

UNITED STATES DISTRICT COURT

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for the

Western District of Washington

MAR - 1 2010

CLERK U.S. DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT TACOMA

In the Matter of the Search of
(Briefly describe the property to be searched
or identify the person by name and address)

The Natural Healing Clinic, owned by Dr. Rick
Marschall, located at 162 S. Barr Rd, Port Angeles,

Case No. MJT0-5035

APPLICATION FOR A SEARCH WARRANT

I, a federal law enforcement officer or an attorney for the government, request a search warrant and state under penalty of perjury that I have reason to believe that on the following person or property (identify the person or describe the property to be searched and give its location):

The Natural Healing Clinic, owned by Dr. Rick Marschall, located at 162 S. Barr Road, Port Angeles, WA 98362, as more fully described in Attachment A

located in the Western District of Washington, there is now concealed (identify the person or describe the property to be seized):

As fully described in Attachment B

The basis for the search under Fed. R. Crim. P. 41(c) is (check one or more):

- ☒ evidence of a crime;
☒ contraband, fruits of crime, or other items illegally possessed;
☒ property designed for use, intended for use, or used in committing a crime;
☐ a person to be arrested or a person who is unlawfully restrained.

The search is related to a violation of:

Code Section
21 U.S.C. 301 et seq.

Offense Description

The application is based on these facts:

☒ Continued on the attached sheet.

☐ Delayed notice of _____ days (give exact ending date if more than 30 days: _____) is requested under 18 U.S.C. § 3103a, the basis of which is set forth on the attached sheet.



Applicant's signature

Ken Petroff, Special Agent

Printed name and title

Sworn to before me and signed in my presence.

Date: 3/1/10

City and state: Tacoma, Washington



Judge's signature

J. RICHARD CREATURA, U.S. Magistrate Judge

Printed name and title

ATTACHMENT A

THE NATURAL HEALING CLINIC, owned by DR. RICK MARSCHALL, is located at 162 S. Barr Road, Port Angeles, WA 98362. The CLINIC sits on the west side of S. Barr Road and faces S. Barr Road. S. Barr Road intersects Highway 101 and the clinic is located south of Highway 101. The CLINIC is a blue one story building with a blue door which faces east, toward S. Barr Road. There is a wooden sign in front of the CLINIC which reads "RICK MARSCHALL ND" and "ROSE MARSCHALL RC CT."

ATTACHMENT B

ITEMS TO BE SEIZED

The following records, documents, files, or materials, in whatever form, including handmade or mechanical form (such as printed, written, handwritten, or typed); photocopies or other photographic form; and electrical, electronic, and magnetic form (such as tapes, cassettes, hard disks, floppy disks, diskettes, compact discs, CD-ROMs, DVDs, optical discs, Zip cartridges, printer buffers, smart cards, or electronic notebooks, or any other storage medium) that constitute evidence, instrumentalities, or fruits of violations of Title 21, United States Code, Sections 331 & 333, including but not limited to:

1. All unapproved versions of HUMAN CHORIONIC GONADOTROPIN (HCG). The only FDA approved versions of HCG are PREGNYL, OVIDREL, and NOVAREL. Also, any other drugs which appear to lack FDA approval. This would include the packaging, labeling, and containers for these drugs.
2. All documents, records, or materials regarding the ordering, purchase, distribution, receipt, prescription, or sale of HCG from suppliers to DR. RICK MARSCHALL or THE NATURAL HEALING CLINIC. This would include records of DR. MARSCHALL'S distribution, prescription, or sale of HCG to patients.
3. All import records, customs declarations, or correspondence with Customs and Border Protection (CBP), FDA, or the U.S. Postal Service regarding attempts to import HCG.
4. Telephone records, address books, phone lists, personal calendars, daily planners, journals, itineraries, rolodex indices, and contact lists associated with RICK MARSCHALL, THE NATURAL HEALING CLINIC, HCG, OVIDAC, HUCOG, TECHPOOL, BIO-PHARMA OF CHINA, BHARAT SERUMS AND VACCINES OF INDIA, PRATHAM PHARMA OF INDIA, CADILA HEALTHCARE OF INDIA, and KRS GLOBAL BIOTECHNOLOGY.
5. All records pertaining to any off-site business or storage location, (specifically, contracts, receipts, keys, notes, bills, or correspondence) owned, leased, or controlled by RICK MARSCHALL which could be used to store the above listed items.
6. Any documentation related to RICK MARSCHALL'S use of the term "endocrinologist." This would include diplomas, certificates, training courses, or endorsements.

7. Digital devices and/or their components, which include, but are not limited to:
 - a. Any digital devices and storage device capable of being used to commit, further, or store evidence of the offenses listed above;
 - b. Any digital devices used to facilitate the transmission, creation, display, encoding or storage of data, including word processing equipment, modems, docking stations, monitors, cameras, printers, plotters, encryption devices, and optical scanners;
 - c. Any magnetic, electronic or optical storage device capable of storing data, such as floppy disks, hard disks, tapes, CD-ROMs, CD-R, CD-RWs, DVDs, optical disks, printer or memory buffers, smart cards, PC cards, memory calculators, electronic dialers, electronic notebooks, and personal digital assistants;
 - d. Any documentation, operating logs and reference manuals regarding the operation of the digital device or software;
 - e. Any applications, utility programs, compilers, interpreters, and other software used to facilitate direct or indirect communication with the computer hardware, storage devices, or data to be searched;
 - f. Any physical keys, encryption devices, dongles and similar physical items that are necessary to gain access to the computer equipment, storage devices or data; and
 - g. Any passwords, password files, test keys, encryption codes or other information necessary to access the computer equipment, storage devices or data.
8. Evidence of who used, owned or controlled any seized digital device/s at the time the things described in this warrant were created, edited, or deleted, such as logs, registry entries, saved user names and passwords, documents, and browsing history;
9. Evidence of malware that would allow others to control any seized digital device/s such as viruses, Trojan horses, and other forms of malicious software, as well as evidence of the presence or absence of security software designed to detect malware; as well as evidence of the lack of such malware;
10. Evidence of the attachment to the digital device/s of other storage devices or similar containers for electronic evidence;
11. Evidence of counter-forensic programs (and associated data) that are designed to eliminate data from a digital device;
12. Evidence of times the digital device/s was used;
13. Any other ESI from the digital device/s necessary to understand how the digital device was used, the purpose of its use, who used it, and when, subject to the limitations set forth in paragraph 62 of the search warrant affidavit.

THE SEIZURE OF DIGITAL DEVICES AND/OR THEIR COMPONENTS AS SET FORTH
HEREIN IS SPECIFICALLY AUTHORIZED BY THIS SEARCH WARRANT FOR THE
PURPOSE OF CONDUCTING OFF-SITE EXAMINATIONS OF THEIR CONTENTS FOR
THE EVIDENCE, INSTRUMENTALITIES, OR FRUITS OF THE AFOREMENTIONED
CRIMES.

1
2 **AFFIDAVIT**

3 STATE OF WASHINGTON }
4 COUNTY OF PIERCE } ss

5 I, Special Agent Ken Petroff, hereby state as follows:

6 **AFFIANT BACKGROUND**

7 1. I am employed as a Special Agent with the Food and Drug Administration
8 (FDA), Office of Criminal Investigations (OCI). I am responsible for investigating
9 violations of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 et. seq.
10 I have received specialized training by the FDA regarding food and drug laws and
11 investigating violations of the FDCA. I have been employed as a law enforcement officer
12 since 1991. This affidavit is based upon my training, experience, knowledge,
13 involvement in discussions and events more particularly described below, and the
14 knowledge or involvement of others involved in this investigation.

15 **PURPOSE OF AFFIDAVIT**

16 2. This affidavit is submitted in support of a search warrant to be served at
17 THE NATURAL HEALING CLINIC located at 162 S. Barr Road, Port Angeles,
18 Washington 98362 (hereinafter, the Subject Premises). The request for authorization to
19 conduct a search at this location is based upon the development of facts which provide
20 probable cause to believe that evidence of DR. RICHARD (RICK) MARSCHALL's
21 involvement in the following crimes will be located at the Subject Premises: Causing the
22 illegal introduction in interstate commerce of misbranded drugs in violation of 21 U.S.C.
23 §§ 331(a) and 333(a)(2); Receiving in interstate commerce a drug that was misbranded,
24 and the delivery or proffered delivery thereof for pay or otherwise, in violation of
25 21 U.S.C. §§ 331(c) and 333(a)(2); Causing the introduction into interstate commerce of
26 an unapproved new drug, in violation of 21 U.S.C. §§ 331(d) and 333(a)(2); and False
27 Statements, in violation of 18 U.S.C. § 1001.

