

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

US COMPOUNDING, INC.,

Defendant.

**INFORMATION**

24 Cr. 423

**COUNT ONE**  
**(Conspiracy to Commit Mail Fraud)**

The United States Attorney charges:

**OVERVIEW**

1. Between at least in or about 2015 and in or about 2023, DMK Pharmaceuticals Corporation (“DMK”) was named Adamis Pharmaceuticals Corporation (“Adamis”). In May 2023, Adamis merged with DMK and immediately appointed a new Chief Executive Officer. On or about September 6, 2023, Adamis publicly announced that it had changed its name to DMK Pharmaceuticals Corporation. DMK also restructured its executive leadership and appointed a new Chief Financial Officer and a new General Counsel and Corporate Secretary. Before the merger, Adamis was a publicly traded biopharmaceutical company based in California focused on the development of therapeutic drugs. In or about 2016, Adamis acquired U.S. Compounding, Inc. (“USC”), a then-privately held drug compounding company based in Arkansas that supplied prescription medications and compounded drugs intended for animal use. The drugs that USC compounded required a prescription before they could be legally shipped to retail customers.

2. From at least in or about 2015, and continuing until at least in or about 2021, USC violated United States federal laws by distributing a particular adulterated and misbranded

equine drug (the “Drug”) across the United States to end-users pursuant to fabricated prescriptions generated in the name of a Kentucky-based veterinarian (the “Veterinarian”) who was complicit in the scheme. The Veterinarian was a licensed practitioner in some, but not all, states where USC shipped the Drug. The Veterinarian allowed his name and veterinary credentials to be listed on USC’s falsified prescription records in exchange for a commission of all USC’s patient-specific sales of the Drug that were falsely listed as having been prescribed by the Veterinarian (the “Scheme”).

3. In or about 2016, shortly after Adamis acquired USC, an Executive of Adamis (the “Adamis Executive”), an Executive of USC (“USC Executive”), and a veterinary drug sales representative at USC (“Sales Rep 1”), sought to conceal the kickbacks to the Veterinarian by designating the Veterinarian as a consultant for USC. The Adamis Executive, USC Executive, and Sales Rep 1 circulated a consulting agreement for the Veterinarian’s signature, which was never fully executed. Nonetheless, the Adamis Executive, USC Executive, and Sales Rep 1 mutually agreed to maintain the pretext that the Veterinarian was a consultant for the company should the payments ever be questioned.

4. Over the course of the Scheme, USC generated over \$4.2 million in revenue as a result of the illegal sales of the Drug.

5. The Scheme and any conduct outlined in the Statement of Facts predated the appointment of DMK’s current officers.

### **THE FOOD DRUG AND COSMETIC ACT**

6. At all times relevant to this Information, the Food and Drug Administration (“FDA”) was responsible for promoting and protecting public health, including the health of animals. The FDA enforces the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*

(“FDCA”), which, among other things, governs the manufacture and distribution of drugs, including prescription drugs, for humans and animals.

7. Pursuant to the FDCA and related regulations, a drug may be deemed “misbranded” or “adulterated” for several reasons. As relevant here, if a drug requires a prescription, but is dispensed or administered without a valid prescription, that drug is deemed adulterated and misbranded under the FDCA. Compounded medications require a valid prescription in order to be lawfully distributed to consumers in the United States.

8. A prescription is valid where it is issued in the usual course of a veterinarian’s professional practice, that is, where a duly licensed veterinarian has established a veterinarian-client-patient relationship (“VCPR”), and prescribes or dispenses medication to respond to a medical need. A valid VCPR requires that a veterinarian be familiar with the animal receiving treatment and with the client requesting services. Typically, a VCPR is established by physically examining the patient and discussing symptoms and treatment with the client. Further, prescription drugs must only be prescribed for a valid medical purpose, namely, to treat a bona fide medical condition. Veterinary licensing regimes are maintained on a state-by-state basis. Each state maintains its own laws, regulations, and licensing regimes designed to regulate the distribution of drugs within that state. A veterinarian licensed to practice in one state is not necessarily authorized to practice medicine in a separate state where he or she is not licensed.

