IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS
(Kansas City Docket)

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 08-20168-01/02/03/04/05-KHV/DJW
	)	
CRB, INC., dba AMERICAN BIOLOGICS,	)	
	)	
ROBERT W. BRADFORD,	)	
	)	
BRIGITTE G. BYRD,	)	
	)	
JOHN R. TOTH,	)	
and	)	
	)	
CAROLE R. BRADFORD,	)	
	)	
Defendants.	)	
_____	)	

SUPERSEDING INDICTMENT

The Grand Jury charges:

At all material times:

Introduction

1. The defendants in this case,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD,
JOHN R. TOTH, and
CAROLE R. BRADFORD

and others both known and unknown to the Grand Jury, engaged in a conspiracy and scheme to defraud and mislead the United States Food and Drug Administration ("FDA"), to defraud

individuals seeking medical care, and to violate the Federal Food, Drug, and Cosmetic Act (the "FDCA"), Title 21, United States Code, Section 301, *et seq*., by marketing, distributing, receiving, and causing the manufacturing, marketing, distributing, and receiving of a medical device and drugs not approved by the FDA, which conspiracy and scheme resulted in serious bodily injury and death.

The Defendants and the Businesses

2. Defendant **CRB, INC., dba AMERICAN BIOLOGICS** is a for-profit corporation organized under the laws of California, with its principal place of business on Walnut Avenue in Chula Vista, California. **CRB, INC., dba AMERICAN BIOLOGICS** is entirely owned or operated by defendants **ROBERT W. BRADFORD, BRIGITTE BYRD,** and **CAROLE R. BRADFORD**.

3. Defendant **ROBERT W. BRADFORD** is not a medical doctor, and has no medical or science degree from any accredited university in the United States, although he refers to himself as a "doctor" and as a "professor," and claims to be an innovative medical/biochemical pioneer and inventor. Defendant **ROBERT W. BRADFORD** is associated with the following businesses, in the capacities indicated:

a. **CRB, INC., DOING BUSINESS AS AMERICAN BIOLOGICS**. Defendant **ROBERT W. BRADFORD** claims to be CRB, Inc.'s Founder, Director of Research, and Scientific Director.

b. Robert Bradford Research Institute ("The Institute"). The Institute is a for-profit corporation organized under the laws of California, with its principal place of business on Walnut Avenue in Chula Vista, California.

Defendant **ROBERT W. BRADFORD** claims to be the Institute's Chief Executive Officer, Founder, and Director of Research. The Institute claims it has researched and developed four proprietary compounds: Dioxychlor, ostensibly used for the management of infectious microbes; Sulfoxime, ostensibly a broad-based systemic anti-fungal agent; Bio-Rizin, ostensibly to limit histamine production; and Bismacine, ostensibly used to combat bacterial and spirochetal diseases. Through the Institute, he also invented the Bradford Variable Projection Microscope ("Bradford Microscope") ostensibly used to identify pathologies and risk factors in health and disease.

c. RWB Compounds. RWB Compounds is a sole proprietorship, with its principal place of business on Walnut Avenue in Chula Vista, California. Defendant **ROBERT W. BRADFORD** is the sole proprietor of RWB Compounds. This entity was created during the course of the conspiracy.

d. Hospital in Mexico. American Biologics and The Institute are affiliated with a hospital in Tijuana, Mexico. American Biologics provided information about, promotional services for, and admissions services for the hospital. Defendant **ROBERT W. BRADFORD** claims to be the "scientific advisor" to the hospital. Defendant **ROBERT W. BRADFORD** and others conduct human intravenous drug experiments for, among other things, the treatment of Lyme disease at the hospital.

4. Defendant **BRIGITTE G. BYRD** is the Executive Vice President and Chief

Operating Officer of **CRB, INC., dba AMERICAN BIOLOGICS**.

5. Defendant **CAROLE R. BRADFORD** is the wife of Defendant Robert W. Bradford, as well as the Chief Executive Officer, Chairman of the Board, President, and Co-Founder, with Defendant **ROBERT W. BRADFORD**, of **CRB, INC., dba AMERICAN BIOLOGICS**.

6. Defendant **JOHN R. TOTH** was a medical doctor, licensed in Kansas to practice internal medicine. Defendant **JOHN R. TOTH** was the incorporator, director, and registered agent of The Luke Center for Integrative Health, Inc., a for-profit corporation organized under the laws of Kansas, with its principal place of business on S.W. 10th Street in Topeka, Kansas.

The Scheme to Defraud

7. The FDCA was enacted to ensure that drugs and medical devices sold for human use are safe and effective for their intended uses, and that the labeling of such drugs and medical devices contain true and accurate information.

8. The FDA is the agency of the United States responsible for enforcing the provisions of the FDCA. The FDA's responsibilities include, among other things, regulating the manufacturing, labeling, and distribution of drugs, drug components, and medical devices shipped and received in interstate commerce.