1 3. RICHARD MARSCHALL is the sole proprietor of THE NATURAL
2 HEALING CLINIC. The Subject Premises are more fully described in Attachment A of
3 this affidavit. Because this affidavit is being submitted for the limited purpose of
4 securing a search warrant, I have not included each and every fact known to me
5 concerning this investigation. I have set forth only those facts which I believe are
6 necessary to establish probable cause supporting the issuance of a search warrant.

7 **RELEVANT LAW**

8 **The Food, Drug and Cosmetic Act**

9 4. Under the FDCA, "label" means a display of written, printed, or graphic
10 matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term
11 "labeling" is defined as all labels and other printed or graphic matter upon any article or
12 any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

13 5. Under the FDCA, "drugs" are defined as, among other things: (A) articles
14 recognized in the official United States Pharmacopeia, official Homeopathic
15 Pharmacopeia, or official National Formulary, or any supplement to any of them; (B)
16 articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of
17 disease in man or other animals; (C) articles (other than food) intended to affect the
18 structure or any function of the body of man or other animals; and (D) articles intended
19 for use as a component of any articles specified in clause (A), (B), or (C).
20 21 U.S.C. § 321(g).

21 6. A "new drug" is any drug which is not generally recognized, among experts
22 qualified by scientific training and experience to evaluate the safety and effectiveness of
23 drugs, as safe and effective for use under the conditions prescribed, recommended, or
24 suggested in the labeling thereof. 21 U.S.C. § 321(p)(1). In order to be lawfully
25 marketed, sold or dispensed in the United States, a new drug had to be the subject of a
26 New Drug Application ("NDA") which had been approved by the FDA. 21 U.S.C. § 355.

27 7. A drug intended for use in man which, because of its toxicity, or other
28

1 | potentiality for harmful effect, or the method of its use, or the collateral measures
2 | necessary to its use, is not safe for use except under the supervision of a practitioner
3 | licensed by law to administer such drug; or a drug which is limited by an approved
4 | application under 21 U.S.C. § 355 to use under the professional supervision of a
5 | practitioner licensed by law to administer such drug, can only be dispensed by a
6 | practitioner licensed by law pursuant to a lawful prescription. 21 U.S.C. § 353(b)(1).
7 | These drugs are commonly known as "prescription drugs." Dispensing a prescription
8 | drug without a valid prescription by a licensed practitioner is deemed by statute to be an
9 | act which causes the drug to be "misbranded" while held for sale. 21 U.S.C. § 353(b).

10 | 8. Under the FDCA, every person engaging in the manufacture, preparation,
11 | compounding, or processing of drugs in any establishment which he or she owns or
12 | operates, is required to immediately register his or her name, places of business, and all
13 | such establishments. 21 U.S.C. § 360(c). The terms "manufacture, preparation,
14 | propagation, compounding, or processing" include repackaging or otherwise changing the
15 | container, wrapper, or labeling of any drug in furtherance of the distribution of the drug
16 | from the original place of manufacture to the person who makes the final sale to the
17 | ultimate consumer or user. 21 U.S.C. § 360(a)(1).

18 | 9. A drug is misbranded if, among other things, its labeling is false or
19 | misleading in any particular. 21 U.S.C. § 352(a). A drug is also misbranded if the
20 | labeling on the drug does not bear adequate directions for use. 21 U.S.C. § 352(f)(1).
21 | "Adequate directions for use" means directions under which a layman can use a drug
22 | safely and for the purposes for which it was intended without a doctor's supervision.
23 | 21 C.F.R. § 201.5. This regulation goes on to state: "Directions for use may be
24 | inadequate because....of omission, in whole or in part, or incorrect specification of:
25 | (a) Statements of all conditions, purposes, or uses for which such drug is intended,
26 | including conditions, purposes, or uses for which it is prescribed, recommended, or
27 | suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or

1 uses for which the drug is commonly used."

2 10. Directions under which a layperson can use a drug safely cannot be written
3 for a prescription drug because such drugs can, by definition, only be used safely (if at
4 all) at the direction, and under the supervision, of a licensed practitioner. Approved
5 prescription drugs dispensed pursuant to a valid prescription are exempt from having
6 adequate directions for use by a layperson. But prescription drugs that are unapproved
7 new drugs or dispensed without a valid prescription are necessarily misbranded for
8 lacking adequate directions for use.

9 11. Dispensing a prescription drug without a valid prescription by a licensed
10 practitioner is deemed by statute to be an act which results in the drug being misbranded
11 while held for sale. 21 U.S.C. § 353(b)(1).

12 12. Under the FDCA, the doing or causing of the following acts, among others,
13 is prohibited:

14 a. The introduction or delivery for introduction into interstate
15 commerce of any drug that is misbranded (21 U.S.C. § 331(a)).

16 b. The receipt in interstate commerce of any drug that is misbranded,
17 and the delivery or proffered delivery thereof for pay or otherwise
18 (21 U.S.C. § 331(c)).

19 c. The introduction or delivery for introduction into interstate
20 commerce of an unapproved new drug (21 U.S.C. § 331(d)).

21 d. The doing of any act with respect to a drug, if such act is done
22 while the drug is held for sale (whether or not the first sale) after
23 shipment in interstate commerce, which results in the drug being
24 misbranded (21 U.S.C. § 331(k)).

25
26 **SUBJECT OF INVESTIGATION AND SUMMARY**

27 **Dr. Richard Marschall**

1 13. DR. RICHARD MARSCHALL is a licensed naturopathic physician in the
2 State of Washington. Under Washington state law, naturopathic physicians are allowed,
3 among other things, to prescribe and administer prescription drugs within their practice.
4 According to both Washington State Department of Licensing and Washington State
5 Department of Revenue records, RICHARD MARSCHALL is the sole proprietor of the
6 NATURAL HEALING CLINIC located at Subject Premises. MARSCHALL also
7 advertises his naturopathy practice on two websites, www.drrickmarschall.com and
8 <http://weight-lossdoctor.com>.

9 14. In 1997, the State of Washington Department of Health (DOH),
10 Naturopathy Program charged MARSCHALL with Unprofessional Conduct for
11 diagnosing patients with "functional hypothyroidism" and prescribing prescription thyroid
12 hormone drugs to treat this diagnosis based solely on telephone, email and mail
13 communications, without performing any physical examinations of the patients. In July
14 1998, the DOH suspended MARSCHALL's license for 30 months on the condition that
15 he could continue practicing if he did not treat out-of-state patients without physically
16 examining them and treating them in tandem with a health-care professional from the
17 state where the patient resides. On MARSCHALL's current website, he advertises that he
18 "treats patients from all over the United States. Some patients fly in to see him and others
19 consult with him over the phone."

20 15. The current investigation has revealed that MARSCHALL has been causing
21 the importation of misbranded and unapproved new drugs containing the hormone human
22 chorionic gonadotropin (HCG), in violation of the FDCA. HCG is the active ingredient
23 in several FDA approved drugs, including:

- 24 a. Pregnyl®, manufactured by Baxter Pharmaceutical Solutions LLC
25 for the NDA-holder, ORGANON USA INC., is approved for prepubertal
26 cryptorchidism (undescended testicles in children) not due to anatomical
27

1 obstruction; selected cases of hypogonadotropic hypogonadism
2 (hypogonadism secondary to a pituitary deficiency) in males; and induction
3 of ovulation and pregnancy in the anovulatory, infertile woman in whom the
4 cause of anovulation is secondary and not due to primary ovarian failure,
5 and who has been appropriately pretreated with human menopausal gonadotropins.

6 b. Ovidrel®, manufactured by EMD Serono, is a recombinant HCG
7 indicated for the induction of final follicular maturation and early
8 luteinization in infertile women who have undergone pituitary
9 desensitization and who have been appropriately pretreated with follicle
10 stimulating hormones as part of an Assisted Reproductive Technology
11 (ART) program such as in vitro fertilization and embryo transfer. Ovidrel®
12 is also indicated for the induction of ovulation (OI) and pregnancy in
13 anovulatory infertile patients in whom the cause of infertility is functional
14 and not due to primary ovarian failure.

