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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. RILEY ALAN LEVY, Defendant.	NO. 3:24-cr-00250 TLT VIOLATIONS: 18 U.S.C. § 371—Conspiracy; 21 U.S.C. § 853, 26 U.S.C. § 2461—Criminal Forfeiture SAN FRANCISCO VENUE

INFORMATION

The Attorney for the United States charges:

GENERAL ALLEGATIONS

At all times relevant to this Information, unless otherwise specified:

The Controlled Substances Act

1. The Controlled Substances Act ("CSA"), Title 21, United States Code, Section 801 *et seq*., and its implementing regulations governed the manufacture, distribution, and dispensation of controlled substances in the United States. With limited exceptions for medical professionals, the CSA made it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense a

controlled substance or conspire to do so.

2. The CSA and its implementing regulations set forth which drugs and other substances were defined by law as "controlled substances," and assigned those controlled substances to one of five schedules (Schedule I, II, III, IV, or V) depending on their potential for abuse, likelihood of physical or psychological dependency, accepted medical use, and accepted safety for use under medical supervision.

3. A controlled substance assigned to Schedule II had a high potential for abuse, was highly addictive, and had a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Abuse of a Schedule II controlled substance could have led to severe psychological and/or physical dependence.

4. Pursuant to the CSA and its implementing regulations, Amphetamine-Dextroamphetamine was classified as a Schedule II controlled substance. Amphetamine-dextroamphetamine was sold generically and under a variety of brand names, including Adderall. Other stimulants, including lisdexamfetamine (sometimes sold under the brand name Vyvanse) and methylphenidate (sometimes sold under the brand name Ritalin), also were classified as Schedule II controlled substances.

5. Medical practitioners, such as nurse practitioners and physicians, who were authorized to prescribe controlled substances by the jurisdiction in which they were licensed to practice medicine, were authorized under the CSA to prescribe, or otherwise distribute, controlled substances, if they were registered with the Attorney General of the United States. 21 U.S.C. § 822(b); 21 C.F.R. § 1306.03. Medical practitioners were required to register with the Drug Enforcement Administration ("DEA") in order to prescribe controlled substances. The registration of mid-level practitioners, such as nurse practitioners, was contingent upon the authority granted by the state in which they were licensed. Upon application by the practitioner, the DEA assigned a unique registration number to each qualifying medical practitioner. The DEA was responsible for enforcement of controlled substance laws in the United States.

6. The CSA required all practitioners to be registered in the state in which the patients to which they were prescribing controlled substances were located, regardless of whether the prescribing was taking place via telemedicine. The CSA provided that every person who dispensed, or who

proposed to dispense, any controlled substance shall obtain from DEA a registration issued in accordance with DEA rules and regulations. 21 U.S.C. § 822(a)(2). Under the CSA, such dispensing included prescribing and administering controlled substances. *Id*. § 802(10). DEA was permitted to only register a person to dispense a controlled substance if that person was permitted to do so by the jurisdiction in which his or her patients were located. *Id*. §§ 802(21), 823(f). Thus, unless an applicable exception applied, DEA regulations required a practitioner to obtain a separate DEA registration in each state in which a patient to whom he or she prescribed a controlled substance was located when the prescription was made, regardless of whether the prescription was made via telemedicine.

7. Title 21 of the Code of Federal Regulations, Section 1306.04 governed the issuance of prescriptions for controlled substances; it provided that, to be effective, a prescription for a controlled substance:

> must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

8. Pharmacists were required to exercise sound professional judgment, and to adhere to professional standards, when making a determination about the legitimacy of a controlled substance prescription. 21 C.F.R. §§ 1306.04(a) and 1306.06. Such a determination was made before the prescription was dispensed. The law did not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious medical legitimacy. To the contrary, the pharmacist who deliberately ignored the high probability that a prescription was not issued for a legitimate medical purpose and filled the prescription was subject to prosecution along with the issuing practitioner and others responsible, for knowingly and intentionally distributing controlled substances. Moreover, DEA possessed the authority to revoke a pharmacy's registration based on a finding that its pharmacists had violated the corresponding responsibility rule.

