IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNDER SEAL	)	
	)	
Plaintiff,	)	
	)	Civil Action No:
v.	)	
	)	**FILED UNDER SEAL**
UNDER SEAL	)	
	)	**DO NOT PLACE IN PRESS BOX**
Defendants.	)	**DO NOT ENTER ON PACER**
	)	**DEMAND FOR JURY**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.* DAVID STONEBROOK Plaintiff and Relator, v. MERCK KGaA, DARMSTADT, GERMANY; SIGMA-ALDRICH, CORP.; MILLIPORESIGMA; RESEARCH ORGANICS, LLC Defendants.	)	Civil Action No: **FILED UNDER SEAL** **DO NOT PLACE IN PRESS BOX** **DO NOT ENTER ON PACER** **DEMAND FOR JURY**

COMPLAINT FOR VIOLATIONS OF FEDERAL FALSE CLAIMS ACT

Relator David Stonebrook, on behalf of himself and on behalf of the United States of America brings this *qui tam* complaint against Defendants Merck KGaA, Sigma-Aldrich Corp., Millipore-Sigma, and Research Organics, LLC alleging violations of the False Claims Act (FCA).

JURISDICTION AND VENUE

1. This action arises under the False Claims Act, 31 U.S.C. § 3729 *et seq*. (the "FCA"). Specifically, Defendants caused the submission of false claims in violation of 31 U.S.C. §3729(a)(1)(A). In so doing, Defendants made or used false records material to these false claims, and knowingly concealed or knowingly and improperly avoided an obligation to pay or transmit money or property to the United States.

2. Further, Defendants unlawfully retaliated against Relator in violation of 31 U.S.C. § 3730(h).

3. Accordingly, this Court has jurisdiction pursuant to 28 U.S.C. §1331. Jurisdiction is also authorized under 31 U.S.C. § 3732(a).

4. Venue lies in this judicial district pursuant to 31 U.S.C. § 3732(a), because Defendants qualify to do business in the State of Massachusetts, transact business in the State of Massachusetts, transact business in this judicial district, and can be found here.

PARTIES

5. Defendant Merck KGaA, Darmstadt, Germany (Merck KGaA)[1] is a German multinational company, headquartered in Darmstadt, Germany that operates across healthcare, life sciences and performance materials.

6. Defendant Sigma-Aldrich Corp. is a subsidiary of Merck KGaA that specializes in life sciences and is headquartered in St. Louis, Missouri. In November 2015, Defendant Merck KGaA acquired Sigma-Aldrich Corp. and began operating under the tradename "MilliporeSigma."

7. Defendant MilliporeSigma is a trade name for Sigma-Aldrich Corp. and is a life sciences company headquartered in Burlington, Massachusetts. MilliporeSigma operates Defendant Research Organics, LLC under the trade name SAFC Cleveland.

8. Defendant Research Organics, LLC dba SAFC Cleveland (SAFC Cleveland) is a subsidiary of MilliporeSigma that manufactures, stores, packages, and supplies pharmaceutical components and products. Research Organics, LLC is based in Cleveland, Ohio and operates a pharmaceutical component manufacturing and packaging facility located at 4353 East 49th Street

[1] Merck KGaA, Darmstadt, Germany—the named defendant in this case—uses the firm name "Merck KGaA, Darmstadt, Germany" in the United States and Canada, and uses the firm name "MilliporeSigma" in its life sciences operations. Merck KGaA, Darmstadt, Germany is not affiliated with "Merck & Co., Inc." – which is a multinational pharmaceutical company – based in the United States and operates under and owns the trademark name "Merck" in the United States and Canada.

in Cleveland, Ohio. Research Organics was founded in 1953 and acquired by Sigma-Aldrich, Corp. in 2012—thereafter operating under trade name SAFC Cleveland.

9. Relator David Stonebrook (Relator) has significant experience in Good Manufacturing Practice (GMP) compliance, pharmaceutical manufacturing, pharmaceutical packaging and pharmaceutical "cleanroom" environments. Relator was employed by MilliporeSigma at the SAFC Cleveland facility as GMP Packaging Supervisor from December 8, 2020 to March 3, 2021. In this role, Relator's duties included supervising packaging operations to ensure adherence with safety and quality requirements, leading investigations in equipment failure, foreign material findings and process deviations to determine root causes, and representing SAFC Cleveland's Packaging Department as a member of management during customer audits. Further, Relator performed audits of packaging area and warehouse areas, performed daily review of compliance documentation and communicated necessary changes to higher management and corporate employees, including safety, equipment and regulatory concerns.

10. Relator alerted MilliporeSigma management to the extensive non-complaint conditions at the SAFC Cleveland plant, and informed management that disregard for these non-complaint conditions posed a risk to patient safety and implicated both criminal liability under the Food, Drug and Cosmetics Act and False Claims Act liability. As a result of these reports and recommendations, Relator was terminated in violation of 31 U.S.C. 3730(h).

11. Prior to filing this Complaint, Relator voluntarily disclosed to the United States the information upon which this action is based. Relator is unaware of any prior disclosure of any information materially pertaining to the fraud alleged in this Complaint. To the extent that any public disclosure has taken place as defined by 31 U.S.C. §3730(e)(4)(A), Relator is the original source of the information for purposes of that Section. Relator has knowledge that is independent

of and materially adds to any purported publicly disclosed allegations or transactions and has voluntarily provided that information to the United States before filing this Complaint as contemplated by 31 U.S.C. §3730(e)(4)(B)(2).

APPLICABLE LAW

A. The False Claims Act

12. The FCA, 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who: (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or (3) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government is liable to the United States for a civil monetary penalty of not less than $5,500 and not more than $11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]), plus treble damages. 31 U.S.C. § 3729(a)(1)(A), (B), (G).

13. Under the FCA, (1) the terms "knowing" and "knowingly" (A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. 31 U.S.C. § 3729(b)(1).

14. The FCA defines the term "claim" as (A) any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. 31 U.S.C. § 3729(b)(2).

15. The FCA defines the term "obligation" as an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment. 31 U.S.C. § 3729(b)(3).

16. Additionally, the FCA provides that any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations the FCA. *See* 31 U.S.C. § 3730(h).

B. FDA Production and Packaging Requirements—Which Defendants Violated Thereby Rendering Drugs Adulterated.

17. Pharmaceutical Quality affects every American, and therefore the FDA regulates the quality and safety of pharmaceuticals carefully.

18. The FDA defines the term "drug," in part, as…"(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement…and (B) "articles intended for use in the diagnosis, cure, treatment, or prevention of disease in man or other animals; (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a 'component' of any [of the above] articles." 21 U.S.C. § 321(g)(1).

19. Therefore, the Components manufactured, stored and packaged at SAFC-Cleveland—many of which are recognized in the United States Pharmacopoeia—are "drugs" as defined by the FDA and must meet all FDA standards, regulations and requirements. If a drug does not meet FDA standards related to proper and safe manufacture, storage and shipping, the drug is deemed "adulterated." 21 U.S.C. § 351.

20. If a drug is "adulterated," the drug may not be sold, transported or received in the United States and therefore may not be sold to the United States Government. 21 U.S.C § 331. Knowingly selling an "adulterated" drug is a felony. 21 U.S.C. § 333(a)(2).

21. A drug shall be deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

22. A drug shall also be deemed "adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B). In context of this statute, the term "current good manufacturing practice" "includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j).

23. Introducing adulterated and misbranded pharmaceutical products into the

marketplace and knowingly selling adulterated and misbranded drugs to the United States has been the subject of numerous enforcement actions, including actions under the False Claims Act.[2] Accordingly, misrepresentations that pharmaceutical components were manufactured and packaged in clean, safe and non-contaminated environments are material to payment and therefore such a misrepresentation results in false claims. *See Universal Health Services, Inc. v. U.S.*, 136 S.Ct. 1989, 2003 (2016).

1. Specific cGMP Requirements for Pharmaceutical Components.

24. The primary regulatory standards for ensuring pharmaceutical quality are the Current Good Manufacturing Practice (cGMP) regulations, often simply called Good Manufacturing Practice (GMP) regulations. GMPs require pharmaceutical manufacturers and facilities that produce pharmaceutical components to provide assurance regarding the identity, strength, quality and purity of drug products by establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviation, and maintaining reliable testing laboratories.

