SUPREME COURT OF THE STATE OF NEW YORK

NEW YORK COUNTY

PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York Plaintiff, - against – Robert G. Kramer, Defendant	**COMPLAINT** Index number:

Plaintiff, People of the State of New York, by its attorney, Letitia James, Attorney General of the State of New York ("OAG" or "Plaintiff"), alleges as follows against Defendant Robert G. Kramer ("Kramer" or "Defendant Kramer"):

NATURE OF THE ACTION

1. In the midst of the COVID-19 crisis, Defendant Kramer, the then-CEO of Emergent BioSolutions Inc. ("Emergent"), engaged in illegal insider trading of Emergent stock. Kramer entered into the illegal trades while in possession of material nonpublic information regarding serious and unresolved contamination issues Emergent faced in manufacturing COVID-19 vaccine drug substance for AstraZeneca PLC ("AstraZeneca").

2. Kramer sold over $10 million worth of Emergent stock while the contamination and production problems remained undisclosed to the public and just days before the stock's price began a steady decline following analyst concerns about production.

3. Operation Warp Speed was an effort by the U.S. government to support the rapid development of COVID-19 vaccine candidates. On June 1, 2020, Emergent joined the federal government's effort by committing space in Emergent's plant located in Bayview, Maryland, to

support the rapid development and distribution of COVID-19 vaccines. Emergent also entered into lucrative partnerships with both AstraZeneca and Johnson & Johnson to produce drug substance for the companies' COVID-19 vaccine candidates.

4. On June 11, 2020, Emergent publicly announced an agreement, valued at $87 million, to provide development and manufacturing services for AstraZeneca's COVID-19 vaccine candidate, ChAdOxl nCOV-19 (AZD1222) (the "Product" or "AZD1222"), at Emergent's Bayview facility.

5. On July 27, 2020, Emergent announced a second contract with AstraZeneca, publicly valued at $174 million, which provided for contract development and manufacturing ("CDMO") services for vaccine drug substance production by Emergent between July 2020 and June 2021 at large scale for commercial supply. Emergent's two contracts with AstraZeneca were worth a combined value of $261 million.[1]

6. In the week following Emergent's announcement of its CDMO contract with AstraZeneca, Emergent's stock price climbed 29.5%, going from $94.78 on July 27, 2020, to close at $134.46 on August 5, 2020.

7. As development of the manufacturing process progressed over the fall of 2020, Emergent experienced serious manufacturing difficulties, particularly with contamination of AZD1222. Specifically, Emergent discovered excess bioburden (bacteria) and elevated endotoxin (a type of toxin released by bacteria) in multiple drug substance batches, as early as

[1] The manufacturing and production contracts Emergent secured with AstraZeneca were its second foray into manufacturing a COVID-19 vaccine substance. On April 23, 2020, prior to the U.S. government's announcement of Operation Warp Speed, Emergent secured a contract to manufacture vaccine substance for Johnson & Johnson also at Emergent's Bayview facility. On July 2, 2020, the parties entered into a second large scale drug substance manufacturing agreement which expanded the term of the agreement and was valued at more than $480 million. The two vaccines would later become cross-contaminated.

September 26, 2020. Kramer, as CEO, knew of the contamination at least as early as October 6, 2020.

8. In early October, these contamination issues led to the rejection and destruction of multiple batches of vaccine drug substance, each containing potentially millions of dose-equivalents of vaccine.

9. Because of the serious, continuing and unresolved contamination, Emergent and AstraZeneca agreed to pause production of AZD1222 to investigate the root cause, and ultimately aborted, rejected or destroyed multiple batches. These manufacturing issues led to Emergent's inability to meet the rapid production schedule anticipated in its contracts with AstraZeneca.

10. In mid-October 2020, shortly after learning of the contamination problems at Emergent, Defendant Kramer asked his investment adviser to complete a Rule 10b5-1 stock trading plan (the "Trading Plan") which would allow Kramer to exercise stock options and simultaneously sell the acquired shares. Kramer had not implemented such a Trading Plan since 2016.

11. On November 13, 2020, while Emergent was in an all-hands-on-deck manufacturing crisis and still in the midst of an internal investigation of the unresolved contamination and manufacturing problems that had not been disclosed to the public, Defendant Kramer finalized and entered into the Trading Plan. The terms of the Trading Plan required the immediate sale of shares upon Emergent's stock reaching a preset price.

12. The Martin Act, New York General Business Law § 352 *et seq.*, forbids fraudulent practices, including the trading of stock by company insiders in possession of material nonpublic information. No statute, rule or law permits Rule 10b5-1 trading plans to be used as a

way of evading insider trading laws when an insider is aware of material nonpublic information at the time the trading plan is adopted.

13. Defendant Kramer realized proceeds of $10,121,079.50 on the sale of Emergent stock under his Trading Plan. On January 15, January 20, January 21 and February 8, 2021, Defendant Kramer exercised various Emergent stock options to purchase Emergent stock at prices ranging from $25.62 to $30.86 per share. Pursuant to the Trading Plan, Defendant Kramer then immediately sold multiple lots of the shares he had acquired. Kramer sold 19,026 shares on January 15, then sold 2,232 shares on January 20, another 21,900 shares on January 21, followed by the sale of an additional 45,397 shares on February 8, 2021. These Emergent stock sales were consummated at weighted average sales prices ranging between approximately $106 and $120 per share, significantly higher than Kramer's purchase price.