15 c. Novarel®, manufactured by DRAXIS Specialty Pharmaceuticals
16 Inc., Quebec, Canada for Ferring Pharmaceuticals Inc., Parsippany, NJ
17 07054, is indicated for prepubertal cryptorchidism not due to anatomic
18 obstruction, selected cases of hypogonadotropic hypogonadism
19 (hypogonadism secondary to a pituitary deficiency) in males, and induction
20 of ovulation and pregnancy in the anovulatory, infertile woman in whom the
21 cause of anovulation is secondary and not due to primary ovarian failure,
22 and who has been appropriately pretreated with human menopausal gonadotropins.

23 16. Numerous other uses of HCG are known to occur, although the FDA has
24 not approved any HCG drug for other uses. HCG has gained popularity as a weight loss
25 aid despite no evidence that it is safe or effective in promoting weight loss. Indeed, the
26 approved labeling of Pregnyl®, Ovidrel® and Novarel® all contain the following
27 warning statement:

1 HCG HAS NOT BEEN DEMONSTRATED TO BE
2 EFFECTIVE ADJUNCTIVE THERAPY IN THE
3 TREATMENT OF OBESITY. THERE IS NO
4 SUBSTANTIAL EVIDENCE THAT IT INCREASES
5 WEIGHT LOSS BEYOND THAT RESULTING
6 FROM CALORIC RESTRICTION, THAT IT CAUSES A
7 MORE ATTRACTIVE OR "NORMAL" DISTRIBUTION
8 OF FAT, OR THAT IT DECREASES THE HUNGER AND
9 DISCOMFORT ASSOCIATED WITH
10 CALORIE-RESTRICTED DIET.

11 18. Despite the lack of scientific evidence of safety and efficacy of using HCG
12 for weight loss, on his website www.DRRICKMARSCHALL.com, MARSCHALL refers
13 to himself as a "Weight-Loss Doctor" and advertises the use of HCG as a weight loss
14 drug. MARSCHALL'S web site claims: "Patients who went through the HCG injections
15 lost 1 pound a day and kept the weight off to 70% over the period of 1936-1956."
16 Another claim on this website reads: "Your body will sculpt the fat from the hips,
17 buttocks, thighs, nape of the neck, breasts and belly, leaving the healthy fat alone and
18 giving you the body you had as a young adult."

19 THE INVESTIGATION

20 The First Seizure of HCG Intended for Marshall

21 19. In February of 2009, Customs and Border Protection (CBP) officers at the
22 International Mail facility at JFK Airport in New York detained and examined an
23 incoming parcel from India which was addressed to RICK A. MARSCHALL at the
24 Subject Premises. After finding the parcel contained human drugs, CBP referred the
25 package to FDA's New York District Office. The package contained 15 boxes of a
26 product called HUCOG, CHORIONIC GONADOTROPHIN INJECTION in 5000 IU
27 units. The labeling on the boxes revealed the HUCOG was manufactured by Techpool
28 Bio-Pharma of China and marketed by Bharat Serums and Vaccines, Limited of India.
The package indicated that it was mailed to MARSCHALL from Pratham Pharma of

1 Mumbai, India.¹

2 20. On approximately February 6, 2009, FDA Compliance Officer Kristen
3 Campbell of the New York Office sent a Notice of FDA Detention to RICK A.
4 MARSCHALL at 162 South Barr Road, Port Angeles, Washington (Subject Premises).
5 The Detention Notice advised MARSCHALL that "A mail shipment addressed to you
6 from a foreign country is being held by the post office at the request of the U.S. Food and
7 Drug Administration (FDA)." The FDA Detention Notice also stated that the Chorionic
8 Gonadotropin was subject to refusal of admission into the United States because the
9 article appeared to be "Misbranded" under 21 U.S.C. § 352(f)(1) and thus could be
10 refused entry pursuant to 21 U.S.C. § 381(a)(3): "The article appears to lack adequate
11 directions for use, and does not appear to be exempt from the requirement for such
12 directions." ("A drug shall be deemed to be misbranded unless its labeling bears adequate
13 directions for use." 21 U.S.C. §352(f)(1)). The Detention Notice advised MARSCHALL
14 that if he had good reason to believe that the product complied with the law, he could
15 discuss the matter with FDA Compliance Officer Kristen Campbell.

16 21. On February 17, 2009, Kristen Campbell received an email from
17 RICKMARSCHALL@MSN.COM regarding this HCG detention. The content of the
18 email is as follows:

19 Dear Kristen,

20 I am an endocrinologist, a hormone expert. I use Human Chorionic
21 Gonadotropin to treat infertile patients. I require it in 5,000 units ampules
22 most of the time. Some times I use 10,000 unit ampules which I can get
23 from American pharmaceutical manufacturers. But American
24 manufacturers do not make 5,000 unit ampules. HCG has only a 60 day
shelf life so when I need 5,000 unit ampules to treat over a longer period of
time I must purchase them from pharmaceutical manufacturers who make it

25 ¹ I was unable to find a website for Pratham Pharma while searching the Internet. I did find an
26 Internet article on the website, behindonlinepharma.com, in which the authors, a group of investigative
27 journalism graduate students from Columbia University in New York City, describe purchasing the drug
28 Prozac from an Internet website. The Prozac was delivered to the authors from Pratham Pharma with the
same return address (in India) as that listed on RICK MARSCHALL'S package. According to the
authors, the package was shipped through India Post and the U.S. Postal Service before reaching them.

1 that way and they happen to be in other countries. I have been in practice
2 23 years and I have a lot of experience with HCG. The HCG that I get from
3 these suppliers works just as well as the HCG I get from US manufacturers
4 and cost about the same.

5 I hope you will release my shipment soon, I have several patients in need of
6 treatment. If I can answer any other questions you have please email me.

7 Dr. Rick Marschall

8 FDA did not release the shipment of HCG to MARSCHALL.

9 22. On February 19, 2009, after receiving the email from MARSCHALL,
10 Kristen Campbell sought the advice of FDA Consumer Safety Officer Bill Nychis of
11 FDA's Center for Drug Evaluation and Research (CDER). Nychis has experience in
12 dealing with imported HCG. Nychis advised Campbell to keep the HCG under detention
13 since it appeared to be an unapproved new drug.

14 27. Neither of MARSCHALL's websites mentions treating patients for
15 infertility. Both websites discuss the use of HCG for weight loss.

16 28. MARSCHALL's primary website states, "I am primarily a bariatric
17 endocrinologist, though family medicine has been the backbone of my practice." I have
18 searched the Washington DOH website and have been unable to find a definition for a
19 bariatric endocrinologist. The DOH website glossary does provide a definition for an
20 endocrinologist. "An endocrinologist is a medical doctor who specializes in diseases and
21 disorders of the endocrine system (such as thyroid diseases and diabetes)." According to
22 the DOH, as well as MARSCHALL's own websites, DR. MARSCHALL is a
23 Naturopathic Doctor (ND), not a Medical Doctor (MD).

24 29. Soon after initiating this investigation in June of 2009, I learned that
25 Investigator Carol Neva of DOH was also investigating DR. MARSCHALL. Investigator
26 Neva was and is investigating MARSCHALL for prescribing HCG to a patient without a
27 proper examination of that patient. In November of 2009, Investigator Neva and I
28 discussed whether DR. MARSCHALL could rightfully refer to himself as an

1 endocrinologist as he does on his website. On November 2, 2009, Carol Neva forwarded
2 me an email from Susan Gragg, Naturopathy Program Manager at the DOH. Ms. Gragg
3 advised that a naturopath cannot refer to himself as an endocrinologist. According to Ms
4 Gragg, "An Endocrinologist is an MD or DO physician who is board certified either in
5 Internal Medicine AND sub-specialty board certified in Endocrinology, Diabetes, and
6 Metabolism or sub-specialty board certified in Pediatric Endocrinology." Ms. Gragg
7 stated that "bariatrics" refers to the causes, preventions, and treatments of obesity.
8 Bariatrics is not specific to a particular profession.

