

DAG/CJB

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF ALABAMA  
SOUTHERN DIVISION**

**UNITED STATES OF AMERICA**

**v.**

**NATALIE REED PERHACS**

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**CRIM. NO. 16-00024-CG**

**USAO NO. 16R00063**

**VIOLATION: 18 USC § 371**

**INFORMATION**

**THE UNITED STATES ATTORNEY CHARGES:**

**INTRODUCTION**

**BACKGROUND ON SUBSYS SUBLINGUAL FENTANYL SPRAY**

1. Fentanyl, a Schedule II controlled substance, is an extremely powerful opioid pain killer that is approximately 100 times as potent as morphine. Fentanyl drugs are commercially produced by several different pharmaceutical companies. One such company is “Company A,” a specialty pharmaceutical company based outside the state of Alabama.

2. On January 2, 2012, the FDA approved an instant-release fentanyl sublingual spray. The product, which is marketed under the brand name Subsys, had only one FDA-approved indication: *“For the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”*

3. Subsys is intended to be sprayed underneath the tongue of an opioid-tolerant cancer patient. Since the fentanyl in Subsys is absorbed through a transmucosal barrier under the tongue, the cancer patient receives rapid relief from his or her breakthrough cancer pain.

4. Subsys comes in individual spray doses at varying strengths — 100mcg, 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, and 1600mcg.

5. Subsys is the only FDA-approved product “Company A” has on the market.

#### **THE TIRF REMS PROGRAM**

6. Due to its instant-release delivery system, Subsys is one of several fentanyl drugs that are grouped into the category of transmucosal instant-release fentanyl (“TIRF”) drugs.

7. Since there is high risk potential for misuse, abuse, addiction, and overdose death associated with TIRF drugs, the FDA requires that all practitioners, pharmacists, and patients must be enrolled in an FDA Risk Evaluation & Management Strategy (“REMS”) program before they are allowed to prescribe, dispense, or take a TIRF drug like Subsys.

8. As part of the TIRF REMS program, the prescriber and the patient must fill out and sign a Patient-Prescriber Agreement Form prior to Subsys being prescribed.

#### **OFF-LABEL PRESCRIBING OF SUBSYS AT PPSA**

9. Xiulu Ruan, M.D. and John Patrick Couch, M.D. are physicians who formerly practiced medicine in Mobile, Alabama. Between January 2011 and the date of their arrests on May 20, 2015, Dr. Ruan and Dr. Couch jointly owned and co-directed a pain management clinic named Physician’s Pain Specialists of Alabama (“PPSA”), which had two clinic locations in Mobile, Alabama.

10. Located adjacent to one of the PPSA clinics was C&R Pharmacy, which was also jointly owned by Dr. Ruan and Dr. Couch.

11. At PPSA, Dr. Ruan and Dr. Couch treated several thousand patients whose services were paid for by both private and federally-funded health insurance providers.

12. Of the thousands of patients treated at PPSA, very few had cancer.

13. On or about March 26, 2012, Company A rolled out their instant release fentanyl drug, Subsys.

14. On April 25, 2012, Dr. Ruan wrote his first prescription for Subsys — 60 spray doses of Subsys 100mcg. The patient's federally-funded health insurance provider was billed \$1,312.29 for this prescription.

15. Dr. Couch also wrote his first Subsys prescription on April 25, 2012 — 120 spray doses of Subsys 600mcg. The patient's private health insurance provider was billed \$6,307.94 for this prescription.

16. Once Dr. Ruan and Dr. Couch began prescribing Subsys in April 2012, they quickly became two of the top Subsys prescribers in the entire nation.

17. At certain points during 2012 and 2013, Dr. Ruan was the #1 prescriber of Subsys in the entire United States. Due to the enormous volume of Subsys prescriptions Dr. Ruan was writing, certain individuals within Company A referred to Dr. Ruan as one of the company's "*three whales*."

18. Not only did Dr. Ruan and Dr. Couch broadly prescribe Subsys off-label to non-cancer patients, but they also prescribed it off-label numerous times to certain non-cancer patients whose health insurance providers continued paying for the drug. For example:

A. Between September 11, 2012 and April 1, 2015, Dr. Ruan wrote 31 prescriptions for Subsys to a non-cancer patient in her 20s. This patient's federally-funded health insurance provider was billed \$179,286.141 for these Subsys prescriptions.

B. Between December 13, 2012 and May 18, 2015, Dr. Couch wrote 28 prescriptions for Subsys to a non-cancer patient in his 30s. This patient's

federally-funded health insurance provider was billed \$465,062.57 for these Subsys prescriptions.

