UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

UNITED STATES OF AMERICA,	)	
	)	CAUSE NO. Enter cause number
Plaintiff,	)	18 U.S.C. § 371
	)	21 U.S.C. §§ 331(a), (k), and 333(a)(1)
v.	)	
	)	
PAUL J. ELMER and	)	-01
CAPRICE R. BEARDEN,	)	-02
	)	
Defendants.	)	1:17-cr-0113 JMS-TAB

INDICTMENT

The Grand Jury charges that:

GENERAL ALLEGATIONS

1. Pharmakon Pharmaceuticals, Inc. (Pharmakon) was incorporated in the State of Indiana on or about July 2, 2008, and located most recently in Noblesville, Indiana.

2. Pharmakon compounded sterile drugs for public, private, and military hospitals and medical centers located throughout the United States, including Indiana, Louisiana, Illinois, Texas, Virginia, Kentucky, New York, Maryland, Georgia, Mississippi, California, and Oklahoma. Compounding is generally a practice in which a licensed pharmacist combines, mixes, or alters ingredients of a drug to create a medication.

The Defendants

3. **PAUL J. ELMER** was the President and owner of Pharmakon; he was a licensed Indiana pharmacist and a Fishers, Indiana resident. At all times relevant to this Indictment, **ELMER** exercised control over the operation of Pharmakon.

4. **CAPRICE R. BEARDEN** was the Director of Compliance of Pharmakon, and a Carmel, Indiana resident. At all times relevant to this Indictment, **BEARDEN** exercised control over the quality management and compliance at Pharmakon. She reported to **ELMER**.

The Food and Drug Administration

5. The United States Food and Drug Administration (FDA) is a federal agency that is part of the United States Department of Health and Human Services. The FDA is responsible for protecting the health and safety of the public by enforcing the Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. That responsibility includes ensuring that drugs for use in humans are safe and effective for their intended uses, and by ensuring that the labeling of such drugs bears true and accurate information. Pursuant to this responsibility, the FDA has published and administered regulations relating to the approval, manufacture, labeling, and distribution of drugs.

6. To enforce the FDCA, the FDA has authority to investigate suspected violations of the Act. That investigative authority includes inspections at the place the drugs are manufactured, processed, and held for introduction into interstate commerce, extending to all things that bear upon whether drugs are adulterated and misbranded.

7. Under the FDCA, a drug is deemed adulterated if it is represented as a drug the name of which is recognized in an official compendium and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium.

8. On January 23, 2014, Pharmakon registered with the FDA as an "outsourcing facility." Under the FDCA, an outsourcing facility was defined as a facility at one location that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all of the pertinent requirements.

9. The FDA inspected Pharmakon three times during the course of two years: in March 2014, April 2014, and February 2016. All three FDA inspections occurred after Pharmakon registered with the FDA as an outsourcing facility.

10. When a compounded drug is either defective or potentially harmful, recalling the drug from the marketplace is the most effective means to protect consumers. When a company recalls a drug, the company may contact and work with the FDA to carry out the recall. Under some circumstances, the FDA will publicize the recall to alert the public to a health hazard.

Pharmakon Compounded and Provided Hospitals With Adulterated Drugs

11. Health care providers, including hospitals, placed orders for compounded drugs with Pharmakon for a wide range of drugs, including: morphine sulfate, epinephrine, fentanyl, midazolam, phenylephrine, and promethazine. Doctors and nurses typically prescribed and administered these drugs to patients located in a hospital or medical center. Pharmakon obtained drug components from out-of-state suppliers to compound the orders. Once an order was placed and Pharmakon began the process of compounding the drug order, Pharmakon assigned the order a lot number for purposes of identification.

12. In most instances, **ELMER** and **BEARDEN** caused the compounded drugs to be tested for potency, in order to ensure that the strength of the drug was what it was purported to be on its label. **ELMER** and **BEARDEN** used Testing Company 1 for some potency testing, from at least as early as July 2013 through August 2015. They used Testing Company 2 for some potency testing, from at least as early as August 2015 through March 2016. Both Testing Companies 1 and 2 used specifications provided by Pharmakon and by the official United States Pharmacopeia to measure the drugs' potency.

13. Despite such testing, **ELMER** and **BEARDEN** uniformly caused compounded drugs to be shipped to health care providers before receiving the test results. After the drugs were shipped, from at least as early as July 2013 through February 2016, **BEARDEN** received notice of approximately 70 potency failures, in that drugs were weaker or stronger than the strength indicated on their labels. These potency failures were also referred to as out-of-specification test results, in that the drugs were outside of a target potency range that was typically 90% to 110%. **ELMER** received notice of potency failures as early as October 2013.

14. Until Pharmakon compounded and distributed 2,460% potent morphine sulfate in February 2016, neither **ELMER** nor **BEARDEN** notified customers and the FDA of any potency failures.

March 2014 FDA Inspection
(Inspection #1)

15. From March 5, 2014 through March 13, 2014, the FDA conducted its first onsite inspection of Pharmakon in Noblesville, Indiana. **ELMER** was present for portions of the inspection, and **BEARDEN** was present for the entire inspection.

16. On March 6, 2014, **BEARDEN** falsely told FDA investigators that Pharmakon had never received any out-of-specification test results, despite the fact that **ELMER** and **BEARDEN** had previously received notice of multiple potency failures. On January 30, 2014, Testing Company 1 notified **BEARDEN** of these failures relating to drugs that Pharmakon had distributed:

- 267% potent fentanyl, lot # E16069DK1C (which Pharmakon distributed to Hospital 1, in Virginia); and
- 200% potent midazolam, lot #s E0433735C and E1016227C (which Pharmakon distributed to Hospital 2, in Indiana).

On February 3, 2014, a managing pharmacist at Pharmakon notified **ELMER** that the lot of fentanyl and the lots of midazolam were over-potent. In addition, on March 11, 2014, **BEARDEN** was notified that lot # E0923255R, of phenylephrine, was 130% potent. The FDA did not learn of any of these potency failures until after the March 2014 inspection, and even then, was able to discover only the 200% potent midazolam.

17. The FDA discussed its inspectional findings with **ELMER** at the conclusion of the inspection. This did not include a discussion of any specific out-of-specification results since FDA, despite asking for such information, was not informed that any out-of-specification results existed. The FDA, however, did observe numerous conditions at Pharmakon that failed to comply with FDA regulations and documented these observations in a form presented to **ELMER**.

FDA Discovers Issue With Midazolam and Conducts April 2014 Inspection (Inspection #2)

18. On or about March 26, 2014, an employee at Hospital 2 in Indiana noticed that the labeling on a syringe of midazolam listed two conflicting strengths of midazolam, a drug used for sedation or anesthesia. One was the strength Hospital 2 had ordered, and the other was double that amount. As a result, Hospital 2 contacted Pharmakon to look into the issue and discovered that the drugs were actually double the strength that Hospital 2 had ordered.

19. On March 28, 2014, Hospital 2 filed a report on MedWatch – FDA's Safety Information and Adverse Event Reporting Program – relating to the two lots of midazolam (lot #s E0433735C and E1016227C). Hospital 2's report indicated that the hospital had administered the drugs to 13 infants in the neonatal intensive care unit.

20. In response to the MedWatch report filed by Hospital 2, on April 2, 2014, FDA began its second onsite inspection of Pharmakon. The inspection ended on April 6, 2014.

Again, **ELMER** and **BEARDEN** were present. The FDA again discussed its findings with **ELMER** at the conclusion of the inspection. As with the first inspection, the FDA observed numerous conditions at Pharmakon that failed to comply with FDA regulations.

21. During the inspection, the FDA investigated the two lots of midazolam identified by Hospital 2 in its MedWatch report. **ELMER** and **BEARDEN** failed to inform the FDA that Testing Company 1 had notified them that the two lots were double the strength indicated on their labeling almost two months before Hospital 2's phone call to Pharmakon. Specifically, on January 30, 2014 – over a month before the first FDA inspection – Testing Company 1 emailed **BEARDEN** that the two lots of midazolam were 200% potent, and therefore double the strength that was indicated on the labeling for the two lots. **BEARDEN** did not respond to the email, so on February 1, 2014, Testing Company 1 forwarded the January 30 email to a Pharmakon pharmacist, who forwarded the email to **ELMER** and **BEARDEN** on February 3, 2014.

22. By the time **ELMER** and **BEARDEN** had received these emails, Pharmakon had already shipped both lots of midazolam to Hospital 2 on January 20 and 21, 2014. Neither **ELMER** nor **BEARDEN** took action to correct the over-potency of the two lots that Pharmakon had already distributed to Hospital 2. Specifically, neither **ELMER** nor **BEARDEN** notified Hospital 2, nor did Pharmakon issue a recall of the midazolam at that time. After this second FDA inspection began, Pharmakon did then recall both lots.

23. After this FDA inspection, **ELMER** and **BEARDEN** indicated to the FDA, in a signed letter, that they first became aware of issues with the two lots of midazolam when Hospital 2 notified them of an error in the labeling on the drugs. In fact, **ELMER** and **BEARDEN** first became aware of the issues with the two lots of midazolam two months earlier when they received out-of-specification test results from Testing Company 1.

May 2015 FDA Warning Letter:
FDA Warns ELMER that Pharmakon is Putting Patients at Risk

24. On May 21, 2015, the FDA issued to **ELMER** a Warning Letter, in which the FDA stated that there were "serious deficiencies in your practices for producing sterile drug products, which put patients at risk." Referring to the over-potent midazolam, the FDA stated that "it appears Pharmakon [was] producing drugs that violate the FDCA."

2,460% Potent Morphine Sulfate and the February 2016 FDA Inspection (Inspection #3)

25. On or about February 3, 2016, Pharmakon distributed 2,460% potent morphine sulfate, an opioid typically used for relief of moderate to severe acute and chronic pain, to Hospital 2, in Indiana, as well as to Hospital 4, in Illinois. Three infants at Hospital 2 received the morphine sulfate (lot # E52418EV11C) which was nearly 25 times the strength indicated on its label. One infant was taken by emergency helicopter to a nearby children's hospital. On February 12, 2016, Hospital 2 filed a MedWatch report concerning the over-potent morphine sulfate compounded and distributed by Pharmakon. Pharmakon recalled this lot.

26. From February 18, 2016 to March 16, 2016, the FDA conducted its third onsite inspection of Pharmakon. Again, **ELMER** and **BEARDEN** were present for the inspection.

27. During this inspection, **BEARDEN** told FDA investigators that Pharmakon had never received any out-of-specification test results before the 2,460% morphine sulfate failure.

28. In fact, from July 8, 2013 up until February 18, 2016, **BEARDEN** received approximately 70 potency test failure notices from Testing Companies 1 and 2, indicating that drugs including morphine sulfate, midazolam, fentanyl, cefazolin, and promethazine were either under- or over-potent. **BEARDEN** discussed the out-of-specification test results with **ELMER**, a licensed pharmacist, and until Pharmakon compounded and distributed 2,460% potent

morphine sulfate in February 2016, **ELMER** determined that Pharmakon should not contact any individuals and entities – including physicians and hospitals – who received the drugs, nor conduct any product recalls before FDA intervention, because the health care providers had likely already used the drugs, and because notification would lead to the loss of customers, and, therefore, a loss of profit. In addition, until February 2016, Pharmakon did not initiate contact with FDA in connection with any potency failures.

