**UNITED STATES DISTRICT COURT**

**SOUTHERN DISTRICT OF CALIFORNIA**

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| UNITED STATES OF AMERICA,<br>Plaintiff,<br>v.<br>JENNINGS RYAN STALEY,<br>Defendant. | Case No.: 20mj1407<br><br>COMPLAINT FOR VIOLATION OF:<br>Title 18 U.S.C. § 1341<br>Mail fraud (felony) |

The undersigned complainant being duly sworn states:

On or about April 10, 2020, within the Southern District of California, defendant JENNINGS RYAN STALEY, having devised a scheme and artifice to defraud, and for obtaining money or property by means of false and fraudulent pretenses, representations, and promises, for the purpose of executing such scheme, knowingly caused to be delivered by mail a package containing a "COVID-19 Treatment Pack," in violation of Title 18, United States Code, Section 1341.

The complainant states that this complaint is based on the attached Statement of Facts incorporated herein by reference.

Special Agent Terrence Mycka
Federal Bureau of Investigation

Sworn and attested to under oath by telephone, in accordance with Federal Rule of Criminal Procedure 4.1, this 15th day of April, 2020.

THE HON. JILL L. BURKHARDT
U.S. MAGISTRATE JUDGE

## STATEMENT OF PROBABLE CAUSE

I, Terrence Mycka, being duly sworn, hereby depose and state as follows:

### A. COVID-19 and anti-malarial drugs hydroxychloroquine and chloroquine

1. According to the web site for the World Health Organization ("WHO"), COVID-19 is an infectious disease caused by a newly discovered coronavirus. This new virus was unknown before the outbreak began in Wuhan, China, in December 2019. The most common symptoms of COVID-19 are fever, tiredness, and dry cough, although around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. On March 11, 2020, the WHO recognized the outbreak as a "pandemic." As of April 5, 2020, the WHO's web site reported over 1.1 million cases worldwide, with over 60,000 deaths. The web site stated, "At this time, there are no specific vaccines or treatments for COVID-19. However, there are many ongoing clinical trials evaluating potential treatments."

2. According to the web site of the Centers for Disease Control and Prevention ("CDC"), on a page entitled "Information for Clinicians on Therapeutic Options for COVID-19 Patients," (updated April 7, 2020) "[t]here are no drugs or other therapeutics approved by the US Food and Drug Administration to prevent or treat COVID-19." The page also addresses two drugs, hydroxychloroquine and chloroquine, which are "oral prescription drugs that have been used for treatment of malaria and certain inflammatory conditions. Hydroxychloroquine and chloroquine are under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19."

3. In a letter dated March 28, 2020, the FDA noted that "[c]hloroquine phosphate and hydroxychloroquine sulfate are not FDA-approved for treatment of COVID-19." The letter encouraged the conduct of clinical trials to determine the effectiveness of these drugs in treating COVID-19. However, the FDA letter determined that "[b]ased on the totality of scientific evidence available to FDA, it is reasonable to believe that chloroquine phosphate

and hydroxychloroquine sulfate may be effective in treating COVID-19," and that circumstances warranted the emergency approval of the drugs. Accordingly, the FDA letter authorized "the emergency use of chloroquine phosphate and hydroxychloroquine sulfate, . . . when clinical trials are not available, or participation is not feasible," subject to the specific terms of the authorization letter. These terms included requirements that the medications be distributed from the Strategic National Stockpile to public health authorities, and that they "may only be used to treat adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible."

**B. Skinny Beach offers hydroxychloroquine to healthy people**

4. Skinny Beach Med Spa ("Skinny Beach") is a business based in San Diego, California. On a recent visit, the web site for Skinny Beach, skinnybeach.com, stated, "Welcome to Skinny Beach, where you will enjoy access to world-class beauty innovations at affordable prices." It advertises services such as weight loss programs, hyperbaric oxygen therapy, botox, tattoo removal, hair removal, and fat transfer. The web site lists an address of 4645 Carmel Mountain Road, Suite #208, in San Diego, as well as addresses in Del Mar and San Juan Capistrano.

5. On Monday, March 30, ABC 10 News San Diego ran a story on Skinny Beach, with the title, "Accusations of 'unethical' COVID-19 treatment at Carmel Valley medical spa." The piece reported that Skinny Beach and its operator, Dr. Jennings Staley, were offering COVID-19 "family resistance packs" for approximately $4,000. The piece included on-camera statements by Dr. Staley, who complained that he had received death threats. Staley added, "I knew it would be a little bit controversial because there was the controversy around the fact that hydroxychloroquine wasn't approved until Sunday night but I didn't think people would be so angry."

6. On March 27, 2020, Skinny Beach sent an e-mail from hello@skinnybeach.com to its mailing list advertising COVID-19 treatment packs. The e-mail from Skinny Beach included a link to a third-party website at the bottom of the

message that said, "CLICK HERE TO PURCHASE COVID-19 TREATMENT PACKS." Screen shots taken from the third-party web site, go.booker.com, on March 28, 2020, describe Skinny Beach's offer of a "COVID-19 Concierge Medicine Pack (Family)" for $3,995.00:

> Dr. Staley is offering a concierge medicine experience for the next 30 days to a few clients who desire guidance and medical management during these times.
> The concierge medical package is available on a limited basis and will include:
> - at home and in-store intravenous Drips
> - Exclusive access to medical hyperbaric oxygen chamber at separate rates
> - COVID-19 Updates and 24/7 access to Dr. Staley and his team to answer your questions and help you through this time
> - Anti-anxiety treatments to help you avoid panic if needed and help you sleep
> - Hydroxychloroquine and Azithromycin for you and all members of your family. Choose to keep your meds at home or safely held in our office with YOUR NAME ON IT. Each individual needs a prescription.
> - COVID-19 ELISA testing IgC and IgM to determine if you are infected currently or previously
> - If you experience respiratory distress you will be sent via EMS to a local ED. Dr. Staley will notify the ED as to your status and health info
>
> Dr. Staley will see each patient via telemedicine to perform a risk assessment and intake evaluation.
>
> If anyone develops symptoms such as fever and body aches, you will be immediately evaluated by telemedicine and followed closely to determine need to activate your treatment kit. We will follow the clinical guidelines set forth by Harvard Medical School and the CDC.
>
> Includes: Hydroxychloroquine 200mg x 5[,] Azithromycin 250mg x 5[,] Vitamin C 500mg x 30[,] Zinc 220mg x 30

7. From the foregoing, it appears that Skinny Beach was offering to sell, as part of its "COVID-19 Concierge Medicine Pack (Family)" for $3,995.00, 200 mg tablets (apparently 20 tablets in total for a family of four) of anti-malarial hydroxychloroquine to anyone willing to buy them, and that Dr. Staley would instruct the customer when to "activate" the medications by taking them. The offer also included, without further specification, "[a]nti-anxiety treatments to help you avoid panic if needed and help you sleep."

**C. An Undercover Agent Responds to Skinny Beach's Offer**

8. An undercover agent ("UC") of the FBI responded by email to Skinny Beach's offer. The UC stated that he had a wife and three children, that his father would be coming to live with the family, and that he wanted to learn more about purchasing six COVID-19 treatment packs.

9. On Friday, April 3, 2020, the UC received a call from Dr. Staley, who said that he was calling about his "COVID-19 management program."[1] Staley explained how the offer worked. After purchasing a "COVID-19 treatment kit," the patient can either pick it up, or have it mailed to him or her. In the event someone in the household "gets sick," Staley will "activate" the kit, meaning he will tell the household how much of their medications to take. "I will be dosing it. I will activate it. You will own and possess these kits." Staley explained that the medication would be taken not only by the sick person, but also by everyone else in the household, to protect them from getting the virus (i.e., to "prophylax" them). "When someone gets sick, we will start the loading on that person. We will load them and prophylax all of you."

10. On the call, Staley said that he was selling anti-malarial medication that "cures the disease," identifying the medication as hydroxychloroquine. "It's incredible. There's never been before, except for hepatitis C, in the history of medicine been a situation where a medication is completely curative of a virus." Staley explained that "you could be short of breath and coughing at noon today, and if I start your hydroxychloroquine loading dose, you'll feel 99% better by noon tomorrow." He described it as an "amazing cure" and a "miracle cure" that was "perfectly engineered." Staley also discussed another anti-malarial – mefloquine – that he would sell the UC if he ran out of hydroxychloroquine. When asked if either medication will cure the disease, Staley responded, "100%." He added that both medications will also prevent you from getting COVID-19: "you're immune for at least 6 weeks." Staley referred to the medication he offered as a "magic bullet." "It's preventative and curative. It's hard to believe, it's almost too good to be true. But it's a remarkable

[1] Quotes from recordings in this affidavit are based on my review of the recordings and are approximate.

clinical phenomenon." Staley also stated, "I've never seen anything like this in medicine, just so you know. Really, I can't think of anything. That, you've got a disease that literally disappears in hours."

11. Staley claimed that he "got the last tank of hydroxychloroquine smuggled out of China on Sunday night." He said that "the broker smuggled it out," and "tricked customs" by saying that it was "sweet potato extract." He said that the drug was coming in the form of a crystalline powder weighing eight kilograms, that would constitute 8,000 doses, and that needed to be made into gelatin capsules. He said he had received a DHL shipping notice and that he expected the package to arrive later that day.

12. Staley also described obtaining hydroxychloroquine from Teva Pharmaceuticals, and said he had the medication in his office and the UC could pick it up. He claimed that he had been mailing out kits all day, and stated that he had only six kits remaining at the moment; but later added that he expected another shipment of "180" the following day. Staley said he had a buyer coming from Scottsdale, Arizona that afternoon; and that Staley would potentially be selling the hydroxychloroquine powder to the government of the United Kingdom.

13. Staley told the UC that the UC's earlier contact by email had been with Staley's wife. Staley also mentioned he had a $10,000 investor. And during the call, which was on speaker phone, a third individual identified as "Mike" also spoke. Staley explained that Mike is an assistant at Skinny Beach who runs the hyperbaric oxygen equipment.

14. At one point in the call, the UC asked, "If I'm hearing you right, if I buy these kits from you, then that's going to pretty much guarantee that neither my kids, my dad, my wife, any of us get sick, and if we are, it's going to cure us, right?" Staley responded, "Guaranteed." He then qualified his answer, saying, "Now, there's always exceptions, your dad could come here and die of a heart attack." Later in the call, when the UC used the word "guarantee" again, Staley responded, "A little red flag goes off when I hear the word guarantee. . . . There are no guarantees in life. There are no guarantees of anything." During

the call, Staley repeatedly invited the UC to "google" one topic or another to substantiate Staley's claims, and made reference to several scientific or medical studies.

15. At the end of the call, Staley agreed to sell the UC six treatment kits for the family price of approximately $4,000. He also stated that each person would get their own "hydroxychloroquine Z-pack kit," with their name on it, and added, "you can sell it on eBay for 2500 a pop."

**D. Dr. Staley offers the UC a controlled substance**

16. On Monday, April 6, the UC spoke by telephone again to Dr. Staley. Staley said he had set aside four portions of hydroxychloroquine, and two portions of chloroquine. He added that he had just received an additional delivery of hydroxychloroquine "from Del Mar." Staley provided the UC with the phone number for Staley's wife, Amanda, to arrange for payment.

17. During the discussion, Staley volunteered: "Did you need Viagra, Xanax … I have IV fluids if you have a nurse in the house. We ship you that." The UC responded, laughing, "Yeah, I mean, who doesn't need those things." Staley added, "It comes with your concierge package so if you want a bottle of the Viagra 100mg as long as you don't have any nitrates or coronary artery disease. Do you want a bottle of the 100mg Viagra?" The UC responded affirmatively. Staley then asked, "And then you need any Xanax?" The UC responded, "Yeah, why not?" Staley then said, "OK, just take half a tab. It helps you sleep, and there's a lot of panic going on right now. So just tell Amanda that you got those too, that it's courtesy, that she gets your date of birth and everything, so I can put it into the pharmaceutical record."

