IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA, Plaintiff, vs. ROBERT HARSHBARGER, JR., d/b/a AMERICAN INHALATION MEDICATION SPECIALISTS, INC., Defendant,	)	Case No. 12-40119-01-JAR Count 1: 21 U.S.C. § 331(a) Count 2: 18 U.S.C. § 1341 Counts 3-7: 18 U.S.C. § 1347 Counts 1-7: 18 U.S.C. § 2

INDICTMENT

The Grand Jury charges:

At all material times:

INTRODUCTION

1. **ROBERT HARSHBARGER, JR.**, is a registered pharmacist in the state of Tennessee who owns and operates American Inhalation Medication Specialists, Inc., ("AIMS"), a pharmacy located in Kingsport, Tennessee.

2. From in or about January 2004, through in or about August 2009, the exact dates being unknown to the Grand Jury, **ROBERT HARSHBARGER, JR.**, doing business as AIMS, engaged in a scheme to defraud Kansas Dialysis Services, L.C. ("Kansas Dialysis"), Kansas Dialysis patients, and various health

care benefit programs, including Medicare and Medicaid, by selling Kansas Dialysis a misbranded drug, by causing Kansas Dialysis to administer unwittingly a misbranded drug to its patients, and by causing false claims to be submitted to the various health care benefit programs for a misbranded drug. The misbranded drug was a non-FDA-approved iron sucrose product, which was administered to kidney dialysis patients in Kansas.

3. As a result of the scheme to defraud, Kansas Dialysis paid over $875,000 to **ROBERT HARSHBARGER, JR.**, and his business, AIMS. Additionally, health care benefit programs paid over $845,000 for the misbranded drug, and patients paid for the misbranded drug. Had Kansas Dialysis, the patients, and the health care benefit programs known they were paying for a misbranded drug, they would not have done so.

THE FOOD, DRUG, AND COSMETIC ACT

Purpose of the Act

4. The Food and Drug Administration ("FDA") is the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs are safe and effective for their intended uses. FDA's responsibilities include regulating the manufacture and distribution of drugs, including prescription drugs, shipped or received in interstate commerce,

as well as the labeling of such drugs. FDA carries out its responsibilities by enforcing the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* and other pertinent laws and regulations.

5. In enacting the FDCA, Congress sought to prevent America's drug supply from being compromised, and determined that the public interest in the purity of prescription drugs and pharmaceutical products distributed to American consumers warrants the imposition of high standards of care on those who distribute those products to the public. Under the FDCA, the responsibility for maintaining the quality and safety of drugs is not placed on the innocent public that purchases drugs, but is instead placed on those who sell and distribute drugs.

6. Under the FDCA, consumers have a right to expect that drug distributors will be vigilant and responsible in matters that affect the public health. Furthermore, consumers receiving pharmaceutical products from distributors in the United States have an expectation that the pharmaceuticals they are receiving are safe and have been approved by the FDA.

Drugs

7. The FDCA defines a "drug" as –

a. articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

b. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

c. articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

d. articles intended for use as a component of any articles specified in clause (a), (b), or (c). *See* 21 U.S.C. § 321(g)(1).

8. According to 21 U.S.C. § 353(b)(1), some drugs intended for human use can be dispensed only upon the valid prescription of a practitioner licensed by law to administer such drugs. These drugs are known as "prescription drugs." A drug is a prescription drug if, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A).

9. Iron sucrose is a "prescription drug" under the foregoing definitions.

Labeling

10. The term "labeling" is defined as "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." *See* 21 U.S.C. § 321(m). Labeling includes "brochures, booklets, mailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound prints, and similar pieces of printed, audio, or visual matter descriptive of a drug and references published . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor." *See* 21 C.F.R. § 202.1(i)(2).

11. The term "label" is defined as a display of written, printed, or graphic matter upon the immediate container of any article. *See* 21 U.S.C. § 321(k).

Misbranded Drugs

12. The FDCA states that a drug is deemed to be misbranded if, among other things:

a. its labeling is false or misleading in any particular, including material omissions. *See* 21 U.S.C. §§ 352(a), 321(n).

b. unless, in package form, it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. *See* 21 U.S.C. § 352(b).

c. the drug is offered for sale under the name of another drug. 21 U.S.C. § 352(i)(3).

