

ORIGINAL

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF GEORGIA MAR 28 2006

ATLANTA DIVISION

LUTHER D. THOMAS, Clerk  
By: Deputy Clerk

UNITED STATES OF AMERICA	:	
	:	CRIMINAL INDICTMENT
v.	:	
	:	NO. 1:06CR1534
LAURA BROWN, and	:	
STEPHEN MARK VAN ROOYEN	:	
aka MARK DEHAVILLAN,	:	
	:	
Defendants.	:	

THE GRAND JURY CHARGES THAT:

COUNTS ONE THROUGH TWENTY-FIVE

THE SCHEME

1. From in or about Spring 2002 and continuing through in or about the date of this Indictment, in the Northern District of Georgia and elsewhere, the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, did knowingly and willfully devise and intend to devise a scheme and artifice to defraud individuals suffering from ALS, multiple sclerosis, and other incurable diseases, and to obtain money from said individuals by means of materially false and fraudulent pretenses and representations.

2. The scheme was carried out by the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, providing false and misleading information to individuals suffering from incurable diseases

regarding the current state of the science of stem cell treatment.

#### **The Defendants**

3. BIOMARK INTERNATIONAL (hereinafter "BIOMARK"), is a company advertising treatment for amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, Parkinson disease, muscular dystrophy, and other incurable diseases. BIOMARK claimed to treat these diseases through the use and injection of stem cells derived from cord blood, for a fee ranging from \$10,000.00 to \$32,000.00 and at times negotiated by the customer.

4. BIOMARK had a website, [www.biomark-intl.com](http://www.biomark-intl.com), which reflected business locations in Atlanta, Georgia, Miami Beach, Florida, and Canada. BIOMARK's local address, as identified on the website, was 3180 Mathieson Drive, Suite 607, Atlanta, GA 30305. The building located at Mathieson Drive, Atlanta, GA, is a residential condominium. BIOMARK also had a business address of 4775 Collins Avenue, Suite 2102, Miami Beach, Florida. The multi-level structure at 4775 Collins Avenue contains residential condominiums.

5. The defendant LAURA BROWN was the Co-Director of BIOMARK, and also served as a consultant to patients who sought her advice on the treatment of various diseases using stem cell treatment.

6. The defendant STEPHEN MARK VAN ROOYEN, aka MARK

DEHAVILLAN, was the CEO and founder of BIOMARK.

**FDA STATUTES AND REGULATIONS**

7. The United States Food and Drug Administration (FDA) is charged by federal statute and regulation with responsibility for protecting the health and safety of the American public by, among other things, ensuring the safety and effectiveness of drugs distributed in the United States.

8. Under the Public Health Service Act (PHS Act), the term "biological product" is defined as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." Title 42, United States Code, Section 262(i).

9. Under the PHS Act, no person is permitted to introduce or deliver for introduction into interstate commerce any biological product unless, among other things, a biologics license is in effect for the biological product. Title 42 United States Code, Section 262(a)(1).

10. Biological products are exempt from the requirements of 42 U.S.C. § 262(a) only if they are the subject of an Investigational New Drug Application (IND). Title 42, United States Code, Section 262(a)(3) and Title 21, Code of Federal Regulations, Section 601.21.

11. Stem cells derived from cord blood indicated for the treatment of ALS, Parkinsons disease, muscular dystrophy, and other incurable diseases are biological products within the meaning of Title 42, United States Code, Section 262(I).

12. Under the Food, Drug, and Cosmetic Act (FD&C Act), many biological products are also drugs within the meaning of the 21 U.S.C. § 321(g). Biological products that are not licensed under 42 U.S.C. § 262(a) and that meet the FD&C Act's definition of a drug are subject to the FD&C Act's drug provisions, such as provisions related to drug adulteration, drug misbranding, and "new drugs," including the requirement that all "new drugs" must have an approved new drug application before marketing. Under 42 U.S.C. § 262(j), biological products that are licensed under 42 U.S.C. § 262(a) and that meet the FD&C Act's drug definition are exempt from compliance with the FD&C Act's "new drug" approval provisions; however, they are still subject to the FD&C Act's drug provisions related to adulteration and misbranding.

