IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

CASE NO. 1:17cv15

UNITED STATES OF AMERICA,

Plaintiff,

v.

$8,000,000 in Funds in the form of a wire transfer from Baxter Healthcare Corporation,

Defendant.

VERIFIED COMPLAINT OF FORFEITURE *IN REM*

Plaintiff, United States of America, by and through Jill Westmoreland Rose, United States Attorney for the Western District of North Carolina, brings this Complaint for Forfeiture *In Rem* and alleges as follows in accordance with Supplemental Rule G(2) of the Federal Rules of Civil Procedure:

Nature of the Action

1. This is a civil forfeiture action against the above-captioned $8,000,000 in funds that constitute or are derived from a violation of 21 U.S.C. § 331 and are therefore subject to forfeiture pursuant to 18 U.S.C. § 981(a)(1)(C).

The Defendant In Rem

2. The defendant consists of $8,000,000 in U.S. funds ("the Funds") in the form of a wire transfer from Baxter Healthcare Corporation ("Baxter"), to be seized with consent of Baxter.

Jurisdiction and Venue

3. Plaintiff brings this action *in rem* in its own right to forfeit and condemn the Funds. This Court has jurisdiction over this action commenced by the United States under 28 U.S.C. § 1345; over this action for forfeiture under 28 U.S.C. § 1355(a); and over this particular action under 18 U.S.C. § 981(a)(1)(C).

4. This Court has *in rem* jurisdiction over the Funds under 28 U.S.C. § 1355(b). Upon the filing of this Complaint, the Plaintiff requests that the Court issue an Arrest Warrant *In Rem* pursuant to 28 U.S.C. § 1355(d) and Supplemental Rule G(3)(C).

5. Venue is proper in this district pursuant to 28 U.S.C. § 1355(b)(1), because the acts or omissions giving rise to the forfeiture occurred in this district.

Basis for Forfeiture

6. The Funds are subject to forfeiture pursuant to 18 U.S.C. § 981(a)(1)(C) as property constituting, derived from, or traceable as proceeds to a violation of 21 U.S.C. § 331, a federal health care offense within the meaning of 18 U.S.C. § 24, namely a violation of 21 U.S.C. § 331 relating to a health care benefit program involving the introduction into interstate commerce of an adulterated drug.

7. To the extent that it is necessary to do so, Plaintiff also intends to rely on the provisions of 18 U.S.C. § 984 to establish that the Funds are the property subject to forfeiture as set forth in paragraph 6 above.

Facts

8. The below facts alleged in this Complaint are Verified by Special Agent Paul Pierce of the United States Food and Drug Administration ("FDA").

9. During the relevant time period, from July 2011 to November 2012, Baxter was a

Delaware corporation and a subsidiary of Baxter International, Inc., headquartered in Deerfield, Illinois. Baxter owned and operated the North Cove manufacturing facility in Marion, North Carolina ("North Cove"). At North Cove, Baxter manufactured large-volume sterile intravenous ("IV") solutions and related products. North Cove produced approximately 1.5 million bags of IV solution per day, supplying approximately 60% of the IV solutions used in the United States. North Cove had twelve production lines, occupied approximately 1.4 million square feet, and was the largest IV solutions plant in the world.

10. Baxter employed over 2,000 people at North Cove. Baxter's employees at North Cove included quality employees, who were responsible for ensuring the quality of Baxter's products made at North Cove; human resources employees, who were responsible for employment matters at North Cove; and maintenance employees, who were responsible for maintaining the equipment and facilities Baxter used to make IV solutions at North Cove, including utilities and Heating, Ventilation, and Air Conditioning ("HVAC") systems, among numerous other types of employees at North Cove.

11. IV solutions were drugs that the FDA regulated under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399f ("FDCA"). The FDCA prohibited the introduction or delivery for introduction in interstate commerce of an adulterated drug. 21 U.S.C. § 331(a).