25. GMP regulations mandate specific requirements for pharmaceutical "Components." 21 C.F.R. § 211.80.

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[2] The following cases demonstrate the Department of Justice has taken criminal action, and pursued False Claims Act liability against pharmaceutical manufacturers that knowingly produce products in contaminated environments and specifically mold infested air filtration systems, similar to those at SAFC Cleveland. *See United States ex rel. Christopher Wall v. Baxter International, Inc. et al.*, No. 13cv42 (W.D.N.C.) Department of Justice Press Release "Baxter Healthcare Corporation Pay More Than $18 Million to Resolve Criminal and Civil Liability Relating to Sterile Products. Available at: https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability.
See also United States ex rel. Eckard et al. v. Smith Kline Beechem d.b.a GlaxoSmithKline, PLC et al., No. 1:04-cv-10375-JLT (D. Mass.)(GlaxoSmithKline subsidiary pled guilty to criminal charges related to the manufacture and distribution of certain adulterated drugs and agreed to pay $600 million to resolve related civil allegations under the False Claims Act.)

26. "Components" are defined by the FDA as "any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." 21 C.F.R. § 210.3(b)(3).

27. Components are sometimes called "Ingredients," in FDA regulations. There are two categories of components used in finished pharmaceutical production: inactive ingredient (often called excipients) and active ingredient (often called active pharmaceutical ingredient (API)).

28. "Ingredients are drugs and drugs are required to conform with current good manufacturing practice."[3]

29. "Ingredient manufacturers are responsible for the quality and safety of the material they produce for use in finished pharmaceuticals."[4]

30. "Finished pharmaceutical manufacturers are also responsible for their selection, qualification, and use of ingredients in finished pharmaceuticals."[5]

31. Specifically, cGMP regulations require that "there must be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing and approval or rejection of Components." 21 C.F.R. § 211.80(a).

32. "Components shall at all times be handled and stored in a manner to prevent contamination." 21 C.F.R. § 211.80(b).

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[3] U.S. "FDA Questions and Answers on Current Good Manufacturing Practices—Control of Components and Drug Product Containers and Closures." Citing 21 U.S.C. § 351(a)(2)(B) Available at https://www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practices-control-components-and-drug-product

[4] *Id.*

[5] *Id.* citing 21 CFR part 211, subpart E

33. "Each lot of a component that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination." 21 C.F.R. § 211.84(d)(5).

34. "Each lot of a component…with potential for microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use." 21 C.F.R. § 211.84(d)(6).

C. FDA Labeling Requirements—Which Defendants Violated Thereby Rendering Drugs Misbranded.

35. The FDA requires that drug labeling must be truthful and not misleading.

36. If a drug's labeling is false or misleading, the drug is deemed "misbranded." 21 U.S.C. § 352.

37. Misbranded drugs may not be sold, transported or received in the United States and therefore may not be sold to the United States Government. 21 U.S.C § 331. Knowingly selling an "adulterated" drug is a felony. 21 U.S.C. § 333(a)(2).

38. "The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

39. "If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising

relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual." 21 U.S.C. § 321(n).

D. The United States' Purchase of Pfizer-BioNTech COVID-19 Vaccine.

40. On July 22, 2020, the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DOD) announced an agreement with U.S.-based pharmaceutical company Pfizer Inc. for large-scale production and nationwide delivery of 100 million doses of a COVID-19 vaccine in the United States following the vaccine's successful manufacture and approval.

41. As a result of the July 2020 agreement, the federal government owned 100 million doses of the Pfizer vaccine initially produced. The July 2020 agreement also established that, upon gaining FDA approval, the Pfizer vaccine would be delivered throughout the United States.

42. HHS and DOD paid $1.95 billion for the production and nationwide delivery of the first 100 million doses of the vaccine, with the ability to acquire up to an additional 500 million doses.

43. On December 11, 2020, the FDA authorized the Pfizer-BioNTech Covid-19 Vaccine for emergency use and doses began shipping and being administered immediately.

44. On December 23, 2020, the United States—through HHS and DOD—agreed to purchase an additional 100 million doses of COVID-19 vaccine from Pfizer. Under this agreement, Pfizer contracted to manufacture and deliver up to 100 million doses of its COVID-19 vaccine to Government designated locations. Pfizer agreed to deliver at least 70 million doses by June 30, 2021 and the remainder of the 100 million doses would be delivered to the Government no later than July 31, 2021. The December 23, 2020 agreement also included options for an additional 400 million doses of the Pfizer vaccine.

45. The Pfizer vaccine is provided at no cost to all Americans. Vaccine administration costs for private-sector administration partners are covered by either private insurance, Medicare, or Medicaid. For uninsured Americans, an HHS program reimburses providers at Medicare rates from the provider relief fund.

46. On February 11, 2021, HHS and DOD purchased an additional 100 million doses of COVID-19 from Pfizer, Inc. As of the February 11 agreement, the U.S. government had purchased a total of 300 million doses of the Pfizer-BioNTech Covid-19 Vaccine, which were scheduled to be delivered in regular increments through the end of July 2021.

47. Under these federal contracts, each dose of the Pfizer-BioNTech Covid-19 Vaccine cost $19.50.

48. In total, as of February 2021, the U.S. Government has purchased approximately $6 billion worth of the Pfizer-BioNTech Covid-19 Vaccine.

E. The United States' Purchase of Moderna mRNA-1273 COVID-19 Vaccine.

49. On August 11, 2020, the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DoD) announced an agreement with Moderna to manufacture and deliver 100 million doses of Moderna's COVID-19 vaccine, called mRNA-1273. According to this agreement, the federal government will own these 100 million vaccine doses.

50. If Moderna met timely shipping incentives, the federal government would pay $1.5 billion[6] to manufacture and deliver the vaccine doses to government-designated locations across the country or roughly $15 per dose.

[6] This payment is in addition to $955 million that HHS paid to Moderna to help accelerate development and large-scale manufacture of the Moderna mRNA-1273 vaccine.

51. Pursuant to the August 11, 2020 agreement with Moderna, the United States has an option to acquire up to an additional 400 million doses of the vaccine.

52. On December 11, 2020, the United States, through HHS and DoD agreed to purchase an additional 100 million doses of Moderna's mRNA-1273 COVID-19 vaccine. Under the agreement, Moderna will leverage its U.S.-based manufacturing capacity to fill, finish and ship vials of mRNA-1273 as the bulk material is produced.

53. To meet demand for its COVID-19 Vaccine, Moderna partnered with pharmaceutical manufacturer Lonza Ltd. to enable larger scale manufacture of Moderna's mRNA1273 COVID-19 vaccine. Lonza's COVID-19 Vaccine manufacturing includes a facility in Portsmouth, New Hampshire that has capacity to produce 100 million doses of Moderna's mRNA1273 COVID-19 vaccine annually.

54. As of December 11, 2020, the United States owned 200 million doses of the Moderna mRNA-1273 COVID-19 vaccine.

55. Vaccine administration costs for private-sector administration partners will be covered by healthcare payers: private insurance, Medicare or Medicaid, and an HHS program to cover COVID-19 costs for the uninsured which is reimbursing the provider at Medicare rates from the federally funded provider relief fund.

56. On February 11, 2021, the United States purchased an additional 100 million doses of the Moderna mRNA-1273 COVID-19 vaccine, bringing the U.S. government's confirmed order commitment to 300 million doses. Subsequent to the initial 100 million doses, purchased by the United States in August 2020 at roughly $15 per dose, Moderna increased the cost charged to the United States to $16.50 per dose.

57. As of February 11, 2021, Moderna supplied 41 million released doses of its COVID-19 vaccine to the U.S. Government, and more than 22 million Americans had received the Moderna vaccine.

DEFENDANTS' FALSE CLAIMS ACT VIOLATIONS

A. Defendants' Unsanitary, Contaminated and Non-Compliant Conditions.

58. Relator was hired as a GMP Packaging Supervisor at the SAFC Cleveland Facility on December 8, 2020. In this role, Relator's duties included supervising packaging operations to ensure adherence with safety and quality requirements, leading investigations in equipment failure, foreign material findings and process deviations to determine root causes, and representing SAFC Cleveland's Packaging Department as a member of management during customer audits. Further, Relator performed audits of packaging areas and warehouse areas and performed daily review of compliance documentation.

