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; EMD MILLIPORE; RESEARCH ORGANICS, LLC** *Defendants.*	Civil Action No: 1:21-cv-10866-DJC **AMENDED COMPLAINT** **DEMAND FOR JURY**

AMENDED COMPLAINT FOR VIOLATIONS OF FEDERAL FALSE CLAIMS ACT

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

PRELIMINARY STATEMENT

1. Defendants are one of the world's leading manufactures and suppliers of components for major pharmaceutical companies, including producing, packaging, and selling TRIS and HEPES to Pfizer and Moderna for use in their Covid-19 vaccines sold to the United States government.

2. Relator had significant experience in Good Manufacturing Practice ("**GMP**") compliance, pharmaceutical manufacturing, pharmaceutical packaging, and pharmaceutical "cleanroom" environments, and was hired as GMP Packaging Supervisor at Defendants' facility in Cleveland, Ohio (the "**Facility**") where he oversaw the packaging of TRIS and HEPES from

supersacks that hold several tons of product into smaller packaging for shipment.

3. Relator observed that the conditions in these packaging rooms where TRIS and HEPES were being repackaged at the Facility do not comply with GMP standards, including because the air handling and dust collection systems servicing these rooms were highly contaminated with mold, other contaminants, and residue from other components packaged in those rooms. This posed a serious danger to patient health and also plainly violated the obligations that Pfizer and Moderna had to provide GMP compliant Covid-19 vaccines to the United States government.

4. Relator made numerous attempts to bring these serious issues to the attention of Defendants' management, including initially in discussions, and then in writing. Defendants, instead of correcting these serious issues, fired him.

5. Defendants no doubt knew that Moderna and Pfizer were required to provide GMP compliant Covid-19 vaccines to the United States government in exchange for billions of dollars in payment, including because components used in a pharmaceutical product must be GMP compliant pursuant to Code of Federal Regulations, and because GMP compliance was required by the publicly available agreements between the U.S. government and Pfizer and Moderna for the purchase of Covid-19 vaccines. Defendants nonetheless sold TRIS and HEPES to Pfizer and Moderna for use in their Covid-19 vaccines knowing they were not GMP compliant, causing Pfizer and Moderna to, upon information and belief, unknowingly make false claims to the U.S. government.

JURISDICTION AND VENUE

6. This action arises under the False Claims Act, 31 U.S.C. § 3729 et seq. (the "**FCA**") because, *inter alia*, Defendants caused the submission of false claims to the United States

government in violation of 31 U.S.C. § 3729(a)(l)(A). 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. Further, Defendants unlawfully retaliated against Relator in violation of 31 U.S.C. § 3730(h).

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

8. Defendant Merck KGaA, Darmstadt, Germany ("**Merck KGaA**") is a German multinational company, headquartered in Darmstadt, Germany that operates across healthcare, life sciences and performance materials.

9. Defendant Sigma-Aldrich Corp. ("**Sigma-Aldrich**") is a subsidiary of Merck KGaA that specializes in life sciences and is headquartered in St. Louis, Missouri.

10. Defendant EMD Millipore ("**EMD Millipore**") is a life sciences company headquartered in Burlington, Massachusetts. In November 2015, Merck KGaA, after acquiring Sigma-Aldrich, combined EMD Millipore and Sigma-Aldrich, which then operated as EMD Millipore by way of the tradename MilliporeSigma.

11. Defendant Research Organics, LLC d/b/a SAFC Cleveland ("**SAFC Cleveland**", together with the other three defendants, "**Defendants**") is a subsidiary of EMD Millipore, having been acquired by Sigma-Aldrich in 2012, that manufactures, stores, packages, and supplies pharmaceutical components and products. SAFC Cleveland is based in Cleveland, Ohio and

operates a pharmaceutical component manufacturing and packaging facility located at 4353 East 49th Street in Cleveland, Ohio (the "**Facility**").

12. 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 Defendants at the Facility as "GMP Packaging Supervisor" from January 4, 2021 to March 3, 2021. His duties included but were not limited to: 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; representing the Facility's Packaging Department as a member of management during customer audits; performing audits of packaging areas, and warehouse areas; performed a daily review of compliance documentation and communicated necessary changes to higher management and corporate employees, including safety, equipment, and regulatory concerns.

FACTS

I. TRIS AND HEPES MANUFACTURED AND PACKAGED AT THE FACILITY FOR USE IN PFIZER AND MODERNA COVID-19 VACCINES

13. In or around October 2020, Relator applied for the position of GMP Packaging Supervisor at the Facility by submitting his resume detailing his extensive relevant experience in the areas of compliance, pharmaceutical manufacturing, pharmaceutical packaging, and pharmaceutical "cleanroom" environments. His former positions included Bulk Adjuvant Manufacturing Supervisor at GlaxoSmithKline, Manufacturing Manager at Philips Healthcare, and Production Supervisor at Tyson Foods, among others.

14. The duties for the GMP Packaging Supervisor as detailed by Defendants included the following responsibilities:

a. "Maintain constant improvements in packaging quality products, reducing costs, and following good manufacturing practices (GMP)"

b. "Immediate coaching responsibility for seeing that products are produced to GMP Standards"

c. "Maintains GMP quality by establishing and maintaining organization standards"

d. "Create SOP's for Receiving, Packaging, Shipping, and Warehousing to meet GMP standards/requirements"

e. "Provide guidance and direction to the packaging GMP personnel"

f. "Monitor and maintain a safe and clean work environment through housekeeping and safety policy administration."

g. "Coaching all employees on safety and its importance"

h. "Supervise, train, and develop employees"

i. "Ensure all employees follow the standard operational and working practices"

j. "Adjust daily work schedule as needed to meet customer requirements"

k. "Initiating, coordinating and enforcing systems, policies and procedures"

l. "Read and interpret documents such as safety rules operating and maintenance instructions and procedure manuals"

m. "Write routine reports and correspondence"

n. "Review nonconformances with the objective of taking action to eliminate future occurrences."

15. Defendants selected Relator to interview for the position of GMP Packaging

Supervisor. Relator's first-round panel interview for the position with Defendants, which occurred on October 15, 2020, with the following four individuals in managerial positions who all worked at the Facility:

a. Eric Tackett, Facility Director;

b. Greg Janetta, Head of Quality Control;

c. Joseph Viskocil, Operations Manager; and

d. Anthony Whitmarsh, Materials Manager.

16. Relator was then selected by Defendants for a second round of one-on-one interviews with Mr. Tackett, Mr. Viskocil, and Mr. Whitmarsh, all of which occurred on November 19, 2020.

17. During these interviews, the interviewers repeatedly and excitedly discussed that the products manufactured and packaged at the Facility were being used to make Covid-19 vaccines, plainly using this fact to persuade Relator to join the company. Relator was indeed excited to participate in the development of the Covid-19 vaccines because he believed these products were essential for combating the ongoing Covid-19 pandemic. Relator indicated during his interviews that this was one of the primary reasons he was excited to join the company.

18. After going through this lengthy review and interview process, Relator was given an offer letter, dated December 8, 2020, for the position of GMP Packaging Supervisor, and began his employment with Defendants on January 4, 2021.

19. Upon starting his employment with Defendants, Relator quickly learned it was common knowledge among management and the employees at the Facility that TRIS[1] and HEPES[2] products manufactured and packaged in the Facility were used in the Pfizer and Moderna Covid-19 vaccines. This was reiterated frequently during daily 8:30 a.m. meetings with the management at the Facility.