9. Beginning in or about September 2001, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD,** and others developed a strategy for marketing a medical device and drugs as a means to ostensibly diagnose and treat Lyme disease, which defendants **CRB, INC., dba AMERICAN BIOLOGICS**, **ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE**

R. BRADFORD, and others claimed was a disease that was under-diagnosed and was the underlying cause of many illnesses the medical community was not addressing, and could not address.

10. Lyme disease is transmitted to humans from the bite of infected deer ticks. Typical symptoms include fever, headache, fatigue, and a characteristic skin rash called erythema migrans.

11. Beginning in or about April 2004, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD,** and others wrote, and defendants **CRB, INC., dba AMERICAN BIOLOGICS**, **ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD,** and others distributed through The Bradford Research Institute, a report or monograph entitled "Lyme Disease, Potential Plague of the Twenty-First Century – Detection Problems Resolved by imaging with the Bradford Variable Projection High Resolution Microscope."

12. In this monograph, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD,** and others stated, among other things, that: (1) "Lyme disease has the ability to mimic many other diseases," and is commonly "associated" with a number of diseases as well, including but not limited to syphilis, depression, and Alzheimer's disease; (2) "it is estimated that Lyme disease may be a contributing factor in more than 50% of chronically ill people;" and, (3) most patients diagnosed as suffering from Chronic Fatigue Syndrome actually have Lyme disease.

13. Defendants, **CRB, INC., dba AMERICAN BIOLOGICS**, **ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD**, and others created and

executed a marketing plan through which they promoted a false "epidemic" of Lyme disease and created a demand for a microscope the defendants manufactured and claimed could diagnose the disease, and for drugs that defendants manufactured and claimed could cure the disease. The monograph made factual statements and cited sources as authority for those statements in order to convey credibility to the reader, when in truth and in fact those sources were false and misleading.

14. Neither the medical device nor the drugs that the defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD,** and others manufactured, marketed, and distributed had been reviewed and approved by the FDA for any reason.

Medical Device - The Microscope

15. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, and **CAROLE R. BRADFORD** under the auspices of the Bradford Research Institute, manufactured and sold a medical device called the Bradford High Resolution Variable Projection Microscope ("Bradford Microscope").

16. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, and **CAROLE R. BRADFORD** the Bradford Research Institute, and others, represented to purchasers that the Bradford Microscope: (1) enabled practitioners to perform functional assessments of their patients' health status; (2) was ideal for both clinical and research applications; (3) allowed the clinician-practitioner to, within minutes, quickly, easily, and cost-effectively detect subtle biochemical shifts that occur in the body thereby opening the way for innovative treatments as well as therapeutic follow-up and

management of diseases and metabolic imbalances; and (4) detected Lyme disease.

17. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and the Bradford Research Institute marketed the Bradford Microscope and various Bradford Peripheral Blood Assessments ("Bradford Assessments") as part of "The International Metabolic Research and Development Project" that defendant **ROBERT W. BRADFORD** falsely claimed was "registered" with the FDA.

18. The FDA did not approve or clear the Bradford Microscope or the Bradford Assessments for use or marketing in the United States for the assessment or diagnosis of Lyme disease, nor any other disease.

19. The FDA did not approve or clear any manufacturing and marketing of the Bradford Microscope and the Bradford Assessments in the United States.

Drugs - "Antimicrobial Treatment"

20. In conjunction with the Bradford Microscope and the Bradford Assessments, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others marketed a "protocol" of drugs that defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others, manufactured in a make-shift laboratory located in **CRB, INC., dba AMERICAN BIOLOGICS**' office in Chula Vista, California.

21. To manufacture these drugs, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R.**

BRADFORD, and others, purchased several chemicals that were not certified or intended by their manufacturers for use in foods, drugs, or cosmetics for humans or animals.

22. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others, received these chemicals in California in interstate commerce. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others, manufactured various drugs with these chemicals, then shipped these drugs through interstate commerce to a pharmacy in Colorado Springs, Colorado, where the pharmacy dissolved the drugs into aqueous solutions, based on "protocols" that were specific directions issued by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD,** and **CAROLE R. BRADFORD**.

23. Defendant **ROBERT W. BRADFORD** developed what he termed an "Antimicrobial Treatment" for diseases, including Lyme disease. As part of the "Antimicrobial Treatment" defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others manufactured the drugs Bismacine, Dioxychlor, Bio-Rizin, and Sulfoxime. This "Antimicrobial Treatment" involved the intravenous injection of these drugs.

24. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, and **CAROLE R. BRADFORD** made available "Antimicrobial Kits" containing Dioxychlor, Bio-Rizin, and Sulfoxime. Users purchased these drugs individually as well. The monograph directed that users take varying doses of these drugs in interval stages, and combined the use of these drugs with other nutrients and vitamins.

25. Bismacine is the trademarked name for an intravenous drug invented by defendant **ROBERT W. BRADFORD**, manufactured by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others at **CRB, INC., dba AMERICAN BIOLOGICS**. Bismacine is sometimes further dissolved into an aqueous solution and marketed and distributed by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others.