59. Upon starting in this role, Relator recognized that the SAFC Cleveland Facility was far from GMP compliant and in fact did not even meet basic sanitary practices.

60. The significant deficiencies in the SAFC Cleveland Facility extend throughout the facility's operations. However, as GMP Packaging Supervisor, Relator immediately focused on correcting GMP violations in the Packaging operations.

61. One critical issue that Relator recognized was the unsanitary and mold infested air handling systems at SAFC Cleveland.

62. Proper air handling systems are particularly important in pharmaceutical manufacturing and packaging environments. Airborne pathogens and microbial contamination of pharmaceutical products is a major concern and can easily contaminate pharmaceutical products, thereby endangering patient safety.

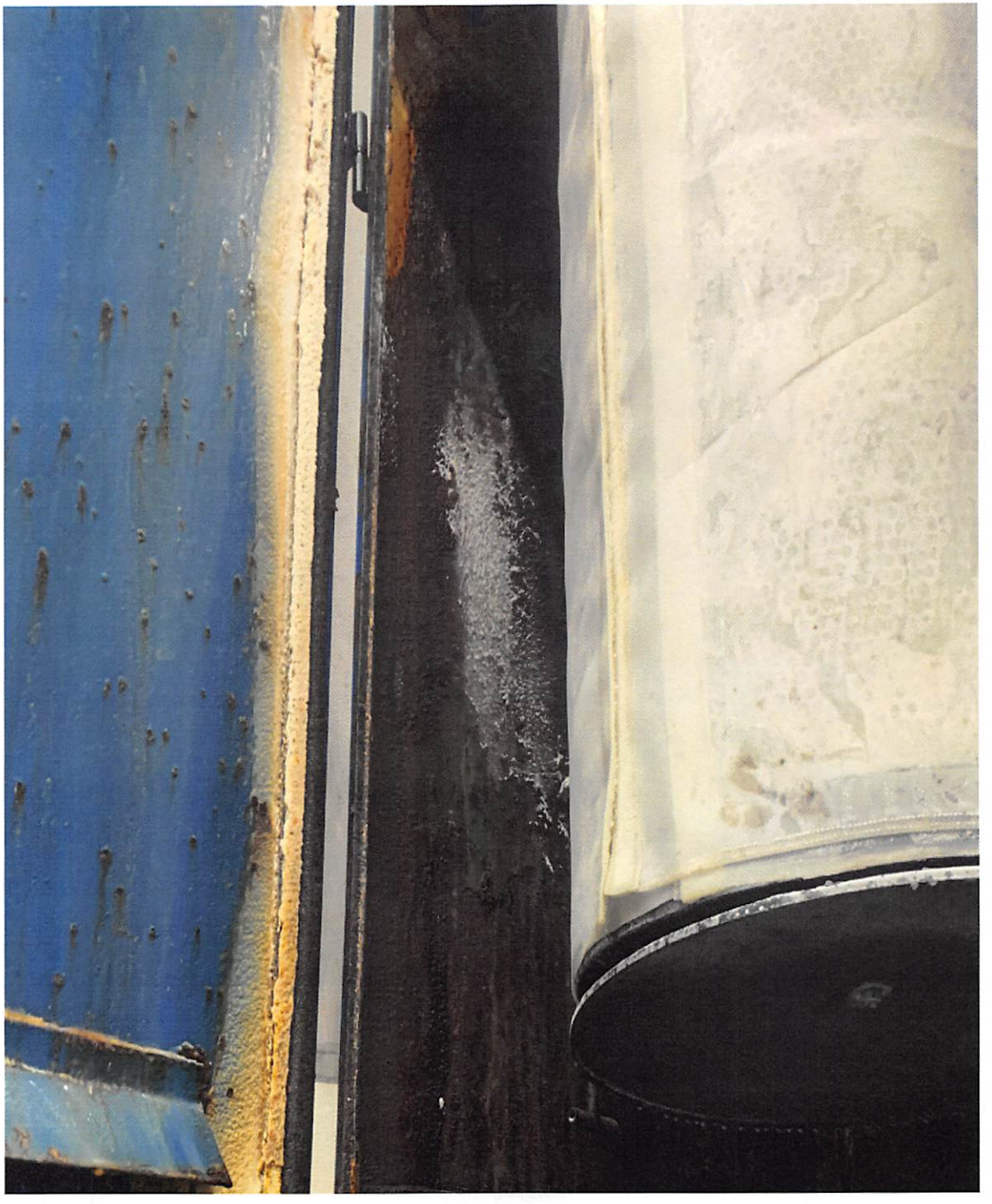
63. In Relator's experience in other pharmaceutical manufacturing and shipping facilities, pharmaceutical grade air filtration systems should have High Efficiency Particulate Air (HEPA) filters. Moreover, it is axiomatic that air filtration systems are routinely monitored and documented to prevent mold and contamination.

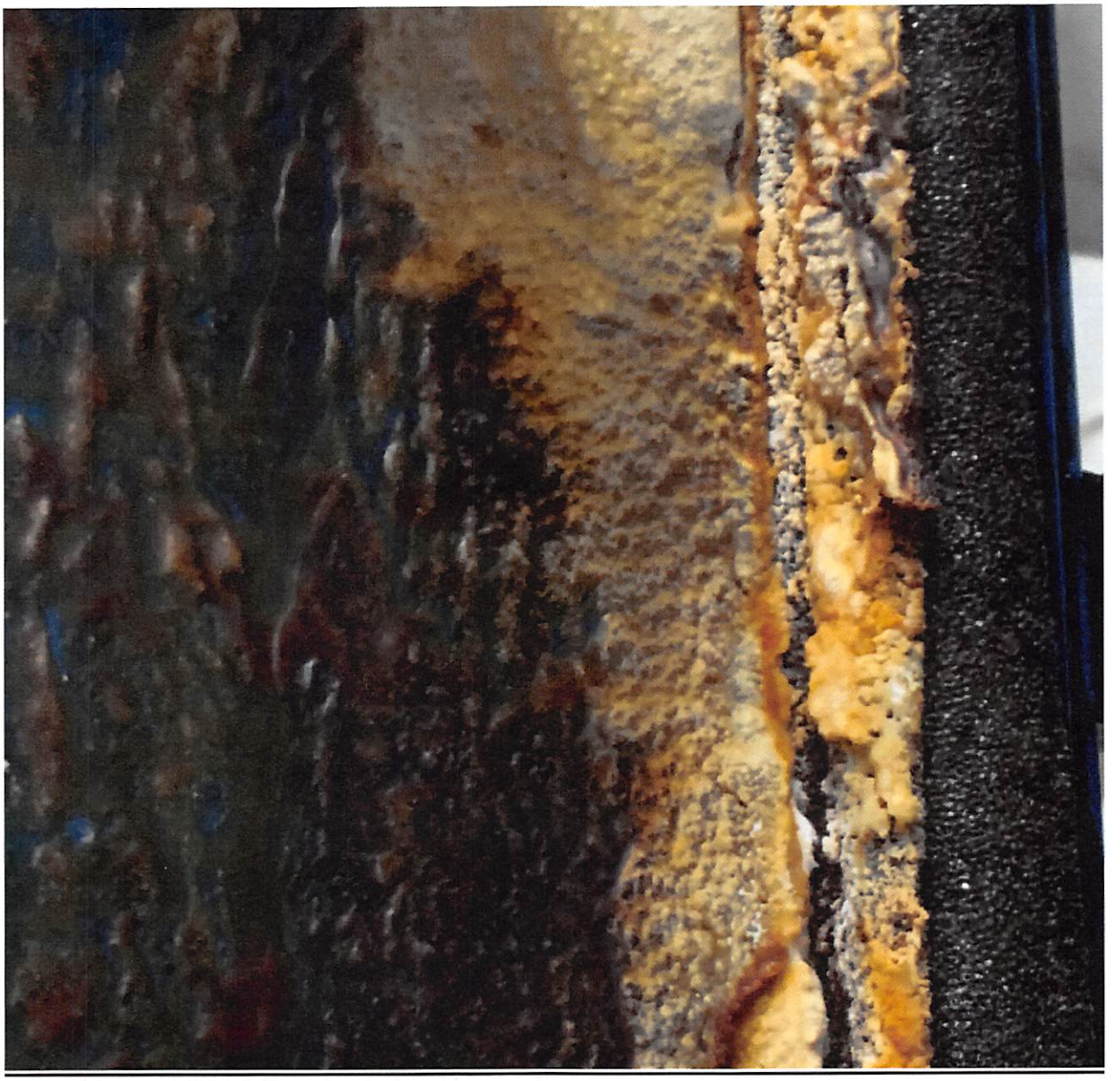
64. Not only did SAFC Cleveland not have appropriate HEPA filtration systems but the outdated and over-taxed air filtration system was covered in mold and therefore simply recycled contaminated air throughout SAFC Cleveland's Packaging Suites.