9. Pursuant to their corresponding responsibility, Pharmacy No. 1, Pharmacy No. 2, and Pharmacy No. 3 adopted policies to ensure that controlled substance prescriptions were issued for a legitimate medical purpose in the usual course of professional practice, and that pharmacists were acting in the usual course of professional practice in filling such prescriptions. 21 C.F.R. §§ 1306.04(a) and 1306.06. In order to exercise their corresponding responsibility, Pharmacy No. 1, Pharmacy No. 2, and Pharmacy No. 3 employed pharmacists who reviewed relevant information about the prescription, including documentation and evidence provided by the practitioner or others regarding whether the prescription was issued for a legitimate medical purpose in the usual course of professional practice. Pharmacy No. 1, Pharmacy No. 2, and Pharmacy No. 3 in the ordinary course relied on information transmitted by the practitioner or others acting on the practitioner's behalf.

The Ryan Haight Act

10. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was enacted to stem the increase in the use of controlled substances purchased on the Internet. The Act mandated, with limited exceptions, that the dispensing of a controlled substance by means of the Internet be predicated on a valid prescription issued by a practitioner who has conducted at least one in-person medical evaluation of the patient. The Act was codified in Title 21 of the United States Code.

11. Title 21, United States Code, Section 841(h) provided that it was unlawful to "knowingly or intentionally— writ[e] a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of [Title 21, United States Code,] [S]ection 829(e) …."

12. Title 21, United States Code, Section 829(e)(1) provided that, "[n]o controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription."

13. Title 21, United States Code, Section 829(e)(2)(A) provided that in order for a prescription to be valid it had to be "issued for a legitimate medical purpose in the usual course of practice by— (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner."

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14. Title 21, United States Code, Section 829(e)(2)(B)(i) provided that an "in-person medical evaluation" was "a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals."

15. Title 21, United States Code, Sections 829(e)(3) and 802(54) provided that the requirement of conducting at least one in-person medical evaluation did not apply in certain circumstances involving "the practice of telemedicine" where the Secretary of Health and Human Services ("HHS") has declared "a public health emergency" and it "involve[d] patients located in such areas, and such controlled substances, as the Secretary [of HHS], with the concurrence of the Attorney General, designate[d]…" 21 U.S.C. § 802(54)(D).

16. Title 21, United States Code, Section 802(54) provided that "[t]he term 'practice of telemedicine' means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in [S]ection 1395m(m) of [T]itle 42 …."

17. Title 42, United States Code, Section 1395m(m)(1) and implementing regulations, including Title 42, Code of Federal Regulations, Section 410.78, provided that a telecommunications system meant "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner," and "include[d] store-and-forward technologies that provide for asynchronous transmission of health care information" only in "telemedicine demonstration program conducted in Alaska and Hawaii."

18. On or about January 31, 2020, the Secretary of HHS declared a national public emergency under Title 42, United States Code, Section 247d as a result of the spread of the novel coronavirus COVID-19 within the United States.

19. In response to the COVID-19 Public Health Emergency as declared by the Secretary, pursuant to the authority under Section 319 of the Public Health Service Act (42 U.S.C. § 247), the DEA granted temporary exceptions to the Ryan Haight Act and DEA's implementing regulations under Title

21, United States Code, Section 802(54)(D), thereby allowing the prescribing of controlled medications via telemedicine encounters—even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient—in certain circumstances in order to prevent lapses in care.

20. These emergency flexibilities involving telemedicine allowed, during the pendency of the COVID-19 Public Health Emergency, the prescribing of controlled substances without first conducting an in-person examination only if all of the following conditions were met: the prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice; telemedicine communication was conducted using an audio-visual, real-time, two-way interactive communication system; and the practitioner was acting in accordance with applicable federal and state laws. The principal purpose of these policies was to limit the spread of COVID-19 by enabling patient access to medically necessary controlled substances through telemedicine, without otherwise altering the existing legal prohibitions on writing prescriptions that contravene federal or state laws.