26. The active ingredient in Bismacine is Bismuth Citrate. Bismuth is a heavy metal that may cause renal complications, as the kidneys have difficulty filtering heavy metals from the bloodstream.

27. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others marketed and distributed Bismacine as a treatment for a variety of medical conditions, including Lyme disease.

28. Dioxychlor is the trademark of an intravenous drug invented by defendant **ROBERT W. BRADFORD**, manufactured by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others at **CRB, INC., dba AMERICAN BIOLOGICS**. It is further dissolved into an aqueous solution and marketed and distributed by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others.

29. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W.**

BRADFORD, BRIGITTE G. BYRD, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others marketed and distributed Dioxychlor to treat a variety of medical conditions, including Lyme disease.

30. Sulfoxime is the trademark of an intravenous drug invented by defendant **ROBERT W. BRADFORD**, manufactured by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others at **CRB, INC., dba AMERICAN BIOLOGICS**. It is further dissolved into an aqueous solution and marketed and distributed by defendants **CRB, INC., dba AMERICAN BIOLOGICS**, **ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others.

31. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others marketed and distributed Sulfoxime to treat a variety of medical conditions, including Lyme disease.

32. Bio-Rizin is the trademark of an intravenous drug invented by defendant **ROBERT W. BRADFORD**, manufactured by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others at **CRB, INC., dba AMERICAN BIOLOGICS**. It is further dissolved into an aqueous solution and marketed and distributed by defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others.

33. Defendants **CRB, INC., dba AMERICAN BIOLOGICS**, **ROBERT W.**

BRADFORD, BRIGITTE G. BYRD, **JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others marketed and distributed Bio-Rizin to treat a variety of medical conditions, including Lyme Disease.

34. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others profited from the sale of both the medical device and the drugs described herein. For example, for the period April 2004 to August 2006, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD**, and others, received over $400,000.00 for the Bradford Microscope and the drugs described herein.

35. **CRB, INC., dba AMERICAN BIOLOGICS**, the Bradford Research Institute, RWB Compounds, **ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH,** and **CAROLE R. BRADFORD**, are not registered with the FDA in any capacity as producers, manufacturers, preparers, propagators, compounders, and processors of either drugs or medical devices.

36. Because defendant **JOHN R. TOTH** knew that health care benefit programs would not pay for "alternative" therapies, he established the Alternative Therapies Health Association ("ATHA") as a separate entity from his licensed medical practice to bill patients for "alternative" therapies, and to receive payment from patients for those "alternative" therapies. Defendant **JOHN R. TOTH** operated ATHA out of The Luke Center for Integrative Health, Inc.

37. Defendant **JOHN R. TOTH** profited by charging his patients for his use of the Bradford Microscope and the intravenous injection of the drugs described herein. For example,

defendant **JOHN R. TOTH**, through ATHA, charged patients approximately $100 for each use of the Bradford Microscope, and approximately $320 for each intravenous "Antimicrobial Treatment."

COUNT 1 – CONSPIRACY
18 U.S.C. § 371

38. The Grand Jury incorporates by reference Paragraphs 1-37 as though fully restated and re-alleged herein.

39. Beginning in or about April 2004, and continuing through December 2008, the exact dates being unknown to the Grand Jury, in the District of Kansas and elsewhere, the defendants,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD,
JOHN R. TOTH, and
CAROLE R. BRADFORD,

knowingly and willfully combined, conspired, confederated, and agreed with each other and with other persons, both known and unknown to the Grand Jury:

a. to commit offenses as set forth in Counts 2-25 against the United States, that is:

(1) mail fraud, in violation of Title 18, United States Code, Sections 2 and 1341;

(2) introducing and causing the introduction of misbranded drugs into interstate commerce, in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), 352(a), and 352(o) and Title 18, United States Code, Section 2;

(3) receiving, and causing the receipt of, misbranded drugs in interstate commerce, and delivering them, and causing them to be delivered, for pay and otherwise, in violation of Title 21, United States Code, Sections 331(c), 333(a)(2), 352(a), and 352(o) and Title 18, United States Code, Section 2;

(4) introducing, and causing the introduction of, an adulterated and misbranded medical device into interstate commerce, in violation of Title 21, United States Code, Sections 331(a), 351(f)(1)(B), 352(o), and 333(a)(2) and Title 18, United States Code, Section 2; and

b. to defraud the United States and departments and agencies thereof, namely, the FDA, by impairing, impeding, and obstructing by craft, trickery, deceit, and dishonest means, the FDA's lawful and legitimate functions of regulating drugs and medical devices.

Manner and Means

40. Defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH, CAROLE R. BRADFORD**, and others used the following manner and means in furtherance of the conspiracy and scheme. In so doing, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH, CAROLE R. BRADFORD**, and others, at times, used and perverted otherwise lawful conduct to further the conspiracy and scheme.

