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CRIMINAL COMPLAINT (UNDER SEAL)

COPY

UNITED STATES DISTRICT COURT	CENTRAL DISTRICT OF CALIFORNIA
UNITED STATES OF AMERICA v. VINOD CHANDRASHEKM PATWARDHAN, M.D.	DOCKET NO. ED 08-0283M MAGISTRATE'S CASE NO.

LODGED
CLERK, U.S. DISTRICT COURT
AUG 13 2008
CENTRAL DISTRICT OF CALIFORNIA
BY DEPUTY

Complaint for violation of 21, United States Code, Sections 331(a), 331(a)(1), 352(f)(1) and 333(a)(2).

NAME OF MAGISTRATE JUDGE	UNITED STATES MAGISTRATE JUDGE	LOCATION
HONORABLE OSWALD PARADA		RIVERSIDE, CA

DATE OF OFFENSE	PLACE OF OFFENSE	ADDRESS OF ACCUSED (IF KNOWN)
JULY 30, 2008	SAN BERNARDINO COUNTY	

COMPLAINANT'S STATEMENT OF FACTS CONSTITUTING THE OFFENSE OR VIOLATION:

Beginning on an unknown date and continuing until on or about July 30, 2008, in San Bernardino County, within the Central District of California, defendant VINOD CHANDRASHEKM PATWARDHAN, M.D. knowingly and intentionally introduced and delivered for introduction into interstate commerce one or more drugs that was misbranded due to lack of adequate directions for use, with the intent to defraud or mislead, in violation of Title 21, United States Code, Sections 331(a), 352(f)(1), and 333(a)(2).

BASIS OF COMPLAINANT'S CHARGE AGAINST THE ACCUSED:
(See attached affidavit which is incorporated as part of this Complaint)

MATERIAL WITNESSES IN RELATION TO THIS CHARGE:

Being duly sworn, I declare that the foregoing is true and correct to the best of my knowledge.	SIGNATURE OF COMPLAINANT **William M. Crawford** OFFICIAL TITLE SPECIAL AGENT United States Federal Drug Administration - Office of Criminal Investigations

Sworn to before me and subscribed in my presence,

SIGNATURE OF MAGISTRATE JUDGE(1)	DATE
OSWALD PARADA	AUGUST 13 2008

1) See Federal Rules of Criminal Procedure rules 3 and 54.

JBW:ii

AFFIDAVIT

I, William M. Crawford, being duly sworn, hereby depose and state:

I.

INTRODUCTION

1) I am a Special Agent ("SA") with the Office of Criminal Investigations of the United States Food and Drug Administration ("FDA/OCI") and have been so employed since December 2002. I am currently assigned to the Los Angeles Field Office where my investigation responsibilities include, but are not limited to, investigating violations of the Federal Food, Drug and Cosmetic Act ("FD&C Act") 21 U.S.C. 301, et seq. Before joining FDA/OCI, I was a SA with the Immigration and Naturalization Service ("INS") for approximately eight years. Before becoming a SA with the INS, I was a Border Patrol Agent for approximately five years.

2) This affidavit is made in support of a complaint and arrest warrant against VINOD CHANDRASHEKM PATWARDHAN, M.D. ("PATWARDHAN") for violation of the following sections of the United States Code: Title 21, United States Code, Sections 331(a), 352(f)(1), and 333(a)(2) (introducing or delivering for introduction into interstate commerce any

drug that is misbranded due to lack of adequate directions for use, with the intent to defraud or mislead).

3) This affidavit is based on my personal knowledge of this investigation, my review of documents pertaining to this investigation, and my discussions with other law enforcement personnel with knowledge about the facts in this investigation. This affidavit is intended only to set forth probable cause for the requested complaint. It does not purport to set forth all of my knowledge of this matter.

II.

REGULATORY BACKGROUND

4) The United States Food and Drug Administration ("FDA") is the federal agency within the United States Department of Health and Human Services charged with the responsibility for protecting the health and safety of the American public by enforcing the FD&C Act. One of the purposes of the FD&C Act is to ensure that all drugs sold for consumption or administration to humans and animals are safe and effective for their intended uses before they may be legally marketed in interstate commerce and bear labeling containing only true and accurate information. The FDA's responsibilities under the FD&C Act include

regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce.

5) The FD&C Act defines a "drug" to include, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and articles intended for use as a component of any such articles. 21 U.S.C. § 321(g).

6) A drug is misbranded if, among other things:

a) Its labeling is false or misleading in any particular (21 U.S.C. § 352(a));

b) The labeling on the drug does not bear adequate directions for use (21 U.S.C. § 352(f)(1));

c) The labeling on the drug does not bear such adequate warnings against use in those pathological conditions, and by children, where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration and application, in such manner and form, as is necessary for the protection of users (21 U.S.C. § 352(f)(2));

d) The drug is a prescription drug dispensed without a valid prescription (21 U.S.C. § 353(b)(1)); or the drug is a prescription drug and its label does not bear the symbol "Rx only" (21 U.S.C. § 353(b)(4)).