13. Under the FD&C Act, the term "drug" includes articles which are (1) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; or (2) intended to affect the structure or any function of the body of man. Title 21, United States Code, Sections 321(g)(1)(B) and (C).

14. Stem cells derived from cord blood indicated for the treatment of ALS, Parkinsons disease, muscular dystrophy, and other incurable diseases are drugs within the meaning of Title 21, United States Code, Section 321(g).

15. The FD&C Act prohibits the introduction or delivery for introduction into interstate commerce, or the causing thereof, of any drug that is adulterated or misbranded. Title 21, United States Code, Section 331(a).

16. Under the FD&C Act, a drug is deemed to be misbranded unless its labeling bears adequate directions for use. Title 21, United States Code, Section 352(f)(1).

17. Under the FD&C Act, the term "label" means a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k).

18. Under the FDCA, the term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

#### **MANNER AND MEANS**

19. The defendants, LAURA BROWN and STEPHEN VAN ROOYEN, recruited customers with the representation that science had proven the therapeutic power of stem cells and that BIOMARK was simply making it available to the world. The BIOMARK website

stated that "[a]ll ALS research now cites the promise of Stem Cells as the only answer."

20. The therapy as advertised by the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, was an injection of 1.5 million stem cells in the abdomen. A BIOMARK information packet explained that "[o]nce in the body, [stem] cells migrate to the site of the disease and begin producing the needed cells."

21. The defendants, LAURA BROWN and STEPHEN VAN ROOYEN, caused every customer to be injected with the same type and quantity of cells, regardless of their disease. The defendants, LAURA BROWN and STEPHEN VAN ROOYEN, obtained the cells from blood banks, which shipped the cells from locations in Texas and elsewhere to BIOMARK in Florida. BIOMARK shipped the cells from Florida to their customers' homes or to the offices of medical practitioners in various localities who would perform the injections for BIOMARK customers.

22. BIOMARK's stem cells were distributed in vials, which the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, caused to be labeled as containing 1.5 million stem cells.

23. The defendants, LAURA BROWN and STEPHEN VAN ROOYEN, placed numerous false, misleading, and inaccurate statements on the BIOMARK website and in other advertisements. The information has no scientific credibility and misled people who were seeking

treatment and cures for serious diseases.

24. BIOMARK's website partially quoted stem cell studies conducted by the University of Minnesota. The website implied that the research was related to the treatment of various diseases with stem cells. However, the author of the studies stated that the claims made by BIOMARK were false and misleading.

25. In an informational form entitled "Pre-Clinical Trial - Neurodegenerative Disease Treatment with Cord Blood Stem Cells: ALS/PLS," BIOMARK made several claims regarding the treatment of neurodegenerative diseases using stem cells derived from cord blood and provided findings from "pre-clinical" trials purporting to support their claims. The information on BIOMARK'S website minimized the risks to the patient and emphasized purported benefits. Further, the use of the term "Pre-Clinical Trial" is used to indicate studies involving non-humans.

26. No Investigation New Drug Application (IND), Biologics License Application (BLA), or New Drug Application (NDA) are on file with the FDA for BIOMARK. An IND would be necessary to perform a clinical trial in this country.

27. Even in studies conducted under a valid IND, a company may charge a fee for a product used in a study only if the sponsor of the IND petitions the FDA and is approved to recover its costs pursuant to 21 C.F.R. §312.7(d). The defendants, LAURA

BROWN and STEPHEN VAN ROOYEN, did not take any of these steps.