65. The SAFC Cleveland Facility has several Packaging Suites which SAFC Cleveland misrepresents to be compliant with GMP controls. In these packaging suites, pharmaceutical components are packaged. The packaging process generally involves unloading and sifting large quantities of pharmaceutical components from large bulk containers and re-packaging those components into smaller containers that ultimately will be delivered to the customer. During this process, the pharmaceutical components are exposed to the open air in these rooms for extended periods. Therefore, air quality of the packaging clean rooms is paramount to prevent risk of contamination.

66. The dust collection systems and ductwork in the SAFC Cleveland facilities covering Packaging Suites D, E, and F are woefully deficient. In fact, the filters and housing units that comprise the dust collection system above Packaging Suites D, E, and F have an obvious abundance of mold growth. Therefore, pharmaceutical product packaged within these rooms was constantly exposed to mold infested air, despite MilliporeSigma's misrepresentations that the facilities met GMP compliant standards. Photos of these mold infested dust collection filters are

pictured below, with increasing magnification demonstrating mold growth:





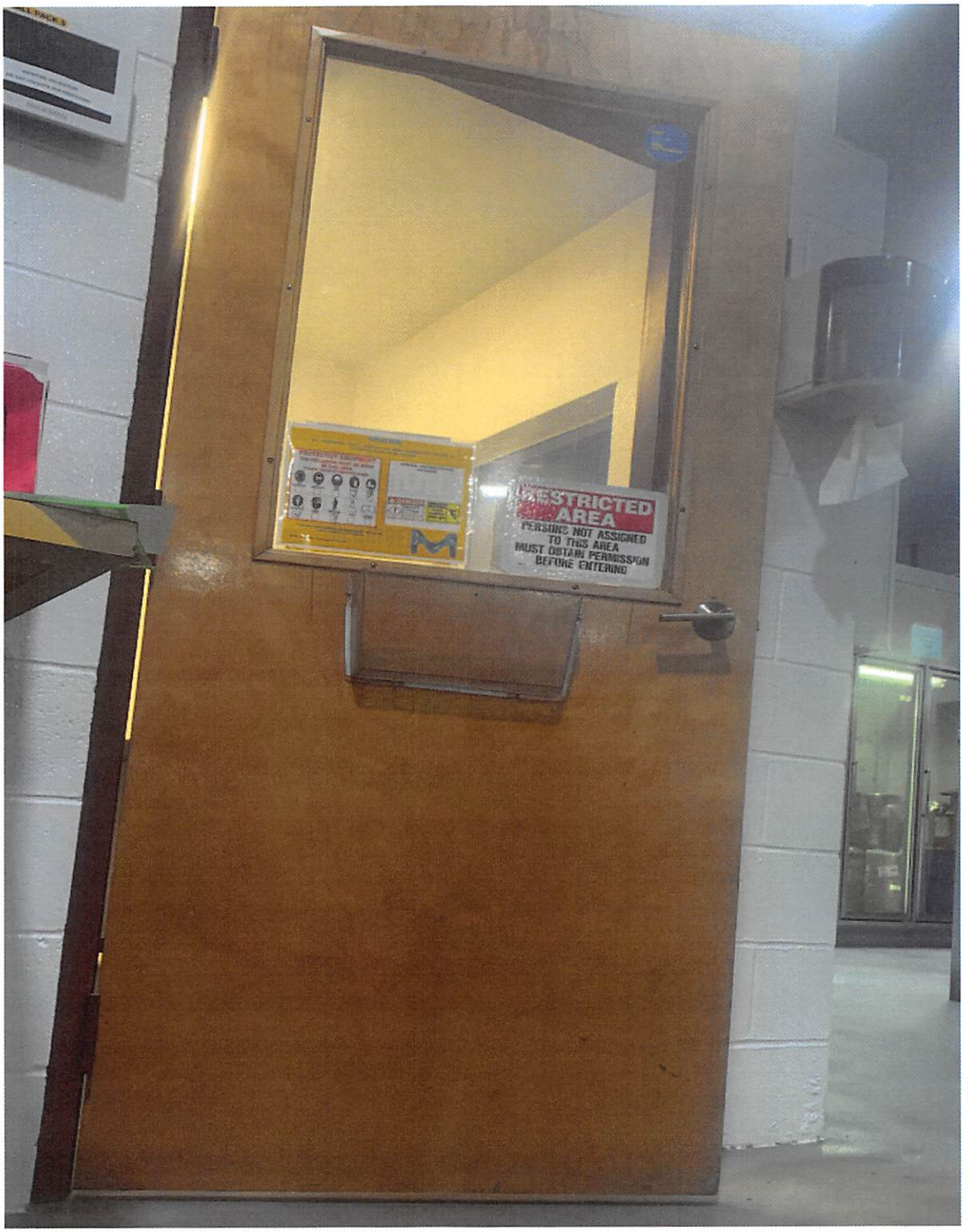
67. The growth of mold in the dust collection system and throughout the Packaging Suites at Cleveland is unsurprising because SAFC did not have adequate cleaning and sanitation practices. Instead of carefully monitoring and documenting the sanitation and cleaning of the air filtration systems and the packaging rooms as required, SAFC Cleveland staff often sprayed down the Packaging Suites and equipment, including the air filters in the packaging rooms, with water.

68. Mold growth is further caused by using water to spray down equipment in a window-less, poorly ventilated indoor room. These cleaning methods are grossly out of compliance with appropriate GMP standards for the packaging and handling of Pharmaceutical Components.

69. Additional facility and equipment deficiencies contributed to the contaminated environment in the purportedly GMP Compliant Packaging Suites. For instance, the door between the warehouse area and SAFC Cleveland's "small" packaging rooms—where GMP products were packaged—was a simple wooden door with an approximately two-inch gap between the bottom of the wooden door and floor.

70. In an actual GMP Compliant facility all entrances to a cleanroom would be hermetically sealed and open only to enter or exit. This is required to prevent airflow from open and contaminated areas outside of the clean room.

71. However, the entrances to the small packaging rooms were often left open. Even when the doors were closed, the large 2-inch gap of each door allowed free air flow in and out of the room—promoting the further contamination and adulteration of drug product labeled GMP compliant. A photo of the non-compliant work area is below:



72. Additionally, SAFC Cleveland could not adequately monitor nor attempt to control the contaminated facility because SAFC Cleveland did not have proper humidity and temperature controls in its purported "small" packaging rooms.

73. Humidity and temperature control is a fundamental requirement for pharmaceutical manufacturing or packaging facilities and GMP compliance.

74. SAFC Cleveland's deficient humidity and temperature control caused excess moisture in the Packaging Suites and exacerbated the mold problems to the extent that excess moisture caused water stains on the windows of Packaging Suites. These water stains are clear indicators of excess moisture and probable mold infestation that can easily contaminate pharmaceutical components. Below is a photo of such water stains:

75. Finally, the SAFC Cleveland facility did not even adequately clean its packaging equipment and would leave residue of pharmaceutical components on equipment that would then be used to package completely different components—inherently risking cross-contamination, quality and purity of components. A photo of the "hopper" used to package bulk materials into

separate packages, with clear adulterating residue is pictured below:

B. Defendants' False Statements and Adulterated and Misbranded Pharmaceutical Components.

76. The SAFC Cleveland facility produces and packages hundreds of different pharmaceutical components and sells these components to hundreds of customers to use as ingredients in FDA-approved finished drug products.