14. Shortly after Kramer completed these sales of stock on February 8, 2021, information about some of Emergent's struggles was revealed to the public. After reaching a high of $125.19 per share on February 12, 2021, Emergent's stock price began a steady decline from which it has not recovered. As of the date of this filing, Emergent stock currently trades at approximately $12 per share.

15. Defendant Kramer's actions violated the Martin Act.

PARTIES

16. Plaintiff is the People of the State of New York, represented by Letitia James, Attorney General of the State of New York, and is authorized to bring this action in the name and on behalf of the People of the State of New York pursuant to the Martin Act.

17. Defendant Kramer was employed by Emergent for more than two decades in multiple roles. He joined Emergent as its Chief Financial Officer in 1999. In that role, he was

responsible for financial accounting and reporting, budgeting and analysis, and investor relations. From March 2018 to April 2019, Defendant Kramer was Emergent's Chief Operating Officer, responsible for supervising manufacturing operations, among other duties. Defendant Kramer became the CEO of Emergent on April 1, 2019. As CEO, Defendant Kramer was responsible for management of the entire company. Kramer retired from Emergent on August 1, 2023.

JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action, jurisdiction over Defendant Kramer, and authority to grant the relief requested pursuant to the Martin Act.

19. The Martin Act authorizes the Attorney General to commence a civil action for restitution, disgorgement and other relief against any person or corporation engaging or participating in fraudulent practices in the issuance, exchange, purchase, sale, promotion, negotiation, advertisement, investment advice, or distribution of securities or commodities within or from New York State.

20. The transactions complained of were arranged and executed for Kramer by Defendant Kramer's investment adviser, Merrill Lynch, on the New York Stock Exchange through its block trading desk in New York. The stock sales at issue were made pursuant to a Trading Plan which provided that it be governed by New York law. On November 13, 2020, Defendant Kramer signed the Trading Plan and agreed that his transactions were governed by New York law.

21. New York investors, including New York State employee retirement funds, bought, sold, and held hundreds of thousands of shares in Emergent stock during the relevant period.

22. Pursuant to C.P.L.R. 503, venue is proper in New York County because Plaintiff's office is located in this county.

FACTUAL ALLEGATIONS

A. Emergent Secures and Publicizes Multimillion Dollar Contracts from AstraZeneca

23. In light of the COVID-19 emergency, the federal government announced Operation Warp Speed on May 15, 2020, with the goal of coordinating efforts in the public and private sectors to get vaccines for the coronavirus produced and approved as quickly as possible.

24. One week later, on May 21, 2020, AstraZeneca, a multinational pharmaceutical company headquartered in Cambridge, United Kingdom, announced its vaccine candidate, AZD1222.

25. On June 10, 2020, AstraZeneca and Emergent entered into a Master Services Agreement pursuant to which Emergent would produce bulk drug substance for AZD1222.

26. On June 11, 2020, Emergent issued a press release announcing the agreement to support the manufacturing of AZD1222.[2]

27. Emergent's Form 8-K filed with the SEC on June 11, 2020, stated that "[o]n June 10, 2020, Emergent entered into an agreement with AstraZeneca to provide CDMO services, technology transfer, analytical testing, drug substance process and performance qualification and will reserve certain large-scale manufacturing capacity through 2020." In the press release, Emergent valued the agreement at approximately $87 million.

28. On July 24, 2020, Emergent and AstraZeneca entered into a Master Services Agreement to produce drug substance at large scale for commercial supply. On that same date,

[2] https://www.emergentbiosolutions.com/press/news-release-details-emergent-biosolutions-signs-agreement-be-us-manufacturing-0/

the parties also agreed on a Manufacturing Product Schedule and Work Order for the large-scale manufacturing of AZD1222.

29. On July 27, 2020, Emergent issued a press release announcing that it had signed a COVID-19 vaccine manufacturing agreement with AstraZeneca pursuant to which "Emergent will provide contract development and manufacturing services beginning in 2020 to produce drug substance at large scale for commercial supply." In the press release, Emergent also announced that the "Agreement is valued at approximately $174 million through 2021 and brings the total AstraZeneca commitment to $261 million."

30. In response to the announcements, Emergent's stock price almost doubled in price, increasing from a low of $68.11 on June 11, 2020, to a high of $134.46 on August 5, 2020.

31. Pursuant to the Manufacturing Product Schedule and Work Order dated July 24, 2020, Emergent agreed to manufacture up to 95 vaccine drug substance batches by April 30, 2021, and 120 batches by June 30, 2021. Each batch contained several million dose-equivalents of COVID-19 vaccine drug substance. The expected production schedule called for up to 15 batches (12 initial, 3 additional) of AZD1222 at Emergent's Bayview, Maryland, manufacturing facility, Area 1[3], from July 1 through November 30, 2020. The expected production schedule included the manufacture of up to 80 batches of AZD1222 (32 initial, 48 additional) at Bayview Area 3 from September 1, 2020, through April 30, 2021, and 25 additional batches in Area 3 from May 1 through June 30, 2021.

32. Emergent's November 19, 2020, CDMO Executive Management Team Budget Review projected 79 batches of AZD1222 in 2021 for revenue of $158 million.

[3] Emergent's manufacture of AstraZeneca and Johnson & Johnson's COVID-19 vaccine candidates was scheduled to take place in separate areas within Emergent's Bayview facility.

B. Emergent's Manufacture of AZD1222 Suffers from Early Microbial Contamination

33. Emergent's production, manufacture and quality control of AZD1222 was led by Sean Kirk ("Kirk"), Executive Vice President, Manufacturing and Technical Operations, and Adam Havey ("Havey"), Executive Vice President and Chief Operating Officer. Both Kirk and Havey reported directly to Defendant Kramer and kept him apprised of Emergent's progress.