12. The FDA implemented Good Manufacturing Practices regulations which governed the manufacture of drugs including IV solutions. A drug was adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B), if it was not manufactured according to FDA's current Good Manufacturing Practices regulations, 21 C.F.R. Parts 210 and 211.

Lines 10 and 11 at North Cove

13. From July 2011 to November 2012, Production Lines 10 and 11 at North Cove each had separate clean rooms used to fill bags with sterile IV solutions. Hospitals used these IV bags to treat their patients by putting the sterile IV solution directly into the bloodstreams of patients.

14. Approximately 20% of the IV bags made at North Cove, which is approximately 300,000 IV bags a day, were filled in the Line 11 clean room. Approximately 9% of all the IV bags used in the United States were filled in the Line 11 clean room.

15. Each of the clean rooms for Lines 10 and 11 had approximately 120 high-efficiency particulate absorption ("HEPA") filters installed in the ceiling of the room. Air was pushed into the clean rooms through the HEPA filters so that the filters could catch particles in the air before entering the clean rooms. The filters in the clean room for Line 10 and above belts A, B, C and D in the clean room for Line 11 had ceiling grates mounted underneath them. These filters were not visible without removing the ceiling grates or screens.

16. Once a year, Baxter shut down Lines 10 and 11 for regularly scheduled maintenance. Line 10's annual shutdown occurred in or about December, while Line 11's annual shutdown occurred in or about July. During these shutdowns, the HEPA filters installed in the ceilings of the clean rooms of Lines 10 and 11 were inspected and tested. According to North Cove policy and standard operating procedures, during these shutdowns, Baxter maintenance employees were required to replace HEPA filters that failed PAO (Poly Alpha Olefin) testing, which tested each filter's ability to filter the air. Baxter maintenance employees also sometimes replaced excessively stained or discolored filters, including those filters with discoloration from contaminants such as mold. Baxter maintenance employees were required to

record the reason for each filter replacement.

Stained or Moldy HEPA Filters at North Cove

17. HEPA filters at North Cove occasionally became discolored or stained, including potentially with mold. When Baxter maintenance employees discovered such HEPA filters, they replaced them with a new filter. Baxter quality employees kept track of and documented the number of HEPA filters that were replaced and the reasons therefor, including mold, stain, and discoloration.

18. In approximately 2006, Baxter HVAC employees were told to stop using the word "mold" on paperwork at North Cove to describe the condition of HEPA filters. Instead of using the word "mold," Baxter HVAC employees were told to use the words "stain" or "discoloration" to describe such HEPA filters on paperwork at North Cove. At about the same time, Baxter's quality trend reports that summarized the number of HEPA filters that were replaced and the reasons therefor, changed the title of one of the trending categories from "mold/stain" to "stain."

July 2011 Shutdown

19. In July 2011, during the regularly scheduled maintenance shutdown at North Cove, a Baxter HVAC Technician ("Reporting Employee") saw what he believed to be mold on approximately 15 HEPA filters in the Line 11 clean room. The suspected mold was on the side of the HEPA filters that faced the inside of the clean room. A co-worker of the Reporting Employee, another HVAC Technician at North Cove ("HVAC Technician #1") who was working with the Reporting Employee, also saw these suspected moldy HEPA filters. During this shutdown, the Reporting Employee showed a HEPA filter that had staining on it to the Superintendent of Utilities at North Cove.

20. The Superintendent of Utilities was a mid-level manager in the North Cove

Maintenance Department and reported to the Director of Facilities. The Director of Facilities was the highest level maintenance employee at North Cove. The HVAC Supervisor reported to the Superintendent of Utilities. All of the HVAC Technicians at North Cove, including the Reporting Employee, reported to the HVAC Supervisor.

21. The Reporting Employee and HVAC Technician #1 began replacing the HEPA filters they believed to be moldy. When approximately five of those HEPA filters remained to be changed in the Line 11 clean room, the HVAC Supervisor told the Reporting Employee and HVAC Technician #1 to stop changing the filters. As a result, the five remaining HEPA filters believed to be moldy, some of which were directly over equipment used to fill IV bags with solution, were left in the ceiling of the Line 11 clean room.