41. During the course of and in furtherance of the conspiracy and scheme, defendants

CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD, and others manufactured and caused the manufacture of the Bradford Microscope for sale in interstate commerce, and marketed it as, and falsely represented it to be a medical device for the diagnosis of diseases, including Lyme disease.

42. During the course of and in furtherance of the conspiracy and scheme, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD**, **BRIGITTE G. BYRD, CAROLE R. BRADFORD**, and others manufactured and caused the manufacture of misbranded drugs, including Bismacine, Dioxychlor, Bio-Rizin, and Sulfoxime, and shipped and sold these misbranded drugs in interstate commerce.

43. During the course of and in furtherance of the conspiracy and scheme, defendants **CRB, INC., dba AMERICAN BIOLOGICS ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others distributed and caused the distribution in interstate commerce, misbranded drugs, including Bismacine, Dioxychlor, Bio-Rizin, and Sulfoxime, some of which were intravenously injected into individuals seeking medical treatment.

44. During the course of and in furtherance of the conspiracy and scheme, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others received and caused the receipt in interstate commerce, and thereafter delivered for pay and otherwise, misbranded drugs, including Bismacine, Dioxychlor, Bio-Rizin, and Sulfoxime.

45. During the course of and in furtherance of the conspiracy and scheme, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G.**

BYRD, **CAROLE R. BRADFORD**, and others failed to register with the FDA in any capacity as producers, manufacturers, preparers, propagators, compounders, and processors of either drugs or medical devices, knowing they were required to do so.

46. During the course of and in furtherance of the conspiracy and scheme, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others made material misrepresentations and omitted material facts to diagnose, and caused the diagnosis of, Lyme disease in individuals.

47. During the course of and in furtherance of the conspiracy and scheme, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH, CAROLE R. BRADFORD**, and others made material misrepresentations and omitted material facts to promote the use of intravenous injections of Bismacine, Dioxychlor, Bio-Rizin, and Sulfoxime to treat disease, including Lyme disease.

48. During the course of and in furtherance of the conspiracy and scheme, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH**, **CAROLE R. BRADFORD**, and others intravenously injected, and caused the intravenous injection of, Bismacine, which resulted in one individual in Kansas (B. G.) experiencing renal failure, and one individual in Kansas (B. W.) lapsing into a coma and eventually dying.

Overt Acts

49. In furtherance of the conspiracy and scheme, and to accomplish their purposes and objectives, one or more coconspirators committed in the District of Kansas and elsewhere the

following overt acts, among others:

a. Each of the factual allegations set forth in Counts 2-20, as described below, is incorporated and alleged as though stated herein, as an individual overt act done in furtherance of the conspiracy.

b. On or about August 9, 2001, in Chula Vista, California, defendant **CAROLE R. BRADFORD,** on behalf of **CRB, INC., dba AMERICAN BIOLOGICS**, entered into a "Nondisclosure Agreement" with a pharmacy in Colorado relating to **CRB, INC., dba AMERICAN BIOLOGICS'** "development, production, marketing and sale of certain drugs and related information and items . . ."

c. On or about September 4, 2001, in Chula Vista, California, defendant **CAROLE R. BRADFORD,** on behalf of **CRB, INC., dba AMERICAN BIOLOGICS**, entered into a licencing agreement with a pharmacy in Colorado relating to **CRB, INC., dba AMERICAN BIOLOGICS'** production and sale of Bio-Rizin, Dioxychlor, and Sulfoxime.

d. On or about October 27 through October 30, 2004, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH,** and **CAROLE R. BRADFORD** attended a meeting of the American Academy of Environmental Medicine in Hilton Head, South Carolina, where defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others promoted and advertised the Bradford Microscope and Antimicrobial Treatment to attendees, including defendant **JOHN R. TOTH**.

e. On or about November 3, 2004, defendants **CRB, INC., dba AMERICAN**

BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, and **CAROLE R. BRADFORD** mailed and caused to be shipped from California to defendant **JOHN R. TOTH** in Kansas monographs from the Bradford Research Institute entitled "Lyme Disease, Potential Plague of the Twenty-First Century."

f. On or about November 3, 2004, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others, mailed a letter, and caused a letter to be mailed to defendant **JOHN R. TOTH**, regarding the Bradford Microscope.

g. On or about November 16, 2004, defendant **JOHN R. TOTH** entered into a contract with **CRB, INC., dba AMERICAN BIOLOGICS** to purchase a Bradford Microscope.

h. On or about November 16, 2004, defendant **BRIGITTE G. BYRD** signed a Microscope System Work Order for customer and defendant **JOHN R. TOTH**.

i. On or about November 29, 2004, defendant **JOHN R. TOTH** received in interstate commerce a Bradford Microscope.

j. On or about December 2, 2004, defendant **JOHN R. TOTH** signed a Confidential Participation Agreement for Training in the International Metabolic Research and Development Project with Bradford Research Institute.