34. During this time, Defendant Kramer, who resided in Michigan, spent five weeks at a time onsite at Bayview. Kramer received regular updates from his direct reports, including Kirk and Havey. Kramer spoke to Kirk on a near daily basis and spoke to Havey multiple times per week during Operation Warp Speed. Kramer additionally held separate one-on-one meetings with Kirk and Havey on at least a weekly basis.

35. As a matter of safety, pharmaceutical products generally undergo bacterial contamination tests including for endotoxin (toxic components of bacteria which can cause dangerous reactions) and bioburden (bacterial colonies). These tests ensure the safety and usability of pharmaceuticals, including vaccines. Tests that exceed certain levels can trigger "alerts" or "alarms," and result in the destruction of pharmaceutical or vaccine drug substance batches.

36. On or about September 26, 2020, Emergent began noticing indices of contamination in its production of AZD1222, including elevated levels of endotoxin and excess bioburden.

37. On or about October 1, 2020, Emergent began an investigation into "initial indications of microbial contamination" in the early batches of AZD1222.

38. On October 2, 2020, following procedures defined by the U.S. Food & Drug Administration ("FDA") for quality management, Emergent discovered a deviation[4] in its vaccine manufacturing process that it classified as "Critical." The deviation related to an "endotoxin event" on the same date. In the context of FDA manufacturing rules, critical deviations mean that a batch of drug substance is likely unusable. 21 U.S.C.S. § 331(a) and 21 C.F.R. § 210.1.

39. Kirk and Havey met with AstraZeneca at least once a week to discuss Emergent's progress in successfully manufacturing AZD1222. They also frequently had larger meetings with AstraZeneca which included Emergent's partners in the federal government.

40. On October 5, 2020, during a regularly scheduled weekly meeting to review the progress of the COVID-19 project, Emergent notified the U.S. government's Biomedical Advance Research and Development Authority ("BARDA"), a Department of Health and Human Services ("HHS") working group that was involved in the management of Operation Warp Speed, that Emergent had aborted two batches of AZD1222. Each aborted batch meant the destruction of millions of dose-equivalents of vaccine drug substance.

41. On October 6, 2020, Kirk provided Defendant Kramer with a copy of a PowerPoint presentation, including slides about the aborted, contaminated batches discussed at the previous day's meeting.

42. On October 13, 2020, key managers and employees working for both Emergent and AstraZeneca concluded that five out of the first seven batches of AZD1222 produced by Emergent were likely to be lost to contamination due to alarm level tests for endotoxin and

[4] A deviation is a term in FDA-regulated industries defined as follows: "Discrepancy – Datum or result outside of the expected range; an unfulfilled requirement; may be called non-conformity, defect, deviation, out-of-specification, out-of-limit, out-of-trend" https://www.fda.gov/media/71023/download

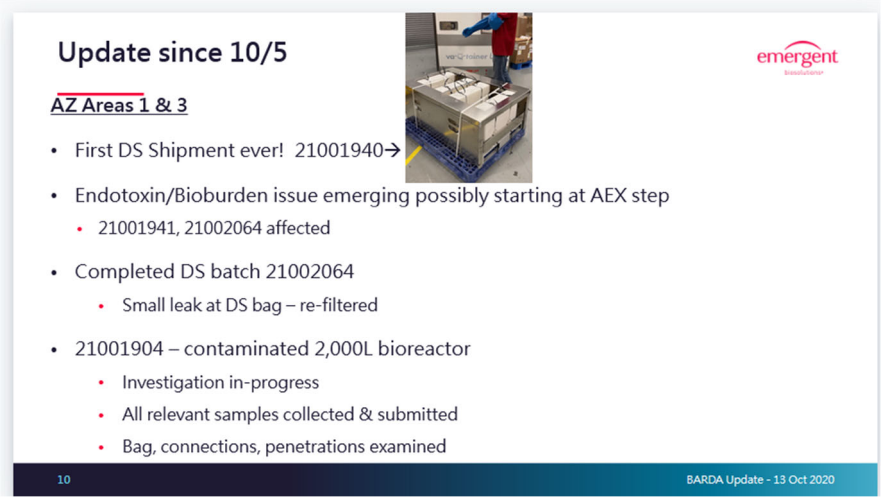
bioburden (tests that indicated the presence of unacceptably high levels of toxic bacteria), and discussed the possible need to stop manufacturing in order to investigate the cause of the contamination.

43. That same day, Emergent's Quality Assurance Chief sent an email to Havey stating ". . . [W]e're likely to lose 5 of 7 batches to date due to contamination issues . . . . My question is if we need to stop production to investigate [the ongoing contamination issue]."

44. On October 13, 2020, Kirk emailed senior leadership at AstraZeneca saying that Emergent had "all hands on deck to evaluate the current challenges …". An AstraZeneca EVP replied: "The situation is indeed worrisome and we are very concerned."

45. On October 13, 2020, Kirk also told Defendant Kramer that he worried that the concerning bioburden test results would likely be discussed in a meeting later that day with AstraZeneca and BARDA. Later in the day, Kirk sent Defendant Kramer an email stating "Bob, Drawing your attention to Slide 10. Couple of issues last week. I can cover in today…with [BARDA] meeting if they come up. The bioburden issue may create some tension between us and [AstraZeneca] and could require a process change…."