20. These daily morning management meetings, which typically lasted around thirty minutes, were led by Eric Tackett, the Facility Director, and there were approximately twenty members of Facility management typically in attendance. During these meetings, the managers discussed, *inter alia*, the packaging schedules, including for TRIS and HEPES, frequently mentioning how these products were slated for use in Pfizer and Moderna's Covid-19 vaccines.

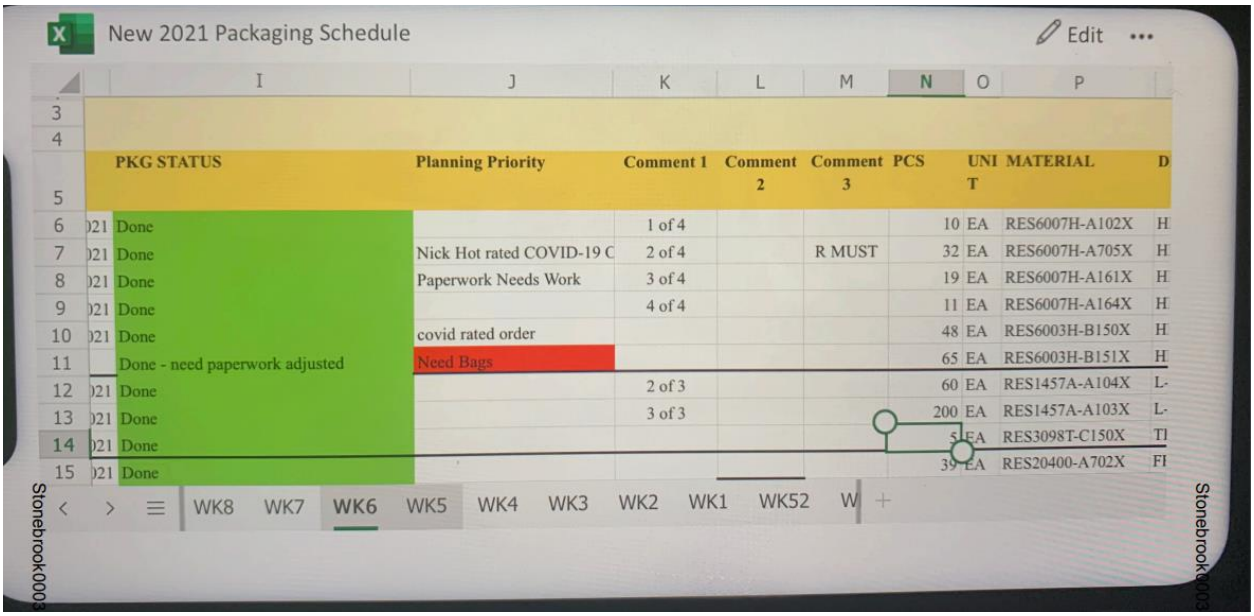
21. During these discussions, it was commonly understood that when an order of TRIS or HEPES was labeled "Covid hot," "Covid rated," or "rated Covid," that meant it was a priority to assure these were packaged and shipped as soon as possible as they were timely and critically needed for the manufacture of Covid-19 vaccines by Pfizer and/or Moderna; TRIS and HEPES were regularly announced during these meetings as being "Covid hot," "Covid rated," or "rated Covid," so that the managers knew to prioritize work on these components.

22. Reflecting the discussions at these daily morning meetings, the following is a picture taken by Relator on his mobile phone which depicts an example of a packaging schedule

[1] TRIS – which includes or is known as "Tromethamine," "TRIS Hydrochloride," "TRIS HCL," "Tris(hydroxymethyl)aminomethane)," "2-Amino-2-(hydroxymethyl)-1,3-propanediol," "BIS-TRIS Hydrochloride," "BIS-TRIS," "BIS-TRIS Propane," (collectively or individually, or any compound related to any of these, "**TRIS**") – is a buffering agent that is used to adjust or stabilize the pH balance of a solution and is frequently utilized as a buffer and excipient in biological products such as vaccines.

[2] HEPES – which includes or is known as "HEPES, Hemisodium Salt," "HEPES, Sodium Salt," "Hydroxyethylpiperazine ethane sulfonic acid," "4-(2-Hydroxyethyl)piperazine-1-ethanesulfonic acid," "N-(2-Hydroxyethyl)piperazine-N′-(2-ethanesulfonic acid)," (collectively or individually, or any compound related to any of these, "**HEPES**") – is a zwitterionic sulfonic acid buffering agent, that is used to maintain enzyme structure and help the enzyme function at low temperatures.

at the Facility. In row 10 of this scheduling order, it lists a 48-barrel order of HEPES, denoted as RES6003H, as a "covid rated order":



23. The following are images of this order of HEPES packaged and ready to be shipped to Pfizer, noting that each image shows the 48 barrels and "Pfizer" is written in black marker on one or more barrels that are in the first row in each picture[3]:

[3] The fact that this "covid rated order" is being shipped to Pfizer can also be easily confirmed by Defendants by matching the batch number on the labels on the front of these barrels (Batch # CDBF4762) to the batch number listed on the packaging schedule for this order (which is also Batch # CDBF4762).

24. A screenshot taken by Relator of Defendants' customer list reflects that TRIS manufactured and packaged at the Facility was also being shipped to Pfizer and to Moderna (via one of Moderna's manufacturers, Lonza[4]):

[4] https://www.fiercepharma.com/manufacturing/moderna-aims-for-a-billion-covid-19-shots-a-year-lonza-manufacturing-tie-up; https://www.lonza.com/news/2021-06-02-07-02.

62350	35407744	Lonza	3860	3.0	05/08/09	30970T	Tromethamine, USP	RES30970T-A159X
62350	35407744	Lonza	Q20073, 10160	24.0	06/28/17	3098T	TRIS HCl	RES3098T-B185X
19100	49456361	Pfizer, INC	R000000606, TMS	6.0	10/30/19	3094T	TRIS UP	RES3094T-B172X
19100	49456361	Pfizer, INC	LAB-2422, 01014	17.0	12/15/17	3094T	TRIS UP	RES3094T-B153X
19100	49456361	Pfizer, INC	LAB-2429, 01040	16.0	08/04/17	3098T	TRIS HCl	RES3098T-B151X
19100	49456361	Pfizer, INC	01056, TMS-00000	18.0	07/06/18	6003H	Hepes	RES6003H-B150X
62350	35407744	Lonza	3860	3.0	05/08/09	30970T	Tromethamine, USP	RES30970T-A159X
62350	35407744	Lonza	Q20073, 10160	24.0	06/28/17	3098T	TRIS HCl	RES3098T-B185X

25. FDA documentation for the Pfizer Covid-19 vaccine, available to the public on the FDA website, clearly states that TRIS is a component of the Pfizer Covid-19 vaccine,[5] as well as the Moderna vaccine.[6] Similarly, the European Medicines Agency has confirmed that TRIS is an

[5] https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-Covid-19-vaccine-emergency-use-children-5-through-11-years-age ("The new formulation of the vaccine developed by Pfizer Inc. contains TRIS buffer, a commonly used buffer in a variety of other FDA-approved vaccines and other biologics, including products for use in children. The FDA evaluated manufacturing data to support the use of Pfizer-BioNTech Covid-19 Vaccine containing TRIS buffer and concluded it does not present safety or effectiveness concerns."); https://www.fda.gov/media/153409/download at 12 (Meeting document from FDA's Vaccines and Related Biological Products Advisory Committee ("**VRBPAC**")'s October 26, 2021 meeting, convened to determine whether to authorize Pfizer's Covid-19 vaccine in 5- to 11-year-olds, which describe the usage of TRIS in the Pfizer Covid-19 vaccine); https://www.fda.gov/media/153447/download at 14 (Briefing documents from VRBPAC's October 26, 2021 meeting, which describe the usage of TRIS in the Pfizer Covid-19 vaccine); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9822354/ (Peer reviewed study discussing the use of TRIS in the Pfizer Covid-19 vaccine).