k. On or about December 2 through December 4, 2004, defendants **ROBERT W. BRADFORD** and **CAROLE R. BRADFORD** traveled to Topeka to train defendant **JOHN R. TOTH** and others in the use of the Bradford Microscope to purportedly diagnose Lyme disease and other diseases, and about **ROBERT W. BRADFORD'S** protocol for

treating Lyme Disease, which included the intravenous injection of Bismacine, Dioxychlor, Sulfoxime, and Bio-Rizin.

l. On or about December 16, 2004, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others entered into an Agreement and Addendum with a pharmacy in Colorado for the exclusive processing rights for Bismacine. This Agreement and Addendum added Bismacine to the list of drugs included in the original Licensing Agreement **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others entered into on or about September 4, 2001, with a pharmacy in Colorado for the exclusive processing rights for Dioxychlor, Bio-Rizin, and Sulfoxime.

m. On or about December 29, 2004, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others, shipped and caused to be shipped from California to Kansas a monograph from the Bradford Research Institute entitled "Lyme Disease, Potential Plague of the Twenty-First Century."

n. On or about January 1, 2005, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD**, and others had the monograph "Lyme Disease, Potential Plague of the Twenty-First Century" published in the Townsend Letter, a publication about alternative medicine.

o. On or about January 3, 2005, defendant **JOHN R. TOTH**, and others, held

a meeting with patients at The Luke Center to discuss diagnosing Lyme disease with the Bradford Microscope and to discuss treating Lyme disease with the Bradford protocol of intravenous injections of Bismacine, Dioxychlor, Bio-Rizin, and Sulfoxime.

p. On or about January 3, 2005, defendant **JOHN R. TOTH** sold to B. W. a copy of the monograph from the Bradford Research Institute entitled "Lyme Disease, Potential Plague of the Twenty-First Century."

q. On or about January 6, 2005, defendant **BRIGITTE G. BYRD** sent to a pharmacy in Colorado via facsimile an altered chemical Certificate of Analysis regarding bismuth.

r. On or about January 7, 2005, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, CAROLE R. BRADFORD**, and others transmitted and caused to be transmitted to a pharmacy in Colorado the first shipment of raw Bismacine in a peanut butter jar with what was described as a large, unidentified brown chunk in the jar.

s. On or about March 23, 2005, defendant **ROBERT W. BRADFORD** mailed and caused to be mailed from California to defendant **JOHN R. TOTH** in Kansas monographs from the Bradford Research Institute entitled "Lyme Disease, Potential Plague of the Twenty-First Century."

t. On or about April 11, 2005, defendant **JOHN R. TOTH** infused B. G. with Bismacine.

u. On or about April 18, 2005, defendant **JOHN R. TOTH** infused B. W. with Bismacine causing renal failure and lapse into a coma.

v. On or about April 19, 2005, defendant **JOHN R. TOTH** admitted B. G. into a hospital for renal failure.

w. On or about May 2, 2005, and on or about May 13, 2005, defendant **JOHN R. TOTH** ordered Bismacine from a pharmacy in Colorado, which the pharmacy shipped to defendant **JOHN R. TOTH** through interstate commerce.

x. Beginning on or about May 10, 2005, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others updated the written information in the monograph and elsewhere about Bismacine by eliminating references to American Biologics and adding contraindications and warnings.

y. On or about May 17, 2005, defendant **BRIGITTE G. BYRD** wrote a letter to defendant **JOHN R. TOTH**, responding to his request for defendant **ROBERT W. BRADFORD'S** curriculum vitae, stating in pertinent part: "[**CAROLE R. BRADFORD]** also discussed your request for Dr. Bradford's curriculum vitae with me . . . while [Dr. Bradford] personally offered you some Bismacine from his own therapeutic supply from the hospital he is involved with in Mexico, including his C.V. in your endeavors would directly involve American Biologics. Please understand we, 'American Biologics,' must walk a very defined straight line as a nutritional supplement company and the manufacturer of the BVPM Microscope System."

z. On or about May 31, 2005, defendants **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others sent an invoice to a pharmacy in Colorado for Bismuth Citrate,

charging the pharmacy for the material used to create Bismacine.

aa. On or about the following dates, defendant **JOHN R. TOTH** ordered from a pharmacy in Colorado the Antimicrobial Kit, which contained misbranded drugs, manufactured by defendants **CRB, INC., dba AMERICAN BIOLOGICS**, **ROBERT W. BRADFORD, BRIGITTE G. BYRD**, **CAROLE R. BRADFORD**, and others, and caused their introduction into interstate commerce, each order being an overt act in furtherance of the conspiracy:

Shipped On or About Date	**Location Shipped/ Location Received**
Dec. 10, 2004	Colorado/Kansas
Jan. 27, 2005	Colorado/Kansas
Jan. 28, 2005	Colorado/Kansas
Feb. 4, 2005	Colorado/Kansas
Feb. 10, 2005	Colorado/Kansas
Feb. 25, 2005	Colorado/Kansas
March 7, 2005	Colorado/Kansas
March 15, 2005	Colorado/Kansas
March 18, 2005	Colorado/Kansas
April 11, 2005	Colorado/Kansas