18. Xanax is the brand name for the drug alprazolam, a type of benzodiazepine, and a Category IV Controlled Substance under the Controlled Substances Act. Staley's offer of the drug to the UC as part of the "concierge package," along with Staley's online marketing of "anti-anxiety treatments" as part of the package, suggests that Staley is routinely distributing this controlled substance without any sort of medical examination or demonstration of need.

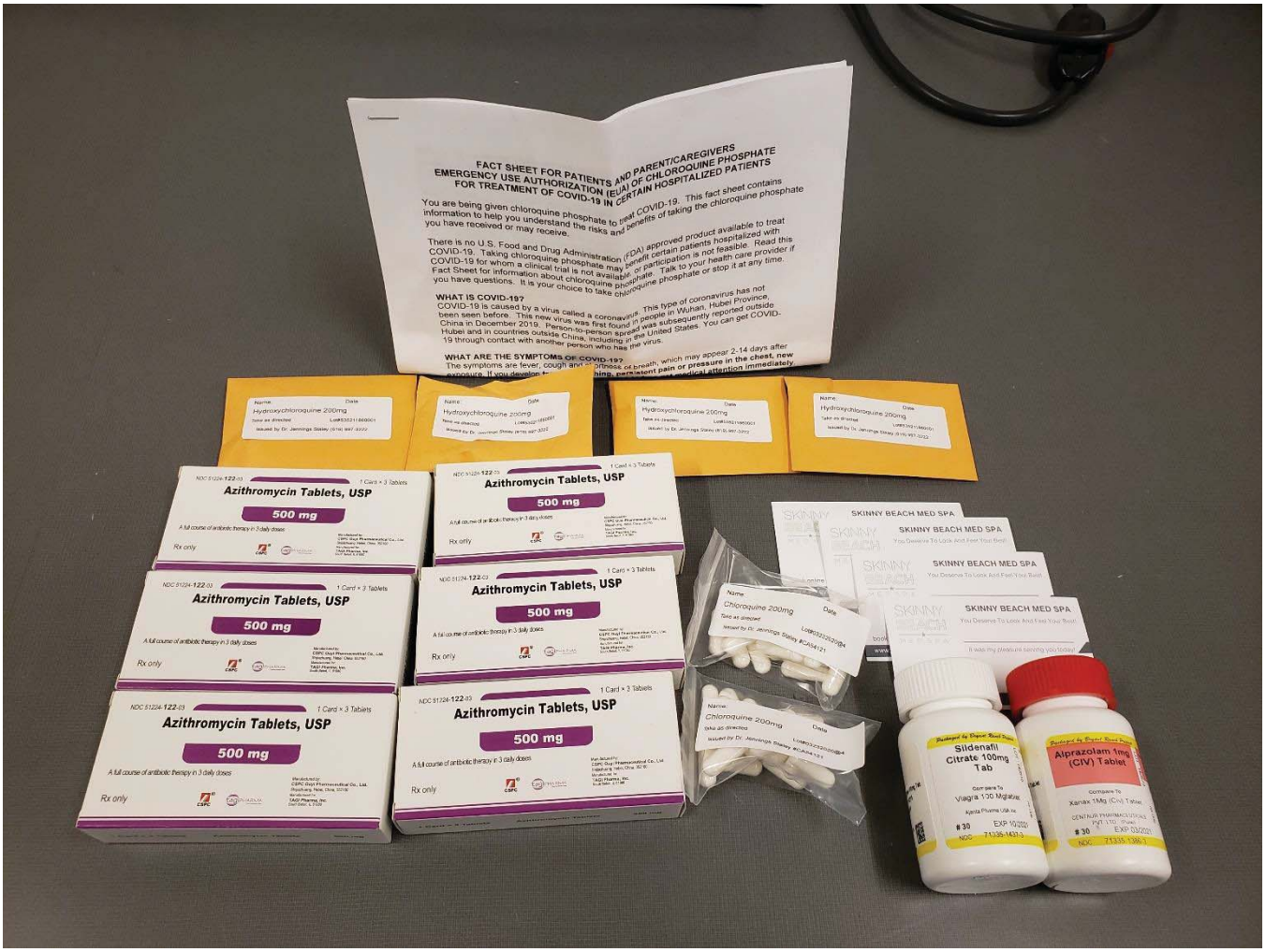
19. The Controlled Substances Act, 21 U.S.C. § 841(a)(1), provides that "[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute . . . a controlled substance." Another portion of the CSA provides that every person who distributes a controlled substance "shall obtain annually a registration issued by the Attorney General in according with the rules and regulations promulgated by him." 21 U.S.C. § 822(a). Relevant regulations provide that "[a] prescription for a controlled substance to be effective must be issued for ***a legitimate medical purpose*** by an individual practitioner ***acting in the usual course of his professional practice***." 21 C.F.R. § 1306.04(a) (emphasis added). Likewise, the regulations permit "[a]n individual practitioner" to "dispense directly a controlled substance" listed in Schedule IV without a prescription "***in the course of his/her professional practice***." 21 C.F.R. § 1306.21(b) (emphasis added). Whether or not a prescription is issued, these regulations do not grant authorization to physicians to distribute controlled substances as Staley did here, without any medical examination whatsoever.