7) The FD&C Act prohibits doing or causing the following act: the introduction or delivery for introduction into interstate commerce of any drug that is misbranded or adulterated. 21 U.S.C. § 331(a). "Interstate commerce" is defined in the FD&C Act to include commerce between any State or Territory and any place outside thereof. 21 U.S.C. § 321(b). This includes commerce between a foreign country and a resident in any state.

8) The FD&C Act imposes strict liability misdemeanor punishment for violations of 21 U.S.C. § 331 that are committed without mens rea, see 21 U.S.C. § 333(a)(1), and imposes felony punishment if the acts are committed "with the intent to defraud or mislead." See 21 U.S.C. § 333(a)(2).

III.

STATEMENT OF PROBABLE CAUSE

9) On or about April 2, 2008, I received from Customs and Border Protection Officer Eric Dandrow, via electronic mail, the following materials:

a) A citizen's complaint: Officer Dandrow indicated in the electronic mail message that he received the complaint from Person A. In Person A's complaint, Person A expressed concern that her employer, PATWARDHAN, a Medical Doctor, was illegally obtaining and importing unapproved prescription drugs from India and Honduras and then administering those drugs to cancer patients undergoing chemotherapy.

b) Photographs of prescription drugs inside a gym bag: Attached to the electronic mail message from Officer Dandrow were photographs taken by Person B, a medical assistant who is employed by PATWARDHAN.[1] According to the complaint, Person B took the photographs while inside PATWARDHAN's office. The photographs showed a gym bag containing numerous vials of drugs. The drugs depicted in the photographs clearly show the labels of the

[1] Person B has been interviewed in connection with the investigation. (See paragraphs 11 and 15 of this affidavit.)

individual vials, which indicate that they are Docetax 80, 80mg, and Pemnat, 500mg. The writing on the labels is in English. Neither packaging materials nor instructions for the use of the drugs can be seen in the photograph.

c) A photograph of an invoice: Also attached to Officer Dandrow's electronic mail message was an additional photograph taken by Person B. This photograph clearly shows an invoice for the purchase of drugs with a signature that purports to be that of PATWARDHAN.[2] The invoice reflects the purchase of Docetax 80mg and two other drugs, the names of which were illegible, from Arihant Chemist, Peth, Pune, India. The invoice, which is dated February 3, 2008, is in the amount of $888,900.00.

10) On May 13, 2008, I interviewed Person A, who told me the following:

a) In or about August 2007, Person A began working for PATWARDHAN. Her duties for PATWARDHAN involved managing personnel, including maintaining payroll records. Person A has access to all financial aspects of the business located at 918 West Foothill Blvd., Suite B,

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[2] As described below in paragraph 11(c), I later learned from Person B that she found this invoice inside the gym bag described above in subparagraph 9(b), which contained the prescription drugs.

Upland, California (the "Patient Examination Location"), and 942 West Foothill Blvd., Upland, California (the "File Storage Location").

b) I showed Person A the photograph of the invoice that was sent to me by Officer Dandrow, discussed above. Person A reviewed the signature on the invoice that purports to be that of PATWARDHAN. Based on her familiarity with PATWARDHAN's actual signature, Person A confirmed that the signature that purports to be that of PATWARDHAN was his actual signature. Person A told me that she is very familiar with PATWARDHAN's actual signature because she is exposed to his actual signature frequently in the course of her employment.

c) In February 2008, Person A saw a gym bag which contained vials of cancer drugs inside PATWARDHAN's office at the File Storage Location. Based on her experience up to that point, Person A understood that approved drugs were sent to PATWARDHAN's office via only Federal Express or other widely recognized courier services. Later that same day, Person A saw Person C, a claims processor employed by PATWARDHAN, bring the gym bag, which contained the vials of cancer drugs, from PATWARDHAN's office at the File Storage Location to the

Patient Examination Location. Person C, while carrying the gym bag, told Person A that the drugs were PATWARDHAN's and she asked Person A where she should put the gym bag. Person A took the gym bag with the drugs from Person C and walked up to PATWARDHAN, who was in the office at the Patient Examination Location at the time. While holding the gym bag full of drugs, Person A asked PATWARDHAN where she should put the bag. In response to Person A's question, PATWARDHAN appeared to become very upset and in a loud and commanding voice ordered her to never touch the bag again and to not get involved. Person C, Person D,[3] Person E (a medical assistant of PATWARDHAN), and several patients witnessed PATWARDHAN yelling at Person A.

d) