knowingly purchased non-FDA approved copper IUDs from an internet-based company, and then knowingly inserted them in his patients. In those instances, SINGH falsely billed health care benefit programs and his patients for the insertion of non-FDA approved copper IUDs, using CPT and HCPCS code numbers J7300 and 58300. He did so with the knowledge that he had not inserted genuine ParaGard IUDs.
- 13. SINGH knowingly failed to advise his patients that he had inserted non-FDA approved copper IUDs in them, and he failed to advise those patients of the medical risks associated with the insertion of non-FDA approved copper IUDs.
- 14. Many patients who had non-FDA approved copper IUDs inserted by SINGH later reported medical complications, including sexual and reproductive health problems. Some of these patients ultimately switched doctors, and after doing so, learned that they had had non-FDA approved IUDs inserted by SINGH when their new doctor removed the IUDs.
- 15. For example, SINGH inserted a non-FDA approved copper IUD in patient R.V. in April 2009. Thereafter, the IUD was removed from patient R.V. by a different doctor, and it was confirmed to be a non-FDA approved IUD. Patient R.V. had medical complications she associated with the IUD SINGH inserted and complained to the Osteopathic Medical Board of California about it. In response, SINGH sent two different letters to the Medical Board. In each, he falsely asserted that he had inserted a genuine ParaGard IUD in patient R.V. Through the letters, SINGH attempted to continue to conceal his scheme to defraud the patient, health care benefit programs, and the Medical Board.
- 16. As another example, after SINGH inserted a non-FDA approved copper IUD in Patient N.K. in April 2009, she complained to SINGH of discomfort and medical complications she associated with the IUD. Rather than remove the IUD, SINGH re-inserted it. Thereafter, Patient N.K. returned to SINGH and complained again of discomfort she associated with the IUD. In response, SINGH removed the IUD, and inserted another non-FDA approved copper IUD in July 2010. Patient N.K. continued to Information 4

endure discomfort and medical complications she associated with the IUD, and ultimately went to another doctor who removed the IUD SINGH had inserted and confirmed that SINGH had inserted a non-FDA approved copper IUD.

- 17. After inserting non-FDA approved copper IUDs, SINGH knowingly submitted false and fraudulent claims to health care benefit programs, including Anthem Blue Cross, Tri-Care, Self-Insured Schools of California, Hawaii Medical Assurance Association, Blue Shield, Robert F. Kennedy Medical Plan, Operating Engineers Health & Welfare Fund, and Bakersfield Family Medical Group, for reimbursement for purportedly inserting genuine ParaGard IUDs. Specifically, SINGH knowingly billed these health care benefit programs using CPT and HCPCS code numbers J7300 and 58300, and falsely represented that he had inserted genuine ParaGard IUDs. He knew, and expected, that such claims would be paid with a check mailed to him by such health care benefit programs. Additionally, SINGH knowingly collected payments from his patients after knowingly misrepresenting that he had inserted a genuine ParaGard and failing to disclose that he had actually inserted a non-FDA approved copper IUD.
 - 18. At all relevant times, SINGH acted with the intent to defraud in carrying out this scheme.

IV. MAILING

19. On or about the date set forth below, in the County of Kern, State and Eastern District of California, and elsewhere, defendant SINGH, for the purposes of executing and attempting to execute said scheme described above, with the intent to defraud, knowingly caused the mail matter and item described below to be placed an in authorized depository for mail matter, and to be sent and delivered by the United States Postal Service as set forth below:

| COUNT | APPROX. DATE | DESCRIPTION |
|-------|--------------|--|
| | OF MAILING | |
| 1 | 9/22/10 | Check (#G0003451144) in the amount of \$783.79, made |
| | | payable to Paul S. Singh DO Inc., mailed by Tri-Care to Paul |
| | | S. Singh DO Inc., PO Box 2240, Tehachapi, California 93581, |

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| 1 | associated with payment on a fraudulent claim related to | | |
| 2 | patient N.K. | | |
| . 3 | All in violation of Title 18, United States Code, Section 1341. | | |
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| 5 | FORFEITURE ALLEGATION: [18 U.S.C. § 981(a)(1)(C), 982(a)(4), 982(a)(7) | | |
| 6 | and 28 U.S.C. § 2461(c) – Criminal Forfeiture] | | |
| 7 | 20. Upon conviction of one or more of the offenses alleged in Count One of this information, | | |
| 8 | defendant PAUL S. SINGH shall forfeit to the United States, pursuant to 18 U.S.C. § 981(a)(1)(C), | | |
| 9 | 982(a)(4), 982(a)(7), and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes or is | | |
| 10 | derived from proceeds traceable to or which are the gross receipts of said violations, to include any | | |
| 11 | property, real or personal, tangible or intangible, which is obtained, directly or indirectly, as a result of | | |
| 12 | such violations, including but not limited to the following: | | |
| 13 | a) A sum of money equal to the amount of proceeds obtained directly or indirectly, | | |
| 14 | as a result of such offenses, for which defendant is convicted. | | |
| 15 | 21. If any property subject to forfeiture as a result of the offenses alleged in Count One of | | |
| 16 | this information, for which defendant is convicted: | | |
| 17 | a. cannot be located upon the exercise of due diligence; | | |
| 18 | b. has been transferred or sold to, or deposited with, a third party; | | |
| 19 | c. has been placed beyond the jurisdiction of the court; | | |
| 20 | d. has been substantially diminished in value; or | | |
| 21 | e. has been commingled with other property which cannot be divided without | | |
| 22 | difficulty; | | |
| 23 | it is the intent of the United States, pursuant to 18 U.S.C. § 982(b)(1), incorporating 21 U.S.C. § 853(p), | | |
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to seek forfeiture of any other property of said defendant, up to the value of the property subject to forfeiture.

BENJAMIN B. WAGNER

United States Attorney

PATRICK R. DELAHUNTY

Assistant U.S. Attorney

Information