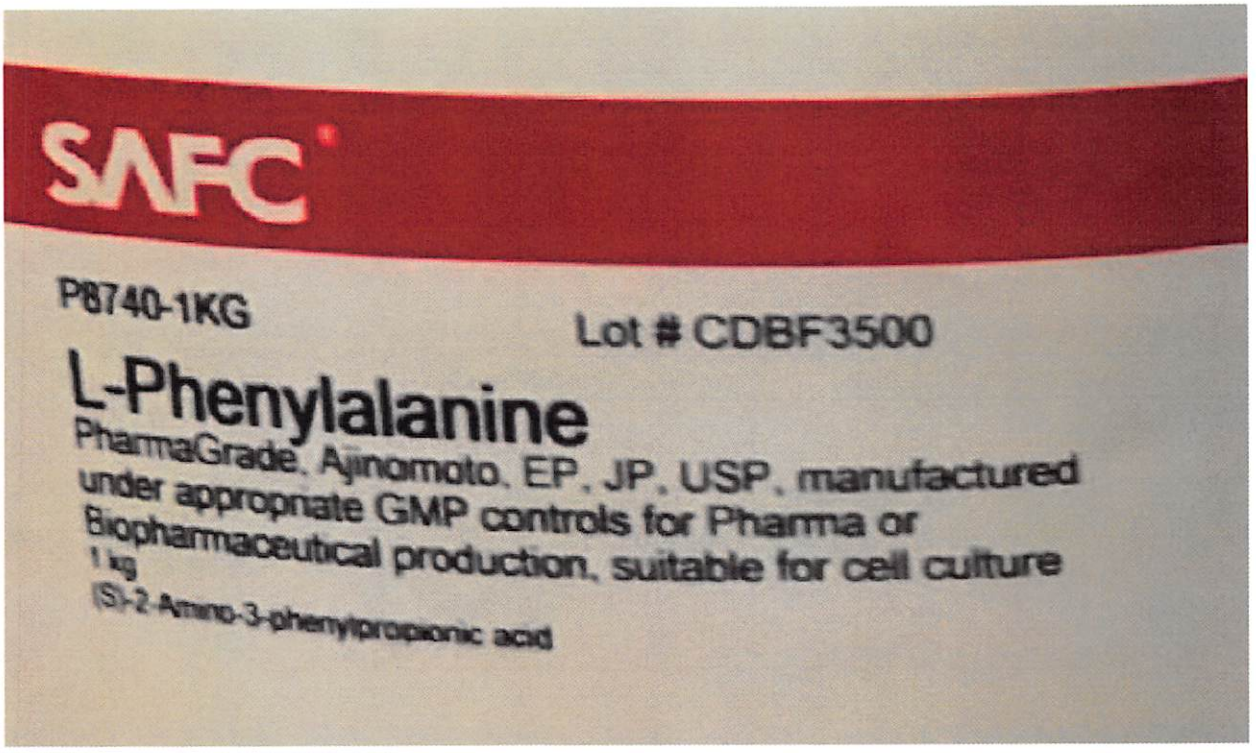
77. Relator witnessed that these products are held and packaged in the contaminated environment described above, which are clearly insanitary conditions and woefully deficient from GMP standards. Therefore, these products are "adulterated" and may not be introduced into interstate commerce. 21 U.S.C. § 351(a)(2)(B); 21 U.S.C. § 331. However, Defendants falsely label and falsely represent to customers that these products are manufactured, stored and packaged under safe and GMP Compliant controls. In so doing, these products are not only adulterated, but also misbranded. 21 U.S.C § 352.

78. The following are examples of Adulterated and Misbranded products—held and packaged in SAFC Cleveland's unsanitary and contaminated environment—specifically Packaging Suites D, E, and F and the "small packaging suites"—and sold to specific customers pursuant to false representations.

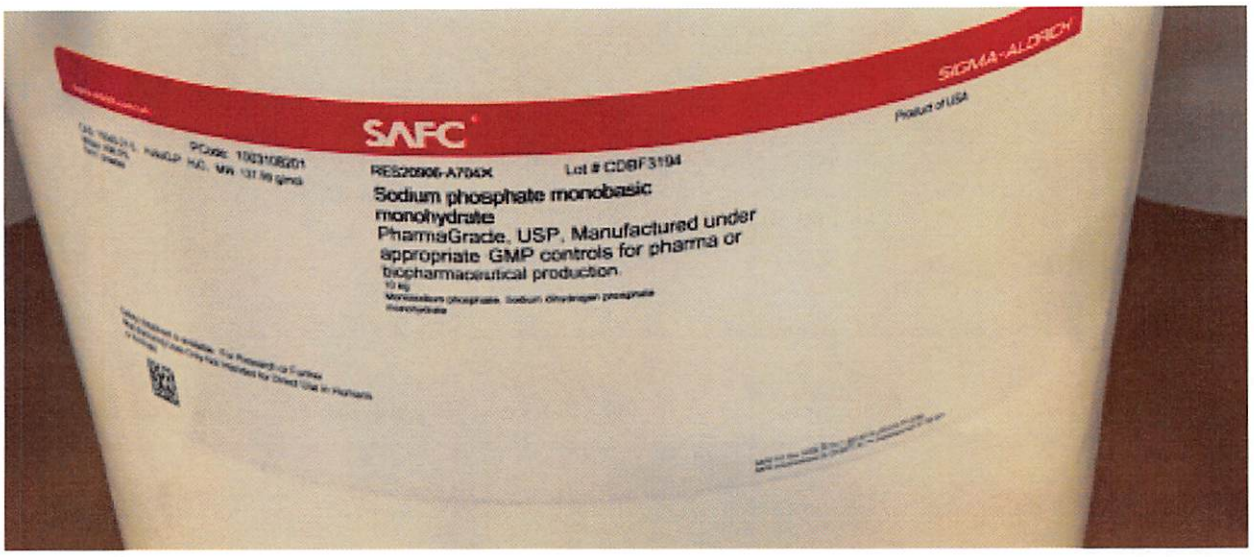
- L-tyrosine, USP[7] was sold to multiple pharmaceutical companies, including Genentech, Inc. These products have been sold to Genentech since January, 15, 2010.
- Calcium chloride dihydrate, USP was sold to multiple pharmaceutical companies, including Boehringer Ingelheim. These products have been sold to Boehringer Ingelheim since June 24, 2013.
- L-phenylalanine, USP was sold to multiple pharmaceutical companies, including Becton Dickinson and Company. These products have been packaged at SAFC Cleveland and sold to Becton Dickinson and Company since September 10, 2012.

[7] The denotation "USP" means the drug is listed in the United States Pharmacopeia and therefore is undoubtedly defined as a "drug" by the FDA and must meet all FDA and GMP requirements.

A photo of Defendants falsely labeled L-phenylalanine, which falsely represents GMP compliance is below:



- Sodium phosphate monobasic monohydrate, USP was sold to multiple pharmaceutical companies, including Abbott Laboratories. This component was manufactured and packaged at SAFC Cleveland and sold to Abbott Laboratories since June 27, 2014.



1. Defendants' False Statements and Adulterated Components Used in the COVID-19 Vaccines Purchased by the United States.

79. The most critical components manufactured and packaged in SAFC Cleveland's contaminated conditions are those that are components for the respective Pfizer-BioNTech COVID-19 Vaccine and Moderna mRNA-1273 COVID-19 Vaccine.

i. SAFC Cleveland's Manufacture, Packaging and Sale of HEPES to Pfizer for the Pfizer-BioNTech COVID-19 Vaccine.

80. SAFC Cleveland manufactures and packages HEPES, a zwitterionic sulfonic acid buffering agent, that is used to maintain enzyme structure and help the enzyme function at low temperatures. HEPES is sold directly from SAFC Cleveland to Pfizer.

81. As described above, the Pfizer COVID-19 Vaccine is critical to combatting the COVID-19 Pandemic, and the United States has spent billions of dollars to purchase hundreds of millions of doses of the Vaccine.