46. Slide 10, labeled "Update since 10/5", notes some of the contamination identified as of October 13, 2020:



47. The following day, on October 14, 2020, in response to an email from an AstraZeneca employee regarding agenda items for an October 16, 2020, weekly BARDA meeting, an expert at HHS sent an email to AstraZeneca requesting the addition of the following new agenda item: "the QC [quality control] testing model provided by Emergent and proposed strategy related to downstream endotoxin failures."

48. On October 15, 2020, a member of the AstraZeneca team replied to HHS's expert and requested Emergent's participation in the discussion regarding its quality control and proposed strategy for handling its endotoxin failures.

49. Because of the serious, unresolved contamination problems, Emergent and AstraZeneca agreed to pause production of multiple batches of AZD1222, each containing up to millions of dose-equivalents of vaccine drug substance, and multiple batches were ultimately aborted or rejected and destroyed.

C. In the Midst of Serious, Undisclosed Contamination Issues, Defendant Kramer Pursued a Rule 10b5-1 Trading Plan

50. In mid-October, with knowledge of the destruction of multiple batches of AZD1222 due to contamination issues and after an internal investigation was underway,

Defendant Kramer sought to exercise his Emergent stock options to purchase stock and then immediately sell it off.

51. As part of Kramer's compensation and incentive package, he regularly received options to purchase shares of Emergent stock. In October 2020, Kramer held 231,764 options to purchase Emergent stock at exercise prices ranging from $25.62 to $61.44.

52. On Sunday October 11, 2020, Defendant Kramer called and spoke to his investment adviser at Merrill Lynch. He asked him about entering into the Trading Plan to sell Emergent stock.

53. On October 12, 2020, Defendant Kramer sent an email to his investment adviser with a summary of his stock options saying: "Please review and lets [*sic*] discuss the best way to incorporate this into my portfolio investment planning."

54. On October 14, 2020, in a scheduled call, Defendant Kramer again spoke with his investment adviser to discuss drafting a Rule 10b5-1 plan.

55. On October 16, 2020, Defendant Kramer and his investment adviser again had a phone conversation where they discussed the Trading Plan, including the type of equity awards that could be covered under the plan and the limit price.

56. On October 20, 2020, Merrill Lynch sent Defendant Kramer a draft of the Trading Plan. Under the draft Trading Plan, once a 60 day 'cooling-off' period after signing the Trading Plan had passed, Defendant Kramer would exercise his options and sell the stock when the price was greater than $100. At the time of drafting the Trading Plan, the price of Emergent stock was approximately $100, and had traded at over $111 a few days prior.

D. Emergent's Contamination Problem Intensifies at the End of October

57. Defendant Kramer was fully aware of the escalating manufacturing problems. Kirk and Havey, reporting directly to Defendant Kramer, met and spoke regularly with Kramer throughout the investigation into the contamination problems and kept Kramer fully apprised of the continuing and unresolved problems at Emergent's Bayview facility where AZD1222 was being manufactured.

58. Defendant Kramer's handwritten diary from October 21, 2020, notes "at scale contamination," "bioburden/endotoxin," "pushing for downstream filtration step," and that "AZ has resisted."

59. On October 23, 2020, an AstraZeneca SVP emailed Kirk and stated: "The situation is clearly deeply concerning as [also] the most recent batch has endotoxin/Bio hits and my understanding is that we now have found it in the buffer solution. This really makes me concerned that we may have a bigger and more systematic issue at the Site . . . ."

60. The same day, an AstraZeneca EVP emailed Kirk stating: "We remain very concerned and sincerely hope that EBS [Emergent] can turn this around rapidly . . . . While I understand your point on the speed of what we are doing, I must share that others in our partner network have performed more reliably to date. We are simply nervous that the US supply chain is falling behind."

61. The increasing concerns about contamination led to a "Senior Leader Call" that included Kirk and Havey, the AstraZeneca SVP, and representatives of BARDA, where AstraZeneca executives expressed "concerns at a number of levels" about "Emergent's ability to meet our expectations (and commitments.)"

62. On October 25, 2020, Kirk texted Havey complaining that "Issues keep piling up. This was last night. The AZ meeting is 8:30am on Tuesday at bayview. They asked to do a gemba[5] walk and I said 'no'."

63. During a meeting that took place the following day on October 26, 2020, a slide from a COVID-19 Projects Update PowerPoint presentation highlighted multiple vaccine batches as "late, can't recover," and contained a revised manufacturing schedule identifying the number of batches that were reduced in 2020 and early 2021.

64. On the morning of October 26, 2020, Kirk texted Havey and told Havey that he had given Defendant Kramer the "full landscape."

65. As Emergent's CEO, Defendant Kramer was aware of Emergent's continuing contamination problems and understood that the U.S. government was expressing concern about the ability of Emergent to implement AstraZeneca's process in accordance with Operation Warp Speed.

E. Emergent Promoted the AstraZeneca Contracts in SEC Filings and Analyst Calls but Failed to Disclose the Serious, Unresolved Contamination Issues

66. On November 6, 2020, Emergent filed its 3Q2020 10-Q quarterly report with the SEC which touted its contracts for the production of AZD1222 but omitted any mention of Emergent's serious and unresolved manufacturing and contamination problems with AZD1222.