[6] https://www.fda.gov/media/144434/download at 11 (Briefing documents from VBRPAC's December 17, 2020 meeting, convened to determine whether to authorize Moderna's Covid-19 vaccine in individuals 18 and older, which describe the use of TRIS in Moderna Covid-19 vaccine); https://www.fda.gov/media/159309/download at 3 (FDA Fact Sheet on Moderna Covid-19 vaccine indicating TRIS in ingredients); https://www.fda.gov/media/155675/download at 11 (Package insert for Moderna Covid-19 vaccine reflecting TRIS is an ingredient); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8023205/ (Peer reviewed study discussing the use of TRIS in the Moderna Covid-19 vaccine).

ingredient in the final product of the Pfizer Covid-19 vaccine[7] and Moderna Covid-19 vaccine,[8] as well as that HEPES is a final product in the Pfizer Covid-19 vaccine.[9]

26. Not only was the fact that these materials from the Facility were being used in the Covid-19 vaccines discussed in the daily morning management meetings, it was also commonly discussed amongst the Facility's employees. For example, at a workplace pizza party that Relator attended on February 17, 2021, in Building 9, Anthony Whitemarsh, the Facility Materials Manager, welcomed new team members, including Relator, and spoke on the importance of the various products they were producing, including the fact that some of these were being used for Covid-19 vaccines. The Facility employees attending the pizza party were clearly excited that they were assisting in the Covid-19 vaccine effort.[10]

27. In sum, Relator, as GMP Packaging Supervisor at the Facility, was informed by Defendants' management and reviewed documents reflecting that TRIS and HEPES manufactured and packaged at the Facility were intended for use in the Pfizer and Moderna Covid-19 vaccines.

II. DEFENDANTS' KNOWELDGE THAT THE COMPONENTS USED IN THE PFIZER AND MODERNA COVID-19 VACCINES MUST BE GMP-COMPLIANT

28. As explained in detail in Section IV below, federal law requires that components used in pharmaceutical products, such as TRIS and HEPES, must be GMP compliant.

29. This requirement is also reflected in the publicly available contracts between the

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[7] https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-x-0044-g-epar-assessment-report-extension_en.pdf at 13 (listing TRIS and "trometamol" as an ingredient in the Pfizer Covid-19 vaccine).

[8] https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-Covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf at 16, 44 (listing TRIS and "tromethamol hydrochloride" as an ingredient in the Moderna Covid-19 vaccine).

[9] https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf at 16 (stating that Pfizer "should implement a relevant testing strategy to ensure that HEPES (Pfizer) raw material, included in the formulation buffer of FP [the final product], is free from contaminating RNases[.]").

[10] Tricene, a different product, was also manufactured and produced at the Facility, and in the same packaging rooms that have the issues detailed above, and was sold for use in the rapid antigen tests produced by Roche and Abbott.

U.S. government and Pfizer to purchase billions of dollars of Pfizer's Covid-19 vaccine (the "**US-Pfizer Contracts**") which require "GMP manufacturing," "GMP production," "GMP Covid-19 pandemic supply of RNA-based Covid-19 vaccine on US soil," and to "ensure conformity with § 501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code ('U.S.C.') § 351(a)(2)(B)), regarding good manufacturing practices ('GMP')."[11] The agreements cited in the foregoing footnote are hereby incorporated by reference as if fully set forth in this pleading, and which reflect, *inter alia*, an $11.2 billion purchase of Covid-19 vaccine from Pfizer by the Department of Defense (Army) and a $1.95 billion purchase of Covid-19 vaccine from Pfizer by the Department of Defense (Army).

30. Similarly, the requirement to provide GMP product is also reflected in the publicly available contracts between the United States government and Moderna to purchase billions of dollars of Moderna's Covid-19 vaccine (the "**US-Moderna Contracts**") which require "GMP material," "adherence to … GMP," and a "plan for addressing areas of non-conformance to FDA regulations for …. GMP." [12] The agreement cited in the foregoing footnote are hereby incorporated by reference as if fully set forth in this pleading, and which reflect, *inter alia*, an $8.2 billion purchase of Covid-19 vaccine from Moderna by the Department of Defense (Army) and a $.43 billion purchase of Covid-19 vaccine from Moderna by ASPR-BARDA (Health and Human Services).

31. Given the federal regulations requiring that components used in the Covid-19 vaccines, as in all drugs and vaccines, must be GMP compliant, and given that this is also reflected

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[11] *See* https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf ($1.95B); https://www.hhs.gov/sites/default/files/vaccine-production-contract-with-pfizer.pdf ($11.2B).

[12] *See* https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf ($0.43B); https://www.hhs.gov/sites/default/files/vaccine-contract-with-moderna-modifications-p00001-p00002-p00003.pdf ($8.2B).

in the foregoing agreements, and Defendants, collectively being an industry leader in supplying components for drug and vaccine manufacture, were obviously aware that components used in the Covid-19 vaccines, including TRIS and HEPES, needed to be GMP compliant.

32. Upon information and belief, Pfizer and Moderna would only include GMP components in their Covid-19 vaccines to be sure they adhered to the requirements of their contracts with the federal government and, hence, Defendants told or led Pfizer and Moderna to believe that the TRIS and HEPES products purchased from them were GMP compliant.

33. By selling their TRIS and HEPES products to Pfizer and Moderna with knowledge that those products would be used in their Covid-19 vaccines, Defendants implied that these components had complied with all of the conditions necessary for Pfizer and Moderna to receive payment from the U.S. government, including that these components were GMP compliant.

34. Accordingly, when Pfizer and Moderna contracted with the Federal government under stipulated conditions of GMP compliance, and subsequently sought and collected payment for the Covid-19 vaccines, Defendants caused Pfizer and Moderna to impliedly certify compliance with the applicable FDA regulations, rendering such claims for payments false, within the meaning of the False Claims Act. Upon information and belief, Pfizer and Moderna were not aware these claims for payment were false and such knowledge was only held by Defendants.

35. The US-Pfizer Contracts for procurement of Covid-19 vaccines were public knowledge and made media headlines as early as July 2020[13] and the US-Moderna Contracts for procurement of Covid-19 vaccine were public knowledge and made media headlines in the summer of 2020.[14] As such, beyond being aware of the applicable federal regulations requiring

[13] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600.

[14] See https://www.biopharma-reporter.com/Article/2020/08/13/Moderna-lands-US-COVID-19-vaccine-contract-

components used in drugs and vaccines to meet GMP standards, Defendants were also aware, or should have been aware, of the US-Pfizer Contracts and the US-Moderna Contracts stipulating GMP compliance and thus, by extension, Defendants impliedly certified compliance with applicable GMP regulations, thereby rendering such an implied certification false within the meaning of the False Claims Act.

36. Defendants therefore had knowledge that the vaccines contracted for had to contain GMP-compliant components and had knowledge that they would be impliedly certifying GMP compliance via their transactions with Pfizer and Moderna for the US-Pfizer Contracts and the US-Moderna Contracts.