29. During this third FDA inspection, the FDA obtained records of numerous potency failures. The FDA then requested additional information, including, among other things, Standard Operating Procedures (SOPs) relating to the compounding process and quality control at Pharmakon and documentation known as "batch records" for individual lots of drugs, all of which set forth the various individuals who verified and performed quality control checks on drugs before release.

30. The FDA again discussed its findings with **ELMER** at the conclusion of the inspection. Again, the FDA observed numerous conditions at Pharmakon that failed to comply with FDA regulations.

COUNT 1
Conspiracy
18 U.S.C. § 371

31. Paragraphs 1 through 30 are hereby realleged and incorporated by reference as if set forth herein.

32. Beginning on or about January 23, 2014, through on or about March 16, 2016, in the Southern District of Indiana, the defendants,

PAUL J. ELMER and
CAPRICE R. BEARDEN,

did knowingly and willfully combine, conspire, confederate and agree to:

A. Defraud the United States by interfering with and obstructing, through deceitful and dishonest means, the lawful functions of the FDA; and

B. Commit an offense against the United States by corruptly obstructing, influencing and impeding, and endeavoring to obstruct, influence and impede, the due and proper administration of the law under which pending proceedings were being had before an agency of the United States, to wit, inspections by the FDA of Pharmakon in Noblesville, Indiana, pursuant to the FDA's statutory inspection authority set forth in Title 21, United States Code, Section 374, in violation of Title 18, United States Code, Section 1505.

PURPOSE OF THE CONSPIRACY

33. It was the purpose of the conspiracy for **ELMER** and **BEARDEN** to prevent any negative effect upon Pharmakon's business that would result from the FDA's and the public's knowledge that Pharmakon was compounding and distributing numerous drugs that were under- and over-potent.

MANNER AND MEANS

The defendants used the following manner and means – among others – to carry out the objects and purpose of conspiracy:

34. **ELMER** and **BEARDEN** caused the distribution of compounded drugs to customers located both inside and outside of the State of Indiana.

35. **ELMER** and **BEARDEN** caused these drugs to be tested for potency, and beginning at least as early as about July 2013, were notified that some of the drugs had failed potency testing.

36. Despite knowledge of these repeated drug potency failures, until distributing 2,460% potent morphine sulfate, **ELMER** and **BEARDEN** failed to notify customers and the

FDA of the fact that they had distributed numerous drugs that were not the strength they purported to be, because they feared that Pharmakon's business would be negatively affected by recalling products from customers and because they sought to thwart the FDA's efforts to learn about the extent of and causes of the potency failures.

37. During the first and third FDA inspections, **BEARDEN** lied about Pharmakon's never having received any out-of-specification drug potency test results.

38. **ELMER** learned of **BEARDEN**'s lies during or shortly after the FDA's inspections and took no action to correct her and to inform the FDA of the extent of Pharmakon's drug potency failures.

39. During the third FDA inspection, **ELMER** directed at least one Pharmakon employee to backdate records of compounded drugs.

40. **ELMER** and **BEARDEN** failed to investigate the root causes of the drug potency failures and otherwise failed to make changes in Pharmakon's compounding operations to reduce the incidence of these failures.

41. Instead, under the direction and supervision of **ELMER** and **BEARDEN,** Pharmakon continued to distribute under- and over-potent drugs, shipping these drugs before receiving the potency test results.

OVERT ACTS

In furtherance of the conspiracy, and to accomplish its purpose, at least one of the co-conspirators committed or caused to be committed, in the Southern District of Indiana, and elsewhere, at least one of the following overt acts, among others:

42. On or about March 6, 2014, during the first FDA inspection, **BEARDEN** falsely told FDA investigators that Pharmakon had not received any out-of-specification drug potency test results.

43. On or about April 23, 2014, after the second FDA inspection, **BEARDEN** and **ELMER** signed a letter to the FDA which falsely indicated that Pharmakon's first notification that midazolam lot #s E0433735C and E1016227C had any issues, was on March 26, 2014 – when Hospital 2 notified Pharmakon.