The Defendant

21. Defendant Riley Alan Levy was a resident, at various times, of the Northern District of California and the District of Arizona. Levy was the Executive Leader, Operations and Strategy for Telehealth Company 1.

22. Telehealth Company 1 was a self-proclaimed "digital health company" that operated on a subscription-based model where individuals ("Telehealth Company 1 members") paid a monthly fee to Telehealth Company 1. Telehealth Company 1 advertised that it provided online diagnosis, treatment, and refills of medication for attention deficit hyperactivity disorder ("ADHD"). Telehealth Company 1's principal place of business was within the Northern District of California.

COUNT ONE: (18 U.S.C. § 371 – Conspiracy)

23. All previous paragraphs of this Information are realleged and incorporated by reference as though fully set forth herein.

24. From in or around October 2021, and continuing through in or around January 2023, in San Francisco, in the Northern District of California, and elsewhere, the defendant,

RILEY ALAN LEVY,

knowingly and intentionally conspired and agreed with Chief Executive Officer 1, Clinical President 1,

Telehealth Company 1, and others, known and unknown to the Attorney for the United States, to violate Title 21, United States Code, Sections 841(h)(1) and (4) by knowingly and intentionally delivering, distributing, or dispensing mixtures and substances containing detectable amounts of Schedule II controlled substances, namely Amphetamine-Dextroamphetamine, by means of the Internet, and aiding and abetting such activity.

Purpose of the Conspiracy

25. It was the purpose of the conspiracy for Levy, Chief Executive Officer 1, Clinical President 1, Telehealth Company 1, and others to unlawfully enrich themselves by: (a) conspiring to provide Telehealth Company 1 members with prescriptions for Adderall and other stimulants that were not for a legitimate medical purpose in the usual course of professional practice; (b) enabling Telehealth Company 1 members to obtain Adderall and other stimulants from pharmacies by, among other things, providing prescriptions, transmitting health care insurance information to pharmacies, making false and fraudulent representations to pharmacies, seeking to obstruct efforts by pharmacies to exercise their corresponding responsibility, and causing pharmacies to submit false and fraudulent claims for reimbursement to health care insurance plans; (c) concealing and disguising the unlawful prescription of Adderall and other stimulants, the submission of false and fraudulent claims to health care insurance plans, and the receipt and transfer of the proceeds of the conspiracy; (d) increasing revenue and causing the value of Telehealth Company 1 to increase through the illegal distribution of controlled substances to Telehealth Company 1 members who paid subscription fees to Telehealth Company 1 on a monthly basis in exchange for medically unnecessary Adderall and other stimulants; and (e) diverting proceeds of the conspiracy for their personal use and benefit, for the use and benefit of others, and to further the scheme.

Manner and Means of the Conspiracy

26. The dishonest and deceitful manner and means by which Levy, Chief Executive Officer 1, Clinical President 1, Telehealth Company 1, and others sought to accomplish the purpose and object of the conspiracy included, among other things, the following:

27. Levy knew that Chief Executive Officer 1 founded Telehealth Company 1 in order to provide easy access to prescriptions for Adderall and other stimulants by means of the Internet. Levy

knew that Clinical President 1 joined Telehealth Company 1 as Clinical President in order to advance this shared goal.

28. Levy knew that Telehealth Company 1 acquired thousands of members by intentionally targeting drug seeking patients and advertising that members could obtain easy access to prescriptions for Adderall and other stimulants in exchange for payment of a monthly subscription fee to Telehealth Company 1.

29. Levy knew that Chief Executive Officer 1, Clinical President 1, and others hired doctors and nurse practitioners (collectively, "Telehealth Company 1 prescribers") to work for Telehealth Company 1 and paid the Telehealth Company 1 prescribers to diagnose Telehealth Company 1 members with ADHD and issue prescriptions for Adderall and other stimulants regardless of whether the prescriptions were for a legitimate medical purpose in the usual course of professional practice.