9 **THE SECOND SEIZURE OF HCG INTENDED FOR MARSCHALL**

10 30. In June or July of 2009, a second package of HCG mailed from Pratham
11 Pharma in Mumbai, India, and addressed to RICK A. MARSCHALL at the Subject
12 Premises was stopped and examined by CBP at JFK Airport in New York. The package
13 contained 15 boxes of OVIDAC, CHORIONIC GONADOTROPHIN INJECTION, HCG
14 5000 IU. OVIDAC is manufactured by Cadila Healthcare Limited of India and marketed
15 by German Remedies (a division of Cadila Healthcare Limited) of Mumbai, India. Once
16 again, the package was referred to the FDA's New York District Office.

17 31. On July 2, 2009, FDA Compliance Officer Helen Jacobs sent a Notice of
18 FDA Detention to RICK MARSCHALL at the Subject Premises. The Detention Notice
19 advised MARSCHALL that his shipment of Chorionic Gonadotropin was being detained
20 because "The article appears to be a new drug without an approved new drug
21 application." Pursuant to 21 U.S.C. § 355, "No person shall introduce or deliver for
22 introduction into interstate commerce any new drug, unless an approval of [a new drug
23 application] is effective with respect to such drug." The Detention Notice advised
24 MARSCHALL that if he had good reason to believe that the product complied with the
25 law, he could discuss the matter with Compliance Officer Helen Jacobs.

26 32. On July 14, 2009, Helen Jacobs received an email from the address
27 RICKMARSCHALL@MSN.COM which read as follows:

1 Helen Jacobs, Compliance Officer

2 Dear Helen,

3 This letter is regarding a 15 piece shipment of 5,000 units of chorionic
4 gonadotropin (cg). I currently purchase CG in 10,000 unit amounts from 4
5 different American pharmaceutical companies who ONLY manufacture CG
6 in this amount for the treatment of certain patients. I would be happy to
7 provide you with evidence of these purchases if necessary. I must prescribe
8 CG in 5,000 unit doses to other patients but these amounts can only be
9 purchased from companies outside the U.S. This is the only prescription
10 medicine I purchase outside of the United States but it is necessary for my
11 patients. Please release this purchase and consider keeping this letter on file
12 for future purchases if possible.

13 Sincerely,
14 Dr. Rick Marschall

15 FDA did not release the shipment of HCG to MARSCHALL.

16 33. After receiving MARSCHALL'S email, Helen Jacobs contacted Bill Nychis
17 of FDA's Center for Drug Evaluation and Research for advice. Nychis explained that the
18 FDA approved products which contain HCG are utilized to promote ovulation induction,
19 and therefore increase the chances of pregnancy. The drug Pregnyl® is FDA approved
20 and contains HCG. In an email to Jacobs on July 14, 2009, Nychis stated, "Pregnyl
21 consists of a lyophilized powder and a sterile diluent for reconstitution prior to injection.
22 It is FDA's position that the lyophilized powder is not an active pharmaceutical ingredient
23 (API), but a finished drug product. If DR. MARSCHALL wishes to import a similar
24 product, it must be the subject of an approved New Drug Application (NDA).
25 Consequently, if such product does not have NDA approval, we can detain it as an
26 unapproved new drug. In the world of performance enhancing drugs, HCG is
27 increasingly used in combination with various anabolic, androgenic steroid (AAS) cycles.
28 Unapproved HCG is also imported and used for weight loss."

34. I have checked the FDA Center for Drug Evaluation and Research database
for approved New Drug Applications (NDA's) for both HUCOG and OVIDAC and have
found that neither drug has received FDA approval.

TRASH SEARCHES CONDUCTED AT

MARSCHALL'S RESIDENCE AND CLINIC

35. MARSCHALL's residence is located at 196 S. Barr Road in Port Angeles. The residence sits directly behind (just west of) the NATURAL HEALING CLINIC. Murrey's Olympic Disposal of Port Angeles is the trash collection service in the area where the clinic is located. According to Customer Information records obtained from Murrey's, the trash collection account at 196 S. Barr Road in Port Angeles, Washington, is in the name of RICK MARSCHALL with a phone number of (360) 457-1515. The trash collection account at the Subject Premises, is in the name of NATURAL HEALING, with a phone number of (360) 457-1515.

36. On July 30, 2009, I observed the trash collector from Murrey's pick up the trash from THE NATURAL HEALING CLINIC at the Subject Premises and the MARSCHALL residence at 196 S. Barr Road in Port Angeles, WA. The trash from the two locations was not separated from each other, but was not intermingled with trash from any other locations. Among other items in the trash, I found a foil and plastic package for HUCOG, 5000 IU, CHORIONIC GONADOTROPHIN INJECTION. The lyophilized powder of HCG had been removed but the small vial of Sodium Chloride for injection was intact. HUCOG is the same product seized by CBP and detained by FDA at JFK Airport in February of 2009. I also found an empty cardboard box and package insert for OVIDAC HCG 5000 IU, CHORIONIC GONADOTROPHIN INJECTION. OVIDAC is the same product seized by CBP and detained by FDA at JFK Airport in July of 2009.

37. On January 14, 2010, I conducted another trash search at the NATURAL HEALING CLINIC and the MARSCHALL residence. On this occasion, I rode with the Murrey's Disposal driver and observed him place plastic trash bags from the NATURAL HEALING CLINIC into a trash barrel. We then backed into the driveway of 196 S. Barr Road, and I observed the driver place plastic trash bags from the MARSCHALL residence into a separate trash barrel. I searched the contents of both barrels. In the trash

1 collected from the NATURAL HEALING CLINIC, I found some empty cardboard boxes
2 bearing the name GBTRX, INC of Boca Raton, Fl. There were adhesive labels on the
3 boxes containing the following information:

4 KRS GLOBAL BIOTECHNOLOGY INC. (GBTRX)
5 791 Park of Commerce Blvd, Boca Raton, FL 33487
6 RICK MARSHALL [sic]
162 S. Barr Rd. Port Angeles, WA 98362
HCG 5000 IU INJECTABLE

7 I also found an empty cardboard box of OVIDAC HCG 5000 IU, CHORIONIC
8 GONADOTROPHIN INJECTION. I found an empty glass vial of OVIDAC
9 CHORIONIC GONADOTROPHIN INJECTION with an accompanying small glass vial
10 of Sodium Chloride for injection. The OVIDAC packaging is identical to what I found
11 when searching the trash from both MARSCHALL's residence and THE NATURAL
12 HEALING CLINIC on July 30, 2009. This would indicate that MARSCHALL has been
13 able to successfully obtain the unapproved and misbranded foreign HCG drugs despite
14 the two Detention Notices he received from FDA.

15 38. The packaging of HCG from KRS GLOBAL BIOTECHNOLOGY of
16 Florida indicates that MARSCHALL may have found a domestic source of HCG. It is
17 also reasonable to believe that MARSCHALL wanted to find a domestic supplier of HCG
18 in order to avoid having any more of his foreign HCG orders detained by FDA.

19 39. On its website, WWW.GBTRX.COM, GLOBAL BIOTECHNOLOGY is
20 described as a "compounding pharmacy." Traditionally, a true compounding pharmacy
21 basically provides drugs in specific dosages or delivery methods which are customized for
22 a specific patient who is unable, for some medical reason, to take a commercially
23 available approved drug product in its original form. However, according to information
24 I obtained from consultations with FDA experts on the matter, I have learned that there
25 are compounding pharmacies which illegally obtain finished foreign drugs (such as HCG)
26 and re-package or re-label the drugs for sale in the United States. Unless the HCG which
27 was contained in the empty GLOBAL BIOTECHNOLOGY boxes found during the most
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1 recent trash search was compounded from an FDA approved drug, it appears that RICK
2 MARSCHALL ordered an unapproved, misbranded version of HCG from GLOBAL
3 BIOTECHNOLOGY.

4 **INTERVIEW OF A PATIENT WHO OBTAINED HCG FROM MARSCHALL**

5 40. On October 8, 2009, I spoke with DOH Investigator Carol Neva. Neva has
6 initiated a DOH investigation into MARSCHALL for the improper prescribing of HCG.
7 Neva told me that a patient of MARSCHALL's had obtained a prescription for HCG for
8 weight loss. On January 8, 2010, I interviewed the patient who requested anonymity.
9 The patient will be referred to as Source 1.