THE SCHEME TO DEFRAUD

13. **ROBERT HARSHBARGER, JR.**, through AIMS, supplied Kansas Dialysis with what Kansas Dialysis believed to be Venofer©, an FDA-approved iron sucrose drug manufactured by American Regent. Venofer© is a prescription drug used to replenish the body's iron stores in adult patients with iron deficiency anemia associated with chronic kidney disease.

14. Chronic kidney disease is caused by damage to the kidneys which often results from high blood pressure and diabetes. Chronic kidney disease means that, over time, the kidneys do not function properly and cannot filter waste from the blood. Dialysis is a process that filters the blood when the kidneys no longer can.

15. American Regent is the sole approved manufacturer of Venofer©. American Regent and its authorized wholesalers/distributors are the only source

for FDA-approved Venofer©. Venofer© is the leading iron sucrose drug sold for iron deficiency associated with kidney disease, and it is the only iron sucrose drug that is FDA-approved for both pre-dialysis and post-dialysis treatment. There are no approved generic iron sucrose drugs.

16. Venofer© is administered either through a dialysis line or intravenously for non-dialysis patients.

17. **ROBERT HARSHBARGER, JR.**, invoiced Kansas Dialysis for Venofer©. But, in truth and in fact, as he well knew, **ROBERT HARSHBARGER, JR.**, was supplying Kansas Dialysis with misbranded iron sucrose products obtained from other than American Regent and its authorized wholesales/distributors, including from sources in China.

18. In or about September 2004, AIMS received a shipment of eight (8) kilograms of iron sucrose (also known as iron saccharate) from Qingdao Shengbang Chemical Company in Qingdao, China. **ROBERT HARSHBARGER, JR.**, continued to receive iron sucrose from China through at least June 2009, including shipments of iron sucrose from Shanghai Rory Fine Chemicals Co., Ltd., in Shanghai, China.

19. On or about August 4, 2009, a Kansas Dialysis employee made a recorded telephone call to **ROBERT HARSHBARGER, JR.**, under the guise that

Kansas Dialysis was being questioned by an American Regent sales representative about Kansas Dialysis's source for their Venofer©. The Kansas Dialysis employee asked **ROBERT HARSHBARGER, JR.**, about the source for the drug being provided in the pre-filled syringes. **ROBERT HARSHBARGER, JR.**, informed that he was supplying Kansas Dialysis with Venofer© that he was purchasing from a Florida pharmacy. **ROBERT HARSHBARGER, JR.**, expressed concern about American Regent stirring up trouble and stated: "They are going to try to get the FDA after us for repackaging, and I would rather not deal with the FDA."

20. On or about August 25, 2009, in response to a letter from Kansas Dialysis, **ROBERT HARSHBARGER, JR.**, left a voice mail message at Kansas Dialysis, informing that his source for the Venofer© was Cardinal Health, an authorized wholesaler of pharmaceuticals. But, in truth and in fact, the first purchase of Venofer© AIMS made from Cardinal Health occurred on July 24, 2009.

21. On or about September 16, 2009, **ROBERT HARSHBARGER, JR.**, confirmed that he received iron sucrose from China for approximately four (4) years because it was cheaper than purchasing Venofer©.

22. Venofer© was not provided in pre-filled syringes from the approved manufacturer, American Regent, or from any of its authorized wholesalers/ distributors. American Regent and its authorized wholesalers/distributors packaged and sold Venofer© in single-use, colorless, 5 milliliter glass vials (ampules).

23. The American Regent 5 milliliter ampules are labeled as Venofer©, with the National Drug Code 0517-2340-10, a unique universal product identifier for human drugs that registered drug manufacturers use. The American Regent label also contains the name and address of the manufacturer (American Regent, Inc., Shirley, NY 11967), a lot number, and an expiration date. Additionally, the Venofer© ampules contain the following label information:

> Each 5 mL contains: 100 mg elemental iron (as iron sucrose) in water for injection. The drug product contains approximately 30% sucrose w/v (300 mg/mL) and has a pH of 10.5-11.1. The osmolarity of the injection is 1250 mOsmol/L. Product contains no preservatives. Store at 25°C (77° F) [See USP]. Do not freeze. Sterile. Usual dosage: see package insert.

24. The labels on the syringes **ROBERT HARSHBARGER, JR.**, provided had lot numbers, code numbers, and a "use by" date, and contained the following information:

Each ml contains 20 mg elemental iron Sterile
Nonpyrogenic Rx only For Intravenous Injection or
Infusion Discard after single use (For Single-Use Only)
Store At Controlled Room Temperature (59° - 86° F)
and Protect From Light

The labels on the syringes did not have the name or address of the manufacturer. But, the invoices from AIMS indicated that the syringes were filled with Venofer©.

