

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

v.

VELOXIS PHARMACEUTICALS, INC.,

Defendant

Criminal No. 26cr10221

Violation:

Count One: Conspiracy to Commit Violations
of the Anti-Kickback Statute
(18 U.S.C. § 371)

INFORMATION

At all times relevant to this Information:

General Allegations

Relevant Entities and Individuals

1. Veloxis Pharmaceuticals, Inc. (“Veloxis”) was a pharmaceutical company, incorporated in Delaware, with a principal place of business in Cary, North Carolina. Effective March 2020, Veloxis was acquired by Asahi Kasei Corporation, headquartered in Tokyo, Japan. Veloxis did business throughout the United States, including in the District of Massachusetts.

2. Employee 1 was an executive at Veloxis who served as Veloxis’s Vice President of Market Access between July 2016 and June 1, 2022, and as Vice President of Sales between October 2021 and March 22, 2023.¹

3. Employee 2 was an employee at Veloxis who served as: a Transplant Account Manager, Senior Transplant Specialist, and Senior Transplant Account Manager between June 29, 2015 and December 3, 2019; a National Account Executive in Market Access between December

¹ “Market Access” was a business unit within Veloxis intended to promote insurance coverage of and access to Envarsus.

3, 2019 and August 9, 2021; and the Director of Access and Patient Support between August 9, 2021 and March 22, 2023.

4. Employee 3 was an employee at Veloxis in Market Access who served as: a Regional Account Executive between November 2014 and July 2016; a National Account Executive between August 2016 and June 2022; and a Strategic Accounts Manager between June 2022 and March 22, 2023.

5. Employee 4 was an employee at Veloxis who served first as a Transplant Account Manager and then as: a Key Account Manager between August 2018 and August 2021; a National Account Executive in Market Access between August 2021 and April 2022; and a Regional Sales Director between April 2022 and June 2023.

6. Surgeon 1 was a surgeon at a Washington, D.C. hospital who specialized in organ transplant surgery.

7. Surgeon 2 was a surgeon at a Colorado hospital who specialized in organ transplant surgery.

8. Surgeon 3 was a surgeon at a Pennsylvania hospital who specialized in organ transplant surgery.

9. Nephrologist 1 was a nephrologist who worked for an Illinois-based hospital and later an Arizona-based hospital.

10. Pharmacist 1 was a pharmacist affiliated with a Massachusetts-based hospital.

11. Pharmacist 2 was a pharmacist affiliated with an Illinois-based hospital.

12. Pharmacist 3 was a pharmacist who served as the Director of Transplant Research for an Illinois-based hospital.

13. Pharmacist 4 was a pharmacist affiliated with a Colorado-based hospital.

14. Administrator 1 was a hospital administrator employed at a New Jersey-based hospital.

Veloxis's Sale of Envarsus XR

15. Veloxis manufactured and sold a single drug, Envarsus XR (“Envarsus”). Envarsus is a specialized extended release once-a-day drug approved by the U.S. Food & Drug Administration (“FDA”) for use as an immunosuppressant in adult kidney transplant recipients. The active pharmaceutical ingredient in Envarsus is tacrolimus, a calcineurin inhibitor. Envarsus is one of several tacrolimus-based drugs that the FDA has approved for use in adult kidney transplant recipients.

16. Kidney transplant surgery involves the transplantation of a kidney from a living or deceased donor into a patient suffering from end-stage renal disease or other forms of kidney failure.

17. Following transplant surgery, kidney transplant recipients require daily immunosuppressant drugs for the lifespan of the transplanted kidney to prevent rejection of the transplanted organ by the recipient’s immune system. Generally, the average lifespan of a transplanted kidney is between 12 and 15 years for a kidney transplanted from a deceased donor and between 12 and 20 years for a kidney transplanted from a living donor.

18. The most common immunosuppressant drug regimen for kidney transplant recipients involves a combination of a tacrolimus-based drug, like Envarsus, together with other immunosuppressants.

19. On or about July 10, 2015, the FDA approved Envarsus for use in adult kidney transplant patients converted from another tacrolimus-based immunosuppressant drug regimen. On or about December 19, 2018, the FDA approved Envarsus for *de novo* use with kidney

transplant patients, *i.e.*, for use in new kidney transplant patients as part of an initial immunosuppressant drug regimen.