10 41. Source 1 told me he/she was referred to DR. MARSCHALL by a friend
11 who had been prescribed HCG by MARSCHALL for the purpose of losing weight. The
12 friend told Source 1 that he/she had lost 25 pounds while using HCG. Source 1 called
13 MARSCHALL'S office and MARSCHALL conducted a "phone consultation."
14 MARSCHALL asked about Source 1's medical history and any medications Source 1 was
15 taking. Source 1 paid \$500 by credit card to MARSCHALL and was sent a weight loss
16 kit. The kit consisted of one vial labeled as HCG (a clear liquid), needles for injection, 3
17 bottles of supplements/vitamins, and an unknown substance which was kept in Source 1's
18 freezer.

19 42. Source 1 stated he/she self injected the HCG for three days then stopped the
20 program. Source 1 noticed no changes in his/her weight as a result of the HCG use.
21 Source 1 sold the remainder of the weight loss kit to a co-worker. This co-worker's
22 mother is a Registered Nurse in the State of Washington who eventually sent the vial of
23 HCG to Investigator Neva, prompting the Washington DOH investigation.

24 43. Source 1 told me MARSCHALL never told him/her that HCG is primarily a
25 drug used to treat infertility in women. Source 1 also stated that MARSCHALL never
26 mentioned the possibility of any side effects from using the drug. I have checked the
27 websites of the three FDA-approved drugs which contain HCG: Novarel, Ovidrel, and .

1 Pregnyl. The website for each drug states that these drugs should only be prescribed by
2 physicians experienced or thoroughly familiar with infertility treatments. In addition, the
3 websites for Novarel and Pregnyl list adverse reactions possible from the use of their
4 drugs. These adverse reactions include ovarian hyperstimulation syndrome which is a
5 serious medical problem that can happen when the ovaries are overstimulated. There is
6 also the possibility of rupturing ovarian cysts which can result in internal bleeding.

7 44. Source 1 reiterated that he/she never had a face to face meeting with
8 MARSCHALL. This is the same conduct for which MARSCHALL was disciplined by
9 DOH in 1998.

10 45. On February 9, 2010, I met with Investigator Neva and took custody of the
11 vial of HCG which had been received by Source 1. The glass vial contains a clear liquid
12 and bears a label which reads:

13 **DR. RICK MARSCHALL, TELEPHONE 360-457-1515**

14 **MEDICATION: HCG 10,000 IU LOT # 204127**

15 **INJECT .15 ML UNDER SKIN DAILY. SKIP EVERY 7TH DAY**

16 The label bears the name of Source 1 and the date 2/12/09. This label is covering what
17 appears to be the original label on the vial which has a green border. The words
18 "chorionic gonado" are legible on the original label. I have sent this vial to FDA's
19 Forensic Chemistry Center for analysis.

20 **FEDERAL VIOLATIONS OF LAW**

21 46. Based on the inserts contained with the packages of HUCOG and OVIDAC
22 which MARSCHALL attempted to import, the articles appear to meet the FDA definition
23 of a drug at 21 U.S.C. § 321(g). Both inserts contain statements that the HCG (either
24 HUCOG or OVIDAC) is used in the treatment of infertility, a recognized medical
25 condition. Likewise, MARSCHALL's website clearly indicates he uses HCG as a
26 weight-loss treatment, and makes no mention of treating children with undescended
27 testicles or woman for infertility, or any other condition for which any HCG drug has

1 been approved. On the "Services" link of his primary website, MARSCHALL lists
2 numerous services he provides at THE NATURAL HEALING CLINIC, including Artery
3 Chelation Therapy, Gluten Intolerance, Weight-Loss Doctor, and others. The treatment
4 of infertility is not listed among the services offered by MARSCHALL.

5 47. Injectable HCG used to treat prepubertal cryptorchidism, infertility, or as a
6 weight loss treatment is not safe to use except under the supervision of a licensed
7 practitioner, and is thus a prescription drug as defined at 21 U.S.C. § 353(b).

8 48. As previously noted, it is impossible to write adequate directions for a
9 layperson to use a prescription drug, and thus, absent a statutory or regulatory exemption,
10 all prescription drugs are misbranded pursuant to 21 U.S.C. § 352(f)(1). Unapproved new
11 drugs are not exempt from the application of 21 U.S.C. § 352(f)(1). Thus, the Indian and
12 Chinese HCG that MARSCHALL attempted to import, as well as the foreign HCG that
13 he appears to have succeeded in illegally importing, are misbranded drugs, since they are
14 prescription drugs lacking adequate directions for use.

15 49. As previously explained, 21 U.S.C. § 331(a) prohibits the introduction or
16 delivery for introduction into interstate commerce of any drug that is misbranded.
17 Similarly, 21 U.S.C. § 331(c) prohibits the receipt in interstate commerce of any drug that
18 is misbranded, and the delivery or proffered delivery thereof for pay or otherwise. The
19 causing of both of these acts is also prohibited under 21 U.S.C. § 331. There is probable
20 cause to believe DR. RICK MARSCHALL violated 21 U.S.C. § 331(a) by causing the
21 introduction into interstate commerce, from India to the U.S., of misbranded drugs. The
22 HUCOG and OVIDAC ordered from India by MARSCHALL were misbranded in that
23 they lacked adequate directions for use. Likewise, there is probable cause to believe
24 MARSCHALL violated 21 U.S.C. § 331(c) by receiving in interstate commerce
25 misbranded drugs (HUCOG and OVIDAC) and delivering those drugs to the two patients
26 described above, as well as others. His website and the trash most recently recovered
27 from his property provide probable cause that he continues to offer misbranded drugs for
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1 sale to patients.

2 50. The Chinese and Indian drug products also meet the definition of new
3 drugs, since these drugs are not generally recognized as safe and effective for the uses
4 described in their labeling. Thus, when MARSCHALL ordered these drugs from India,
5 he caused the introduction into interstate commerce of unapproved new drugs, in
6 violation of 21 U.S.C. §331(d).

7 51. Based on the evidence gathered in this investigation, there is probable cause
8 to believe RICK MARSCHALL has committed these violations with the intent to defraud
9 and/or mislead the Food and Drug Administration and Customs authorities, as well as at
10 least two of his patients. As previously described, on February 17, 2009, in an email
11 response to the first FDA detention notice, MARSCHALL claimed to be "an
12 endocrinologist, a hormone expert" using the HCG to "treat infertile patients;" that he
13 needed these drugs in 5000 unit ampules; and no U.S. FDA-approved HCG drug comes in
14 5000 IU vials. As previously noted, according to the DOH Naturopathy Program, a
15 naturopathic doctor (ND) cannot refer to himself as an endocrinologist (which is an MD
16 or DO who is board certified in Internal Medicine and sub-specialty board certified in
17 Endocrinology). Furthermore, based on information obtained from MARSCHALL'S own
18 website, it appears the intended use of the HCG was not for infertility treatment but for
19 weight loss. Source 1 told me he/she purchased the HCG from MARSCHALL in 2009,
20 and it was understood that he/she had received the HCG for the purpose of losing weight.
21 There is probable cause to believe that MARSCHALL made the misrepresentations to
22 mislead FDA in an attempt to facilitate the successful introduction of unapproved,
23 misbranded new drugs into the United States. I believe this conduct constitutes felony
24 violations of 21 U.S.C. §§ 331(a), (c), and (d).

25 52. On his website, www.drrickmarschall.com, MARSCHALL claims to be a
26 "bariatric endocrinologist." There is probable cause to believe this misleading claim is
27 made to persuade potential patients that MARSCHALL holds specialized training in
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1 endocrinology. It is reasonable to believe that an overweight person seeking assistance in
2 losing weight would consider MARSCHALL'S false claim of being an endocrinologist as
3 a material fact to consider when seeking professional assistance. This conduct also
4 supports felony violations of 21 U.S.C. §§ 331 (a) (c) and (d).

5 53. Likewise, MARSCHALL's misrepresentations to FDA Compliance Officer
6 Kristen Campbell in February of 2009, claiming to be "an endocrinologist, a hormone
7 expert" importing HCG to treat infertility, were materially false statements made to a
8 member of the executive branch of the federal government acting in their official
9 capacity, about a matter within the jurisdiction of the FDA, and thus, false statements in
10 violation of 18 U.S.C. §1001.