19. October 2013 was the highest volume Subsys prescribing month at PPSA. During the 23 days PPSA was open that month, Dr. Ruan and Dr. Couch combined to write a total of 110 prescriptions for Subsys, 33 of which were written for patients who had previously never been prescribed Subsys. Nearly all of these prescriptions were written off-label to non-cancer patients. All of these prescriptions were filled at C&R Pharmacy, which then billed federally-funded and private health insurance providers a total of \$572,626.62.

20. In total, between April 25, 2012 and the date of his arrest on May 20, 2015, Dr. Ruan wrote at least 1,812 prescriptions for Subsys to 428 different patients. During this same time period, Dr. Couch wrote at least 872 prescriptions for Subsys to 190 different patients.

21. All of these 2,684 Subsys prescriptions were filled at C&R Pharmacy which was owned by Dr. Couch and Dr. Ruan.

#### **COUNT ONE**

22. The United States Attorney incorporates numbered paragraphs 1–21 of this Information as if fully set forth herein.

23. From on or about April 5, 2013, through on or about May 20, 2015, in the Southern District of Alabama, Southern Division, and elsewhere, the defendant,

#### **NATALIE REED PERHACS,**

did willfully, knowingly, and unlawfully combine, conspire, confederate, and agree with others to commit an offense against the United States, to-wit:

to knowingly and willfully offer, pay, solicit, and receive any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for purchasing, leasing, ordering, and arranging for, or recommending

purchasing, leasing, and ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program, in violation of Title 42, United States Code, Section 1320a-7b(b).

**OBJECT OF THE CONSPIRACY**

24. The objective of this conspiracy was for Company A to illegally pay kickbacks in the forms of speaking fees and honorariums to Xiulu Ruan, M.D. and John Patrick Couch, M.D. to induce, and in exchange for, their prescribing Subsys to PPSA patients.

**MANNER AND MEANS**

25. The manner and means of this conspiracy included, but were not limited to the following:

**A. Developing Dr. Ruan into the Number One Prescriber of Subsys**

26. Company A received FDA approval for Subsys on January 2, 2012. Within the first month, some of Company A's executives had already identified Dr. Ruan as an important prospective prescriber.

27. In order to cultivate Dr. Ruan into the prolific prescriber he would become, Company A provided Dr. Ruan with his own personal sales representative for the last two quarters of 2012 and the first quarter of 2013. This sales representative, identified herein as "Executive 1," was specifically hired because of his prior relationship with Dr. Ruan when he worked for another pharmaceutical company.

28. It was Executive 1's responsibility to ensure that Dr. Ruan continued to write prescriptions for Subsys, as well as to push Dr. Ruan to increase dosage strength. The latter role is evident from automated e-mails Company A's sales representatives received when one of their doctors prescribed a low-strength Subsys prescription. The following is an example of these e-

mails:

*If you have a 100MCG or 200MCG script in ANY size, please report back to your manager within 24 hours on WHY the low does was used and HOW the doctor plans to titrate to effective dose.*

29. A majority of Executive 1's pay was based on commissions generated by the number and dosage strength of prescriptions written by Dr. Ruan. An individual identified herein as "Executive 2" explained this to Executive 1 in an e-mail when Executive 1 first started with Company A in July 2012.

*[Dr. Ruan's previous sales representative] made 7k off Dr. Ruan last quarter. He wrote 1500 units and 26 prescriptions. So, that's basically 1 script every 3rd day for 60 days. If he wrote just 1 script every day and a low # of units (like he did last quarter) you would make 22K. If he does 2 Subsys a day for one straight quarter, you would make at least 40 grand for the quarter!*

30. By October 2012, Executive 1 had developed Dr. Ruan into the number one Subsys prescriber in the nation. In an October 24, 2012 e-mail from Executive 2 to regional sales managers and to others that Executive 1's relationship with Dr. Ruan as an example for other sales representatives to follow: *"Point of interest that I implore you to drive home with your representatives: The number 1 prescribing doctor has written 206 prescriptions to date (Dr. Ruan). Fact: Dr. Ruan is visited at least 5 days a week by an [Company A] representative (sometime 7)."*

31. However, Dr. Ruan did not become the number one prescriber of Subsys just because Executive 1 spent so much time at PPSA. Rather, beginning in August 2012, Dr. Ruan and Dr. Couch were both paid to conduct speakers programs on behalf of Company A. While the purported purpose of the speakers programs was for chosen doctors to convince fellow doctors to prescribe Subsys, the speaker programs, in reality, were a façade used by Company A to funnel illegal kickback payments to high volume Subsys prescribers.

**B. Company A Hires Natalie Perhacs as a Kickback to Dr. Ruan**

32. In late 2012, **NATALIE REED PERHACS** worked for a durable medical equipment company in the Southern District of Alabama. It was in this capacity that she met Dr. Ruan and Dr. Couch.