44. On or about February 4, 2016, after receiving an email from **BEARDEN** that discussed Pharmakon's failure to correct problems at Pharmakon previously identified by the FDA, **ELMER** told **BEARDEN** in an email "[p]lease do not send this in an email."

45. On or about February 18, 2016, during the third FDA inspection, **BEARDEN** falsely told FDA investigators that Pharmakon had not received any out-of-specification potency test results before learning of the potency failure of morphine sulfate lot # E52418EV11C.

46. On or about February 18, 2016, during the third FDA inspection, **ELMER** asked a Pharmakon pharmacist to backdate drug batch records while the FDA was requesting batch records.

All in violation of 18 U.S.C. § 371.

COUNTS 2-4
Introduction of Adulterated Drugs Into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 351

47. Paragraphs 1 through 30 are hereby realleged and incorporated by reference as if set forth herein.

48. On or about the dates specified as to each count listed below, in the Southern District of Indiana, and elsewhere, the defendants,

PAUL J. ELMER and
CAPRICE R. BEARDEN,

responsible corporate officers of Pharmakon, introduced and delivered for introduction into interstate commerce drugs as set forth in each count below, that were adulterated in the following way:

A. The drugs were purported to be and represented as drugs which were recognized in an official compendium and the strength of such drugs differed from the standard set forth in such compendium, pursuant to 21 U.S.C. § 351(b).

Count	Approximate Date	Drug	Potency	Recipient
2	1/9/2014	Fentanyl, lot #E16069DK1C	267% potent	Hospital 1, in Virginia
3	5/5/2015	Promethazine, lot #E083327Z2R	45% potent	Hospital 3, in Maryland
4	2/3/2016	Morphine sulfate, lot #E52418EV11C	2,460% potent	Hospital 4, in Illinois

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 351.

COUNTS 5-10
Adulterating Drugs While Holding for Sale After Shipment in Interstate Commerce
21 U.S.C. §§ 331(k), 333(a)(1), and 351

49. Paragraphs 1 through 30 are hereby realleged and incorporated by reference as if set forth herein.

50. On or about the dates specified as to each count listed below, in the Southern District of Indiana, the defendants,

PAUL J. ELMER and
CAPRICE R. BEARDEN,

responsible corporate officers of Pharmakon, did an act with respect to drugs set forth in each count below, while such drugs were being held for sale after the shipment of a drug component in interstate commerce, that resulted in such drugs being adulterated in the following way:

A. The drugs were purported to be and represented as drugs which were recognized in an official compendium and the strength of such drugs differed from the standard set forth in such compendium, pursuant to 21 U.S.C. § 351(b).

Count	Approximate Date	Drug	Potency	Component Supplier	Recipient
5	1/20/2014	Midazolam, lot #E0433735C	200% potent	Outside the State of Indiana	Hospital 2, in Indiana
6	1/21/2014	Midazolam, lot #E1016227C	200% potent	Outside the State of Indiana	Hospital 2, in Indiana
7	7/2/2014	Fentanyl citrate, lot #E30152DK5C	52% potent	Outside the State of Indiana	Hospital 5, in Indiana
8	11/18/2014	Midazolam, lot #E34082DK8C	7% potent	Outside the State of Indiana	Hospital 2, in Indiana
9	10/8/2015	Phenylephrine, lot #E0353613R	124% potent	Outside the State of Indiana	Hospital 2, in Indiana

10	2/3/2016	Morphine sulfate, lot #E52418EV11C	2,460% potent	Outside the State of Indiana	Hospital 2, in Indiana

All in violation of 21 U.S.C. §§ 331(k), 333(a)(1), and 351.

A TRUE BILL:

[redacted]

JOSH J. MINKLER
United States Attorney

By: _____
Cindy J. Cho
Assistant United States Attorney

_____ for
David A. Frank
Trial Attorney