67. Defendant Kramer concealed Emergent's problems during Emergent's 3Q2020 analyst earnings call on November 5, 2020. Specifically, Defendant Kramer told analysts that Emergent had met the goal of establishing the manufacturing process for its COVID-19 vaccine contracts with both AstraZeneca and Johnson & Johnson, stating "…we were to have established

[5] A Gemba Walk is a business term derived from Japanese crime fiction; "genba" meaning "the actual place", where management walks the "crime scene" looking for the source of the problems.

a large-scale manufacturing infrastructure and tech-transfer their candidates to this infrastructure to our Bayview facility outside of Baltimore during 2020 and early into 2021, and that is essentially complete. The second commitment of obligation, if you will, is to manufacture and supply drug substance to their vaccine candidates in support of their global supply chain goals..."

68. Defendant Kramer also responded to questions regarding Emergent's overall procurement and contracting outlook without acknowledging the existence of any problems, including the ongoing unresolved bioburden and endotoxin contamination problems, the rejected and destroyed vaccine drug substance batches, manufacturing delays, or their impact on the vaccine drug substance production schedule.

69. At the time of Defendant Kramer's statements on November 5, 2020, Emergent had not yet successfully completed what is known as a Process Performance Qualification ("PPQ") batch—a successful batch of drug substance according to a replicable set of procedures that will produce successful batches without further changes—of AZD1222. Without a PPQ batch, the tech transfer process was not complete, the FDA could not issue an authorization, and Emergent was not prepared to begin manufacturing commercial batches of AZD1222.

F. In Early November, the Contamination Issue Remained Unresolved

70. At the beginning of November 2020, at AstraZeneca's urging, Emergent initiated a "war room" approach to its bioburden investigation.

71. On Friday, November 6, 2020, Kirk complained in a group text that Emergent's failures to take promised actions and deliver results was hurting Emergent's relationship with AstraZeneca, stating "If we don't get more active on the floor leadership dealing with this stuff then we are doomed from a credibility perspective. We are currently at a significant relational deficit with AZ and need to get aggressive to get out of this hole."

72. On Saturday November 7, 2020, as Emergent staff were still working through the weekend and overwhelmed by the number of problematic test results, Kirk exchanged the following texts with Havey expressing his concern over the situation:

> Sean Kirk <[redacted phone number]>
> 2020-11-07T09:51:26.0000000Z
> Endotoxin hits throughout ppq 1 in area 1. This is in addition to the endotoxin hit we got on the first run in area 3. Call with AZ is at noon. Word is they are going to tell us they want to come in Monday and assess our overall operational readiness.
>
> Havey, Adam <[redacted phone number]>
> 2020-11-07T10:01:21.0000000Z
> What's your position?
>
> Havey, Adam <[redacted phone number]>
> 2020-11-07T10:01:31.0000000Z
> What are mike and Sue saying?
>
> Sean Kirk <[redacted phone number]>
> 2020-11-07T10:13:20.0000000Z
> We have a prep call at 11. I'm not sure I have a position. it's not like I can't tell them they can't come with all the concerns they have
>
> Havey, Adam <[redacted phone number]>
> 2020-11-07T10:13:42.0000000Z
> Understood
>
> Havey, Adam <[redacted phone number]>
> 2020-11-07T10:14:12.0000000Z
> The area 1 hits are concerning...
>
> Sean Kirk <[redacted phone number]>
> 2020-11-07T10:25:12.0000000Z
> At this point everything is concerning. Like fighting the Chinese army
>
> Havey, Adam <[redacted phone number]>
> 2020-11-07T10:38:50.0000000Z
> Sorry, I wasn't trying to pile on or be glib. I was just thinking out loud

73. On Saturday November 7, 2020, senior AstraZeneca executives spoke with members of the Emergent Executive Management Team and expressed their concerns about the lack of progress in resolving the bioburden contamination problem. Emergent understood that

the situation at that time was urgent and severe. In an internal AstraZeneca email summarizing the meeting, one AstraZeneca manager said: "We where [*sic*] very clear with them that we need to see a totally different level of senior leadership from their side from now on and that we are bringing in the cavalry in form of our most experienced SME-s/Leaders…"

74. Over the course of the weekend, AstraZeneca management suggested to Kirk and others at Emergent that production be halted and the schedule slowed down while Emergent continued to investigate the source of the contamination, so as not to lose additional batches of vaccine.

75. Defendant Kramer was aware of the escalating situation. On Sunday November 8, 2020, Kirk texted Defendant Kramer to update him on conversations Kirk had with AstraZeneca's leadership and with BARDA over the weekend and notifying Kramer that he may be receiving a call regarding same:

> Sean Kirk <[redacted phone number] (IMessage)>
>
> Bob sorry to bother you but could you please give me a call when you have a couple minutes. Would like to update you on some conversations with AstraZeneca leadership and Ba[r]da this weekend. You make it a call from [G]eneral Perna [head of BARDA] so I wanted to give you an update in the event that happens

76. On Monday, November 9, 2020, Defendant Kramer texted Kirk about the pressure they were under:

> Kramer, Robert <[redacted phone number]>
> 2020-11-09T14:59:42.0000000Z
> Let's talk before our call with Perna. I'm open until 4:30 PM.
>
> Sean Kirk <[redacted phone number]>
> 2020-11-09T15:05:53.0000000Z
> I will call at 4 or just before. Having a challenging day. Ows/ barda asking for me to run bayview full time
>
> Kramer, Robert <[redacted phone number]>

2020-11-09T15:11:55.0000000Z
I know, I spoke to Adam.

Sean Kirk <[redacted phone number]>
2020-11-09T16:40:55.0000000Z
Az presented it as their gift to us to slow down. Such bullshit.

Kramer, Robert <[redacted phone number]>
2020-11-09T16:41:30.0000000Z
For sure.