33. By early November 2012, Dr. Ruan had developed a certain affection for **PERHACS**.

34. In an e-mail sent on November 7, 2012, Dr. Ruan asked **PERHACS**, *"Well, I want to ask you a personal question and hopefully you would not be offended. Are you involved with someone now? . . . . You don't have to answer any of these if you do not feel comfortable."*

35. Thereafter, Dr. Ruan went out of his way to try to get **PERHACS** hired as a sales representative with a pharmaceutical company. Between November 10, 2012 and November 19, 2012, Dr. Ruan reached out to individuals he knew at three different pharmaceutical companies and explained why they should hire **PERHACS** for their sales force. None of these companies hired **PERHACS**. Dr. Ruan continued to reach out to pharmaceutical contacts over the next several months on behalf of **PERHACS**.

36. Between November 2012 and March 2013, on multiple occasions, Dr. Ruan also asked **PERHACS** to join him for dinner or attend exotic car shows with him. **PERHACS** did not go to dinner or to car shows with Dr. Ruan. In addition, in February 2013, Dr. Ruan asked **PERHACS** if he could pay her to be his personal speech coach so that he could improve his public speaking skills.

37. Despite Dr. Ruan's concern about his public speaking skills, Executive 1 continued to set up paid speakers programs for Dr. Ruan during the first quarter of 2013. In turn, Dr. Ruan continued to prescribe high volumes of Subsys off-label to non-cancer patients at

PPSA.

38. By late March of 2013, Company A decided to promote Executive 1 from Dr. Ruan's personal sales representative to regional director. As explained by Executive 2 to Executive 1 in an April 8, 2013 e-mail:

*What you have been able to accomplish with Dr. Ruan got your promoted to management. I realize we may lose all of Dr. Ruan's business if you are not his rep. At this point, I am tired of being pressured by Dr. Ruan. Dr. Ruan should continue to support you and Subsys, as you are now in a more critical role to assist him in his endeavors (more than ever).*

39. Due to the concern that Dr. Ruan would stop prescribing Subsys if Executive 1 was no longer his personal sales representative, finding a suitable replacement who would please Dr. Ruan was of paramount importance.

40. On March 26, 2013, Dr. Ruan sent an e-mail to **PERHACS** explaining that he recommended her to Executive 1:

*Natalie, I recommended you to [Executive 1], the regional director of [Company A]. I talked to him today and there might be a position open for you. I highly recommended you to him. I think the chance for you to be taken is greater than 90%. They have very competitive compensation package based on sales. I think it is a job on which you can show your capability. . . . BTW, I am a national speaker as well as on the advisory board for this company. Dr. Couch is also a speaker for this company. We both know this product well. I hope you can get it this time.*

41. The following day, Dr. Ruan sent Executive 1 another e-mail recommending that Company A hire **PERHACS** to be Dr. Ruan's new Subsys sales representative. **PERHACS** was then contacted about the position, which **PERHACS** explained to Dr. Ruan on March 28, 2013:

*The conversation with [Executive 1] went well. [Executive 1] respects your opinion so much he is willing to give me a chance based on your recommendation. He did not mention his concern to me about not knowing more doctors, but either way, I'll build relationships and grow business . . . . Thank you for the powerful recommendation.*

42. On April 1, 2013, one day before **PERHACS** was supposed to meet about the Company A sales representative position, Dr. Ruan sent **PERHACS** the following e-mail



explaining very basic product information regarding Subsys:

*Natalie, Subsys is sublingual spray of Fentanyl, used for breakthrough cancer pain. Read the following links a few times, then you will be ready. Link 2 and 3 may be too much, but they will get you beyond what [Executive 1] knows about the opioid. Good luck!*

<http://www.breakthroughcancerpain.org/an-introduction-to-breakthrough-cancer-pain>

<http://en.wikipedia.org/wiki/Fentanyl>

<http://en.wikipedia.org/wiki/Opiate>

43. On April 2, 2013, **PERHACS** was hired by Company A to be the personal sales representative for one of their most important prescriber in the entire country — Dr. Ruan.

44. Company A did not hire **PERHACS** because of her experience or her knowledge of controlled substance or because of her knowledge of Subsys. Rather, Company A hired **PERHACS** to induce, and in exchange for, Dr. Ruan continuing to prescribe Subsys to PPSA patients after Executive 1 moved into management.

**C. Off-Label Prescribing and Kickbacks Following the Hire of Perhacs**

45. **PERHACS** began with Company A on April 5, 2013. **PERHACS** received limited training in the product, sales, or compliance.

46. On April 8, 2013, the “Dr. Ruan territory,” formerly overseen by Executive 1, was eliminated and **PERHACS** was placed in charge of a larger sales territory which included both Dr. Ruan and Dr. Couch.