20. Additionally, another section of the CSA expressly provides that no controlled substance that is a prescription drug may be "delivered, distributed, or dispensed by means of the Internet without a valid prescription," 21 U.S.C. § 829(e), and the CSA defines this phrase to refer "to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet." 21 U.S.C. § 802(51). Distribution of a controlled substance in violation of Section 829 is also a criminal offense if done knowingly. 21 U.S.C. § 842(a)(1), (c)(2)(A).

**E. Staley and his wife ship drugs to the UC**

21. Later in the afternoon on April 6, the UC called the number provided by Staley, and spoke to "Amanda." She took his credit card number and a mailing address, and when the UC mentioned the Viagra and Xanax, she said, "OK, I'll remind him, I'll put it in the notes. He'll be the one doing it."

22. FBI received the requested medication on Thursday, April 9, 2020. As depicted below, the shipment included azithromycin tablets in a box; generic Xanax and Viagra in bottles; hydroxychloroquine in small brown envelopes; and chloroquine in small, clear plastic bags:




23. Also included, as shown above, was a "fact sheet for patients and patient/caregivers" for emergency use authorization of chloroquine to treat COVID-19, issued by the FDA; and some Skinny Beach business cards.

**F. FBI interviews Dr. Staley, and he makes false statements**

24. On Friday, April 10, 2020, another agent and I conducted an interview of Dr. Staley at Skinny Beach. I advised Staley at the outset that the interview was entirely voluntary. During the interview, I also advised Staley that it was a crime to lie to a federal agent.

25. During the interview, Staley touted the effects of hydroxychloroquine in treating COVID-19. I asked him whether he was communicating to patients that the drug "is a cure, is 100% curative?" Staley replied, "No, I would be careful not to say that. You know, you could put something like that in quotes if someone else called it that, possibly. But I – If we ever said that it's a cure that would've been a mistake. Because you don't know that they have COVID-19. We don't know – It's not definitive that it cures it, right? We don't know enough about the spectrum of the disease." Staley added, "We know it works," but that a study should be done to determine, "at what stage of the disease would it work is more important, and what's the minimum effective dose?" Staley was again asked whether Skinny Beach has told potential clients that the treatments are a "100% effective cure" for COVID-19. Staley said, "No, that would be foolish. We would never say anything like that." As demonstrated by Staley's sales pitch to the UC, his statements to me were false.