37. The false claims – by way of the implied certification of compliance with GMP requirements delineated in the US-Pfizer Contracts and the US-Moderna Contracts – were material to the U.S. government's decision to purchase the Covid-19 vaccines for the pandemic, and such a false claim operated in significant part to proximately cause the U.S. government to make these purchases. The U.S. government relied on Pfizer's and Moderna's representations, both of whom, upon information and belief, relied upon Defendants' certifications of GMP compliance.

III. DEFENDANTS SOLD TRIS AND HEPES TO PFIZER AND MODERNA KNOWING THOSE COMPONENTS WERE NOT GMP COMPLIANT

A. Relator Observes and Documents the Facility Is Not GMP Compliant

38. Upon starting as a GMP Packaging Supervisor at the Facility, Relator quickly observed that the Facility was not GMP compliant, nor did it meet basic sanitary practices. Relator observed that these issues extended throughout the operations at the Facility. As GMP Packaging Supervisor, he immediately focused on correcting GMP violations in the packaging operations.

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worth-up-to-8bn; *see also* https://www.reuters.com/article/us-health-coronavirus-moderna-vaccine/u-s-inks-1-5-billion-deal-with-moderna-for-100-million-doses-of-covid-19-vaccine-idUSKCN2572T5.

39. One of the main issues that Relator observed at the Facility was its unsanitary and mold-infested air filtration and dust collection systems ("**air filtration systems**").

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

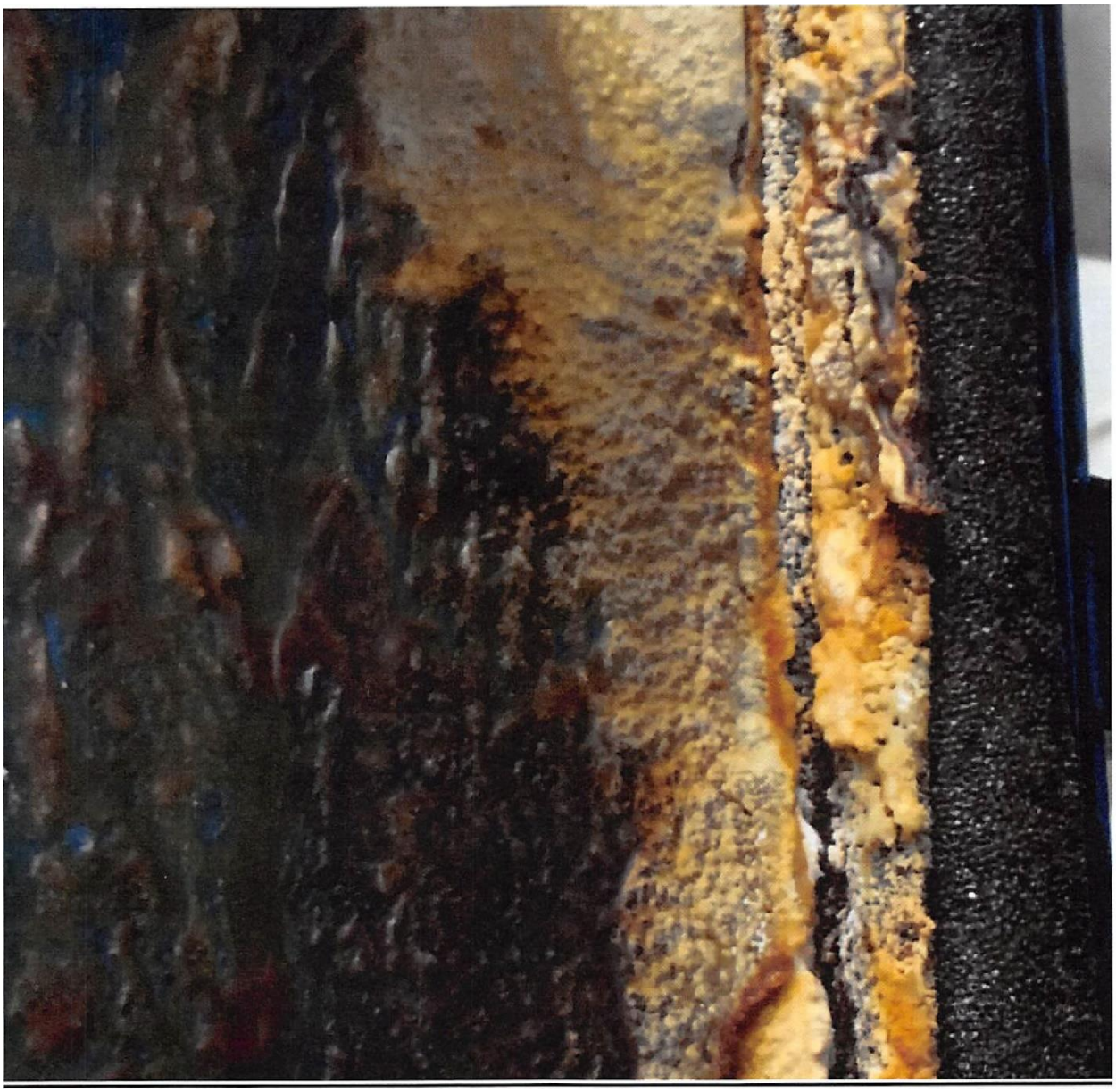
41. In Relator's experience in other pharmaceutical manufacturing and shipping facilities, they include pharmaceutical-grade air filtration systems with High Efficiency Particulate Air (HEPA) filters, and are routinely maintained, monitored for mold and contamination, and the maintenance and monitoring are systematically documented.

42. Relator observed that the Facility did not have such an air filtration system and that its outdated and inadequate, and hence over-taxed, air filtration system was covered in mold and was therefore recycling contaminated air throughout the Facility's packaging rooms, which added contaminants to the air rather than filtering out contaminants from the air.

43. The Facility has several packaging rooms wherein pharmaceutical components were 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 would ultimately be delivered to the customer. During this packaging process at the Facility, the pharmaceutical components being packaged would be exposed to the air in these rooms for extended periods, making it essential that the air in the packaging rooms was properly filtered so as to not contaminate the pharmaceutical components.

44. Relator, for example, directly observed and documented that the air filtration system and ductwork in the Facility for packaging rooms D, E, and F were woefully deficient and

had an abundance of mold growth. Pharmaceutical products packaged within these rooms were therefore constantly exposed to mold infested air. Photos of the mold infested dust collection filters and ductwork for the air filtration system servicing these packaging rooms at the Facility were taken by Relator, copies of which are included below:



45. The below photos, also taken by Relator at the Facility, are a downward view of the ductwork leading to packaging Room D, where TRIS and HEPES were packaged, and also show mold growth and unsanitary condition, as well as buildup of residual drug product at the base.

46. The growth of mold in the air filtration system and throughout the packaging rooms is an expected result of the Facility's inadequate cleaning and sanitation practices. Instead of carefully monitoring, maintaining, and documenting the monitoring and maintenance that assured the air filtration system was at all times sanitary, clean and free from mold and other contaminants, the Facility staff instead often sprayed down the packaging rooms and equipment, including the air filters in the packaging rooms, with water.

47. Spraying down equipment with water, in a windowless, poorly ventilated indoor room, that already had mold growth, likely further exacerbated the mold growth. These cleaning methods are grossly out of compliance with appropriate GMP standards for the packaging and

handling of pharmaceutical components.