20. Envarsus competed against the generic form of tacrolimus drugs for market share. Tacrolimus is a calcineurin inhibitor, a neurotoxic and nephrotoxic class of immunosuppressants, that when used to manage various autoimmune disorders, serves as essential components for immunosuppression in organ transplantation. Unlike generic tacrolimus, which kidney transplant patients needed to take twice a day, Envarsus needed to be taken only once a day and achieved the same therapeutic effect with a lower dose of tacrolimus. However, generic tacrolimus, with a wholesale acquisition cost (“WAC”) of approximately \$200 to \$400 per month, cost much less than Envarsus, which had a WAC of approximately \$800 to \$1,200 per month.

21. Veloxis marketed Envarsus primarily to surgeons, nephrologists, nurse practitioners, and other health care professionals affiliated with transplant centers and hospitals who could prescribe or order the administration of Envarsus. Veloxis also marketed Envarsus to pharmacists affiliated with transplant centers and hospitals who were responsible for the purchase and clinical review of the medications that transplant health care professionals administered. In addition, Veloxis marketed Envarsus to specialty pharmacies which could purchase and dispense Envarsus for transplant patients after their discharge from the transplant center and/or hospital.

22. Due to the availability of the cheaper generic tacrolimus (and other brand drugs), Veloxis struggled to gain market share in the years immediately following the FDA’s conversion use approval of Envarsus.

23. Beginning in or around 2017, in an effort to increase market share, Veloxis implemented a marketing strategy pursuant to which it promoted Envarsus to health care professionals at strategically important transplant centers and hospitals who could influence the

placement of Envarsus on the formulary and/or protocol of their respective transplant center and/or hospital.

24. Placing Envarsus on “formulary” meant that a transplant center and/or hospital permitted its transplant health care professionals to prescribe and administer Envarsus, along with other treatment options for kidney transplant patients.

25. Placing Envarsus on “protocol” meant that a transplant center and/or hospital standardized the use of Envarsus for kidney transplant patients—that is, protocol lays out the circumstances in which Envarsus would be used as the default tacrolimus drug for kidney transplant patients absent a clinical need for another form of treatment.

26. The influential health care professionals to whom Veloxis promoted Envarsus included individuals who either served on their transplant center’s and/or hospital’s pharmacy and therapeutics (“P&T”) committee, which typically made the determination to place a drug on formulary and/or protocol, or whose position and influence at the transplant center and/or hospital was significant enough to steer the P&T committee’s decision-making in this regard.

27. Veloxis benefitted financially from Envarsus’s placement on a transplant center’s and/or hospital’s formulary or protocol, as a formulary placement meant that the transplant center and/or hospital would likely purchase Envarsus and, more favorably, a protocol placement guaranteed a transplant center’s and/or hospital’s purchase of Envarsus.

28. In or around April 2019, approximately four months after the FDA approved Envarsus for *de novo* use, the FDA announced a shortage of generic tacrolimus. As a result of the shortage, generic tacrolimus became difficult for transplant centers and hospitals to procure, while Envarsus was readily attainable. Veloxis viewed the shortage as a major financial opportunity, and increased its marketing efforts targeted at transplant health care professionals who could influence

the placement of Envarsus on formulary and/or protocol at transplant centers and/or hospitals in response to the shortage of generic tacrolimus.

29. The shortage, extended *de novo* approval, and Veloxis's increased marketing efforts resulted in increased sales of Envarsus.

30. As alleged further below, Veloxis's marketing efforts involved tactics that violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), including but not limited to: taking transplant health care professionals to expensive dinners and on lavish trips under the guise of Market Access "advisory boards"² and making payments to transplant health care professionals pursuant to consulting agreements³ for purported consulting work that was not actually performed. In many instances, Veloxis employees submitted falsified company expense reports to conceal their illegal marketing efforts. This false reporting resulted in Veloxis's failure to properly report the sums it paid to transplant health care professionals, which further obscured its illegal activities.