50. The foregoing is in violation of Title 18, United States Code, Sections 2 and 371.

COUNTS 2-9
MAIL FRAUD

51. The Grand Jury incorporates by reference Paragraphs 1-50 as though fully restated and re-alleged herein.

52. Having devised the above-described scheme and artifice to defraud, on or about the

dates set forth below, within the District of Kansas and elsewhere, the defendants,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD,
JOHN R. TOTH, and
CAROLE R. BRADFORD,

for the purpose of executing the aforesaid scheme and artifice to defraud, and attempting to do so, knowingly deposited and caused to be deposited, the things and matters described below, to be sent and delivered, by the U.S. Postal Service and private and commercial interstate carrier, according to the instructions thereon, and took and received therefrom, such things and matters as described below:

Count	On or About Date Deposited	Thing or Matter	Location Shipped/Location Received
2	November 3, 2004	Lyme Disease Monographs	California/Kansas
3	November 29, 2004	Bradford Microscope	California/Kansas
4	December 29, 2004	Lyme Disease Monographs	California/Kansas
5	January 27, 2005	Dioxychlor	Colorado/Kansas
6	March 23, 2005	Lyme Disease Monographs	California/Kansas
7	April 11, 2005	Dioxychlor	Colorado/Kansas
8	May 2, 2005	Bismacine	Colorado/Kansas
9	May 13, 2005	Bismacine	Colorado/Kansas

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

FOOD, DRUG, & COSMETIC ACT VIOLATIONS

The Food, Drug and Cosmetic Act

54. The FDCA defines “interstate commerce” as (1) commerce between any State or

Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any territory not organized with a legislative body. Title 21, United States Code, Section 321(b). The FDCA requires producers of drugs and medical devices to register with the FDA. New producers, upon first manufacturing, preparing, propagating, compounding, and processing drugs and medical devices, must immediately register their name and place of business. Title 21, United States Code, Section 360(c).

Drugs

55. Under the FDCA, a "drug" is defined, in relevant part, as any article intended for use in the diagnosis, cure, mitigation, treatment, and prevention of disease in man or other animals; and articles (other than food) intended to affect the structure and any function of the body of man or other animals; and articles intended for use as components of other drugs. Title 21, United States Code, Sections 321(g)(1)(B), (C), and (D).

Labeling and Misbranding

56. Under the FDCA, the term "label" means a display of written, printed, and graphic matter upon the immediate container of any article. Title 21, United States Code, Section 321(k). The term "labeling" means all labels and other written, printed, and graphic matter (1) upon any article and any of its containers and wrappers, and (2) accompanying such article. Title 21, United States Code, Section 321(m).

57. Under the FDCA, a drug is misbranded if its labeling (1) is false and misleading in any particular; and (2) is manufactured, prepared, propagated, and processed in an establishment not duly registered pursuant to Title 21, United States Code, Section 360. Title 21, United States Code, Sections 352(a) and 352(o). Labeling that omits information germane to the practitioner and patient

is false and misleading. Title 21, United States Code, Section 321(n). Additionally, factually true statements that bear no clinical relevance may also render labeling misleading.

58. The FDCA makes unlawful the introduction and delivery for introduction into interstate commerce, and the causing thereof, of any drug that is misbranded. Title 21, United States Code, Section 331(a).

59. The FDCA makes unlawful the receipt in interstate commerce, and the causing thereof, of any drug that is misbranded, and the delivery and proffered delivery thereof for pay and otherwise. Title 21, United States Code, Section 331(c).

Medical Devices

60. Under the FDCA, a "device" includes an instrument, apparatus, implant, machine, and other similar or related article, which is intended for use in the treatment and prevention of disease in man, which does not achieve its primary intended purposes through chemical action within and on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes. Title 21, United States Code, Section 321(h).

61. Pursuant to the FDCA, every manufacturer of a new medical device must obtain "clearance" and "approval" from the FDA prior to marketing its medical device. Title 21, United States Code, Sections 360(c) and 360e.

62. All medical devices marketed in interstate commerce in the United States fall into one of three regulatory classes under the FDCA: Class I, which are medical devices subject to the least stringent regulatory requirements; Class II, which are subject to an intermediate level of regulatory requirements; and, Class III, which are medical devices subject to the most stringent regulatory requirements. The classification assigned to each medical device is determined by the

degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of the medical device in its intended use. Title 21, United States Code, Section 360c.

63. The Medical Device Amendments to the FDCA became effective on May 28, 1976. If a medical device was not in commercial distribution before May 28, 1976, it is automatically a Class III medical device by operation of law. Title 21, United States Code, Section 360c(f)(1).