48. The excess moisture in the packaging rooms, caused by the non-validated cleaning procedure of spraying down the rooms with water, even caused water stains on the windows in these rooms. These water stains are clear indicators of excess moisture and a contributor to the mold infestation that can easily contaminate pharmaceutical components. Below is a photo taken by Relator of water stains on the window of packaging room D where TRIS and HEPES were packaged:

49. Compounding all the above issues, the non-validated cleaning procedures in the Facility not only caused excess moisture, exacerbating the mold issue, these improper procedures did not remove the excess material left over after packing a compound, nor did they eliminate the bioburden risk of pathogens remaining on the equipment used for packaging.

50. Defendants were aware of the unsanitary and non-GMP compliant conditions in their Facility at the time TRIS and HEPES were packaged for use in the Pfizer and Moderna Covid-19 vaccines.

B. Defendants Mislead Regulators and Customers Auditing the Facility

51. Defendants also misled their customers during supplier audits of the Facility so that they would not discover the above-described deficiencies.

52. Defendants' customers, many of the world's largest pharmaceutical manufacturers, have a responsibility under federal law to ensure that suppliers of the components used in their finished drug products are conforming to GMP (see 21 C.F.R. § 21l.80(b)) and will therefore conduct audits and site visits of their supplier facilities to ensure such compliance. 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. § 21l.80(b).

53. Relator directly observed Defendants knowingly misleading and misdirecting their customers during site audit visits of the Facility. For instance, Relator observed the Facility Quality Manager, Greg Janetta, leading auditors to specific areas of the Facility that were not problematic, while purposefully avoiding other areas known to be problematic and that would raise concerns of contamination. Mr. Janetta specifically instructed Relator that the packaging rooms should be avoided when conducting site audits specifically to avoid auditors observing the mold-infested air filtration systems servicing these rooms.

54. For example, on or about January 20-22, 2021, one of Defendants' customers, Boehringer Ingelheim, one of the world's largest pharmaceutical companies, conducted a virtual

site audit of the Facility to ensure that the Facility was complying with GMP standards. The audit was conducted via Microsoft Teams, utilizing video and audio recording devices. During this audit, Relator observed Mr. Janetta purposely steering the Boehringer Ingelheim inspectors away from problematic areas, including the mold infested air filtration system. Approximately two thirds of the visual recordings were taken with the tablet's camera pointed to the ground. If Boehringer Ingelheim, or any other customer, knew of the mold problem, it would have deemed this a "critical" audit finding and would have no doubt refused to purchase products that needed to be GMP compliant.

55. Relator, through discussions with Mr. Janetta and other managerial employees, is aware that the Facility routinely conducts audits and site visits in a similar misleading and deceptive manner.

C. Relator Blows the Whistle and Defendants Retaliate

56. Moreover, the Facility is also not GMP compliant because GMP guidelines require the Facility to develop internal reporting systems to assure purity, whereas Defendants instead instill fear and retaliate when an employee, such as Relator, raises compliance concerns via the internal reporting system. This actively discourages internal reporting of contamination and non-GMP compliance issues which is yet another violation of GMP guidelines.

57. Relator had serious concerns that Defendants' conduct resulted in compromising patient safety. For example, the FDA,[15] CDC,[16] and World Health Organization[17] identified an

[15] Coronavirus (Covid-19) Update: June 25, 2021, FDA (June 25, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021.

[16] Julia W. Gargano *et al.*, *Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021*, MMWR (July 9, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm?s_cid=mm7027e2_w.

[17] *COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS): updated guidance regarding myocarditis and pericarditis reported with COVID-19 mRNA vaccines*, World Health Organization (July 9, 2021), https://www.who.int/news/item/09-07-2021-gacvs-guidance-myocarditis-pericarditis-covid-19-mrna-

increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following mRNA Covid-19 vaccination; and there is a causal[18] link[19] between myocarditis[20] and pericarditis[21] and bacterial[22] and fungal[23] pathogens. Bacterial and fungal growth identified in the dust collectors for packaging rooms D and E could easily contaminate pharmaceutical components packaged in those rooms, including TRIS and HEPES which were packaged in these rooms, and their use in Pfizer and Moderna's Covid-19 vaccines could have then contributed to myocarditis and pericarditis in those then exposed to bacterial and fungal contaminants. Myocarditis and pericarditis can be fatal.[24] Deaths resulting from myocarditis after Covid-19 vaccination have been confirmed.[25]

58. Upstream and downstream filtration capabilities in pharmaceuticals manufacturing range from 1μ to .22μ. Once a component used to manufacture a drug or vaccine has been contaminated with a virus smaller than .22μ, it will not be eliminated from the component. For example, coronaviruses (0.125μ), adenoviruses (0.08 μ), influenza (0.1μ), and hepatitis (.042μ) are

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vaccines.

[18] 21 CFR 317.2. *See* "List of qualifying pathogens that have the potential to pose a serious threat to public health," https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=317.2.

[19] Fiorella Calabrese *et al., Myocarditis and inflammatory cardiomyopathy: microbiological and molecular biological aspects*, Cardiovascular Research (Oct. 2003), https://academic.oup.com/cardiovascres/article/60/1/1 1/321091.

[20] *Id.*

[21] Sabine Pankuweit *et al., Bacterial Pericarditis*, American Journal of Cardiovascular Drugs (Sept. 13, 2012), https://link.springer.com/article/10.2165/00129784-200505020-00004.

[22] Ingrid Kindermann *et al., Update on Myocarditis*, Journal of the American College of Cardiology (Feb. 28, 2012), https://www.sciencedirect.com/science/article/pii/S0735109711052004.

[23] Joshua Nosanchuk, *Fungal Myocarditis*, Front Biosci (June 1, 2002), https://pubmed.ncbi.nlm.nih.gov/12045009/.

[24] Thomas Hadberg Lynge *et al., Sudden cardiac death caused by myocarditis in persons aged 1–49 years: a nationwide study of 14 294 deaths in Denmark*, Forensic Sci Res. (Aug. 19, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713107/.

[25] Sangjoon Choi *et al., Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings*, J Korean Med Sci. (Oct. 18, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8524235/.

all smaller than .22μ and hence once they contaminate a component used in a vaccine, they cannot be eliminated with through filtration.

59. As a dedicated GMP specialist, Relator was shocked to discover the dangerous and contaminated conditions at the Facility. Relator was even more disturbed to learn that Defendants had knowledge of these conditions and actively deceived their customers as well as ultimate purchasers, including the United States government when purchasing Covid-19 vaccines and individuals using these products.

60. The scale and impact of this deception was particularly troubling given that Defendants were supplying components for use in the Pfizer and Moderna Covid-19 vaccines which Defendants knew were being purchased by the United States government for billions of dollars and then being distributed to hundreds of millions of people.

61. Shocked, dismayed, and worried about the effects of contamination of components used in these Covid-19 vaccines, Relator resolved to prevent patient harm and fraud upon the United States by reporting the material deficiencies, non-compliance, and fraud to his supervisors.

62. Relator first reported the contaminated conditions and lack of GMP compliance to his immediate supervisor, Anthony Whitmarsh, Materials Manager of the Facility. Specifically, in January 2021, Relator spoke with Mr. Whitmarsh and showed him the non-compliant conditions at the Facility by walking him through the facility and pointing out the serious issues at the Facility detailed above. 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.” When Relator insisted these issues need to be corrected, Mr. Whitemarsh simply ignored Relator’s concerns.