Line 11 HEPA Filter Maintenance Records for the July 2011 Shutdown

22. HVAC Technician #1 wrote on the July 2011 Shutdown maintenance record for the HEPA filters in the Line 11 clean room that certain filters were "changed prior to testing due to discoloration." Below this comment, the Reporting Employee wrote "Filters also had mold." The HVAC Supervisor saw these statements on the maintenance records and signed his name next to them to indicate his review of the statements. The Director of Facilities and the Superintendent of Utilities knew about these statements on the maintenance records, and understood them to mean that the filters at issue had been replaced. The Critical Systems Engineer in North Cove's Maintenance Department (the "Maintenance Critical Systems Engineer"), who did not supervise the Reporting Employee and was not involved with HEPA filters during the Shutdown, also saw these statements.

23. Three North Cove quality employees, including the Critical Systems Engineer in North Cove's Quality Department (the "Quality Critical Systems Engineer"), reviewed shutdown

maintenance records for HEPA filters. The Quality Critical Systems Engineer reviewed and approved the July 2011 Shutdown maintenance record for the HEPA filters in the Line 11 clean room on which the Reporting Employee wrote "Filters also had mold." The Quality Critical Systems Engineer understood the comments on this record to mean that the filters at issue had been replaced. The Quality Critical Systems Engineer complained to the Director of Facilities and Superintendent of Utilities that the Reporting Employee should not have written the word "mold" on this maintenance record because no one should write "mold" on Baxter records as no one could be sure a stain on a filter was mold until it was tested. No one, including the Quality Critical Systems Engineer, told any quality manager about the maintenance records with the notation regarding mold on them. Baxter took no action at that time to address the notation of mold.

Complaints of Moldy HEPA Filters to North Cove's Plant Manager

24. In late October 2011, North Cove's Plant Manager held a plant-wide, face-to-face meeting in which he emphasized that employees should come to him with any quality issues or concerns they might have. After this meeting, the Reporting Employee told North Cove's Plant Manager that approximately five moldy HEPA filters remained in the Line 11 clean room and that he feared his maintenance supervisors would retaliate against him for reporting the moldy filters. The Plant Manager was the highest level manager at North Cove and had overall responsibility for the entire plant. The Plant Manager assigned North Cove's Human Resources Director to investigate the Reporting Employee's moldy filter complaints and his fears of retaliation.

25. The Human Resources Director treated the investigation as a personnel problem between the Reporting Employee and his maintenance supervisors. The Human Resources

Director had no knowledge of or experience with HEPA filters. The Human Resources Director did not address the problem as a quality issue, nor did she tell anyone in the North Cove Quality Department about the Reporting Employee's complaints of moldy filters remaining in the Line 11 clean room or involve any quality employee in her investigation of these mold complaints.

26. When the Human Resources Director talked to the Reporting Employee about his complaints of approximately five moldy HEPA filters above the ceiling grates in the Line 11 clean room, the Reporting Employee gave the Human Resources Director a map showing which HEPA filters remained in the Line 11 clean room he identified as moldy.

27. During her investigation in November and December 2011, the Human Resources Director discussed the Reporting Employee's concerns about moldy HEPA filters remaining in the Line 11 clean room with all of the North Cove maintenance managers above the Reporting Employee, including the Director of Facilities, the Superintendent of Utilities, and the HVAC Supervisor. The Human Resources Director gave the Reporting Employee's map showing the filters he identified as moldy in the Line 11 clean room to the Director of Facilities and the Superintendent of Utilities, and kept a copy for her file.