11 54. Based upon the facts set forth in this affidavit, I submit that probable cause
12 exists to search the premises described in Attachment A for the fruits, evidence, and
13 instrumentalities of crimes, specifically, violations of the following statutes:

- 14 a. 21 U.S.C. § 331(a) - Causing the introduction into interstate
15 commerce of a misbranded drug.
- 16 b. 21 U.S.C. § 331(c) - The receipt in interstate commerce of a
17 misbranded drug and the delivery of such drug for pay.
- 18 c. 21 U.S.C. § 331(d) - Causing the introduction into interstate commerce of
19 an unapproved new drug.
- 20 d. 18 U.S.C. § 1001 - False Statements

21 **SEARCH AND/OR SEIZURE OF DIGITAL DEVICES**

22 55. As set forth above and in Attachment B to this Affidavit, I seek permission
23 to search for and seize evidence, fruits and instrumentalities of the above-referenced
24 crimes that might be found on the Subject Premises, in whatever form they are found. It
25 has been my experience that it is common for people who import and distribute
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1 | unapproved drugs to use digital devices² to communicate with suppliers of these drugs
2 | and to place orders for these drugs. In this instance, DR. RICK MARSCHALL has
3 | communicated with FDA by email using the account, RICKMARSCHALL@MSN.COM.
4 | MARSCHALL is also maintaining two websites: WWW.DRRICKMARSCHALL.COM
5 | and http://WEIGHT-LOSSDOCTOR.COM. It is likely that MARSCHALL uses his own
6 | computer to maintain these websites and to communicate with suppliers of HCG and
7 | potential patients. Due to my training and experience, I know that the ordering and
8 | shipping of products is facilitated by the use of computers. As a result, one form in which
9 | these items maybe found is as electronic evidence stored on a digital device.

10 | 56. Based on my training and experience and my consultation with FDA/Office
11 | of Criminal Investigations Special Agent Robert Blenkinsop, who has approximately
12 | eight years of specialized training and experience in searching for electronic evidence, I
13 | know that every type and kind of information, data, record, sound or image can exist and
14 | be present as electronically stored information on any of a variety of computers, computer
15 | systems, digital devices, and other electronic storage media. I also know that electronic
16 | evidence can be moved easily from one digital device to another. As a result, I believe
17 | that electronic evidence may be stored on any digital device present at the search site.

18 | 57. Based on my training and experience, and my consultation with SA
19 | Blenkinsop, I know that in some cases the items set forth in Attachment B may take the
20 | form of files, documents, and other data that is user-generated and found on a digital
21 | device. In other cases, these items may take the form of other types data – including in
22 | _____

23 | ² The term “digital devices” is used in this Affidavit to refer to any electronic system or device
24 | capable of storing and/or processing data in digital form, including but not limited to central processing
25 | units, laptops or notebook computers, personal digital assistants, wireless communication devices such as
26 | telephone paging devices, beepers, and mobile telephones; peripheral input/output devices such as
27 | cameras, keyboards, printers, scanners, plotters, monitors, and drives intended for removable media,
28 | related communications devices such as modems, cables, and connections, and electronic storage media
such as hard disk drives, floppy disks, compact discs, thumb drives, DVDs, flash drives and memory
chips; and security devices necessary to access data on a digital device such as flash drives containing
encryption keys, key fobs displaying periodically changing codes used to access a computer or cards and
card readers without which a computer might be inaccessible.

1 some cases autonomous device-generated data – found on a digital device.

2 58. Based on my training and experience, and my consultation with
3 SA Blenkinsop, I believe that if digital devices are found on the Subject Premises, there is
4 probable cause to believe that the items set forth in Attachment B will be stored in those
5 digital devices for a number of reasons, including but not limited to the following:

6 a. Once created, electronically stored information (“ESI”) can be stored
7 for years in very little space and at little or no cost. A great deal of electronic information
8 is created, and stored, moreover, even without a conscious act on the part of the device
9 operator. For example, files that have been viewed via the Internet are sometimes
10 automatically downloaded into a temporary Internet directory or “cache,” without the
11 knowledge of the device user. The browser often maintains a fixed amount of hard drive
12 space devoted to these files, and the files are only overwritten as they are replaced with
13 more recently viewed Internet pages or if a user takes steps to delete them. ESI that is so
14 created and stored may include relevant and significant evidence regarding criminal
15 activities, but also, and just as important, may include evidence of the identity of the
16 device user, and when and how the device was used. Most often, some affirmative action
17 is necessary to delete ESI. And even when such action has been deliberately taken, ESI
18 can often be recovered, months or even years later, using forensic tools. This is so
19 because when a person “deletes” a file on a device, the data contained in the file does not
20 actually disappear; rather, that data remains on the storage medium until it is overwritten
21 by new data. As a result, deleted files, or remnants of deleted files, may reside in free
22 space or slack space – that is, in space on the storage medium that is not currently being
23 used by an active file – for long periods of time before they are overwritten. In addition,
24 a computer’s operating system may also keep a record of deleted data in a “swap” or
25 “recovery” file.

26 b. Wholly apart from data created directly (or indirectly) by user-
27 generated files, digital devices – in particular, a computer’s internal hard drive – contain
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1 electronic evidence of how a digital device has been used, what it has been used for, and
2 who has used it. This evidence can take the form of operating system configurations,
3 artifacts from operating systems or application operations, file system data structures, and
4 virtual memory "swap" or paging files. Computer users typically do not erase or delete
5 this evidence, because special software is typically required for that task. However, it is
6 technically possible for a user to use such software to delete this type of information -
7 and, the use of such special software may itself result in ESI that is relevant to the
8 criminal investigation.

9 59. In addition, based on my training and experience, and my consultation with
10 SA Blenkinsop, I believe that although some of the items described in Attachment B to
11 this Affidavit might be found in the form of user-generated data (e.g., discrete word
12 processing, picture and movie "files"), digital devices can contain other forms of
13 electronic evidence as well, including but not limited to the following:

14 a. Forensic evidence of how a digital device was used, the purpose of
15 its use, and when it was used. For example, data on a digital device or electronic storage
16 medium not currently associated with any file can provide evidence of a file that was once
17 on the storage medium, but has since been deleted or edited (e.g., an earlier version of a
18 document). Virtual memory paging systems can leave traces of information on the
19 electronic storage medium that show what tasks and processes were recently active. Web
20 browsers, e-mail programs, and chat programs store configuration information on the
21 storage medium that can reveal information such as online nicknames and passwords.
22 Operating systems can record additional information such as whether peripherals or
23 Universal Serial Bus ("USB") flash storage devices or other external storage media were
24 attached, and the times the digital device was in use. Computer file systems can record
25 information about the dates files were created and the sequence in which they were
26 created.

27 b. Forensic evidence on a digital device can also indicate who used or
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1 controlled it. This "user attribution" evidence is analogous to the search for "indica of
2 occupancy" when executing a search warrant at a residence. For example, registry
3 information, configuration files, user profiles, e-mail, e-mail address books, "chat,"
4 instant messaging logs, photographs, and correspondence (and the data associated with
5 the foregoing, such as file creation and last accessed dates) may be evidence of who used
6 or controlled the digital device or storage medium at a relevant time.

7 c. A person with appropriate familiarity with how digital devices work
8 can, after examining the kind of forensic evidence that is described above in its proper
9 context, draw conclusions about how a particular digital device was used, the purpose of
10 its use, who used it, and when.

11 d. Moreover, the process of identifying the exact files, blocks, registry
12 entries, logs, or other forms of forensic evidence on a digital device that are necessary to
13 draw accurate conclusions is a dynamic process. Although it is possible to specify in
14 advance with particularity a description of the records to be sought, forensic evidence of
15 the type set forth above is not always data that can be identified in advance. Whether ESI
16 on a digital device is evidence may depend on other information stored on the digital
17 device and determining how the particular digital device behaves. Therefore, contextual
18 information necessary to understand the evidence described in Attachment B also falls
19 within the scope of the warrant.

20 e. Further, in finding evidence of how a digital device was used, the
21 purpose of its use, who used it, and when, sometimes it is necessary to establish that a
22 particular thing is not present. For example, although there is no specific evidence
23 concerning the use of malicious software in this investigation, it is possible that such
24 software can be installed on a computer, often without the computer user's knowledge,
25 that can in turn make the computer accessible by others, sometimes without the
26 knowledge of the computer owner. Also, the presence or absence of counter-forensic
27 programs (and associated data) that are designed to eliminate data may be relevant to
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1 establishing the user's intent. To investigate the crimes described in this warrant, it may
2 be necessary to investigate whether any such malicious software is present, and, if so,
3 whether the presence of that malicious software might explain the presence of other items
4 found on the digital device and/or electronic storage medium.