63. When Relator’s repeated verbal reports of the unsanitary conditions to on-site

management were ignored, on February 5, 2021, Relator sent an email to the Facility 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. A copy of this email is pictured below:

Stonebrook000120

Gmail

David Stonebrook <dsstonebrook@gmail.com>

Cleveland site concerns
2 messages

David Stonebrook <david.stonebrook@milliporesigma.com> Fri, Feb 5, 2021 at 5:07 I
To: Eric Tackett <eric.tackett@milliporesigma.com>
Cc: Robert Nass <Robert.Nass@merckgroup.com>, Yvonne Albert <yvonne.albert@milliporesigma.com>, David Hutchinson <david.hutchinson@milliporesigma.com>, Dieter Hofner <dieter.hofner@merckgroup.com>, Christos Ross <christos.ross@milliporesigma.com>

Eric,

Please take a moment to read the DOJ press release linked to below. It discusses GMP violations that occurred at a Baxter Healthcare plant in North Carolina.

https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability

In the end, management's inaction cost Baxter over $18mil and another $2.158mil to settle an employee's whistleblower case. The employee who reported his concerns is still employed by Baxter—the site director and managers above him are not. The attorney that filed the employee's Whistleblower compliant was a former federal prosecutor. The site (..like our own) supplied customers with federal contracts in place.

The entire HEPA filtration system (i.e., the duct work and filter housing units) over Packaging suites D, E and F are exceedingly worse than the one (1) filter that put Baxter in the headlines.

Our SOP on filter maintenance reads:

"..Cleaning of the prefilter should occur when there is a noticeable decrease in performance or at least once a week. Packaging personnel are responsible for the pre-filter cleaning. The condition of the main filter is evaluated on a monthly basis by the Maintenance Department."

If it's not within the budget to replace the air filtration systems, I recommend we increase the frequency of cleanings. I recommend QC start performing routine bioburden testing on the filters (and housing unit). The site should have written procedures that establishes an acceptable CFU range. At GSK and BD, the HEPA filtration system was identified as a CCP in our risk assessments, thus, routine testing by QA or EM personnel was required. This isn't a requirement at Cleveland.

Our labeling for PharmGrade products proports to be "manufactured under appropriate GMP controls for pharma or biopharmaceutical production." However, "appropriate GMP controls," would mean we adhere to 21 CFR §211.113(a) and have *"Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile."* This isn't happening at Cleveland either.

My colleagues in management have confided that they are fearful of you and concerned about job security if they speak up on quality issues and/or process problems. This should never be the case.

I'm in a comfortable enough financial position that I don't have these fears.

I accepted this position with the expectation I would be helping "customers improve human health and life worldwide" (i.e., my Dream Job). Merck Group's reputation is important to me, however, my Christian faith is what guides my decision-making. Its important we always be kind to one another.

As People Leaders, we set the example. If situations occur that hamper our ability to deliver safe products, speaking up should be encouraged.

David Stonebrook

GMP Packaging Supervisor

MilliporeSigma

A business of Merck KGaA, Darmstadt, Germany

MilliporeSigma | 4353 East 49th Street | Cleveland, OH | 44125 | USA

Phone: +1 216 206 5451 | Mobile: +1 216 867 7450 | Email: david.stonebrook@milliporesigma.com

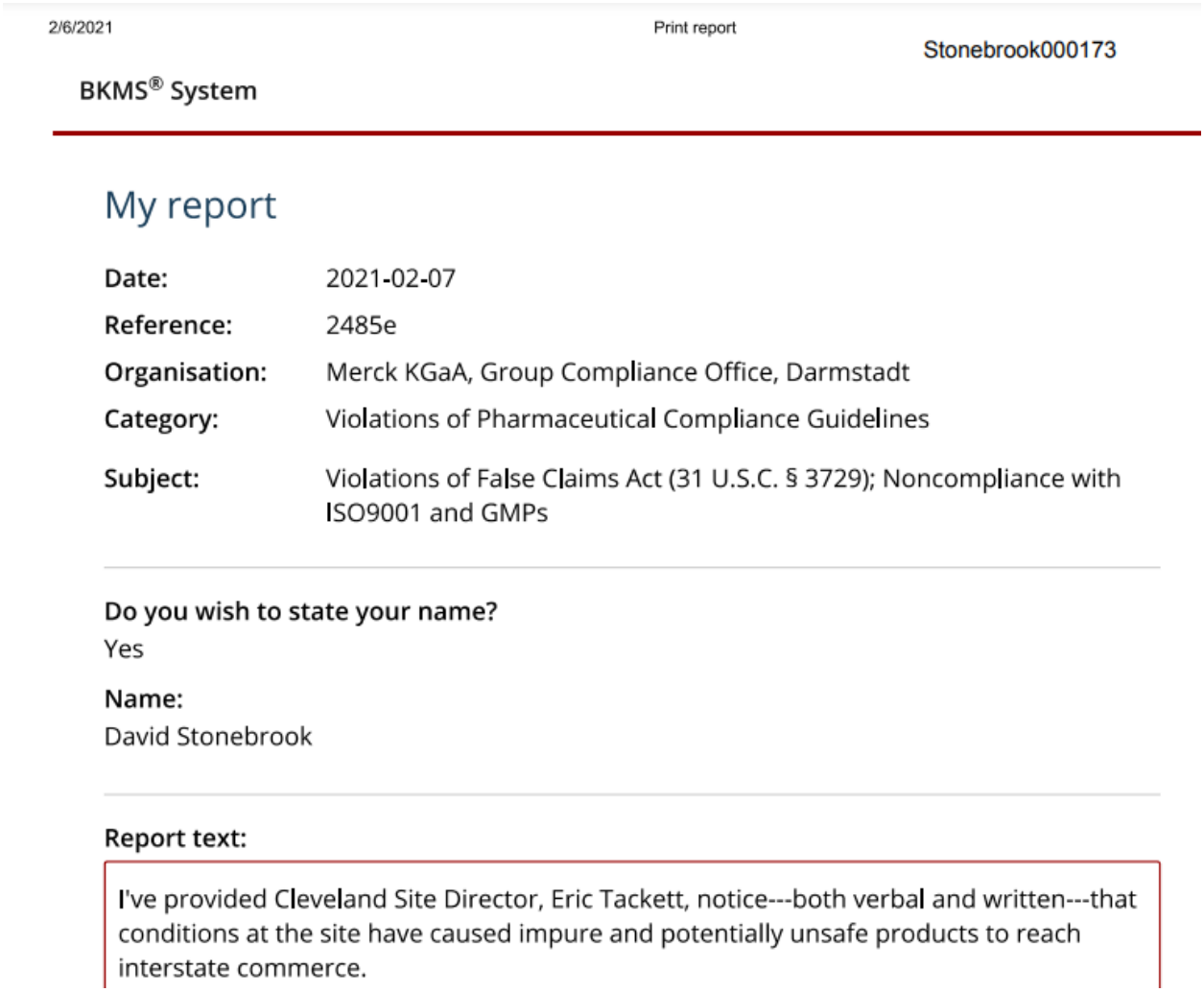
Stonebrook000120

64. In this email, Relator explained that the mold-infested air filtration system at the Facility could result in criminal and False Claims Act liability and provided a link to a Department of Justice Press Release detailing an $18 million dual criminal and False Claims Act settlement regarding these same issues. Relator also highlighted specific provisions of Defendants' Facility 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 report and contrasted those photos with the less severe mold in the air filtrations systems at another facility that led to the aforementioned $18 million False Claims Act settlement.[26]

65. Pictured below is the image from Relator's email depicting the mold that led to the aforementioned $18 million False Claims Act settlement. Note that when juxtaposed with the earlier photos of the Facility's facility, the mold in the photo below was less severe.

[26] Relator also provided images of the false labeling affixed to Facility products which rendered these products misbranded, including sodium phosphate monobasic monohydrate, L-Tyrosine, and L-Phenylalanine.