**EXECUTION OF THE SCHEME**

28. On or about the dates set forth below, each such instance being a separate count of this Indictment, in the Northern District of Georgia and elsewhere, the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, aided and abetted by each other and others known and unknown to the Grand Jury, for the purpose of executing and attempting to execute the aforesaid scheme and artifice, did cause to be transmitted in interstate commerce and foreign commerce, by means of a wire communication, certain signs, signals, and sounds, that is, the individuals listed below wired payments from their financial institutions to the Bank of America, Atlanta, Georgia, Account No. 0325365437, joint bank account of the defendants, LAURA BROWN and STEPHEN VAN ROOYEN.

Count	Date	Customer (patient)	City State	Amount
1	7/11/03	JS	Orlando, FL	\$21,000
2	9/3/03	SS	Los Angeles, CA	\$21,000
3	10/29/03	FC	Bronxville, NY	\$21,000
4	7/28/03	AG	Elk Grove, CA	\$10,000
5	7/11/03	JF	Alberta, Canada	\$21,000
6	10/28/03	JK	Brownstone, MI	\$10,000
7	10/21/03	FB	Williamstown, MA	\$10,000
8	10/14/03	GH	Beaver, UT	\$10,000
9	11/14/03	JR	NY, NY	\$5,000
10	6/3/05	JR	NY, NY	\$20,500
11	10/22/03	KG	Lufkin, TX	\$1,000
12	11/7/03	KG	Lufkin, TX	\$9,000
13	10/31/03	YK	Houston, TX	\$500
14	11/10/03	YK	Houston, TX	\$9,500
15	10/22/03	LK	Eugene, OR	\$5,000



16	11/13/03	RL	Arvada, CO	\$10,000
17	10/22/03	DG	Houston, TX	\$500
18	11/5/03	DG	Houston, TX	\$9,500
19	11/17/03	MS	Whitestone, NY	\$9,000
20	10/31/03	JM	Babylon, NY	\$18,900
21	11/4/03	RB	Philomath, OR	\$10,000
22	10/20/03	MC	Beaver, UT	\$6,000
23	10/23/03	FZ	Mahopac, NY	\$1,000
24	11/12/03	PL	Mesa, AZ	\$10,000
25	11/10/03	AA	Ft. White, FL	\$10,000

All in violation of Title 18, United States Code, Section 1343 and 2.

**COUNTS TWENTY-SIX THROUGH FIFTY-ONE**

**(Introduction of Misbranded Drugs into Interstate Commerce)**

28. The factual allegations of paragraphs 1 through 27 above are realleged and incorporated herein by reference.

29. On or about the dates set forth below, each such instance being a separate count of the Indictment, in the Northern District of Georgia and elsewhere, the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, aided and abetted by each other and others known and unknown to the Grand Jury, did, with intent to defraud or mislead, cause the introduction and delivery for introduction into interstate commerce of misbranded drugs, in that the drugs failed to bear any directions for use.

Count	Date	Customer (patient)	City, State	Misbranded Drug
26	7/21/03	TH	Atlanta, GA	stem cells derived from cord blood
27	7/11/03	JS	Orlando, FL	stem cells derived from cord blood
28	9/3/03	SS	Los Angeles, CA	stem cells derived from cord blood
29	10/29/03	FC	Bronxville, NY	stem cells derived from cord blood
30	7/28/03	AG	Elk Grove, CA	stem cells derived from cord blood
31	7/11/03	JF	Alberta, Canada	stem cells derived from cord blood
32	10/28/03	JK	Brownstone, MI	stem cells derived from cord blood
33	10/21/03	FB	Williamstown, MA	stem cells derived from cord blood
34	10/14/03	GH	Beaver, UT	stem cells derived from cord blood
35	11/14/03	JR	NY, NY	stem cells derived from cord blood
36	6/3/05	JR	NY, NY	stem cells derived from cord blood
37	10/22/03	KG	Lufkin, TX	stem cells derived from cord blood
38	11/7/03	KG	Lufkin, TX	stem cells derived from cord blood
39	10/31/03	YK	Houston, TX	stem cells derived from cord blood
40	11/10/03	YK	Houston, TX	stem cells derived from cord blood
41	10/22/03	LK	Eugene, OR	stem cells derived from cord blood
42	11/13/03	RL	Arvada, CO	stem cells derived from cord blood
43	10/22/03	DG	Houston, TX	stem cells derived from cord blood
44	11/5/03	DG	Houston, TX	stem cells derived from cord blood
45	11/17/03	MS	Whitestone, NY	stem cells derived from cord blood
46	10/31/03	JM	Babylon, NY	stem cells derived from cord blood
47	11/4/03	RB	Philomath, OR	stem cells derived from cord blood
48	10/20/03	MC	Beaver, UT	stem cells derived from cord blood
49	10/23/03	FZ	Mahopac, NY	stem cells derived from cord blood
50	11/12/03	PL	Mesa, AZ	stem cells derived from cord blood
51	11/10/03	AA	Ft. White, FL	stem cells derived from cord blood