5 60. For the reasons set forth above, and as further described in Attachment B to
6 this Affidavit, I seek permission to locate not only user-generated data (e.g., word
7 processing, picture and movie files) that might serve as direct evidence of the crimes set
8 forth above, but also for evidence that establishes how a digital device was used, the
9 purpose of its use, who used it, and when.

10 61. In addition, based on my training and experience and that of SA
11 Blenkinsop, I know that in most cases it is impossible to successfully conduct a complete,
12 accurate, and reliable search for electronic evidence stored on a digital device during the
13 physical search of a search site. This is true for a number of reasons, including but not
14 limited to the following:

15 a. Technical Requirements: Searching digital devices for criminal
16 evidence is a highly technical process requiring specific expertise and a properly
17 controlled environment. The vast array of digital hardware and software available
18 requires even digital experts to specialize in particular systems and applications, so it is
19 difficult to know before a search which expert is qualified to analyze the particular
20 system(s) and electronic evidence found at a search site. As a result, it is not always
21 possible to bring to the search site all of the necessary personnel, technical manuals, and
22 specialized equipment to conduct a thorough search of every possible digital
23 device/system present. In addition, electronic evidence search protocols are exacting
24 scientific procedures designed to protect the integrity of the evidence and to recover even
25 hidden, erased, compressed, password-protected, or encrypted files. Since ESI is
26 extremely vulnerable to inadvertent or intentional modification or destruction (both from
27 external sources or from destructive code embedded in the system such as a "booby

1 trap”), a controlled environment is often essential to ensure its complete and accurate
2 analysis.

3 b. Volume of Evidence: The volume of data stored on many digital
4 devices is typically so large that it is impossible to search for criminal evidence in a
5 reasonable period of time during the execution of the physical search of a search site. A
6 single megabyte of storage space is the equivalent of 500 double-spaced pages of text. A
7 single gigabyte of storage space, or 1,000 megabytes, is the equivalent of 500,000 double-
8 spaced pages of text. Storage devices capable of storing sixty gigabytes of data are now
9 commonplace in desktop computers. Consequently, each non-networked, desktop
10 computer found during a search can easily contain the equivalent of 30 million pages of
11 data, which, if printed out, would completely fill a 20' x 24' x 10' room to the ceiling. Just
12 duplicating a single, sixty megabyte hard drive under laboratory conditions in a manner
13 that ensures that an accurate mirror image has been made takes at a minimum several
14 hours and, in certain cases, can take up to a full day to complete.

15 c. Hidden or Obfuscated Evidence. It is possible that digital device
16 users can conceal data within the devices through a number of methods, including the use
17 of innocuous or misleading filenames and extensions. For example, files with the
18 extension “.jpg” often are image files; however, a user can easily change the extension to
19 “.txt” to conceal the image and make it appear as though the file contains text. Similarly,
20 users can encode communications to avoid using key words that would be consistent with
21 the criminal activity. Users also can attempt to conceal ESI by using encryption
22 technologies. For example, some encryption systems require that a password or device,
23 such as a “dongle” or “keycard,” be used to obtain a readable form of the data. In
24 addition, users can conceal electronic evidence within another seemingly unrelated and
25 innocuous file using a process known as “steganography.” For example, by using
26 steganography, a user can conceal text in an image file in such a way that it cannot be
27 read when the image file is opened using ordinary means. As a result, law enforcement
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1 personnel may have to search all the stored data to determine which particular files
2 contain items that may be seized pursuant to the warrant. This sorting process can take a
3 substantial amount of time, depending on the volume of data stored and other factors.

4 d. Deleted or Downloaded Files. Digital devices allow suspects to
5 delete files to attempt to evade detection or to take other steps designed to frustrate law
6 enforcement searches for information. However, searching authorities can recover
7 electronic files or remnants of such files months or even years after they have been
8 downloaded onto a hard drive, deleted, or viewed via the Internet. When a person
9 "deletes" a file on a home computer, for example, the data contained in the file do not
10 actually disappear; rather, the data remain on the hard drive until they are overwritten by
11 new data. As a result, deleted files, or remnants of deleted files, may reside in free or
12 "slack" space (i.e., in space on the hard drive that is not allocated to an active file or that
13 is unused after a file has been allocated to a set block of storage space) for long periods of
14 time before they are overwritten. A device's operating system may also keep a record of
15 deleted data in a swap or recovery file. Similarly, files that have been viewed via the
16 Internet are automatically downloaded into a temporary Internet directory or cache. The
17 browser typically maintains a fixed amount of drive space devoted to these files, and the
18 files are only overwritten as they are replaced with more recently viewed Internet pages.
19 Thus, the ability to retrieve the residue of an electronic file from a hard drive depends less
20 on when the file was downloaded or viewed than on a particular user's operating system,
21 storage capacity, and computer habits.

22 e. Search Techniques. Because of the above-described technical
23 requirements, volume of evidence, and the ability of suspects to delete, download, hide
24 and/or obfuscate evidence, the analysis of ESI may necessitate any or all of several
25 different digital forensics techniques. Such techniques may include, but are not limited
26 to, surveying various file "directories" and the individual files they contain (analogous to
27 looking at the outside of a file cabinet for the pertinent files in order to locate the
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1 evidence and instrumentalities authorized for seizure by the warrant); "opening" or
2 reading the first few "pages" of such files in order to determine their precise contents;
3 "scanning" storage areas to discover and possibly recover recently deleted data; scanning
4 storage areas for deliberately hidden files; and performing electronic "keyword" searches
5 through all electronic storage areas to determine whether occurrences of language
6 contained in such storage areas exist that are related to the subject matter of the
7 investigation.

8 62. Based on the evidence I have uncovered during the course of this
9 investigation, as well as my training and experience and consultation with SA
10 Blenkinsop, I believe there is a low risk of destruction of the ESI for which there is
11 probable cause. I have no reason to believe that DR. MARSCHALL is intentionally
12 destroying the ESI we seek to search and seize. I have made no prior efforts to seize the
13 ESI through other judicial means. However, based on the facts described above, in
14 particular DR. MARSCHALL's efforts to circumvent the FDCA importation
15 requirements and apparent success in acquiring misbranded drugs from other sources, I
16 believe that the risk of destruction of the ESI we seek would substantially increase if he
17 were made aware of our investigation.

18 63. In accordance with the information in this affidavit, law enforcement
19 personnel will execute the search of digital devices seized pursuant to this warrant as
20 follows:

21 a. The search of digital devices authorized pursuant to this warrant will
22 not be performed by law enforcement personnel who are assigned investigatory
23 responsibilities in this case. That search, and the seizure therefrom of ESI that falls
24 within the scope of Attachment B to this affidavit will be performed, instead, by a
25 separate "ESI Filter Team." The ESI Filter Team will be comprised of one or more law
26 enforcement personnel who have received training commensurate to the task. The ESI
27 Team will not be involved directly in the investigation of the case for which the instant
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1 warrant is authorized.

2 b. I recognize that THE NATURAL HEALING CLINIC is a
3 functioning company and that a seizure and removal of the business's computer network
4 may have the unintended and undesired effect of limiting the clinic's ability to provide
5 service to its legitimate customers who are not engaged in fraudulent activity. In response
6 to these concerns, the agents who execute the search will take an incremental approach to
7 minimize the inconvenience to THE NATURAL HEALING CLINIC's customers and to
8 minimize the need to seize equipment and data. This incremental approach, which will be
9 explained to the ESI Filter Team before the search is executed, will include the
10 procedures outlined in this affidavit.

11 c. Upon securing the search site, the ESI Filter Team will conduct an
12 initial review of any digital devices/systems to determine whether the ESI contained
13 therein can be searched and/or duplicated on site in a reasonable amount of time and
14 without jeopardizing the ability to accurately preserve the data.

15 d. The ESI Filter Team will attempt to create an electronic "image" of
16 all computers that are likely to store the data described in the warrant. Generally speaking,
17 imaging is the taking of a complete electronic picture of the computer's data, including all
18 hidden sectors and deleted files. Imaging a computer permits the agents to obtain an
19 exact copy of the computer's stored data without actually seizing the computer hardware.
20 The ESI Filter Team will then conduct an off-site search for the computer files described
21 in the warrant from the image copy at a later date.