66. Additionally, on February 5, 2021, Relator submitted a formal report through Defendants' "Speak Up" system – *i.e.*, Defendants' internal compliance reporting system that purports to encourage employees to internally report violations.



2/6/2021 Print report Stonebrook000173

BKMS® System

My report

Date: 2021-02-07

Reference: 2485e

Organisation: Merck KGaA, Group Compliance Office, Darmstadt

Category: Violations of Pharmaceutical Compliance Guidelines

Subject: Violations of False Claims Act (31 U.S.C. § 3729); Noncompliance with ISO9001 and GMPs

Do you wish to state your name?
Yes

Name:
David Stonebrook

Report text:

I've provided Cleveland Site Director, Eric Tackett, notice---both verbal and written---that conditions at the site have caused impure and potentially unsafe products to reach interstate commerce.

67. In this February 5, 2021 Speak Up Report, Relator informed Defendants that he previously had informed the Facility Site Director, Eric Tackett, of the inadequate training, deficient written procedures, and staffs' fear of reprisal at the Facility for reporting contamination issues. Relator also reported that he had informed Mr. Tackett that the air filtration system servicing the packaging rooms contained an "abundance of mold" and that "conditions at the site

have caused impure and potentially unsafe products to enter interstate commerce."

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

69. Relator further pointed out the need that the Facility "Introduce more frequent cleaning and bioburden swab test of the duct work and dust collection system." Relator also informed Defendants, via the Speak Up Report, that his previous recommendations to on-site staff on these issues had been ignored. Relator's entire report is copied below:

Report text:

I've provided Cleveland Site Director, Eric Tackett, notice---both verbal and written---that conditions at the site have caused impure and potentially unsafe products to reach interstate commerce.

Inadequate staffing, inadequate training, inadequate written procedures and fear of reprisal has deteriorated the morale amongst my Team. Speaking up, I currently fear for my own job.

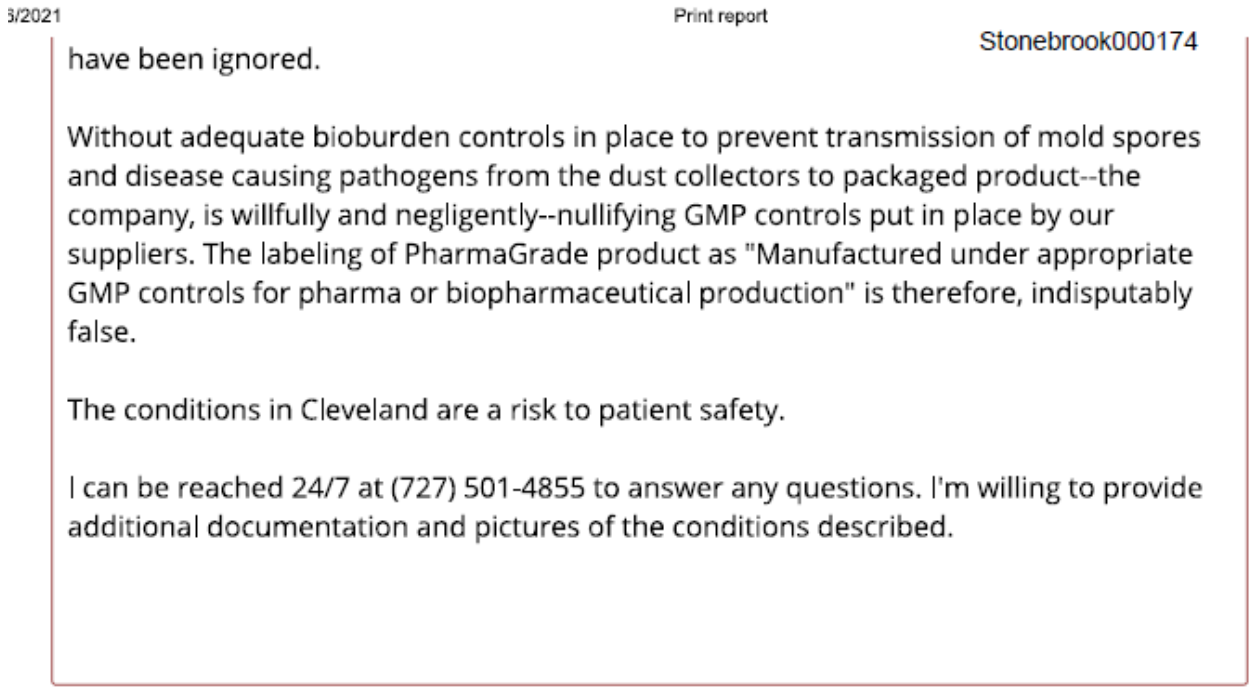
Equipment is past its service life, preventative maintenance is not being performed and necessary capital improvements have been abandoned or postponed.

Most recently, I notified Site Director, Eric Tackett, the dust collection system (i.e., filters and housings units) above Packaging suites D, E and F have an abundance of mold growth.

The ductwork leading from the filter housings to the rooms where PharmaGrade product is packaged is less than 10 feet. I recommended we immediately stop packaging activities, upgrade the dust collection system and introduce adequate HEPA filtration to treat the air within the rooms. Introduce more frequent cleanings and routine bioburden swab test of the duct work and dust collection system. My recommendations

Stonebrook000173

ps://www.bkms-system.net/bkwebanon/action/report/printReport.do?reportBox=1



70. Relator's February 5, 2021 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."

71. On February 6, 2021, Relator forwarded, via email, this February 5, 2021 Speak Up Report to the same group of Defendants' executives he had emailed the day prior.

72. 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, which informed Defendants' executives of the continued unfit conditions in the packaging rooms:

Stonebrook000126

Gmail

David Stonebrook <dsstonebrook@gmail.com>

MilliporeSigma - Cleveland
2 messages

David Stonebrook <david.stonebrook@milliporesigma.com> Mon, Feb 8, 2021 at 10:37 AM
To: Yvonne Albert <yvonne.albert@milliporesigma.com>, Robert Nass <Robert.Nass@merckgroup.com>, Christos Ross <christos.ross@milliporesigma.com>
Cc: Friederike Rotsch <friederike.rotsch@merckgroup.com>, Stefan Oschmann <Stefan.Oschmann@merckgroup.com>

Team,

As you are aware, 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 the rooms identified as being unfit for such task.

Unless change is implemented, it will become incumbent upon me to notify regulators.

David Stonebrook

GMP Packaging Supervisor

MilliPORE SiGMA

73. In response to Relator's formal reports of contaminated conditions, non-compliance, and the culture of ignoring such concerns, on February 11, 2021, Dieter Hofner, Senior Vice President at Merck, had a phone call with Relator which was attended by Melissa Reed, Head of Employee Relations. During that call Relator expressed that the Facility was not fit to manufacture or package yogurt, let alone a component to be used in an injected pharmaceutical product. Mr. Hofner responded by acknowledging that the Facility needed process improvements, clear procedures, and capital improvement investments, and reassured Relator that he would have Defendants' full support and backing in making the needed improvements. Mr. Hofner also asked Relator if he had a suggestion for a temporary solution and Relator suggested temporarily moving all packaging activities to the St. Louis facility until the deficiencies at the Facility were corrected. Nevertheless, Mr. Hofner and Defendants refused to halt operations and continued manufacturing, packaging, and shipping adulterated and misbranded components.

74. On February 22, 2021, Relator sent his supervisors a report demonstrating that the extent of the non-GMP compliant issues even resulted in a bolt from the equipment used in the packaging room ending up in HEPES product shipped to a client, Genentech, a large pharmaceutical company that manufactures pharmaceutical products, including vaccines.