77. By November 10, 2020, Emergent and AstraZeneca had agreed to slow down production and come up with a plan to implement the slowdown, which ultimately included removing three batches from the schedule to further investigate and implement corrective actions.

78. On November 13, 2020, the federal government, AstraZeneca, and Emergent held yet another meeting. A slide from a PowerPoint presentation shown at the meeting discussed the possible source of the endotoxin:

> Endotoxin still present in the downstream process consistent with bioburden proliferation. The endotoxin would be expected to be a result of gram-negative organism in the process. The endotoxin is most likely the result of gram-negative bacteria disruption during the process. This could be organisms introduced and or established in a specific unit operation.

79. As of November 13, 2020, while the endotoxin contamination was attributed to toxic gram-negative bacteria, neither the root cause of the problem nor any solution had yet been established.

G. In the Midst of Unresolved and Worsening AZD1222 Contamination and Manufacturing Problems, Defendant Kramer Executed His Trading Plan

80. While the undisclosed concerns over the persistent contamination problems remained, even to the point of instituting a manufacturing slowdown, Defendant Kramer continued to push forward to finalize his Trading Plan.

81. Emergent's persistent and serious contamination problems and the loss of multiple batches of AZD1222, along with ongoing difficulties in implementing various manufacturing process changes and the impact of these circumstances on Emergent's drug substance manufacturing capability and production schedule, were all material nonpublic information associated with serious risks to Emergent's CDMO business, its reputation and its stock price.

82. On Sunday, November 8, 2020, Defendant Kramer, after being informed of the escalating contamination and manufacturing concerns, reached out again to his investment adviser at Merrill Lynch to ensure the rapid finalization of his Trading Plan.

83. On Monday, November 9, 2020, the same day Defendant Kramer texted with Kirk about AstraZeneca's request for a slowdown of production, Kramer once again called his investment adviser. The investment adviser then sent an email to Emergent Senior Counsel requesting an update on Kramer's vesting schedule and asked him to review the Trading Plan.

84. The next day Emergent and AstraZeneca agreed to slow down production of the vaccine substance.

85. Kramer signed the Trading Plan on November 13, 2020. It became effective that same day.

86. According to Emergent's insider trading blackout calendar, for those not in possession of material nonpublic information, a window was open for placing trades from November 10 to December 17, 2020. Kramer chose to execute the Trading Plan at the beginning of the window, triggering an early date for commencement of a cooling-off period, and an early date for initiation of trades under the Trading Plan.

87. Defendant Kramer entered into the Trading Plan while in possession of material nonpublic information regarding the existence of ongoing serious and unresolved contamination and manufacturing problems impacting an important business unit. Kramer enacted the Trading Plan before the public learned of these serious problems and ultimately traded before the material nonpublic information was disclosed and the stock price fell.

H. The Contamination Problem Continues

88. On November 14, 2020, the day after Kramer's Trading Plan became effective, Emergent and AstraZeneca slowed down Emergent's production timeline to identify and correct the ongoing contamination problem.

89. On November 18, 2020, while bioburden and endotoxin were still appearing in Emergent's Bayview Facility Area 1, a new problem of mold contamination appeared in Emergent's Bayview Facility Area 3.

90. By November 30, 2020, Emergent had failed to meet initial expectations for production of AZD1222. Emergent's original Manufacturing Product Schedule and Work Order set forth an expectation that Emergent would manufacture up to 15 batches of AZD1222 from July 1 through November 30, 2020, in Emergent's Bayview facility Area 1. However, only a single batch was successfully completed in that period.

91. On December 3, 2020, after the appearance of additional contamination, and the failure of additional vaccine batches, Kirk emailed Havey and other Emergent executives the following:

> If we are shutting down Area 3 manufacturing, we will need to be careful with messaging here and make sure we [are] clear on action and path forward with lens of "warp speed manufacturing" meaning that we are taking risks and conditionally releasing supplies through BDS every day with the intent of downstream releasing and defending use of produced material. *Given the*

> *challenges to date, it is not beyond possibility that AZ could cancel our contract given that they have other suppliers on line, therefore messaging is critical*.
>
> (Emphasis added.)

92. The next day, on December 4, 2020, Emergent formally notified AstraZeneca that it had rejected five more batches of AZD1222 due to a "business decision" (made in November) to allow time for Emergent to make changes to mitigate microbial contamination.

93. On December 26, 2020, Havey texted other Emergent executives that "[t]here will be no CDMO business with these big pharma companies now or later if we keep losing batches."

94. On January 14, 2021, Emergent aborted another batch of AZD1222 due to contamination.

95. Between October 2020 and February 2021, Emergent aborted or rejected 14 batches of AZD1222 due to the microbial contamination problem. This translated into the loss of potentially 35-40 million dose-equivalents of AZD1222. While the initial contract provided for up to 95 batches by April 30, Emergent only delivered a fraction of the expected production.

I. Defendant Kramer Sells Emergent Stock Pursuant to His Trading Plan

96. On January 15, 2021, the first set of Defendant Kramer's planned stock sales pursuant to his Trading Plan was executed by Merrill Lynch's New York office on the New York Stock Exchange. Kramer acquired 19,026 shares of Emergent through the exercise of stock options at an exercise price of $25.62 and immediately sold those shares at a weighted average sale price of $106.0076. The stock sale yielded proceeds of $2,016,900.60 for Defendant Kramer.

97. On January 20, 2021, Merrill Lynch executed another round of transactions pursuant to Defendant Kramer's Trading Plan. Kramer acquired 2,232 shares of Emergent stock

through the exercise of stock options at a price of $26.45 and immediately sold those shares at a weighted average sale price of $110.00. These stock sales yielded additional proceeds of $245,520.00 for Defendant Kramer.