64. Class III medical devices cannot be legally marketed in the United States until the manufacturer submits to the FDA a Pre-Market Approval Application and the FDA approves the application. The FDA does not approve a Pre-Market Approval Application unless the information in the Pre-Market Approval Application provides the FDA with reasonable assurance that a medical device is safe and effective when used according to its labeling. Title 21, United States Code, Sections 360c(f)(1) and 360e(a).

65. As an alternative to submitting a Pre-Market Approval Application, the manufacturer of a new Class III medical device can seek to demonstrate to the FDA that its medical device should be classified as a Class I or Class II medical device, or that it is "substantially equivalent" to a legally marketed medical device for which pre-market approval was not required. Title 21, United States Code, Section 360c(a).

66. A manufacturer seeking a determination of "substantial equivalence" can submit to the FDA a "Pre-Market Notification" no later than ninety days before the manufacturer intends to introduce the medical device into interstate commerce. If the FDA makes a finding of "substantial equivalence," the medical device is then cleared for marketing in a manner consistent with the Pre-Market Notification approved by the FDA. Title 21, United States Code, Section 360c(a).

67. The Pre-Market Approval Application and a Pre-Market Notification are separate

methods for obtaining the FDA's permission to market a medical device. Until a medical device is approved for marketing under either the Pre-Market Approval Application process or cleared under the Pre-Market Notification process, whichever is applicable, the medical device cannot be legally marketed. Title 21, United States Code, Section 360c(a).

68. A Class III medical device is adulterated if it is required to have an approved Pre-Market Approval Application and did not have one in effect. Title 21, United States Code, Section 351(f)(1)(B).

69. A medical device of any class is misbranded if the manufacturer of a medical device fails to provide the FDA with the necessary Pre-Market Notification. Title 21, United States Code, Sections 360(k) and 352(o).

70. A medical device of any class is misbranded if it was manufactured by an establishment in any State and not duly registered under Title 21, United States Code, Section 360, and if it was not included in a list required by Title 21, United States Code, Section 360(j). Title 21, United States Code, Section 352(o).

71. The introduction and delivery for introduction into interstate commerce any adulterated and misbranded medical device and the causing thereof violates the FDCA. Title 21, United States Code, Section 331(a).

72. The receipt in interstate commerce of any medical device that is adulterated and misbranded, and the delivery and proffered delivery thereof for pay and otherwise, and the causing thereof, violates the FDCA. Title 21, United States Code, Section 331(c).

COUNT 10
INTRODUCTION OF A MISBRANDED DRUG (BISMACINE)
INTO INTERSTATE COMMERCE

73. The Grand Jury incorporates by reference Paragraphs 1-72 as though fully restated and re-alleged herein.

74. Between on or about October 29, 2004, and on or about April 11, 2005, in the District of Kansas and elsewhere, the defendants,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD,
JOHN R. TOTH, AND
CAROLE R. BRADFORD,

with the intent to defraud and mislead, introduced, and caused the introduction into interstate commerce of, Bismacine, a misbranded drug, in that its labeling was false and misleading in any particular, and the drugs came from an establishment that was not registered with the FDA as required by Title 21, United States Code, Sections 352(a) and 352(o).

75. The foregoing is in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS 11-14
INTRODUCTION OF A MISBRANDED DRUG
INTO INTERSTATE COMMERCE

76. The Grand Jury incorporates by reference Paragraphs 1-75 as though fully restated and re-alleged herein.

77. On or about the dates below, in the District of Kansas and elsewhere, the defendants,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD, and
CAROLE R. BRADFORD,

with the intent to defraud and mislead, introduced, and caused the introduction into interstate commerce of the following misbranded drugs, in that their labeling was false and misleading in any particular, and the drugs came from an establishment that was not registered with the FDA as required by Title 21, United States Code, Sections 352(a) and 352(o):

Count	On or About Date	Misbranded Drugs
11	January 27, 2005	Dioxychlor
12	April 11, 2005	Dioxychlor
13	May 2, 2005	Bismacine
14	May 13, 2005	Bismacine

78. The foregoing is in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNT 15
RECEIPT OF A MISBRANDED DRUG (BISMACINE) INTO INTERSTATE COMMERCE and THE DELIVERY THEREOF FOR PAY AND OTHERWISE

79. The Grand Jury incorporates by reference Paragraphs 1-78 as though fully restated and re-alleged herein.

80. Between on or about October 29, 2004, and on or about April 11, 2005, in the District of Kansas and elsewhere, the defendants,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD,
JOHN R. TOTH, and
CAROLE R. BRADFORD,

with the intent to defraud and mislead, received, and caused the receipt in interstate commerce of Bismacine, a drug as defined by Title 21, United States Code, Section 321(g)(1), and delivered and

caused to be delivered the drug for pay and otherwise, while the drug was misbranded in that its labeling was false and misleading in any particular, and the drugs came from an establishment that was not registered with the FDA as required by Title 21, United States Code, Sections 352(a) and 352(o).