82. Relator has first-hand knowledge that the HEPES Components sold to Pfizer and ultimately sold to the United States are adulterated because they were manufactured and packaged in contaminated facilities at SAFC Cleveland. Specifically, the HEPES Components sold to Pfizer, and ultimately the United States were packaged in SAFC Cleveland's contaminated

packaging suites. Packaging Suite D is treated by the mold infested air filtration system pictured above and is impacted by the other significant GMP violations detailed *supra.*

83. Relator has first-hand knowledge that the HEPES Components sold to Pfizer and ultimately sold to the United States are misbranded because Defendants have falsely represented that the HEPES Components sold to Pfizer are manufactured under proper controls. Specifically, the SAFC Product Documentation for HEPES, Product Number RES6003H-B7—which is the product supplied to Pfizer for its COVID-19 Vaccine—clearly purports the product to be "PharmaGrade, Manufactured under appropriate controls for use as a raw material in pharma or biopharmaceutical production, suitable for cell culture."

84. The SAFC Product Regulatory Datasheet details that the site of Manufacturing, Packaging and release is SAFC Cleveland.

85. Because the HEPES product manufactured and packaged at SAFC Cleveland was subject to mold infestations, produced and packaged by improperly maintained equipment and in violation of GMP requirements for pharmaceutical components, it is adulterated, and Defendants' labeling is false and misleading.

86. Defendants sold adulterated and misbranded HEPES Components that it knew would be used in the Pfizer COVID-19 Vaccine and that ultimately would be purchased by the United States. Specifically, SAFC Cleveland Order Number: 1003204605, Batch number: CDBF4762 corresponding to 48 separate 50 kilogram drums of HEPES was released from the SAFC Cleveland facility and sent to Pfizer on February 19, 2021.

87. SAFC Cleveland packaging and shipping systems noted that this Order was for the Pfizer COVID-19 Vaccine.

ii. SAFC Cleveland's Manufacture, Packaging and Sale of Tromethamine and TRIS hydrochloride to Lonza for the Moderna COVID-19 Vaccine.

88. SAFC Cleveland manufactures and packages pharmaceutical components TRIS hydrochloride and Tromethamine, USP.[8] Tromethamine, USP is a buffering agent that is used to adjust or stabilize the pH balance of a solution and can be used to treat metabolic acidosis—a condition where the body produces too much acid or when the kidneys are not removing enough acid from the body. TRIS hydrochloride is similar to Tromethamine, but contains additional hydrochloride molecules and is also used to stabilize the pH balance of a solution.

89. Tromethamine and TRIS hydrochlroride are both ingredients in the Moderna COVID-19 Vaccine. Specifically, Tromethamine and TRIS hydrochlroride are "acid stablizers" in the Moderna Vaccine and ensure the stability of the vaccine after production and until it is administered to a patient.

90. As described above, the Moderna COVID-19 Vaccine is critical to combatting the COVID-19 Pandemic, and the United States has spent billions of dollars to purchase hundreds of millions of doses of the Moderna Vaccine.

91. Relator has first-hand knowledge that Tromethamine and TRIS hydrochlroride, manufactured under unsanitary conditions at SAFC Cleveland (SAFC product number RES3193T-A7), are sold to Lonza, Ltd. and used to manufacture the Moderna COVID-19 Vaccine.

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[8] Tromethamine, USP is often referred to as "Tris," "Tris(hydroxymethyl)aminomethane" or "2-Amino-2-(hydroxymethyl)." TRIS hydrochloride is often referred to as "TRIS," "TRIS HCL," "TRIS hydrochloride," "Tris(hydroxymethyl)aminomethane hydrochloride," "Trizma® hydrochloride," and "Tromethane hydrochloride"

92. Specifically, these Components sold to Lonza Ltd. and ultimately the United States were packaged in SAFC Cleveland's contaminated packaging suites. Packaging Suite D is treated by the mold infested air filtration system pictured above and is impacted by the other significant GMP violations detailed *supra.*

93. Defendants sold adulterated and misbranded Tromethamine and TRIS HCL drug components that it knew would be used in the Moderna Vaccine and that ultimately would be purchased by the United States.

94. Further, the Tromethamine sold to Lonza for use in the Moderna Vaccine is misbranded because Defendants' label provides that the Tromethamine was "manufactured under appropriate controls for use as a raw material in pharma or biopharmaceutical production." This labeling is false and misleading because the Tromethamine and TRIS HCL was actually manufactured and packaging in a contaminated environment—specifically Packaging Suite D at the SAFC Cleveland plant—pictured above.

C. Defendants' False Statements, Knowledge of Contaminated and Non-Complaint Conditions and Intentional Deception to Induce the Purchase of Non-Complaint Components.

95. Defendants have specific knowledge of the unsanitary and non-complaint conditions in their own facility. In fact, as early as 2007, the SAFC Cleveland facility was operated by Research Organics, whose management acknowledged that it could not legally manufacture certain products because it did not have GMP-compliant facilities. This assessment and acknowledgement of the lack of GMP facilities was conducted by Amy Mutere, who was then the Site Quality Manager for Research Organics, and by Michael McCormick, a former EHS Manager for Research Organics.

96. Through his experience at SAFC Cleveland, Relator has knowledge that the SAFC Cleveland facility has not made any improvements that would make the facility GMP compliant since Ms. Mutere and Mr. McCormick's assessment, and the facility has only further deteriorated, causing increasing danger of contamination of pharmaceuticals.

97. Defendants provide false and misleading marketing materials to their customers. Specifically, Defendants' marketing materials including promotional PowerPoint presentations, purport that the Cleveland facility has "upgraded its systems to cGMP standards." These false marketing materials purport that "GMP systems include: Documentation and retention, training, process control, laboratory control…and packaging, preservation and storage."

98. Defendants have continually misled their customers and the FDA by intentionally deceiving customers and the FDA during audits and site inspections as detailed more fully, *infra*.

99. Pharmaceutical manufacturers have responsibilities to ensure that suppliers of Components used in finished drug products are conforming to GMP processes. *See* 21 C.F.R. § 211.80(b). Therefore, pharmaceutical manufacturers conduct audits and site visits of their supplier facilities to ensure such compliance.

100. Manufacturers of finished drug products rely on these audits and site visits—as well as assurances and labeling of products from their suppliers—to certify to the purchasers of finished drug products that their supply chain is GMP compliant and that their drugs have "at all times have been handled and stored in a manner to prevent contamination." *See* 21 C.F.R. § 211.80(b).

101. Relator has knowledge that Defendants have a practice of knowingly misleading and misdirecting their customers and the FDA during the site audit visits.

102. For instance, SAFC Cleveland Quality Manager Greg Janetta is instrumental in Defendants' efforts to mislead site auditors. Specifically, Mr. Janetta leads auditors to specific

areas, while specifically avoiding other areas known to be problematic and that would raise concerns of contamination.

103. As addressed above, one major area of concern was the mold-infested dust collection system that circulates air in SAFC Cleveland's packaging suites. Mr. Janetta instructed Relator that this area should be avoided when conducting site audits.

104. Specifically, in or around January 20-22, 2021, SAFC Cleveland customer Boehringer Ingelheim—which is one of the world's largest pharmaceutical companies—conducted a virtual site audit of SAFC Cleveland to ensure that SAFC Cleveland was complying with GMP Standards. The audit was conducted via Microsoft Teams, utilizing video and audio recording devices. During this audit, Mr. Janetta purposely steered the Boehringer Ingelheim inspectors away from problematic areas, including the mold infested air filtration system.

105. At Mr. Janetta's instruction, problematic areas were avoided. Approximately two-thirds of the visual recordings were taken with the tablet PC's camera pointed to the ground. Areas such as the mold infested dust collection system, "small" packaging rooms with non-complaint doors, and locations Boehringer Ingelheim previously identified as opportunities for improvement (OFI) were avoided.

106. If Boehringer Ingelheim (or any other customer) knew of the mold problem, it would have deemed this a "critical" audit finding and would have refused to purchase products from SAFC Cleveland and therefore would not have submitted or caused to be submitted claims to federal healthcare programs for such products.

107. Through Mr. Janetta and other managerial employees, Relator has knowledge that SAFC Cleveland conducts all audits and site visits in such a misleading manner.

108. Due to SAFC Cleveland's pattern and practice of misleading auditors, its marketing materials are false and misleading because these materials claim the facility is "[a]udited to cGMP standards by top producers of biopharmaceutical, pharmaceuticals cell culture media and diagnostic reagents…[and] uses cGMP guidelines to develop internal systems." These false marketing materials do not disclose that SAFC Cleveland actively misleads the auditors by steering them away from contaminated areas.