98. On January 21, 2021, Merrill Lynch executed another round of transactions pursuant to Defendant Kramer's Trading Plan. Kramer acquired 21,900 shares of Emergent stock through the exercise of stock options at $26.45 and immediately sold those shares at a weighted average sale price of $110.03. These stock sales yielded additional proceeds of $2,409,657.00 for Defendant Kramer.

99. In the face of these massive gains, on January 22, 2021, Defendant Kramer called his investment adviser "out of the blue" and said that he was thinking of cancelling his Trading Plan. The investment adviser said that it "was generally frowned upon to do so." Defendant Kramer ultimately did not cancel the Trading Plan.

100. On February 8, 2021, in yet another series of transactions, Defendant Kramer acquired an additional 45,397 shares of Emergent stock through the exercise of options in two tranches, 32,397 shares at a price of $30.86 and 13,000 shares at a price of $30.63 and immediately sold those shares pursuant to his Trading Plan at a weighted average sale price of $120.03 per share. These stock sales yielded further proceeds of $5,449,001.91 for Defendant Kramer.

101. Defendant Kramer's total proceeds from his sales of Emergent stock were $10,121,079.50.

102. This table summarizes these transactions:

Trade Date	Activity Type	Quantity	Total Proceeds
1/15/2021	Sell	19,026	$2,016,900.60
1/20/2021	Sell	2,232	$245,520.00
1/21/2021	Sell	21,900	$2,409,657.00
2/8/2021	Sell	32,397	$3,888,611.91
2/8/2021	Sell	13,000	$1,560,390.00
Total		88,555	$10,121,079.50

103. The limit prices for Defendant Kramer's sales of Emergent stock under his Trading Plan were near the stock price when the Trading Plan was drafted in October 2020.

104. As illustrated in the chart below, shortly after Defendant Kramer completed his sales of stock pursuant to his Trading Plan on February 8, 2021, the market price of Emergent stock began a steady decline from which it has not recovered:

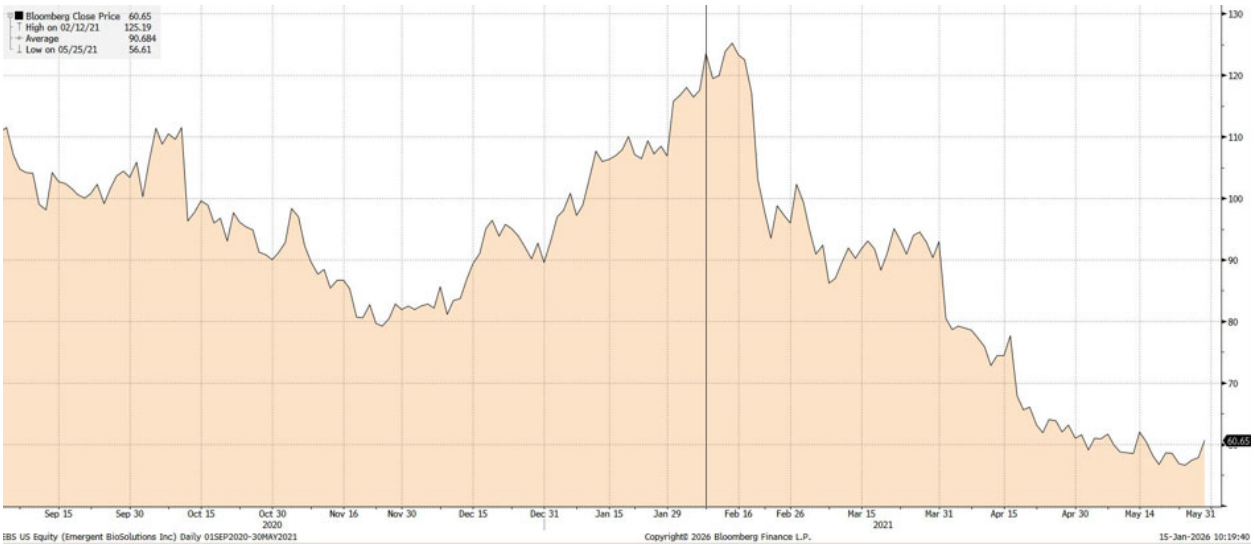


Fig 1. Chart showing Emergent's stock price at close from September 2020 to May 2021. There is a vertical bar on February 8, 2021, after which the stock's price trends steeply downward.

105. On February 18, 2021, Emergent held its final 2020 analyst earnings call to discuss its Q4 results and faced questions from analysts regarding Emergent's slow production of COVID vaccines, focusing on the Johnson & Johnson vaccine.

106. Defendant Kramer broadened the discussion to include AZD1222 but again, concealed the contamination problem:

> So just as a reminder to everyone, our two key deliverables to J&J and it goes for AstraZeneca as well as we stated before, are pretty clear. First, we were to have established a large scale manufacturing infrastructure and tech transfer their candidates to this infrastructure to our Bayview facility outside of Baltimore during 2020 and early into 2021, and that is essentially complete. The second commitment or obligation, if you will, is to manufacture and supply drug substance for their vaccine candidates in support of their global supply chain goals, which they have been pretty open about in terms of the number. And we're right online, Brandon, with doing that timing-wise, as well as capability for both J&J and AstraZeneca.

107. These statements by Defendant Kramer were materially false and misleading because Emergent was then seriously behind on the originally anticipated schedule for production of AZD1222.