The Anti-Kickback Statute

31. The AKS was enacted in 1972 following congressional concern that remuneration provided to those who can influence health care decisions would create incentives in conflict with the best interests of patients or would result in goods and services being provided that are medically unnecessary, of poor quality, or harmful to a vulnerable patient population. Congress strengthened

² Veloxis's Market Access "advisory boards" were comprised of members of Veloxis's Market Access team and various transplant health care professionals. The purported purpose of this advisory board program was for transplant health care professionals to provide strategic guidance and feedback to Veloxis on how to convince insurers to cover and reimburse Envarsus.

³ Veloxis entered into consulting agreements with various transplant health care professionals. The agreements, which often contained little to no detail about the work to be performed in exchange for compensation, set forth the amount to be paid by Veloxis to the transplant health care professional per hour of work performed and the total hours of work authorized per year.

the AKS by amendments in 1977, 1987, and 2010, to ensure that kickbacks masquerading as legitimate transactions did not evade the statute's reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b; Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148. To protect the Medicare and Medicaid programs, among other federal health care programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

32. Section (b) of the AKS bars the solicitation, receipt, offer, or payment of “illegal remunerations.” 42 U.S.C. § 1320a-7b(b). As relevant here, Subsection (b)(2) bars the offer or payment of illegal remuneration and makes it illegal to “knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.” *Id.* § 1320a-7b(b)(2).

33. The AKS does not define or otherwise restrict the broad ordinary meanings of “item,” “service,” or “good.” The terms “good” and “item” under the AKS include prescription drugs such as Envarsus.

34. The AKS defines remuneration to include anything of value, including “cash” or “in-kind” payments. 42 U.S.C. § 1320a-7b(b)(2). Payments, gifts, or meals provided by a pharmaceutical company to health care professionals to induce them to write prescriptions for the company's pharmaceutical products that are ultimately paid for by federal health care programs are all examples of such illegal remuneration.

35. The AKS defines a “Federal health care program” to mean “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government,” except for the health insurance program for federal employees. 42 U.S.C. § 1320a-7b(f). Medicare, Medicaid, and TRICARE—as described further below—are all “health care benefit programs” within the meaning of 18 U.S.C. § 24(b), and “Federal health care program(s)” under the AKS.

The Sunshine Act

36. Concerned that physicians’ treatment decisions could be affected by their financial interests, Congress enacted in 2010 a national disclosure program relating to such financial interests. 42 U.S.C. § 1320a-7h. Initially, it was referred to as the Physician Payment Sunshine Act (the “Sunshine Act”), but the disclosure program is now known as the Open Payments program. All manufacturers operating in the United States and “engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply” must report certain information about physician payments and ownership interests. 42 U.S.C. § 1320a-7h(e)(9).

37. Pursuant to the Open Payments program, “any applicable manufacturer that provides a payment or other transfer of value” to a physician is required to report to the U.S. Department of Health and Human Services (“HHS”) information about the payment or transfer, unless a reporting exclusion applies. 42 U.S.C. § 1320a-7h(a)(1)(A). For each qualifying payment or other transfer of value to a physician, an applicable manufacturer must report to HHS, among other things, the physician’s name, business address, specialty, and National Provider Identifier (“NPI”); the amount of the payment or transfer; the date(s) on which the payment or transfer was provided; and descriptions of the form and nature of the payment or transfer. *Id.*

38. Applicable manufacturers are required to report the specified information on the 90th day of each calendar year, for payments and ownership interests in the preceding calendar year. 42 U.S.C. § 1320a-7h(a)(1)(A). The first reporting deadline was March 31, 2014, for the calendar year 2013. 42 C.F.R. § 403.908(a).

39. Under the Open Payments program, HHS makes certain information about the payments and ownership interests available to the public through a searchable website. 42 U.S.C. § 1320a-7h(c)(1)(C); *see also* <https://www.cms.gov/priorities/key-initiatives/open-payments>.

40. Veloxis is considered a manufacturer and Envarsus is considered a covered drug under the Sunshine Act.

The Relevant Federal Health Care Programs

41. Medicare is a federally funded health care program administered by the Centers for Medicare and Medicaid Services (“CMS”), a federal agency under HHS. 42 U.S.C. § 1395c *et seq.* To be eligible for Medicare, a person must be over the age of 65, be disabled, or have end-stage renal disease. Individuals who are insured or receive benefits through Medicare are often referred to as Medicare “beneficiaries.”