81. The foregoing is in violation of Title 21, United States Code, Sections 331(c) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS 16-19
RECEIPT OF A MISBRANDED DRUG IN INTERSTATE COMMERCE and THE DELIVERY THEREOF FOR PAY AND OTHERWISE

82. The Grand Jury incorporates by reference Paragraphs 1-81 as though fully restated and re-alleged herein.

83. On or about the following dates, in the District of Kansas and elsewhere, the defendants,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD, and
CAROLE R. BRADFORD,

with the intent to defraud and mislead, received, and caused the receipt in interstate commerce of the following drugs as defined by Title 21, United States Code, Section 321(g)(1), and delivered and caused to be delivered the drugs for pay and otherwise, while the drugs were misbranded, in that their labeling was false and misleading in any particular, and the drugs came from an establishment that was not registered with the FDA as required by Title 21, United States Code, Sections 352(a) and 352(o):

Count	On or About Date	Misbranded Drugs
16	January 27, 2005	Dioxychlor

Count	On or About Date	Misbranded Drugs
17	April 11, 2005	Dioxychlor
18	May 2, 2005	Bismacine
19	May 13, 2005	Bismacine

84. The foregoing is in violation of Title 21, United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNT 20
INTRODUCTION OF ADULTERATED & MISBRANDED MEDICAL DEVICE INTO INTERSTATE COMMERCE

85. The Grand Jury incorporates by reference Paragraphs 1-84 as though fully restated and re-alleged herein.

86. From in or about October 2004, through on or about November 28, 2004, within the District of Kansas and elsewhere, the defendants,

CRB, INC., dba AMERICAN BIOLOGICS,
ROBERT W. BRADFORD,
BRIGITTE G. BYRD,
JOHN R. TOTH, and
CAROLE R. BRADFORD,

with the intent to defraud and mislead, introduced, delivered for introduction, and caused to be introduced and delivered for introduction into interstate commerce, namely from California to Kansas, an adulterated and misbranded medical device, namely the Bradford Variable Projection Microscope, a Class III medical device not approved by the FDA.

87. The foregoing is in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2) and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATIONS
FORFEITURE – MAIL FRAUD AND CONSPIRACY TO COMMIT MAIL FRAUD

88. The Grand Jury incorporates by reference Paragraphs 1-87 as though fully restated and re-alleged herein.

89. Upon conviction of one or more of the mail fraud offenses alleged in Counts 1 through 9 of this Superseding Indictment, defendants, **CRB, INC., dba AMERICAN BIOLOGICS, ROBERT W. BRADFORD, BRIGITTE G. BYRD, JOHN R. TOTH**, and **CAROLE R. BRADFORD**, shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 981 (a)(1)(C), and Title 28, United States Code, Section 2461(c), any and all property, real and personal, that constitutes and is derived, directly and indirectly, from proceeds traceable to the offenses. The property to be forfeited includes, but is not limited to, the following:

A. MONEY JUDGMENT

A sum of money equal to the amount of proceeds obtained as a result of the mail fraud offenses set out in Counts 1 through 9, for which the defendants are jointly and severally liable; and

FORFEITURE ALLEGATION
SUBSTITUTE PROPERTY

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

(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 Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of said defendants up to the value of the forfeitable property described above.

91. This is all pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c).

A TRUE BILL

September 9, 2009

s/Foreperson
FOREPERSON

s/Scott C. Rask, #15643 for
LANNY D. WELCH
United States Attorney
District of Kansas
1200 Epic Center
301 North Main
Wichita, Kansas 67202
(316) 269-6481
(316) 269-6484 (fax)
Kan. S. Ct. No. 13267
Lanny.Welch@usdoj.gov

[It is requested that trial be held in Kansas City, Kansas.]

Penalties:

Count 1:	Conspiracy - 18 U.S.C. § 371 NMT 5 years imprisonment; NMT $ 250,000 fine; NMT 3 years supervised release; $ 100 special assessment; Forfeiture Allegation.
Counts 2-9:	Mail Fraud - 18 U.S.C. § 1341 NMT 20 years imprisonment; NMT $ 250,000 fine; NMT 3 years supervised release; $ 100 special assessment; Forfeiture Allegation.
Counts 10-14	Introduction of a Misbranded Drug Into Interstate Commerce - 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f) NMT 3 years imprisonment; NMT $ 250,000 fine; NMT 3 years supervised release; $ 100 special assessment.
Counts 15-19	Receipt of a Misbranded Drug In Interstate Commerce and the Delivery Thereof For Pay or Otherwise - 21 U.S.C.§§ 331(c), and 333(a)(2) NMT 3 years imprisonment; NMT $ 250,000 fine; NMT 3 years supervised release; $ 100 special assessment.
Count 20	Introduction of Adulterated & Misbranded Medical Device Into Interstate Commerce - 21 U.S.C. §§ 331(a), 351(f)(1)(B), and 333(a)(2) NMT 3 years imprisonment; NMT $ 250,000 fine; NMT 3 years supervised release; $ 100 special assessment.