109. Moreover, SAFC Cleveland's representations that it uses cGMP guidelines to develop internal systems is patently false as related to its internal reporting system, because Defendants instill fear and retaliate against any employees who raise compliance concerns. Actively discouraging internal reporting is certainly not within GMP guidelines.

D. Relator's Reports of Defendants' Non-Compliance, False Statements and Defendants' Knowledge of Material Violations.

110. As a dedicated GMP specialist, Relator was shocked to discover the dangerous and contaminated conditions at SAFC Cleveland. Relator was even more disturbed to learn that Defendant had knowledge of these conditions and actively deceived its customers as well as ultimate purchasers—including the United States and patients ingesting contaminated drugs.

111. The scale and impact of this deception was particularly troubling given that Defendants were supplying Components for the Pfizer and Moderna COVID-19 Vaccines distributed to hundreds of millions of people, costing the United States billions of dollars, and threatening the medical response to a global pandemic that had killed more than half a million Americans and nearly 3 million people worldwide at the time of the filing of this Complaint.

112. Shocked, dismayed, and worried about the effects of such contamination upon the Covid-19 vaccination effort, Relator resolved to prevent patient harm and fraud upon the United

States by reporting the material deficiencies, non-compliance, and fraud to his supervisors within Defendants' organization.

113. Initially, Relator reported the contaminated conditions, false labeling, and lack of GMP compliance to his immediate supervisor Anthony Whitmarsh, Materials Manager of SAFC Cleveland. Specifically, in January 2021, Relator spoke with Mr. Whitmarsh and demonstrated Defendants' false labeling and non-compliant conditions at SAFC Cleveland by walking him through the facility and showing him the problems detailed *supra*. Mr. Whitmarsh tacitly acknowledged the problems; but when Relator made recommendations of how to cure the problems and institute compliance, Mr. Whitmarsh simply said: "I didn't hire you to do these things." Thereafter, he ignored Relator's concerns.

114. After making these reports, other staff, including Paul Mares—a Packaging Support Specialist at SAFC Cleveland and Victor Lewis—Packaging Supervisor at SAFC Cleveland noted that the contaminated conditions at SAFC Cleveland had long been recognized by management yet nothing was ever done to correct the issues.

115. Relator's verbal reports of the unsanitary conditions to on-site management were ignored. Therefore, on February 5, 2021, Relator sent an email to SAFC Cleveland Site Director Eric Tackett and to MilliporeSigma and Merck Executives, including: Dieter Hofner, Head of APIs, Excipients and Cell Media Technology (Mr. Tackett's direct supervisor); Robert Nass, Vice President and Head of Quality and Regulatory Management; Yvonne Albert, Head of Human Resources; and Christos Ross, Head of Integrated Supply Chain Operations and Interim CEO of MilliporeSigma.

116. In this email, Relator forewarned MilliporeSigma that the mold-infested air filtration system at SAFC Cleveland could result in criminal and False Claims Act liability and

provided a link to a Department of Justice Press Release detailing a dual criminal and False Claims Act settlement regarding these same issues, which was settled for over $18 Million (a link to this Press Release is provided at fn. 2). In this email, Relator highlighted specific provisions of the SAFC Cleveland Standard Operating Procedure that were being violated and made recommendations to replace the air filtration system or to at least increase the frequency of cleanings. Relator provided images of the mold-infested air filtration system to substantiate his reports, and contrasted the photos with the less severe mold that led to the referenced $18 million False Claims Act settlement. Relator also provided images of the false labeling affixed to SAFC Cleveland products—rendering these products misbranded.

117. Also on February 5, 2021, Relator submitted a formal report through the MilliporeSigma "Speak Up" system—i.e., MilliporeSigma's internal compliance reporting system that purports to encourage employees to internally report violations.

118. In this February 5, 2021 Speak Up Report, Relator informed the Corporate level of MilliporeSigma that he previously had informed SAFC Cleveland Site Director Eric Tackett of the inadequate training, deficient written procedures, and fear of reprisal at SAFC Cleveland. Relator also reported that he had informed Mr. Tackett that the air filtration system circulating air through Packaging Suites contained an "abundance of mold" and that "conditions at the site have caused impure and potentially unsafe products to enter interstate commerce."

119. Relator went on to recommend that in order to prevent further contamination from the mold infested air filtration system SAFC Cleveland must "immediately stop packaging activities, upgrade the dust collection system and introduce adequate HEPA filtration to treat the air within the rooms."

120. Relator further recommended that SAFC Cleveland "[i]ntroduce more frequent cleaning and bioburden swab test of the duct work and dust collection system." Relator also informed MilliporeSigma, via the Speak Report, that his previous recommendations to on-site staff on these issues had been ignored.

121. Relator's February 5 Speak Up Report forewarned "[w]ithout adequate bioburden controls in place to prevent transmission of mold spores and disease causing pathogens from dust collectors to packaged product—the company is willfully and negligently—nullifying GMP controls put in place by our supplier…The conditions in Cleveland are a risk to patient safety."

122. Relator also informed MilliporeSigma that misbranded drugs were being distributed because "[t]he labeling of PharmaGrade product as: 'Manufactured under appropriate GMP controls for pharmaceutical or biopharmaceutical production' is…indisputably false."

123. On February 6, 2021, Relator forwarded, via email, this February 5, 2021 Speak Up Report to this same group of executives he emailed on February 5.

124. On February 8, 2021, Relator sent another email to Yvonne Albert, Robert Nass, and Christos Ross as well as to the CEO of Merck Group, Stafan Oschmann. This email informed Defendants' executives:

> I reported conditions at my site that pose a risk to patient safety, customer confidence and shareholder value. The conditions have been communicated to our Site Director and ignored. Packaging operations continue in rooms identified as being unfit for such tasks. Unless change is implemented, it will become incumbent upon me to notify regulators.

125. In response to Relator's formal reports of contaminated conditions, non-compliance, and culture of ignoring such concerns, MilliporeSigma and specifically Dieter Hofner on February 11, 2021 acknowledged that Relator's concerns were valid and that SAFC Cleveland needed significant facility, equipment, and process improvements. Nevertheless, Mr. Hofner and

MilliporeSigma refused to halt operations and continued manufacturing, packaging, and shipping adulterated and misbranded components.

126. On February 22, 2021, Relator sent his supervisors a report demonstrating the patient harm and dangerous situations caused by the outdated and improperly maintained equipment and facilities at SAFC Cleveland. Specifically, SAFC Cleveland customer Genentech found a large bolt in the HEPES product mix that was produced and packaged at SAFC Cleveland. Relator recognized and informed Merck Group Executives Dieter Hofner and Anne Lombard that the bolt was a specific design of the SAFC Cleveland facility's packaging equipment and therefore the bolt found by Genentech likely came from SAFC Cleveland's site. Relator also noted to Hofner and Lombard that this incident was exemplary of the problems caused by the violations at SAFC Cleveland that he had previously reported.

127. On February 28, 2021, Relator submitted another "Speak Up" Report detailing SAFC Cleveland's violations of the Food Drug and Cosmetic Act, specifically 21 U.S.C. 331—which prohibits the introduction of adulterated and misbranded drugs into interstate commerce. In this report, Relator provided the specific violations occurring at SAFC Cleveland and referenced specific false marketing materials that falsely purported the SAFC Cleveland facility to be GMP Compliant. Relator also reported that he had previously referenced these violations in communications with Merck Executive Deiter Hofner.

128. On March 3, 2021, Relator informed MilliporeSigma Head of Quality Operations Jane Findlay precisely how Millipore's response to his concerns was uninformed and misplaced. Ms. Findlay, who is based in the United Kingdom, did not have personal knowledge of the conditions at SAFC Cleveland. Relator informed Ms. Findlay that she should not rely on self-

serving reports regarding SAFC Cleveland because Quality employees on-site have expressed "an interest in obscuring the true state of Cleveland's operations…due to job security concerns."