42. The Medicare program has four “parts.” Parts A and B are commonly known as “traditional” or “original” Medicare. Part D provides prescription drug benefits, for drugs including Envarsus, to Medicare beneficiaries. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through CMS, contracts with private companies (often known as “sponsors”) that are authorized to sell Part D insurance coverage. CMS regulates and subsidizes such companies pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare beneficiaries enrolled in their plans.

43. Medicaid is a jointly funded federal and state health care program that provides certain health benefits to the disabled, as well as to individuals and families with low incomes and resources.

44. TRICARE is the uniformed services health care program for U.S. military members, retirees, and their families.

45. For eligible beneficiaries, Medicare, Medicaid, and TRICARE cover the cost of Envarsus prescriptions.

Overview of the Conspiracy

46. Beginning in or around October 2016 and continuing through in or around June 2023, Veloxis, its employees, and others known and unknown to the United States Attorney conspired to pay improper remuneration (kickbacks) to transplant health care professionals to induce those transplant health care professionals to prescribe, order, or recommend prescribing or ordering Envarsus for kidney transplant recipients.

47. These kickbacks took several forms. Veloxis provided improper remuneration to transplant health care professionals in the form of lavish meals, expensive trips and resort stays, and personal gifts. Veloxis also made large payments to transplant health care professionals under the guise of consulting agreements. These excessive payments were not for work that was actually performed but, instead, were for time spent in a manner inconsistent with the intended purpose of consulting. In total, from 2016 through 2023, Veloxis paid health care professionals more than \$800,000 in consulting fees and related expenses.

48. Additionally, in certain instances, Veloxis employees facilitated transplant health care professionals' efforts to avoid running afoul of their transplant center's and/or hospital's rules prohibiting the acceptance of improper remuneration, including in the form of trips and gifts, from

pharmaceutical manufacturers. For example, in or around May 2022, Surgeon 2 requested that Veloxis permit him to attend a speaker program hosted by Veloxis during a transplant surgery conference “incognito without registering” and pay for associated expenses.

49. Veloxis intended the improper remuneration it provided to transplant health care professionals to result in increased Envarsus prescriptions, as demonstrated, in part, by communications between Veloxis employees and certain transplant health care professionals. For example, in connection with Surgeon 2’s request to attend the above-referenced speaker program, Employee 1 told Surgeon 2 that he (Employee 1) “need[ed] scripts. Lots of them.” Several months prior, Employee 1 had told Surgeon 2 that he was “over Sales” and needed Surgeon 2 “more than ever,” and that it was “[t]ime to open your Rolodex and make things happen.”

Object and Purpose of the Conspiracy

50. The object of the conspiracy was to commit violations of the AKS. The principal purpose of the conspiracy was to induce prescriptions/orders of Envarsus and thereby increase Veloxis’s net profits.

Manner and Means of the Conspiracy

51. Among the manner and means by which Veloxis, its employees, and its co-conspirators carried out the conspiracy were the following:

- a. hosting lavish meals for transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals for the purpose of inducing those individuals to prescribe, order, or recommend prescribing or ordering Envarsus;
- b. organizing lavish retreats—involving flights, hotel stays, and meals at high-end restaurants—for transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals—for the purpose of inducing

those individuals to prescribe, order, or recommend prescribing or ordering Envarsus;

- c. purchasing large quantities of alcohol for transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals in connection with these lavish meals and retreats, belying any notion that their purpose was educational or otherwise legitimately work related;
- d. paying for the attendance of spouses of transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals (who were not themselves health care professionals) at these lavish meals and retreats, again belying any notion that their intended purpose was educational or otherwise legitimately work related;
- e. submitting falsified company expense reports to conceal these lavish meals and retreats—by falsely adding names to the list of attendees (to decrease the apparent cost per attendee of the meals) and omitting the names of health care professionals who did attend the meals (to avoid Sunshine Act reporting requirements);
- f. approving payments to transplant surgeons, nephrologists, pharmacists, and other health care professionals for consulting work that they did not actually perform; and
- g. providing gifts to transplant health care professionals, including in the form of expensive alcohol.

Overt Acts in Furtherance of the Conspiracy

52. Beginning in or around October 2016 and continuing through in or around June 2023, Veloxis, its employees, and its co-conspirators committed and caused to be committed the following overt acts, among others, in furtherance of the conspiracy:

Market Access Advisory Board Retreats

September/October 2020: Scottsdale, Arizona

53. On or about September 30 through October 1, 2020, Veloxis hosted a Market Access “advisory board” retreat at a resort in Scottsdale, Arizona attended in person by Surgeon 2 and Pharmacists 2, 3, and 4. The event featured a stay at the resort and multiple lavish dinners for the retreat attendees. The lavish dinners included the consumption of high-end alcohol and were attended by spouses of certain retreat attendees. At the time, Veloxis’s internal policy limited the amount Market Access employees could spend on a meal for health care professionals to \$125 per attendee.

54. On or about September 30, 2020, Veloxis paid more than \$265 per attendee for a retreat dinner hosted at a high-end restaurant. Employee 1 submitted an expense report for the dinner and included the names of Employee 3 and three additional health care professionals (non-transplant surgeons) who did not actually attend the dinner. Employee 1, on behalf of Veloxis, added the names of those four non-transplant surgeons to conceal the true cost of the meal (*i.e.*, to artificially reduce the per attendee cost when that cost was in fact significantly higher).

55. During this same Market Access “advisory board” retreat, Veloxis paid more than \$195 per attendee for a dinner at a high-end steakhouse on or about October 1, 2020. Pharmacist 4’s wife also attended the dinner despite not being a member of Veloxis’s Market Access advisory

board. Veloxis's internal policy expressly prohibited any payments for a health care professional's spouse.

56. Employee 1, on behalf of Veloxis, submitted an expense report for the October 1, 2020 dinner that did not identify Surgeon 2 or Pharmacist 4's wife as attendees at the dinner, at least in part to avoid the Open Payments program's reporting requirements.

57. In addition to these dinners, Veloxis paid more than \$486 per night for the hotel stays for Surgeon 2 and Pharmacists 2, 3, and 4 (and Pharmacist 4's wife) at the Scottsdale resort.

58. Veloxis also made consulting payments of more than \$6,500 to Surgeon 2, \$5,400 to Pharmacist 4, \$4,600 to Pharmacist 3, and \$3,400 to Pharmacist 2 for purportedly providing between eight and ten hours of consulting work during the retreat.

February 2021: Scottsdale, Arizona

59. On or about February 15 through 16, 2021, Veloxis hosted a one-day Market Access "advisory board" retreat in Scottsdale, Arizona for Surgeon 2, Nephrologist 1, Pharmacist 3, and Pharmacist 4. Despite the advisory board taking place over the course of a single day, Veloxis paid for a three-night stay at a Scottsdale resort for Nephrologist 1 and her husband, and for dinner costing approximately \$276 for Nephrologist 1 and her husband. Veloxis also paid for two dinners at high-end restaurants for Surgeon 2, Nephrologist 1, Pharmacist 3, Pharmacist 4, and certain of their spouses or guests.

60. In addition, Veloxis paid Nephrologist 1 approximately \$1,725 for three hours of consulting work purportedly provided while Nephrologist 1 was staying at the resort with her husband for three nights with no *bona fide* work-related justification for this extended stay.

July 2021: Vail, Colorado

61. On or about July 16, 2021, Veloxis hosted a Market Access “advisory board” retreat at a resort in Vail, Colorado for Surgeons 2 and 3, Pharmacist 4, and Administrator 1. The purported purpose of the retreat was to discuss strategy for addressing issues with a specific pharmacy benefit manager and “strategy for market access.” In connection with the retreat, Veloxis paid for the resort stays as well as a lavish dinner for Surgeons 2 and 3, Pharmacist 4, and Administrator 1, and for certain of their spouses or guests.

62. Specifically, Veloxis paid more than \$300 per attendee for dinner at a high-end sushi restaurant on or about July 16, 2021. Veloxis paid a total of more than \$2,700 for the dinner. More than \$700 of that amount was for alcohol.

63. Employee 1 submitted an expense report for the dinner that did not identify the spouses of Surgeon 3 and Pharmacist 4 as attendees despite their having attended the dinner. Instead, Employee 1 instructed Employee 2 to provide him (Employee 1) with the names of non-physicians whom Veloxis could falsely list as attendees on the expense report in order to artificially reduce the per attendee cost of the dinner, conceal the excessive amount of alcohol involved, and avoid Sunshine Act reporting requirements. Employee 2 provided the names of seven nurses and pharmacists who did not attend the dinner.

64. Veloxis paid more than \$605 per person for the July 16, 2021 hotel stays for Surgeons 2 and 3, Pharmacist 4, and Administrator 1. Employee 2 submitted an expense report for the hotel stays, and Employee 1 approved that expense report.

65. Veloxis also paid Surgeon 3 approximately \$3,450 for six hours of purported consulting work; Pharmacist 4 approximately \$1,275 for three hours of purported consulting work;

and Administrator 1 approximately \$1,275 for three hours of purported consulting work in connection with the retreat. Employee 1 approved these payments.

December 2021: Philadelphia, Pennsylvania

66. On or about December 2, 2021, Veloxis hosted a Market Access “advisory board” retreat in Philadelphia, Pennsylvania for Surgeons 1, 2, and 3, Pharmacist 4, and Administrator 1. The retreat involved stays at a high-end hotel as well as a lavish dinner. The purported purpose of the retreat was to hold a “Market Access and Payer Discussion.”

67. Veloxis paid more than \$285 per attendee, for a total of more than \$2,000, for this retreat dinner. More than \$400 of the \$2,000 was for high-end alcohol.

68. Veloxis paid more than \$1,400 for Surgeon 2’s two-night hotel stay and more than \$700 for Administrator 1’s one-night hotel stay.

69. Veloxis also made consulting payments to the attendees, with Administrator 1 alone receiving more than \$3,100 for 7.5 hours of purported consulting work in connection with this retreat.

70. Prior to this retreat, Employee 2 exchanged text messages with Surgeon 2, who resided in Colorado, about scheduling the “advisory board” in Philadelphia in early December to coincide with the birthday of Surgeon 2’s father, who resided near Philadelphia.

February 2022: Tucson, Arizona

71. On or about February 14 and 15, 2022, Veloxis hosted a Market Access “advisory board” retreat at a resort in Tucson, Arizona for Surgeons 2 and 3, Nephrologist 1, Pharmacist 2, and Administrator 1. The event involved a stay at the resort and a lavish dinner, with the spouses of certain retreat attendees also in attendance. The purported purpose of the retreat was a “Consultants Meeting.”

72. Veloxis paid for the resort stay of Nephrologist 1, who was then a physician at an Arizona-based hospital, and Nephrologist 1's spouse, despite the fact that they lived only about an hour away from the retreat location.

Dinners for Health Care Professionals

Philadelphia, Pennsylvania Dinners

73. On or about March 16, 2021, Veloxis hosted a dinner at a high-end steakhouse in Philadelphia, Pennsylvania for Surgeons 2 and 3 and Administrator 1. Veloxis paid more than \$250 per attendee for the dinner. Veloxis also paid approximately \$1,300 for a two-night stay at a high-end hotel in Philadelphia for Surgeon 2, who, as alleged above, had family in Philadelphia.

74. Employee 2 submitted, and Employee 1 approved, an expense report for the March 16, 2021 dinner that described the dinner as an "Internal Meeting" and did not identify Surgeons 2 and 3 or Administrator 1 as attendees.

75. Less than two months before the March 16, 2021 dinner, Employee 1 texted Employee 3 that Administrator 1's hospital was "making some noise" and that Administrator 1 had "earned a steak dinner." The day after the March 16, 2021 dinner, Employee 1 texted Employee 3 that he had a "phenomenal night" with Surgeons 2 and 3 and Administrator 1, and that "Sales are going up!"

76. On or about October 12, 2021, Veloxis hosted a dinner at a high-end steakhouse in Philadelphia for Surgeon 3 and Administrator 1. Veloxis paid approximately \$215 per attendee for the dinner. The purported purpose of the dinner was "Training for the new [Regional Access Managers] Team."

77. Employee 1 submitted an expense report for the October 12, 2021 dinner that did not identify Surgeon 3 or Administrator 1 as attendees, in part to avoid Sunshine Act reporting requirements.

78. In addition, Employee 2 instructed Surgeon 3 and Administrator 1 to invoice Veloxis for three hours of purported consulting work in connection with the October 12, 2021 dinner.

Other Dinners

79. On or about May 5, 2021, Veloxis hosted a dinner at a high-end seafood restaurant in Chicago, Illinois for Surgeon 3, Nephrologist 1, and Pharmacist 2. Veloxis paid approximately \$400 per attendee for the dinner. Veloxis also paid for Surgeon 3's travel to Chicago for the dinner—specifically, approximately \$428 for Surgeon 3's flight and approximately \$671 for a one-night stay at a hotel. In addition, Veloxis paid Surgeon 3 approximately \$2,300 for four hours of purported consulting work in connection with the dinner. Employee 2 submitted, and Employee 1 approved, an expense report that described the dinner as an “Internal meeting” despite the attendance of three (external) transplant health care professionals, and did not list Surgeon 3, Nephrologist 1, or Pharmacist 2 as attendees.

80. On or about January 13, 2022, after the May 5, 2021 dinner and the October 12, 2021 dinner (referenced in paragraph 76 above), Surgeon 3 sent Employee 1 a text message stating that he was “delivering all of [the Pennsylvania-based hospital] market for you.” In response, Employee 1 told Surgeon 3 that he (Employee 1) had “just booked a table for 2 on Monday, January 24” at a high-end restaurant in Philadelphia.

81. On or about April 22, 2022, Employee 3 and a Veloxis Medical Science Liaison (“MSL”) hosted a dinner at a high-end steakhouse in West Hollywood, California for Surgeon 1.

Employee 3 told the MSL that the dinner was intended to be an introductory meeting between Surgeon 1 and clinical representatives of a California-based hospital. In fact, the dinner did not include any representatives from the California-based hospital. Only the MSL, Employee 3, and Surgeon 1 attended the dinner, for which Veloxis paid more than \$663 per attendee. Employee 3 submitted, and Employee 1 approved, an expense report for the dinner that did not identify Surgeon 1 as an attendee and falsely listed four non-health care professionals as purported attendees of the “introductory meeting” with Surgeon 1, in order to conceal the illegitimate nature of the dinner, artificially reduce the per attendee cost of the dinner, and avoid Sunshine Act reporting requirements.

Consulting Agreements

Consulting Agreement with Surgeon 1

82. On or about November 12, 2018, Veloxis entered into a consulting agreement with Surgeon 1 pursuant to which Veloxis agreed to pay Surgeon 1 \$300 per hour for a maximum of 15 hours of consulting work per year. The agreement provided only a vague description of the work to be performed.

83. On or about February 14, 2022, Veloxis amended its consulting agreement with Surgeon 1. Under the terms of the new agreement, Veloxis agreed to pay Surgeon 1 \$750 per hour for a maximum of ten hours of consulting work per year.

84. Surgeon 1 submitted invoices to Veloxis for consulting work that he did not actually perform and often for hours in excess of the maximum set by the consulting agreement. Veloxis approved and paid these invoices despite, as alleged below, acknowledging that they reflected “massive overbilling.”

85. Specifically, on or about April 22, 2020, Surgeon 1 sent Veloxis an invoice for 18 hours of purported consulting work related to “surgical interface.” In a text message exchange, Employees 1 and 3 discussed whether Veloxis should pay this invoice. Employees 1 and 3 ultimately decided to approve/pay the invoice because “[h]is [*i.e.*, Surgeon 1’s] group will help us as we move along with greater volume and access challenges.” Employee 1 sent the following text message to Employee 3 in reference to Surgeon 1: “He owes us. Massive over billing.”

86. Later, beginning on or about December 6, 2021, Employees 3 and 4 exchanged text messages regarding Surgeon 1’s submission of another invoice for 18 hours of purported consulting work in connection with a Market Access advisory board for which most other consultant attendees “submit[ed] 6-7 hours for dinner and [advisory] board.” Employee 3 sent Employee 4 a text message stating that Surgeon 1 “does this all the time.”

87. Veloxis also paid for personal travel for Surgeon 1 purportedly in connection with consulting work. For example, on or about March 29, 2022, Surgeon 1 texted Employee 1 requesting that Veloxis pay for his trip to Los Angeles to “see a sick family member” with the pretext that the trip was to “visit with some transplant providers.” Employee 1 approved Surgeon 1’s travel expenses for this trip, which totaled more than \$3,700, including more than \$1,700 for first class plane tickets, more than \$1,500 for two nights of lodging, and more than \$470 for ground transportation. Employee 1 also approved Veloxis’s payment of approximately \$5,250 in consulting fees to Surgeon 1 in connection with this trip. Later, on or about May 7, 2022, Surgeon 1 texted Employee 1 thanking him for “making it possible to visit my cousin in California!” Employee 1 responded to Surgeon 1, “I hope so bro. My ass is on the like [sic] to sell more! I need to use everyone [sic] of your closest friends and please don’t hold back!” Surgeon 1 replied, “No problem my man!”

88. During the relevant period, Veloxis paid Surgeon 1 a total of more than \$100,000 in consulting fees and related expenses.

Consulting Agreements with Pharmacist 1

89. Beginning in or around November 2015, Veloxis entered into a series of consulting agreements with a medical education company owned by Pharmacist 1. Under the terms of the agreements, all consulting work was to be performed by Pharmacist 1, who signed each of the agreements. By allowing Pharmacist 1 to enter into the agreements on behalf of his company (rather than in his personal capacity), Employee 3 understood that Veloxis helped Pharmacist 1 circumvent his employer's restrictions and reporting requirements related to working with pharmaceutical companies.

90. On various occasions in 2019, Pharmacist 1 requested that Veloxis increase the cap on his contractual consulting hours. Between approximately October 1, 2019 and January 2020, Veloxis increased Pharmacist 1's consulting hours from 25 to 145. In addition, in or around May 2020, Veloxis increased Pharmacist 1's hourly rate from \$575 per hour to \$750 per hour.

91. From 2016 through 2023, Veloxis paid Pharmacist 1 a total of more than \$400,000 in consulting fees and related expenses.⁴

Gifts

92. On or about December 25, 2020, Employee 1 sent Surgeon 2 a bottle of gin "that is supposedly the best and it's not in Colorado." Employee 1 told Surgeon 2 that the gift was "[w]ell deserved. Every sip."

⁴ In addition to paying Pharmacist 1 for purported consulting work, Veloxis also hosted and paid for multiple events held at a brewery and restaurant owned by Pharmacist 1.

93. On or about March 1, 2022, Employee 1 texted Surgeon 1 that he (Employee 1) had “approved your tiny invoices today.” Surgeon 1 responded, “Those invoices were just teasers! You owe me big time!?” [sic].” Employee 1 replied, stating that he was “buying you [Pappy Van Winkle] on 24th.”⁵

Net Value Conferred on Veloxis as a Result of the Kickbacks

94. Envarsus is typically prescribed to kidney transplant patients based on a ratio of milligrams of the drug per the patient’s body weight. Medicare, Medicaid, and TRICARE reimbursement for Envarsus is based on its per-milligram price.

95. Based upon (i) the number of milligrams of Envarsus prescribed by physicians as a result of the unlawful payments made by Veloxis in connection with the conspiracy described above and (ii) Veloxis’s net profit per milligram, the net benefit conferred on Veloxis as a result of kickback-tainted Envarsus sales was approximately \$13,392,486.

⁵ Pappy Van Winkle is an expensive bourbon which ranges in price between approximately \$800 and \$4,000 a bottle.

COUNT ONE
Conspiracy to Commit Violations of the Anti-Kickback Statute
(18 U.S.C. § 371)

The United States Attorney charges:

96. The United States Attorney re-alleges and incorporates by reference paragraphs 1 through 95 of this Information.

97. Beginning in or around October 2016 and continuing through in or around June 2023, the defendant,

VELOXIS PHARMACEUTICALS, INC.,

and its employees conspired with others known and unknown to the United States Attorney to commit an offense against the United States, *to wit*, violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), that is, to knowingly and willfully offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to induce the purchase, lease, order, arranging for use, and recommendation of goods, services, and items, namely, Envarsus, for which payment may be made in whole or in part by a Federal health care program.

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

LEAH B. FOLEY
United States Attorney

By: /s/ Christopher Looney
CHRISTOPHER LOONEY
LESLIE A. WRIGHT
Assistant U.S. Attorneys

Date: August 10, 2026