30. Levy knew that Chief Executive Officer 1, Clinical President 1, and others set forth policies and procedures at Telehealth Company 1, including that initial appointments with Telehealth Company 1 members would be scheduled for 30 minutes or less, in order to distribute Adderall and other stimulants to Telehealth Company 1 members, knowing that the time period and available information were insufficient for Telehealth Company 1 prescribers to diagnose ADHD and dispense prescriptions that were for a legitimate medical purpose in the usual course of professional practice.

31. Levy knew that Chief Executive Officer 1, Clinical President 1, and others paid and caused lucrative payments to be made to Telehealth Company 1 prescribers to sign prescriptions and cause pharmacies to dispense prescriptions that were not for a legitimate medical purpose in the usual course of professional practice. Chief Executive Officer 1, Clinical President 1, and others knew and intended for these lucrative payments to cause Telehealth Company 1 prescribers to write prescriptions for Telehealth Company 1 members that were not for a legitimate medical purpose in the usual course of professional practice.

32. Levy knew that Chief Executive Officer 1, Clinical President 1, and others obtained confidential patient information for thousands of Telehealth Company 1 members and provided it to Telehealth Company 1 prescribers in order for Telehealth Company 1 prescribers to write prescriptions for Adderall and other stimulants.

33. Levy knew that Chief Executive Officer 1, Clinical President 1, and others caused Telehealth Company 1 prescribers to prescribe Adderall and other stimulants to Telehealth Company 1 members with whom they lacked a pre-existing practitioner-patient relationship, without an examination, sometimes based solely on a short video or audio communication and limited patient intake documents, or without any video or audio communication at all. Levy knew that Chief Executive Officer 1, Clinical President 1, Telehealth Company 1 prescribers, and others agreed to provide few, if any, medical treatment options besides prescribing Adderall and other stimulants.

34. Levy knew that Clinical President 1, Telehealth Company 1 prescribers, and others signed orders for Adderall and other stimulants for Telehealth Company 1 members, including Medicare and Medicaid beneficiaries, regardless of whether the Telehealth Company 1 member (a) met the Diagnostic and Statistical Manual of Mental Disorders - V criteria for diagnosing ADHD; (b) posed a risk of diversion; and/or (c) was provided dosages, directions, combinations, or quantities of medications beyond those normally prescribed.

35. Levy knew that Chief Executive Officer 1, Clinical President 1, Telehealth Company 1 prescribers, and others agreed that, after an initial consultation with a Telehealth Company 1 member, Telehealth Company 1 prescribers would be paid solely based on "patient load" (the number of patients to whom Telehealth Company 1 prescribers wrote prescriptions each month) and would not be paid for any patient consultation, time, or medical services that Telehealth Company 1 prescribers provided to Telehealth Company 1 members.

36. Levy, Chief Executive Officer 1, Clinical President 1, and others knew that, after an initial consultation with a Telehealth Company 1 member, Clinical President 1 and other Telehealth Company 1 prescribers signed additional monthly prescriptions for Schedule II controlled substances, including Adderall and other stimulants, that were not for a legitimate medical purpose in the usual course of professional practice for Telehealth Company 1 members, including Medicare and Medicaid beneficiaries, (a) without an in-person examination and without seeing, speaking to, and/or otherwise engaging in audio or video communication with Telehealth Company 1 members; and (b) without determining the Telehealth Company 1 members' medical need for the prescriptions. In some instances, Telehealth Company 1 paid Clinical President 1 and other Telehealth Company 1 prescribers to write

prescriptions for Telehealth Company 1 members whom Clinical President 1 and other Telehealth Company 1 prescribers had never seen or had any prior telemedicine consultation with, including for Telehealth Company 1 members in states where Clinical President 1 and other Telehealth Company 1 prescribers were not licensed to write controlled substance prescriptions under state and federal law.