47. **PERHACS’s** primary responsibility at Company A was to increase the volume of Subsys prescribed by Dr. Ruan and Dr. Couch. She accomplished this by numerous means, including, but not limited to: (1) handling insurance prior authorizations for PPSA patients prescribed Subsys; (2) identifying patients who had been at the same strength of Subsys for several months and recommending that Dr. Ruan or Dr. Couch increase the patient’s prescription strength; and (3) setting up and attending paid speaker programs.

48. **PERHACS** was initially very successful in boosting the Subsys prescription volume for both Dr. Ruan and Dr. Couch. Since she was involved in the prior authorization process, **PERHACS** was aware of the diagnoses of the PPSA patients receiving prescriptions for Subsys. **PERHACS** knew that a vast majority of the PPSA patients to whom Dr. Ruan and Dr. Couch prescribed Subsys did not have breakthrough cancer pain. This was also known to individuals within the Company A Reimbursement Center, who received the information from **PERHACS** to generate the prior authorizations to send to patients' healthcare insurance providers.

49. **PERHACS** also set up and attended speaker programs for Dr. Ruan and Dr. Couch. **PERHACS** was aware that not only were meals paid for by Company A during these speaker programs, but that the doctors also received honorariums for "speaking" on behalf of Company A.

50. Throughout her time as a sales representative for Dr. Ruan and Dr. Couch, **PERHACS** scheduled approximately one speaker program per doctor per week. There were some occasions during which Dr. Ruan or Dr. Couch actually spoke to other prescribers about Subsys during these Company A-paid lunches and dinners. However, for a majority of the speaker programs, Dr. Ruan and Dr. Couch either (1) repeatedly spoke to the same prescribers about Subsys, (2) spoke to just the PPSA staff about Subsys, or (3) did not speak about Subsys at all.

51. Neither **PERHACS** nor Company A was concerned with who Dr. Ruan or Dr. Couch spoke to during these speaker programs. This is because the true purpose of the speaker program was not to promote Subsys, but rather funnel kickbacks to high-volume Subsys prescribers.

52. Even outside her responsibilities with Company A, **PERHACS** did anything possible to keep Dr. Ruan and Dr. Couch happy so that they would continue to prescribe Subsys. This included, but was not limited to, helping Dr. Ruan with car show registrations during work hours, joining Dr. Ruan's health products pyramid scheme at his request, and wrote a fraudulent online "patient review" under an alias so as to increase Dr. Ruan's online ratings.

53. The end goal for **PERHACS** was to get Dr. Ruan and Dr. Couch to continue to prescribe Subsys. **PERHACS** had a strong financial incentive to do so, and to turn a blind eye to illegal kickbacks being paid by Company A to Dr. Ruan and Dr. Couch. Despite earning a base salary of only \$40,000.00 per year, commissions from off-label prescriptions written by Dr. Ruan and Dr. Couch resulted in **PERHACS** making over \$700,000.00 between April 2013 and the doctors' arrests on May 20, 2015.

54. To induce, and in exchange for, the 2,684 Subsys prescriptions written by Dr. Ruan and Dr. Couch, Company A hired **PERHACS** at Dr. Ruan's specific request and paid the doctors hundreds of thousands dollars in alleged speaking fees. These actions were done in violation of the Anti-Kickback Statute.

#### **OVERT ACTS**

55. The following overt acts were committed, among others:

(1) On or about May 9, 2013, Dr. Couch received check number 11090 from Company A, payable to John Patrick Couch, in the amount of \$3,200.00.

(2) On or about February 6, 2014, Dr. Couch held a speaker program at Fuego, a restaurant in Mobile, Alabama. This speaker program was hosted and attended by **PERHACS**.

(3) On or about February 13, 2014, Dr. Couch received check number 1920 from Company A, payable to John Patrick Couch, in the amount of \$1,600.00.


(4) On or about April 25, 2014, Dr. Ruan held a speaker program at Osaka Japanese Grill in Mobile, Alabama. This speaker program was hosted and attended by **PERHACS**.

(5) On or about May 1, 2014, Dr. Ruan received check number 3057 from Company A, payable to Xiulu Ruan XLR Properties, LLC. in the amount of \$6,000.00.

(6) On or about October 31, 2014, Dr. Couch received check number 5091 from Company A, payable to John Patrick Couch, in the amount of \$3,750.00.

(7) On or about November 14, 2014, Dr. Ruan received check number 5390 from Company A, payable to Xiulu Ruan XLR Properties, LLC. in the amount of \$3,750.00.

56. All in violation of Title 18, United States Code, Section 371.

  
KENYEN R. BROWN  
UNITED STATES ATTORNEY

FEBRUARY 2015