#### **OPERATION OF THE SCHEME AND ADAMIS’ ACQUISITION OF USC**

9. Beginning in approximately 2015, while USC was still a privately-held corporation, Sales Rep 1 entered into an illegal arrangement with the Veterinarian wherein Sales Rep 1 would use the Veterinarian’s state veterinary licenses to generate false prescriptions for the Drug, in order to justify shipping it directly to consumers, including to consumers in the

Southern District of New York, who otherwise lacked a valid prescription. The Veterinarian was promised a 10% commission of all patient-specific sales generated using his credentials, even though Sales Rep 1, USC Executive, and Sales Rep 1's sales team knew that the Veterinarian did not have a valid VCPR with the clients receiving the medications they were shipping. Sales Rep 1 and his sales team generated approximately \$1 million in sales annually as a result of the false prescription scheme, which comprised approximately one-third of Sales Rep 1's total sales of USC drugs.

10. On March 28, 2016, Adamis announced that it had acquired USC, with USC surviving as a wholly-owned subsidiary of Adamis. Although Adamis was based in California, USC continued to operate in Arkansas, and much of its staff remained employed, including Sales Rep 1 and the USC Executive. Following the acquisition, the Adamis Executive was made aware of the Scheme and the Veterinarian's role in it. The Adamis Executive wanted to grow the Scheme in order to increase USC's and, by extension, Adamis' revenue. In or about October 2016, the Adamis Executive, Sales Rep 1, and the USC Executive discussed entering into a sham "consulting agreement" with the Veterinarian, which purported to employ the Veterinarian as a consultant of USC's for the development of new equine medications. The purpose of the sham agreement was not, however, for consulting services, but to conceal the kickbacks the Veterinarian was being paid as part of the Scheme, by making those payments appear to reflect an hourly fee for consultations. The Adamis Executive, Sales Rep 1, and the USC Executive intended to continue the Scheme and the provision of commission payments to the Veterinarian. Although a consulting agreement was prepared, it was never fully executed. Nonetheless, the Adamis Executive, Sales Rep 1, and the USC Executive intended to put forth the Veterinarian as a consultant if the commission payments were ever questioned. At various points following the

acquisition, the USC Executive, the Adamis Executive, and others discussed expanding the scheme to include other veterinarians in order to illegally enhance USC's revenue.

### **USC'S HISTORY OF STATE DISCIPLINARY ACTIONS**

11. USC was historically subject to a number of state disciplinary actions as a result of its failure to comply with state laws governing the distribution of the drugs USC compounded.

12. In 2008, the Colorado Board of Pharmacy disciplined USC for not complying with data submission requirements required by Colorado's prescription drug monitoring program, despite having received several non-compliance letters from the Board of Pharmacy. In 2010, the Hawaii Board of Pharmacy instituted a reciprocal disciplinary action for USC's failure to report the Colorado disciplinary action.

13. In 2014, the Colorado Board of Pharmacy disciplined USC for distributing a drug into Colorado pursuant to a prescription that was not patient-specific because Colorado only allowed non-resident pharmacies to distribute patient-specific orders in the state. Subsequently: i) the Michigan Board of Pharmacy disciplined USC on the basis that its license had been subject to any civil or administrative penalty as a result of the 2014 action; and ii) the Virginia Board of Pharmacy instituted a disciplinary action on the basis of USC's failure to disclose the Colorado action.

14. In 2015, the South Carolina Board of Pharmacy disciplined USC in connection with the recall of certain products that USC had distributed in South Carolina and issued a temporary suspension of USC's license in connection with USC's inability to substantiate the sterility of certain products.

15. Also in 2015, the Minnesota Board of Pharmacy disciplined USC for compounding and distributing prescription drugs for office use between April 2013 to September 2014.

16. In 2017, USC received a citation from the California Board of Pharmacy for conducting business in the state without a license. After USC was acquired by Adamis, the California Board of Pharmacy denied the application for a change of ownership from USC to Adamis, then penalized USC for continuing to operate in California without approval from the Board of Pharmacy.

17. In 2017, the Texas Board of Pharmacy instituted disciplinary proceedings against USC on two grounds: first, for USC's failure to disclose the 2008 disciplinary action instituted by the Colorado Board of Pharmacy in a prior application for renewal of USC's Texas State license; and second, for operating under the supervision of a pharmacist who was not licensed in Texas, as required under Texas State law, between September 2016 and March 2017. USC did not admit any wrongdoing in connection with the resolution of the second allegation.