37. In order to cause pharmacies to dispense Adderall and other stimulants that were not prescribed for a legitimate medical purpose in the usual course of professional practice to Telehealth Company 1 members, and obstruct, interfere with, and deprive pharmacies of their ability to exercise their corresponding responsibility to ensure that dispensed medications were only for a legitimate medical purpose in the usual course of professional practice, Levy, Chief Executive Officer 1, Clinical President 1, and others, among other things, (a) collected insurance information from Telehealth Company 1 members; (b) transmitted Telehealth Company 1 members' insurance information to pharmacies for the purpose of causing the pharmacies to bill the Telehealth Company 1 members' insurance for dispensing Adderall and other stimulants; (c) made or caused to be made false and fraudulent representations to pharmacies in order to cause them to submit false and fraudulent claims to insurance and dispense Adderall and other stimulants to Telehealth Company 1 members; and (d) created and caused to be created false and fraudulent documents, and submitted and caused the submission of false and fraudulent documents, including pre-authorizations, to insurance companies for the purpose of causing them to pay for Adderall and other stimulants that were dispensed to Telehealth Company 1 members.

38. Levy, Chief Executive Officer 1, Clinical President 1, and others agreed with Telehealth Company 1 prescribers and others to falsely make it appear that the prescriptions written by Telehealth Company 1 prescribers were for a legitimate medical purpose in the usual course of professional practice.

39. Levy, Chief Executive Officer 1, Clinical President 1, and others concealed and disguised the conspiracy by making false and fraudulent representations to other third parties, including media outlets, business partners, and regulatory and credentialing entities. These false and fraudulent representations concerned Telehealth Company 1's business model and its policies, procedures, and practices distributing Adderall and other stimulants. The purpose of these false and fraudulent

representations was to maintain or increase the value of Telehealth Company 1, induce certain third parties to do business with Telehealth Company 1, and forestall, impede, or obstruct government investigations and regulatory action involving Levy, Chief Executive Officer 1, Clinical President 1, Telehealth Company 1, and others.

40. Levy, Chief Executive Officer 1, Clinical President 1, and others sought to conceal and disguise the conspiracy, and prevent, obstruct, mislead, and delay the communication of information or records, and impede, obstruct, or influence the investigation or proper administration of Telehealth Company 1, by refraining from writing down or preserving incriminatory information; using encrypted messaging platforms to communicate about the conspiracy; and seeking to hide or destroy information or records sought in investigations.

Overt Act

41. In furtherance of the conspiracy, and to accomplish its objects and purpose, at least one of the co-conspirators committed and caused to be committed, in the Northern District of California, and elsewhere, at least the following overt act, among others:

42. On or about March 16, 2022, an employee of Pharmacy 1 sent an email to Levy requesting to "chat to understand the policies and procedures that [Telehealth Company 1] [ ] has in place that might help our pharmacists feel more comfortable dispensing controlled substances (specifically Adderall) prescribed by your prescribers." On or about March 16, 2022, Levy sent an email to an employee of Pharmacy 1 that he had compiled "internal documentation . . . into one document [ ] and attached it …." Levy attached to the email a document entitled "General Information Related to [Telehealth Company 1] Practice of Telehealth" that contained false and fraudulent representations.

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

FORFEITURE ALLEGATION: (21 U.S.C. § 853; 26 U.S.C. § 2461)

43. The factual allegations contained in this Information are realleged and by this reference fully incorporated herein for the purpose of alleging forfeiture pursuant to the provisions of 21 U.S.C. §§ 853(a)(1) and (2).

44. Upon a conviction of for the offense alleged above, the defendant,

RILEY ALAN LEVY,

shall forfeit to the United States all right, title, and interest in property constituting and derived from any proceeds the defendant obtained, directly or indirectly, as a result of said violations, and any property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of the said violations, including but not limited to the following property:

(a) the sum of $23,760; and

(b) 4,808 Shares in Telehealth Company 1.

45. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

any and all interest the defendant has in other property shall be vested in the United States and forfeited to the United States pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c).

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All in violation of 21 U.S.C. §§ 853(a)(1) and (2), (p) and Rule 32.2 of the Federal Rules of Criminal Procedure.

DATED: May 1, 2024

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