26. Also during the interview, Staley said that he had purchased 12 kilograms of hydroxychloroquine from a major pharmaceutical supplier in China, and that he expected the package to arrive by DHL air the next Monday (i.e., April 20, 2020). Staley said he also has an additional 35 kilograms of hydroxychloroquine on order from two other pharmaceutical manufacturers in China. He said his goal is to obtain 300 kilograms of hydroxychloroquine, which will make 150,000 kits. Staley said he plans to distribute kits through his new business, covid19medkits.com. He described importation of the drug as "perfectly legal," and said that "it goes through customs." He later stated that when it comes to ordering "non-narcotic meds and vitamins and stuff" from China, it gets through customs, and "we don't have to mislabel it or anything." As evidenced by Staley's statements to the UC that he had hydroxychloroquine smuggled out of China, his statements to me were false.

27. During the interview, Staley said that 80% of the patients that have come in to Skinny Beach concerning COVID-19 have had acute panic disorder. Staley purchases Xanax from a medical supplier and does "in-office" dispensing of the drug. As part of the

COVID-19 treatment packs, Staley has prepared five-pack alprazolam, or Xanax, "baggies" that he will prescribe if patients say they have anxiety and are panicking. Staley explained that he does a CURES database check to make sure the patient is not doctor shopping and the patient must have no rehab or drug abuse history. Staley said that he has not sent out any five-pack baggies yet, "just a couple bottles of, the, umm, home delivery where I went there and I had these meds with me in my go kit, and if they're seeming really hysterical or someone is," Staley asks if they need some help with sleep. Staley instructs the patient to break the Xanax tab, which is 1 mg, in half. Patients are so happy because for about 12 hours, the Xanax dulls the panic. As demonstrated in Staley's interactions with the UC, Staley did not conduct a home visit with the UC.

28. During the interview, Staley offered that he would "take everything down" if asked; asked whether what he was doing was illegal; and said that "my lawyer says it's fine."

**G. Dr. Staley offers hydroxychloroquine for sale on a new web site**

29. On April 13, 2020, I visited the web site "covid19medkits.com." The "Contact Us" page provides, as a business address, the San Diego address for Skinny Beach. The home page advertises, "protect yourself with hydroxychloroquine and Z-Pack, available by online prescription, shipped to your door." The web page offers a "hydroxychloroquine + azithromycin COVI-19 treatment kit" for $595. The text of the offer reads: "Protect yourself against COVID-19 with our exclusive med kits. Each kit contains the two medications which are showing great success on the frontlines against COVID-19: HYDROXYCHLOROQUINE and AZITHROMYCIN. Kits are shipped to you after establishment of a patient-doctor relationship with a healthcare provider from COVID19MEDKITS.COM. Each patient will be evaluated by our medical director online and you will be assigned a risk assessment for complications of COVID-19 which will help us treat you at home with the treatment protocol or, if indicated, protect you from developing the disease with the prevention protocol."[2] It therefore appears that the

[2] A further narrative states, "A French study cited by Trump showed 70% of

"covid19meds" treatment pack, being offered for $595, is a subset of the larger treatment package that was offered by Skinny Beach, focusing on hydroxychloroquine and azithromycin.

**H. CBP records show Dr. Staley importing purported "yam extract"**

30. According to records accessed by U.S. Customs and Border Protection ("CBP"), a package is being shipped via the carrier DHL from mainland China, destined for Skinny Beach at its San Diego address, with Dr. Staley listed as the point of contact. The package was shipped on April 13, 2020, with an estimated delivery date of April 20, 2020. The contents of the package are described as "yam extract." These records are consistent with Staley's statement to the UC that he was smuggling in from China powdered hydroxychloroquine, falsely describing the drug as "yam extract."

**I. Conclusion**

31. As set forth above, Staley devised a scheme to defraud, and to obtain money by means of false and fraudulent pretenses, representations, and promises regarding the curative and preventative efficacy of his COVID-19 treatments; and for the purpose of executing such scheme, on or about April 10, 2020 within the Southern District of California knowingly caused to be delivered by mail a package containing a "COVID-19 Treatment Pack," in violation of Title 18, United States Code, Section 1341.

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the hydroxychloroquine treated patients tested negative for the COVID-19 virus, compared with 12.5% in the control group, while all of those who had received hydroxychloroquine plus azithromycin (6 patients) cleared the virus by this time."