25. In April 2005, an employee of American Regent met with **ROBERT HARSHBARGER, JR.,** and discussed that iron sucrose was unstable in a syringe. In 2005, there were no safety or stability studies about the structure of the drug or its pH (acidity or alkalinity) when the drug was placed in a plastic syringe and stored.

26. **ROBERT HARSHBARGER, JR.**, supplied Kansas Dialysis with the misbranded iron sucrose in pre-filled plastic syringes, which Kansas Dialysis stored at room temperature for up to thirty (30) days.

27. Kansas Dialysis' Administrator had concerns about the stability of the drug in the pre-filled plastic syringes. The Administrator called to question **ROBERT HARSHBARGER, JR.**, about the stability of the drug in the pre-filled syringes. **ROBERT HARSHBARGER, JR.**, explained that he was able to

extend the stability of the drug by using a special room with controlled air flow and having employees wear special space suits when filling the syringes.

28. Using Federal Express, AIMS shipped the pre-filled syringes containing the misbranded iron sucrose from Tennessee to Kansas.

29. Kansas Dialysis used the misbranded iron sucrose **ROBERT HARSHBARGER, JR.,** supplied to treat dialysis patients at its various locations in Kansas, and thereafter billed the health care benefit programs to be reimbursed for what Kansas Dialysis had been led to believe was FDA-approved Venofer©.

30. Health Care Benefit Programs, including Medicare, Medicaid, TriCare, the Veterans' Administration, and Blue Cross/Blue Shield of Kansas, pay for dialysis services provided to their eligible beneficiaries who have chronic kidney disease and End Stage Renal Disease.

31. The Health Care Benefit Programs use nationally assigned billing codes for injectable drugs, such as Venofer©. The national Healthcare Common Procedure Coding System ("HCPCS") has assigned code J1756 for iron sucrose, including Venofer©. Because there is no FDA-approved generic iron sucrose drug, when HCPCS code J1756 is billed, it indicates to the health care benefit programs that the drug being administered is Venofer©.

32. Kansas Dialysis billed the Health Care Benefit Programs using HCPCS code J1756. From in or about January 2004, through in or about August 2009, the following Health Care Benefit Programs paid Kansas Dialysis the following approximate amounts for HCPCS Code J1756:

Health Care Benefit Program	**Amount Paid Kansas Dialysis for J1756**
Medicare	465,680.36
Veterans' Administration	135,812.97
Blue Cross/Blue Shield	187,467.05
Medicaid	46,463.59
TriCare	9,808.92
TOTAL	**845,232.89**

33. As a result of his scheme to defraud, **ROBERT HARSHBARGER, JR.,** exposed dialysis patients to unknown and unreasonable risks, and caused them to receive and pay for misbranded drugs.

COUNT 1
(Introducing Misbranded Drugs into Interstate Commerce)

34. The Grand Jury incorporates herein by reference Paragraphs 1 through 33, as though fully restated and realleged herein.

35. From in or about January 2004, and continuing through in or about August 2009, the exact dates being unknown to the Grand Jury, in the District of Kansas and elsewhere,

ROBERT HARSHBARGER, JR.,

with the intent to defraud and mislead, introduced, and caused to be introduced, into interstate commerce, misbranded drugs within the meaning of: (1) 21 U.S.C. § 352(a), in that its labeling was false and misleading in any particular; (2) 21 U.S.C. § 352(b)(1), in that, in package form, it failed to bear a label containing the name and place of business of the manufacturer, packer, and distributor; and (3) 21 U.S.C. § 352(i)(3), in that it was offered for sale under the name of another drug.

36. The foregoing is in violation of Title 21, United States Code, Section 331(a), and Title 18, United States Code, Section 2, with reference to Title 21, United States Code, Section 333(a)(2).

COUNT 2
(Mail Fraud)

37. The Grand Jury incorporates herein by reference Paragraphs 1 through 36, as though fully restated and realleged herein.

38. From in or about January 2004, and continuing through in or about August 2009, the exact dates being unknown to the Grand Jury, **ROBERT HARSHBARGER, JR.**, knowingly and intentionally devised and executed a scheme to defraud Kansas Dialysis Services and its patients, to whom he sold and distributed misbranded iron sucrose, by representing that the iron sucrose being sold and distributed to Kansas Dialysis Services and its patients was Venofer©, when in truth and in fact, as the defendant well knew, the iron sucrose was not the FDA-approved product Venofer©.