22 e. If based on their training and experience, and the resources available
23 to them at the search site, the ESI Filter Team determines it is not practical to make an
24 on-site search, or to make an on-site copy of the ESI within a reasonable amount of time
25 and without jeopardizing the ability to accurately preserve the data, then the digital
26 devices will be seized and transported to an appropriate law enforcement laboratory for
27 review and to be forensically copied ("imaged,") as appropriate. If employees of THE
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1 NATURAL HEALING CLINIC so request, the ESI Filter Team, to the extent practicable,
2 will attempt to provide the employees with copies of any files not within the scope of the
3 warrant that may be necessary or important to the continuing function of the clinic's
4 legitimate business, prior to leaving the business. If, after inspecting the computers, the
5 ESI Filter Team determines that some or all of this equipment is no longer necessary to
6 retrieve and preserve the evidence, the government will return it as soon as possible, but
7 in any event, no later than 60 days after the date of seizure.

8 f. In order to examine the ESI in a forensically sound manner, the ESI
9 Filter Team will produce a complete forensic image, if possible and appropriate, of any
10 digital device that is found to contain data or items that fall within the scope of
11 Attachment B of this Affidavit. The ESI Filter Team, exclusively, will review the
12 forensic image/s, and/or the seized digital device/s. The ESI Filter Team, exclusively,
13 will segregate, from among the ESI contained in the forensic image/s, and/or on the
14 digital devices, the items and data authorized to be seized under the terms of Attachment
15 B to this affidavit, and copy that ESI, only, to separate storage media. The ESI Filter
16 Team will provide to investigating agents only the ESI as is authorized to be seized under
17 the terms of Attachment B to this affidavit. The ESI Filter Team is authorized to provide
18 such ESI immediately upon its discovery, but will also - as set forth above - electronically
19 copy that ESI, only, to separate electronic storage media, and provide the separate
20 electronic storage media containing the ESI to the investigating agents. The ESI Filter
21 Team will not transmit to the investigatory team ESI to which it has gained access only
22 because the ESI Filter Team was required to segregate seizable from non-seizable data,
23 when that information is not within the scope of the warrant. ^{KP 3-1-10} ~~In this regard,~~ the United
24 States forswears reliance on the "plain view" doctrine in the execution of this warrant.

25 g. In order to search fully for the items identified in the warrant, the
26 ESI Filter Team may examine all of the data contained in the forensic image/s and/or on
27 the digital devices to view their precise contents and determine whether the data fall

1 within the list of items to be seized pursuant to the warrant. In addition, the ESI Filter
2 Team may search for and attempt to recover deleted, hidden, or encrypted data to
3 determine whether the data fall within the list of items to be seized pursuant to the
4 warrant.

5 h. The search techniques that will be used will be those methodologies,
6 techniques and protocols as may reasonably be expected to find, identify, segregate and/or
7 duplicate the items authorized to be seized pursuant to Attachment B to this affidavit.
8 These methodologies, techniques, and protocols may include the use of a "hash value"
9 library to exclude normal operating system files that do not need to be further searched.
10 SA Blenkinsop has informed me that he will only use these hash value libraries to exclude
11 known files, and not in an attempt to locate evidentiary ESI.

12 i. If, after conducting its examination, the ESI Filter Team determines
13 that any digital device is an instrumentality of the criminal offenses referenced above, the
14 government may seek an additional order from the issuing judicial officer authorizing the
15 retention of such items/s, as necessary to, among other things, preserve the
16 instrumentality evidence for trial, ensure the chain of custody, and litigate the issue of
17 forfeiture.

18 j. Unless the government seeks an additional order of authorization
19 from the issuing judicial officer, the government will return any digital device that has
20 been forensically copied, that is not an instrumentality of the crime, and that may be
21 lawfully possessed by the person/entity from whom it was seized, to the person/entity
22 from whom it was seized within 60 days of seizure.

23 64. Unless the government seeks and obtains an order for an extension of time,
24 the government shall provided the issuing judicial officer with a return, within 60 days of
25 seizure, that includes a sworn certificate that:

- 26 a. discloses what ESI it has obtained;
27 b. certifies what ESI it has returned;

1 c. certifies it has returned the actual digital device(s) seized, except
2 those that the judicial officer has by an additional order authorized may be retained;

3 d. certifies it has destroyed any copy made of the ESI that is outside the
4 scope of the warrant.

5 65. The government may seek an additional order authorizing the retention of
6 the complete forensic image of any digital device/s seized under justifiable circumstances,
7 including, but not limited to the following:

8 a. It is not possible, with a reasonable degree of certainty, for the ESI
9 Filter Team to segregate all of the evidence that falls within the scope of Attachment B
10 from the forensic image, in its entirety.

11 b. Data from among the ESI may later be needed as evidence in a trial
12 or another proceeding, in which case the authenticity and the integrity of the evidence and
13 the government's forensic methodology may be contested. A complete forensic image
14 may be required to resolve those issues.

15 c. Destruction of all or any portion of a forensic image could create an
16 opportunity for a defendant to claim, (even falsely), that the ESI that was destroyed
17 included evidence that was exculpatory. Preservation of the forensic image, in its
18 entirety, would permit access by the defendant to such material, and also allow the
19 government, through an additional warrant if necessary, to investigate such a claim.

20 d. The case is one in which a defendant could suggest in his defense
21 that the presence of inculpatory evidence was the result of the independent actions of
22 another (such as a computer "hack," or infection by a malicious computer virus or other
23 "malware"), in which case it may be necessary to investigate such an explanation by,
24 among other things, re-examining the complete forensic image for evidence of that
25 explanation. Preservation of the forensic image, in its entirety, would permit the
26 government, through an additional warrant if necessary, to investigate such a claim.

27 e. The investigation is not yet complete, and it is not possible to predict
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1 all possible defendants against whom evidence found on the digital device might be used.
2 That evidence might be used against persons who have no possessory interest in the
3 digital device, or against persons yet unknown. In any case, currently known and
4 unknown defendants might be entitled, in discovery, to a complete copy of the ESI
5 contained on or in the digital device. Retention of a complete image assures that it will
6 be available to all parties, including those known now and those later identified.

7 66. In order to search for ESI that falls within the list of items to be seized
8 pursuant to Attachment B to this Affidavit, law enforcement personnel will seize and the
9 ESI Filter Team will search the following items (heretofore and hereinafter referred to as
10 "digital devices), subject to the procedures set forth above:

11 a. Any digital device capable of being used to commit, further, or store
12 evidence of the offense(s) listed above;

13 b. Any digital device used to facilitate the transmission, creation,
14 display, encoding or storage of data, including word processing equipment, modems,
15 docking stations, monitors, printers, cameras, plotters, encryption devices, and optical
16 scanners;

17 c. Any magnetic, electronic or optical storage device capable of storing
18 data, such as floppy disks, hard disks, tapes, CD-ROMs, CD-R, CD-RWs, DVDs, optical
19 disks, printer or memory buffers, smart cards, PC cards, memory calculators, electronic
20 dialers, electronic notebooks, and personal digital assistants;

21 d. Any documentation, operating logs and reference manuals regarding
22 the operation of the digital device, or software;

23 e. Any applications, utility programs, compilers, interpreters, and other
24 software used to facilitate direct or indirect communication with the device hardware, or
25 ESI to be searched;

26 f. Any physical keys, encryption devices, dongles and similar physical
27 items that are necessary to gain access to the digital device, or ESI; and
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1 g. Any passwords, password files, test keys, encryption codes or other
2 information necessary to access the digital device or ESI.


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12 **REQUEST FOR SEALING**

13 67. Because of the ongoing nature of the investigation, the disclosure of the
14 contents of this affidavit will jeopardize the progress of the investigation. Accordingly, I
15 request that the Court issue an order that the search warrant and the affidavit in support of
16 application for the search warrant and all attachments be filed under seal until further
17 order from the Court.

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19 
20 KEN PETROFF, Affiant
21 Special Agent
22 Food and Drug Administration (FDA)
23 Office of Criminal Investigations (OCI)

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25 SUBSCRIBED AND SWORN to before me this 1 day of MARCH, 2010.

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28 J. RICHARD CREATURA

United States Magistrate Judge

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