108. On February 19, 2021, Emergent's stock dropped by $14.02, or 11.9%, to close at $103.04 on heavy trading volume.

109. On February 19, 2021, a member of Emergent's board of directors, emailed Defendant Kramer to ask whether there was a problem at the root of the stock's sudden decline in price—down 17.9% over the week of February 12 through February 19, 2021. Defendant Kramer responded: "There are a few concerns by investors [re earnings call last night] relating to the continuity of CDMO business. New speculation that the FDA may not approve the AZ vaccine due to significant inconsistencies in the manufacturing. It's tough to attribute anything to weakness in the share price, but I think these two are contributing to weakness."

110. These statements by Defendant Kramer underscore the significance of AZD1222 and Emergent's manufacturing difficulties to investors.

J. Subsequent Developments

111. In 2020 and early 2021, at the same time that Emergent was manufacturing AZD1222, Emergent was also manufacturing drug substance in its Bayview facility for a different COVID-19 vaccine developed by Johnson & Johnson.

112. On March 5, 2021, Johnson & Johnson detected cross-contamination in one batch of its drug substance with AZD1222. A Johnson & Johnson representative explained at a staff briefing that the cause of the contamination was that "Emergent personnel were not decontaminating properly and disposing of waste properly."

113. As a result of the Johnson & Johnson cross-contaminated batch, along with the media attention it generated, the U.S. government first required heightened supervision of the Bayview facility by Johnson & Johnson and then stopped production of AZD1222 entirely to allow Emergent to concentrate on only one vaccine process.

114. On March 6, 2021, the New York Times published an exposé on Emergent's business practices and lobbying efforts during the previous presidential administration. The article was highly critical of Emergent and accused it of using influence to consume a large portion of the nation's strategic disease prevention stockpile. While reports of difficulty with vaccine production had already brought the share price down in February, after the publication of the New York Times article, Emergent's stock price fell further by $6.37, or 6.87%, to close at $86.23 on March 8, 2021.

115. On April 12, 2021, the FDA conducted an inspection of Emergent's Bayview facility and four days later, on April 16, the FDA requested that Emergent shut down the production of AZD1222.

116. By the time Emergent ceased manufacturing of AZD1222, it had successfully completed only 28 commercially viable batches and had 13 batches in progress. This number was far below the 95 batches originally expected by the Emergent-AstraZeneca agreements through April 2021, let alone the 120 batches originally expected through June 2021.

117. Media outlets widely disseminated the news of the FDA halting production of AZD1222 beginning on April 19, 2021. Following the reports, Emergent's stock price dropped by another $12.02 from its closing price on April 16, 2021, or 15.5%, to close at $65.62 on April 20, 2021, on heavy trading volume. During the month that followed, which included the publication of another exposé from the New York Times detailing Emergent's difficulties and the FDA halting production at the Bayview facility entirely, the stock price dropped as low as $59.10.

118. Defendant Kramer was sued in 2016 for insider trading in connection with the alleged possession of material non-public information regarding Emergent's manufacture of an anthrax vaccine. Defendant Kramer's stock sales in that case were then made pursuant to a Rule 10b5-1 Plan. Defendant Kramer settled that suit in 2019.

CAUSE OF ACTION

Martin Act Securities Fraud – General Business Law § 352 and 352-c

119. The Attorney General repeats and re-alleges the paragraphs above as if fully stated herein.

120. The acts and practices of Defendant Kramer alleged herein violated General Business Law Sections 352 and 352-c, in that Defendant Kramer's actions constituted insider trading of Emergent stock while in the possession of material nonpublic information concerning serious contamination and manufacturing issues in Emergent's production of AZD1222.

121. Defendant Kramer engaged in an artifice, agreement, device or scheme to obtain money, profit or property by means prohibited by General Business Law Section 352-c.

122. Defendant Kramer engaged in a fraudulent practice under GBL Section 352 in that he employed a device, scheme or artifice to defraud or for obtaining money or property by means of a false pretense, representation or promise; employed a deception, misrepresentation, concealment, suppression, fraud, false pretense or false promise; or engaged in a practice or transaction or course of business relating to the purchase, exchange, investment advice or sale of securities or commodities which is fraudulent or in violation of law and which has operated or which would operate as a fraud upon the purchaser.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands that the Court issue an order and judgment against Defendant Kramer as follows:

A. Permanently enjoining Defendant Kramer from engaging in the fraudulent, deceptive and illegal acts alleged herein and from violating the Martin Act, New York General Business Law § 352 *et seq.*;

B. Directing Defendant Kramer to disgorge all amounts obtained in connection with or as a result of the violations of law alleged herein and all moneys obtained in connection with or as a result of the fraudulent practice alleged herein;

C. Directing Defendant Kramer to pay damages caused, directly or indirectly, by the fraudulent and deceptive acts complained of herein plus applicable pre-judgment interest;

D. Awarding costs to the State of New York of two thousand dollars against Defendant Kramer pursuant to CPLR § 8303(a)(6); and

E. Granting such other and further relief as may be just and proper.

Dated: New York, New York
January 15, 2026

LETITIA JAMES
Attorney General of the State of New York

By: _____

T. Austin Brown,
Assistant Attorney General
Investor Protection Bureau

Steven J. Glassman,
Special Counsel in Economic Justice
Economic Justice Division

Kenneth Haim,
Deputy Bureau Chief
Investor Protection Bureau

Shamiso Maswoswe,
Chief of the Investor Protection Bureau
28 Liberty Street
New York, New York 10005

Counsel for the People of the State of New York