18. In 2018, the Kansas Board of Pharmacy instituted disciplinary proceedings in connection with deficiencies related to USC's facilities as reported by the FDA following inspections on August 1, 2005, July 15, 2016, and February 7, 2019, and in connection with prior disciplinary actions that had been taken against USC by other Boards of Pharmacy. The proceedings were dismissed in 2021 when USC announced it was ceasing operations.

19. Also in 2018, the Michigan Board of Pharmacy instituted disciplinary proceedings in connection with deficiencies related to the pharmacist-in-charge's oversight of USC's procedures.

20. In 2019, the Maryland Board of Pharmacy instituted disciplinary proceedings against USC for having dispensed drugs wholesale without a wholesale drug distributor permit, and without valid prescriptions and for distributing drugs into the State of Maryland during periods of time when USC's pharmacy license had lapsed.

**Pharmacist Resignations And The Continuation of the Scheme**

21. In approximately December 2019, the head of the USC pharmacy responsible for fulfilling orders of the Drug ("Pharmacist-1") resigned due to USC's failure to halt the practice of fulfilling orders of the Drug based on unverified prescriptions. Pharmacist-1's replacement ("Pharmacist-2") refused to fulfill any further orders for prescription drugs predicated on unverified prescriptions submitted by USC's sales representatives. Pharmacist-2 raised concerns regarding USC's prescription practices with the Adamis Executive, the USC Executive, and Sales Rep 1, including the concern that the submitted prescriptions did not involve a VCPR and were sometimes submitted by USC sales representatives. Pharmacist-2's concerns were dismissed. In an effort to ameliorate the submission of fraudulent prescriptions, Pharmacist-2 successfully convinced Adamis to implement a new veterinary software platform that was intended to eliminate the involvement of USC's sales representatives in the creation or submission of prescriptions in connection with orders. However, the Adamis Executive, the USC Executive, and Sales Rep 1 insisted that sales representatives be permitted to continue submitting prescriptions through the new software, and ultimately prevailed. Consequently, in or about September 2020, Pharmacist-2 and two other pharmacists employed at USC resigned. A fourth pharmacist employed at USC resigned the following week.

22. Following the pharmacist resignations, sales representatives were permitted to enter prescriptions on behalf of the prescriber and/or the consumer on the new software platform

employed by USC. USC sales representatives continued to submit false prescriptions in conjunction with orders of the Drug. Sales Rep 1 directed the Veterinarian to indicate through the software that the prescriptions issued using his credentials were valid, even though they were not.

23. In or about July 2020, in response to increased perceived scrutiny of USC's operations, USC sales representatives ceased submitting prescriptions for the Drug in the name of the Veterinarian. Although USC sales representatives continued to sell the Drug to individuals, they did not record those transactions as direct-to-consumer sales within USC's internal recordkeeping system. Instead, USC sales representatives falsely classified direct-to-consumer sales of the Drug as sales of office stock to the Veterinarian. Under guidance issued by the FDA, a Veterinarian may buy compounded drugs in bulk without prescriptions so long as the Veterinarian will issue a valid prescription when those drugs are distributed to a consumer or directly dispensed to the receiving animal. USC sales representatives exploited the FDA guidance by concealing illegal sales to consumers through office stock sales to the Veterinarian, thereby avoiding the need to generate false prescriptions. According to USC's internal sales data, sales of the Drug to the Veterinarian's practice increased proportionally as direct-to-consumer sales of the Drug declined.

24. In or about April 2021, the Arkansas State Board of Pharmacy issued an Order and Notice of Hearing directed to the pharmacist who replaced Pharmacist-2. Prior to any hearing, USC settled the allegations and entered into a consent order wherein USC agreed to cease all operations in Arkansas and USC agreed to relinquish its Arkansas State licenses as a pharmacy and wholesale distributor. USC also entered into a resolution in which they made the following factual admissions: i) USC "failed to ensure prescribing veterinarians were licensed in



the state into which product was ordered and/or shipped”; ii) USC “allowed for issuance of veterinary legend products directly to consumers without receipt of a legal prescription”; iii) USC “provided remuneration directly to a veterinarian in connection with a veterinary prescription”; iv) USC “provided veterinary prescriptions drugs to animal owners without the authorization of a licensed veterinarian and a prescription”; and v) USC “filled veterinary prescriptions for patients that did not have a valid practitioner-patient relationship.”