129. Relator also cogently refuted Ms. Findlay's claims that operations at SAFC Cleveland were sufficient because the site is independently audited. In doing so, Relator informed Ms. Findlay of his experience with SAFC Cleveland's intentional manipulation of audits, stating: "[Relator] has been a representative member of leadership in said audits…during these audits and at the direction of Site Leadership, instructions to deliberately avoid areas within the plant were communicated."

130. MilliporeSigma understood Relator's Speak Up reports and the violations reported. For instance, after Relator's initial Speak Up complaint, MilliporeSigma decided to stop packaging L-Tyrosine as GMP Complaint and developed new labeling so its product was no longer misbranded. In response, Relator informed MilliporeSigma that many more improvements were needed.

E. Defendants' Retaliation Against Relator in Violation of 31 U.S.C. 3730(h).

131. On the same day, Relator submitted this February 28, 2021 Speak Up Report, he was placed on administrative leave by Defendants in retaliation for his reports and efforts to prevent false claims from being submitted.

132. On March 3, 2021, Relator was terminated from his employment with MilliporeSigma in clear retaliation for his efforts to prevent false claims from being submitted. Relator's termination came via a Microsoft Teams Meeting with Melissa Reed, Millipore Sigma's Head of Human Resources North America and with Dieter Hofner. These two individuals were at the forefront of MilliporeSigma's response to Relator's concerns, interfaced with Relator regarding his reports, and then personally terminated him for raising such concerns.

COUNT ONE
DEFENDANTS CAUSED TO BE PRESENTED FALSE CLAIMS PROHIBITED BY 31 U.S.C. §3729(a)(1)(A)

133. Relator adopts and incorporates paragraphs 1-132 as though fully set forth herein.

134. By and through the fraudulent schemes described herein, Defendants knowingly – by actual knowledge or in deliberate ignorance or with reckless disregard of the truth or falsity of the information –caused to be presented false or fraudulent claims to the United States for payment or approval, to wit:

a) Defendants operated a pharmaceutical component manufacturing and packaging facility that was unsanitary, contaminated and not in compliance with applicable GMP regulations, thereby causing its drugs—including HEPES sold directly to Pfizer for use in the Pfizer-BioNTech COVID-19 Vaccine and TRIS hydrochloride and Tromethamine, USP sold to Lonza, Ltd. for use in the Moderna mRNA-1273 COVID-19 Vaccine —to be adulterated in violation of 21 U.S.C. § 351.

b) Defendants misled its customers and the FDA through false and misleading labeling and marketing materials, rendering its drugs—including HEPES sold directly to Pfizer for use in the Pfizer-BioNTech COVID-19 Vaccine and TRIS hydrochloride and Tromethamine, USP sold to Lonza, Ltd. for use in the Moderna mRNA-1273 COVID-19 Vaccine—to be misbranded in violation of 21 U.S.C. § 352.

c) Defendants misled its customers and the FDA through deceptive tactics to prevent customer and FDA auditors from discovering that its SAFC Cleveland facility was unsanitary, contaminated and not in compliance with applicable GMP regulations.

d) Defendants distributed its adulterated and misbranded drugs—including HEPES sold directly to Pfizer for use in the Pfizer-BioNTech COVID-19 Vaccine and TRIS hydrochloride and Tromethamine, USP sold to Lonza, Ltd. for use in the Moderna mRNA-1273 COVID-19 Vaccine —throughout the United States in violation of 21 U.S.C. § 331.

135. Defendants' false labeling and false representations induced Defendants' customers to falsely certify that drugs—including the Pfizer-BioNTech COVID-19 Vaccine and Moderna mRNA-1273 COVID-19 Vaccine —was at all times handled and stored in a manner to prevent contamination and was manufactured, stored and packaged under safe and GMP Compliant controls.

136. Defendants' false labeling, false representations and the false certifications made by Defendants customers, including Pfizer and Moderna, were material to the United States' decision to purchase falsely labeled and adulterated drugs.

137. Based on these false representations, including those false representations made by Pfizer and Moderna, the United States paid false claims for pharmaceutical products including for the Pfizer-BioNTech COVID-19 Vaccine and Moderna mRNA-1273 COVID-19 Vaccine vaccine that it would not have paid if not for Defendants' false representations.

138. Defendants' fraudulent actions described herein have resulted in damage to the United States equal to the amount paid or reimbursed to Defendants and others by the United States through HHS and DOD for such false or fraudulent claims.

COUNT TWO
DEFENDANTS MADE OR USED FALSE STATEMENTS OR RECORDS MATERIAL TO A FALSE CLAIM PROHIBITED BY 31 U.S.C. §3729(a)(1)(B)

139. Relator adopts and incorporates paragraphs 1-132 as though fully set forth herein.

140. By and through the fraudulent schemes described herein, Defendants knowingly -- by actual knowledge or in deliberate ignorance or with reckless disregard of the truth or falsity of the information -- made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim or to get a false or fraudulent claim paid or approved by the United States, to wit:

a) Defendants made and used false and misleading labels that falsely claimed its products were manufactured, stored and packaged in accordance with GMP and ISO standards;

b) Defendants made and used false and misleading labels that falsely claimed its products were manufactured, stored and packaged in accordance with GMP and ISO standards.

141. The false records or statements described herein were material to the false claims submitted or caused to be submitted by Defendants customers, including Pfizer and Moderna, to the United States.

142. In reliance upon Defendants' false statements and records, the United States paid false claims submitted by Defendants' customers that it would not have paid if not for those false statements and records.

143. Defendants fraudulent actions described herein have resulted in damage to the United States equal to the amount paid or reimbursed by the United States for such false or fraudulent claims.

COUNT THREE
"REVERSE FALSE CLAIMS" UNDER 3729(a)(1)(G)

144. Relator adopts and incorporates paragraphs 1-132 as though fully set forth herein.

145. By and through the fraudulent schemes described herein, Defendants knowingly – by actual knowledge or in deliberate ignorance or with reckless disregard of the truth or falsity of the information – made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the United States, or knowingly concealed or knowingly and improperly avoided an obligation to pay or transmit money or property to the United States, to wit:

a) Defendants recognized that it had caused adulterated and misbranded drugs to enter the interstate commerce and be purchased by the United States in violation of the Food, Drug and Cosmetics Act;

b) Defendants took no action to satisfy its obligations to inform its customers or the United States that it had purchased adulterated and misbranded drugs;

c) Defendants took no action to repay or refund its customers or the United States despite knowledge that Defendants had fraudulently induced the purchase of adulterated and misbranded drugs but instead continued to manufacture and package drugs in an unsanitary and non-compliant environment and continued introducing these adulterated and misbranded drugs into interstate commerce.

146. As a result of Defendants' fraudulent conduct, the United States has suffered damage in the amount of funds that belong to the United States but are improperly retained by Defendants.

COUNT FOUR
RETALIATION UNDER 31 U.S.C. §3730(h)(1)

147. Relator adopts and incorporates paragraphs 1-132 as though fully set forth herein.

148. Defendants knowingly threatened, harassed, discriminated against, and discharged Relator because of lawful acts done by Relator in efforts to stop or prevent violations of the False Claims Act.

149. As a result of Defendants' retaliatory conduct, Relator has suffered damages of extended periods of lost pay, irreparable harm to his personal and professional reputation, undue hardship forced upon Relator and his family, and extended infliction of emotional distress upon Relator and his family.

PRAYER FOR RELIEF

WHEREFORE, Relator David Stonebrook, on behalf of himself and the United States of America, demands judgment against Defendants as follows:

A. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States has sustained due to Defendants' actions, plus a civil penalty not less than $5,000 and not more than $10,000, as adjusted for inflation by the

Federal Civil Penalties Inflation Adjustment Act of 1990, for each violation of the False Claims Act;

B. That the Court enter judgment against Defendants for retaliation pursuant to 31 U.S.C. § 3730(h) and award Relator two times his back pay, with interest, and compensation for special damages including litigation costs and reasonable attorneys' fees;

C. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

D. That Relator be awarded all costs, attorneys' fees, and litigation expenses;

E. That the United States and Relator receive all relief, both at law and in equity, to which they may be reasonably entitled; and

F. That the Court order any other relief that it deems to be appropriate and just.

DEMAND FOR A JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Respectfully submitted,

Dated: May 25, 2021

/s/ Sonya A. Rao

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FALSE CLAIMS ACT COMPLAINT FILED UNDER SEAL