28. In December 2011, the HVAC Supervisor along with other HVAC technicians inspected the HEPA filters identified by the Reporting Employee as moldy. The HVAC Supervisor reported to the Human Resources Director that they were not as "dirty" as other filters in the Line 11 clean room. The HVAC Supervisor also told the Reporting Employee that the "dirty" filters would be replaced the next time Line 11 would be shut down for its annual maintenance in July 2012. The HVAC Supervisor also told the Reporting Employee that the microbiology lab, which performs air testing in the Line 11 clean room, had not reported to him any air quality issues in Line 11. As a result, the filters that the Reporting Employee identified

as moldy continued to be used in the Line 11 clean room. The Reporting Employee was not satisfied with this decision. Baxter took no further action to address the Reporting Employee's identification of moldy filters at that time.

29. Despite the Reporting Employee's complaints of approximately five moldy HEPA filters in the Line 11 clean room, neither the Human Resources Director, the Director of Facilities, nor the Superintendent of Utilities at North Cove ever looked at the HEPA filters above the ceiling grates in the Line 11 clean room.

December 2011 Shutdown

30. In December 2011, during the regularly scheduled maintenance shutdown at North Cove, the Reporting Employee and HVAC Technician #1 saw seven discolored HEPA filters above the ceiling grates in the Line 10 clean room. The Reporting Employee and HVAC Technician #1 changed all seven filters. For four of the seven discolored filters, the Reporting Employee and HVAC Technician #1 noted on the filter maintenance record: "Changed due to discoloration and possible mold." For three of the seven discolored filters, the Reporting Employee and HVAC Technician #1 noted on the filter maintenance record: "Changed due to discoloration." Three North Cove quality employees, including the Quality Critical Systems Engineer, reviewed this shutdown maintenance record for the Line 10 HEPA filters. Baxter took no action at that time to address these notations of mold.

July 2012 Shutdown

31. During the July 2012 maintenance shutdown, the Reporting Employee and HVAC Technician #1 saw mold on 29 HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room. During this shutdown, the Maintenance Critical Systems Engineer came into the Line 11 clean room. The Reporting Employee asked the Maintenance Critical Systems Engineer

to come over and look at some of the HEPA filters in the Line 11 clean room. The HEPA filters were uncovered and visible because the ceiling grates were down as part of the shutdown. The Maintenance Critical Systems Engineer came over to where the Reporting Employee and HVAC Technician #1 were working. The Reporting Employee then showed the Maintenance Critical Systems Engineer stained HEPA filters in the Line 11 clean room.

32. Immediately after seeing the stained HEPA filters in the Line 11 clean room, the Maintenance Critical Systems Engineer went to talk to the Director of Facilities and the Superintendent of Utilities, who were nearby just outside of Line 11. The Maintenance Critical Systems Engineer told the Director of Facilities and the Superintendent of Utilities about the HEPA filters that the Reporting Employee had just showed him. The Superintendent of Utilities then walked away to place a call. The Director of Facilities told the Maintenance Critical Systems Engineer to tell the Reporting Employee and HVAC Technician #1 to "wipe it off." The Maintenance Critical Systems Engineer understood this to mean to wipe off the grid or grates because it was impossible to wipe off the HEPA filters without damaging them. Neither the Director of Facilities nor the Superintendent of Utilities went into the Line 11 clean room to look at the HEPA filters.

33. The Maintenance Critical Systems Engineer immediately returned to the Reporting Employee and HVAC Technician #1 and told them to "wipe it off." It was impossible to wipe stains or mold off of HEPA filters, so the Reporting Employee and HVAC Technician #1 did not try to do so.

34. The HVAC Supervisor told the Reporting Employee that as long as a HEPA filter did not have a hole in it or leak air, he should not replace it simply because it was stained or discolored. After receiving these instructions, the Reporting Employee and HVAC Technician

#1 left moldy HEPA filters in the ceiling of the Line 11 clean room.

35. During this shutdown, the Reporting Employee took photos of the moldy HEPA filters in the Line 11 clean room. These pictures were saved on the computer system at North Cove, but the Reporting Employee never showed the pictures to the Director of Facilities, the Superintendent of Utilities, the HVAC Supervisor, the Maintenance Critical Systems Engineer, the Human Resources Director, the Quality Systems Engineer, the Laboratory Services Quality Manager, or any other employee in Plant Management.