### **STATUTORY ALLEGATIONS**

25. From at least in or about 2015 through at least in or about 2021, in the Southern District of New York and elsewhere, US COMPOUNDING, INC., the defendant, and others known and unknown, willfully and knowingly combined, conspired, confederated, and agreed together and with each other to commit mail fraud, in violation of Title 18, United States Code, Section 1341.

26. It was a part and an object of the conspiracy that US COMPOUNDING, INC., the defendant, and others known and unknown, knowingly having devised and intending to devise 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 and artifice and attempting so to do, would and did place in a post office and authorized depository for mail matter, a matter and thing whatever to be sent and delivered by the Postal Service, and deposit and cause to be deposited a matter and thing whatever to be sent and delivered by a private and commercial interstate carrier, and take and receive therefrom, such matter and thing, and knowingly cause to be delivered by mail and such carrier according to the direction thereon, and at the place at which it is directed to be delivered by the person to whom it was addressed, such matter and thing, in violation of Title 18, United States Code, Section 1341,

to wit, US COMPOUNDING, INC., utilizing fabricated prescriptions generated in the name of the Veterinarian, deceptively made it appear that compounded drugs manufactured by USC and transmitted to purchasers by United States mail, including purchasers in the Southern District of New York, were legally prescribed when, in truth and in fact, these drugs carried no valid prescription.

(Title 18, United States Code, Section 1349.)

**COUNT TWO**  
**(Drug Adulteration and Misbranding Conspiracy)**

The United States Attorney further charges:

27. From at least in or about 2015 through at least in or about 2021, in the Southern District of New York and elsewhere, US COMPOUNDING, INC., the defendant, together with others known and unknown, willfully and knowingly did combine, conspire, confederate, and agree together and with each other to commit offenses against the United States, to wit, violations of Title 21, United States Code, Sections 331(a) and 333(a)(2).

28. It was a part and an object of the conspiracy that US COMPOUNDING, INC., the defendant, together with others known and unknown, with the intent to defraud and mislead, would and did introduce and deliver for introduction, and would and did cause the introduction and delivery for introduction, into interstate commerce, adulterated and misbranded drugs, as defined by 21 U.S.C. §§ 351(a)(5), 352(a), 352(b), 352(f), 353(f), and 360b, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

**Overt Acts**

29. In furtherance of the conspiracy and to effect the illegal object thereof, US COMPOUNDING, INC., the defendant, and others known and unknown, committed the following overt acts, among others, in the Southern District of New York and elsewhere:

a. Between in or about April 2021 and in or about May 2021, US COMPOUNDING, INC. fulfilled a drug order by mailing a prescription drug with no valid prescription to an address in New York, New York.

b. On or about October 13, 2020, the USC Executive used an encrypted electronic messaging application to communicate with the Adamis Executive regarding avoiding detection of the offense conduct.

(Title 18, United States Code, Section 371.)

**FORFEITURE ALLEGATIONS**

30. As a result of committing the offense charged in Count One of this Information, US COMPOUNDING, INC., the defendant, shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), any and all property, real and personal, that constitutes or is derived from proceeds traceable to the commission of said offense, including but not limited to a sum of money in United States currency representing the amount of proceeds traceable to the commission of said offense.

31. As a result of committing the offense charged in Count Two of this Information, US COMPOUNDING, INC., the defendant, shall forfeit to the United States, pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c), any and all drugs that were adulterated and misbranded when introduced into and while in interstate commerce and while held for sale (whether or not the first sale) after shipment in interstate

**Substitute Assets Provision**

31. If any of the above-described forfeitable property, 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 person;
- 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 subdivided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p) and Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the above forfeitable property.

(Title 18, United States Code, Section 981;  
Title 21, United States Code, Section 853; and  
Title 28, United States Code, Section 2461.)

  
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DAMIAN WILLIAMS  
United States Attorney