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), 352(f), and Title 18, United States Code, Section 2.

**FORFEITURE NOTICE**

32. The allegations of Counts One through Twenty-five of this Indictment are realleged and incorporated herein by reference as though set forth fully herein for the purpose of alleging forfeiture to the United States pursuant to the provisions of Title 18, United States Code, Section 981(a)(1)(C).

33. Pursuant to Rule 32.2(a) Fed. R. Crim. P., the defendants are hereby notified that, if convicted of any of the offenses alleged in Counts One through Twenty-six, each defendant convicted shall forfeit to the United States pursuant to Title 18, United States Code, Section 981(a)(1)(C), his or her interest in any property, real or personal, that constitutes or is derived, directly or indirectly, from proceeds obtained, directly or indirectly, as a result of such violation(s).

**Money Judgment**

34. A sum of money equal to at least \$1.2 million in United States currency, representing the amount of proceeds obtained as a result of the offenses alleged in Counts One through Twenty-six, for which the defendants are jointly and severally liable.

35. Pursuant to Title 21, United States Code, Section 853(p), and as incorporated by Title 18, United States Code, Section 982(b), each defendant shall forfeit substitute property, up to the value of the amount described in paragraph 34 if, by any act or omission of the defendant, the property described in paragraph 33, or any portion thereof, cannot be located upon the exercise of due diligence; has been transferred, sold to or deposited with a third party; has been placed beyond the jurisdiction of the Court; has been substantially diminished in value; or has been commingled with other property which cannot be divided without difficulty. The property subject to forfeiture as substitute assets includes, but is not limited to, the items described in paragraph 34 above, and:

(a) All right, title, and interest in any and all property involved in the offenses charged in Counts One through Twenty-six, and all property traceable to such property, including the following: (1) all money or other property that was the subject of each transaction, transportation, transmission or transfer in violation of the offenses charged in Counts One through Twenty-six; (2) all commissions, fees and other property constituting proceeds obtained as a result of those violations; and (3) all property used in any manner or part to commit or to facilitate the commission of those violations. Such property shall include,

but not be limited to, all items and property set forth above in paragraph 34.

(b) A sum of money equal to the total amount of money involved in the wire fraud charges. If more than one defendant is convicted of an offense, the defendants so convicted are jointly and severally liable for the amount involved in such offense.

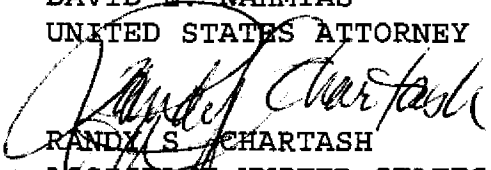
All in accordance with Title 18, United States Code, Section 982(a)(1) and (b), and Rule 32.2(a), Federal Rules of Criminal Procedure.

A True BILL

Merrilee Stephens

FOREPERSON

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