Line 11 HEPA Filter Maintenance Records for the July 2012 Shutdown

36. The Reporting Employee wrote "what appears to be mold on numerous filters" twice on the maintenance records for the HEPA filters in the Line 11 clean room. The HVAC Supervisor saw these statements on the maintenance records and signed his name next to them to indicate his review of the statements. The Maintenance Critical Systems Engineer saw these statements and discussed them with the Quality Critical Systems Engineer. The Maintenance Critical Systems Engineer asked the Reporting Employee how many of the filters still in the Line 11 clean room appeared to be moldy. The Reporting Employee told the Maintenance Critical Systems Engineer that there were 29 HEPA filters in the Line 11 clean room that appeared to be moldy. The Maintenance Critical Systems Engineer then passed this information on to the Director of Facilities.

37. The Quality Critical Systems Engineer showed the Reporting Employee's "mold" comments to the Laboratory Services Quality Manager, who was his immediate supervisor in North Cove's Quality Department. The Laboratory Services Quality Manager showed the comments to the Director of Quality, the highest person in the North Cove Quality Department. The Director of Quality told the Laboratory Services Quality Manager to have an inspection of

the filters done – to take down the ceiling grates to see if the filters were moldy, and if so, replace them. The Laboratory Services Quality Manager told the Quality Critical Systems Engineer that the Director of Quality wanted an inspection of the filters done – take down the ceiling grates to see if the filters were moldy, and if so, replace them. The Quality Critical Systems Engineer contacted the HVAC Supervisor and/or the Superintendent of Utilities and told them that the Laboratory Services Quality Manager and the Director of Quality had instructed them to inspect the filters and replace them as necessary. All of these conversations were short and undocumented.

Human Resources Investigation of Complaint of Moldy HEPA Filters in July 2012

38. In July 2012, the Human Resources Director learned that the Reporting Employee was again complaining that there were moldy HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room. The Human Resources Director started another investigation into these complaints by discussing the complaints with the Director of Facilities and collecting written statements from the Maintenance Critical Systems Engineer, the HVAC Supervisor, the Reporting Employee and HVAC Technician #1.

The Inspection of the Line 11 HEPA Filters in Late July 2012

39. In late July 2012, the Superintendent of Utilities directed the HVAC Supervisor to carry out the inspection (as directed by the Quality Department) of filters above the ceiling grates over Belts A-D in the Line 11 clean room using a map identifying the filters to be inspected. The Superintendent of Utilities states he obtained the map from the Quality Critical Systems Engineer, and that the Quality Critical Systems Engineer created the map. The Quality Critical Systems Engineer denies creating such a map. The map was based on a blank maintenance record (the same type used during the shutdowns) showing the layout of the approximately 120

HEPA filters on Line 11. However, the filters identified on the map were not in the area where the Reporting Employee and HVAC Technician #1 had found mold, and no one consulted with them regarding the correct location of the moldy filters.

40. HVAC Technician #1 and another employee state that they told the HVAC Supervisor around the time of the re-inspection that the filters identified on the map were not where the Reporting Employee and HVAC Technician #1 had seen mold. The HVAC Supervisor inspected the identified filters with two HVAC technicians other than the Reporting Employee and HVAC Technician #1 and reported that they did not find any "discoloration" during their inspection. The HVAC Supervisor then made and signed the following statement on the same pages of the maintenance record where the Reporting Employee had made his mold comments: "On 07-29-12, a follow-up inspection was performed on HEPA filters on Filling Line 11. No discoloration was found on the HEPA filters. No HEPA filters were in need of replacement." The filter map used during this inspection was not kept in Baxter's records.