39. Over the course of the scheme to defraud, Kansas Dialysis Services paid **ROBERT HARSHBARGER, JR.**'s business, American Inhalation Medication Specialists, Inc., at least and approximately $875,412.50 for what Kansas Dialysis Services believed to be Venofer©.

40. On or about at least the following dates, in the District of Kansas and elsewhere, for the purpose of executing the scheme to defraud and attempting to do so,

ROBERT HARSHBARGER, JR.,

knowingly caused shipments of non-FDA approved iron sucrose, a misbranded drug, to be delivered by Federal Express Corporation, a private and commercial interstate carrier, according to the directions thereon, from Tennessee to Kansas:

Date Sent	Date Delivered	Invoice Number	Tracking Number
January 21, 2009	January 23, 2009	9-069-29456	797270078700
February 9, 2009	February 11, 2009	9-093-53100	797323506172
February 19, 2009	February 23, 2009	9-101-75389	796358176084
March 18, 2009	Marcy 20, 2009	9-134-73563	796440336021
March 31, 2009	April 2, 2009	9-150-67729	797466122563
April 1, 2009	April 3, 2009	9-150-67729	796481639761
April 7, 2009	April 9, 2009	9-158-89872	796498751999
April 14, 2009	April 16, 2009	9-167-39021	796519151468
April 23, 2009	April 27, 2009	9-175-36899	796547703911
May 18, 2009	May 19, 2009	9-207-42052	796617072864
May 21, 2009	May 22, 2009	9-207-42052	797616591234
May 27, 2009	May 29, 2009	9-214-82188	797629780677
June 5, 2009	June 9, 2009	9-230-90092	796671182420
June 16, 2009	June 17, 2009	9-239-05907	797686363577
June 19, 2009	June 23, 2009	9-246-70253	796709740988
June 26, 2009	June 30, 2009	9-254-35995	796728955914
July 6, 2009	July 7, 2009	9-262-10071	797738834542
July 8, 2009	July 10, 2009	9-262-10071	796759997508
July 16, 2009	July 20, 2009	9-270-30630	797769782194
August 3, 2009	August 5, 2009	9-293-23352	796829991290

41. The foregoing is in violation of Title 18, United States Code, Sections 2 and 1341.

COUNTS 3 - 7
(Health Care Fraud)

42. The Grand Jury incorporates herein by reference Paragraphs 1 through 36, as though fully restated and realleged herein.

43. From in or about January 2004, and continuing through in or about August 2009, the exact dates being unknown to the Grand Jury, **ROBERT HARSHBARGER, JR.**, submitted and caused to be submitted to health care benefit programs false claims for misbranded drugs. Had the health care benefit programs known that its beneficiaries were receiving misbranded drugs, they would not have paid for them.

44. From in or about January 2004, and continuing through in or about August 2009, in the District of Kansas and elsewhere,

ROBERT HARSHBARGER, JR.,

knowingly and willfully executed and attempted to execute a scheme and artifice to defraud the below-listed health care benefit programs by causing Kansas Dialysis to submit false claims under HCPCS Code J1756 for the FDA-approved iron sucrose drug Venofer©, knowing that he had provided Kansas Dialysis with misbranded drugs that were not FDA-approved, while invoicing Kansas Dialysis

for Venofer©, all in violation of Title 18, United States Code, Sections 2 and 1347:

Count	Health Care Benefit Program	Amount Paid
3	Medicare	465,680.36
4	Veterans' Administration	135,812.97
5	Blue Cross/Blue Shield	187,467.05
6	Medicaid	46,463.59
7	TriCare	9,808.92

FORFEITURE ALLEGATION – COUNTS 2-7

45. Upon conviction of one or more of the mail fraud and health care fraud offenses alleged in Counts 2 through 7 of this Indictment, defendant, **ROBERT HARSHBARGER, JR.**, shall forfeit to the United States, pursuant to 18 U.S.C. § 981(a)(1)(C) and § 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses. The property to be forfeited includes, but is not limited to, a sum of money equal to the amount of proceeds obtained as a result of the mail fraud and health care fraud offenses set out in Counts 2 through 7.

SUBSTITUTE PROPERTY

46. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p), to seek forfeiture of any other property of said defendant up to the value of the forfeitable property described above.

A TRUE BILL.

Dated: November 14, 2012

s/ Foreperson
FOREPERSON

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(It is requested that trial of the above captioned case be held in Topeka, Kansas.)