75. On February 23, 2021, Relator called the FDA to advise it of the non-GMP compliant conditions at the Facility and spoke with Jeffrey Meng, Director of Investigations Branch, Division 3, Detroit, and provided a short overview of the issues at the Facility. Mr. Meng advised that one of his intake coordinators would reach out to discuss Relator's concerns and an intake coordinator from the FDA, Sean Wolski, called Relator that same day and had a two-minute phone call.

76. On February 25, 2021, Relator shared with Melissa Reed that Defendants had a legal and moral duty to ensure patient safety. He informed Ms. Reed that he was committed to helping Defendants bring their operations into compliance to ensure safe pharmaceutical components reached the market.

77. On February 28, 2021, Relator submitted another Speak Up Report detailing the Facility'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 the Facility. Relator also reported that he had previously referenced these violations in communications with Merck Executive, Deiter Hofner.

78. On March 3, 2021, Relator informed EMD Millipore Head of Quality Operations, Jane Findlay, precisely how EMD Millipore's response to his concerns was uninformed and misplaced:

2021 03 02 Stonebrook Letter.docx
24K

David Stonebrook <dsstonebrook@gmail.com> Wed, Mar 3, 2021 at 10:59 AM
To: David Stonebrook <david.stonebrook@milliporesigma.com>

Jane,

I am in receipt of your letter.

You are correct, a venue where you could ask questions, I could concur or correct conclusions is preferred. I was ill Friday and I apologize a meeting with such a format did not materialize.

I welcome a reschedule of the meeting to ensure steps are taken to gain Cleveland's compliance.

Also, I recognize many members of your Team have not been to Cleveland and have relied on information from others, namely site Quality personnel who. a) don't possess the expertise to provide guidance on the matters brought forward or b) have an interest in obscuring the true state of Cleveland's operations, whether on their own accord or under duress due to job security concerns.

The position I find myself now, "on Leave" for missing a meeting due to illness, lends credence to the aforementioned concern my colleagues in QA have had while while responding to your inquiry. (i.e., Speak up on matters that conform to getting product out the door [quickly] and you will be reprimanded). It's dangerous to adopt these disciplinary processes.

Further, certain untoward practices (i.e., deceptive marketing, overstating the site's quality compliance and GMP controls to customers) have been documented as occurring as early as 2001. I am happy to supply you with this documentation. I have been able to share some of this documentation internally.

Regarding your statements, the site is independently audited, I have been a representative member of leadership in said audits. My partipation in these audits is

79. Relator also cogently refuted Ms. Findlay's claims that operations at the Facility were sufficient because the site is independently audited. In doing so, Relator informed Ms. Findlay of his experience with the Facility'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."

80. On the same day Relator submitted the 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.

81. 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 and Dieter Hofner. These two individuals were at the forefront of Defendants' response to Relator's concerns, they interfaced with Relator regarding his reports, and then they personally terminated him for raising such concerns.

82. More recently, on January 20, 2023, just 11 days after the undersigned counsel filed a Notice of Appearance in this matter, Defendants Sigma-Aldrich, EMD Millipore, and Research Organics filed suit against Relator in this Court in case number 1:23-cv-10140, and sent the undersigned a copy of the complaint filed in that action.

IV. THE APPLICABLE LAWS

A. The False Claims Act

83. 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 [l]), plus treble damages. 31 U.S.C. § 3729(a)(l)(A), (B), (G).

84. 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)(l).

85. The FCA defines "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).

86. 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).

87. 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 one or more violations of the FCA. See 31 U.S.C. § 3730(h).

B. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399i

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

89. The FDA defines "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 to any of them; and (B) articles intended for use in the diagnosis, cure, treatment, or prevention of disease in man or other animals; and (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)(l).

90. 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.

91. 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).

92. 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).

93. 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).

94. 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.[27] Accordingly, misrepresentations that pharmaceutical components were manufactured and packaged in clean, safe, and non-contaminated environment are material to payment and therefore such a misrepresentation results in false claims. *See Universal Health Services, Inc. v. United States*, 136 S. Ct. 1989, 2003 (2016).

C. Specific GMP Requirements for Pharmaceutical Components

95. The primary regulatory standards for ensuring pharmaceutical quality are the Current Good Manufacturing Practice regulations, often simply called Good Manufacturing Practices regulations. GMPs require pharmaceutical manufacturers and facilities that produce

[27] 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. 13-cv-42 (W.D.N.C.); Department of Justice Press Release, "Baxter Healthcare Corporation to Pay More Than $18 Million to Resolve Criminal and Civil Liability Relating to Sterile Products," 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. l: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).

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.

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

97. "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).

98. 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)).

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

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

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

102. Specifically, GMP regulations require that "there must be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and

[28] 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. § 35l(a)(2)(B) *available at* https://www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practice-requirements-control-components-and-drug.

[29] *Id.*

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

approval or rejection of Components." 21 C.F.R. § 211.80(a).

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

104. "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).

105. "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).

D. FDA Labeling Requirements

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

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

108. 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).

109. "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).

110. "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).

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

111. Relator adopts and incorporates the above paragraphs as though fully set forth herein.

112. 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 and to Pfizer for use in the Pfizer-BioNTech Covid-19 Vaccine - to be adulterated in violation of 21 U.S.C. § 351.

b) Defendants misled its customers, Pfizer and Lonza (Moderna), and the FDA through, upon information and belief, advising them or leading them to believe they were being supplied GMP compliant TRIS and HEPES, 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 Pfizer for use in the Pfizer-BioNTech Covid-19 Vaccine and 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, Pfizer and Lonza (Moderna), 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 their 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 and to Pfizer for use for use in the Pfizer-BioNTech Covid-19 Vaccine - throughout the United States in violation of 21 U.S.C. § 331.

e) Defendants' frauds caused manufacturers Pfizer and Lonza (Moderna) to use components in manufacturing processes that they may not have chosen to use, absent certifications of GMP compliance.

f) Defendants' fraud caused pharmaceutical manufacturers Pfizer and Moderna to unknowingly submit false claims to the United States government. The integrity of those claims were compromised by Defendants' fraud and unwillingness to correct their practices. Pharmaceutical manufacturers would not submit false claims to the government knowing their products were adulterated. Likewise, the United States government would not have paid claims to pharmaceutical manufacturers, having awareness that components used in FDA regulated manufacturing processes were misbranded, sold to the manufacturer under fraudulent pretenses, or produced and packaged in facilities where contamination of components is probable or hidden from manufacturers.

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

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

115. 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, that it

would not have paid if not for Defendants' false representations.

116. 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)(l)(B)

117. Relator adopts and incorporates the above paragraphs as though fully set forth herein.

118. 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, upon information and belief, false and misleading labels that falsely claimed its products were manufactured, stored, and packaged in accordance with GMP standards;

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

119. 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.

120. 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.

121. 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)(l)(G)

122. Relator adopts and incorporates the above paragraphs as though fully set forth herein.

123. 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; 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.

124. 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)(l)

125. Relator adopts and incorporates the above paragraphs as though fully set forth herein.

126. 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.

127. 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 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.

DATED: March 7, 2023

Respectfully submitted,
SIRI & GLIMSTAD LLP

By: */s/ Aaron Siri*
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Attorneys for Relator

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2023, a copy of the foregoing Amended Complaint was filed electronically through the Court's Electronic Case Filing System.

Dated: March 7, 2023

/s/ Aaron Siri
Aaron Siri