41. The Quality Critical Systems Engineer told the Laboratory Services Quality Manager that an inspection of the HEPA filters in the Line 11 clean room had been done and no mold was found. The Laboratory Services Quality Manager told the Director of Quality that an inspection was done and the HEPA filters were OK. These conversations were short and undocumented. Neither the Director of Quality, nor the Laboratory Services Quality Manager asked how the inspection of the filters was done. No one from the Quality department ever looked at the HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room.

42. The HVAC Supervisor told the Human Resources Director that he had inspected the HEPA filters in the Line 11 clean room and showed the Human Resources Director his report of the results of his inspection written on the Line 11 HEPA filter maintenance record for the

July 2012 Shutdown. The Human Resources Director relied on the HVAC Supervisor's written report of his inspection to conclude that the Reporting Employee's July 2012 complaints of moldy filters in the Line 11 clean room were resolved.

43. Despite the Reporting Employee's renewed complaints of moldy HEPA filters in the Line 11 clean room, neither the Human Resources Director, the Director of Facilities, nor the Superintendent of Utilities ever looked at the HEPA filters in the Line 11 clean room. The filters the Reporting Employee identified as moldy remained.

November 2012 FDA Inspection

44. From November 7 to 16, 2012, the FDA conducted an unannounced inspection of North Cove and found numerous moldy HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room. Subsequent testing revealed several mold species and other particulate matter on the filters.

No Evidence of Product Impact

45. Per the Environmental Monitoring Plans on file with the FDA and incorporated into the FDA-approved new drug applications for the products manufactured at North Cove, there are established limits for how much mold can be present in the air and on surfaces in the fill rooms. During the relevant time frame, Baxter's testing showed no "out of limits" results.

46. There are also established limits for how much mold can be in the solution before it is sterilized, as the purpose of North Cove's terminal sterilization process is to kill contaminates like mold prior to product release. There were no "out of limits" test results.

47. Mold is destroyed at temperatures below 194°F, whereas North Cove sterilizes all product at 250°F prior to release. Mold cannot survive at that temperature. North Cove conducts post-terminal sterilization endotoxin testing, which was at all relevant times within limits.

48. There was no evidence of impact on the IV solutions manufactured at North Cove from the mold found on the HEPA filters above the Line 11 clean room.

49. The conduct identified herein resulted in the introduction into interstate commerce of adulterated products which were, upon information and belief, used in medical procedures. Upon information and belief, those products were, in turn, funded by millions in payments to Baxter from, among other sources, health care benefit programs as defined in 18 U.S.C. § 24. Upon information and belief, the $8,000,000 in funds identified for forfeiture herein constitute or are derived from payments to Baxter that were funded by health care benefit programs as identified in this paragraph.

WHEREFORE, the United States of America respectfully prays the Court that:

1. Due notice be given to all parties to appear and show cause why the forfeiture should not be decreed;
2. Judgment be entered declaring the Funds condemned and forfeited to the United States of America for disposition according to law; and
3. The United States be granted such other and further relief as this Court may deem just and proper, together with the costs and disbursements of this action, including but not limited to the expenses of maintenance and protection of the Funds as required by 28 U.S.C. § 1921.

Respectfully submitted, this the 12 day of January, 2017

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STATE OF NORTH CAROLINA
COUNTY OF MECKLENBURG

VERIFICATION

FDA Special Agent Paul Pierce deposes and says under penalty of perjury:

I am a Special Agent with the United States Food and Drug Administration and one of the agents assigned to this case.

I have read the foregoing Complaint and the factual information contained therein is true according to the best of my knowledge, information, and belief.

Paul Pierce, Special Agent, FDA

STATE OF NORTH CAROLINA
COUNTY OF MECKLENBURG

I certify that the following person personally appeared before me this day, acknowledging to me that he signed the foregoing document: Paul Pierce.

This 29 day of November, 2016.

Notary Public
My Commission Expires: 11/19/2019

Lauren Amanda Fowler Hefferon
NOTARY PUBLIC
Cabarrus County, North Carolina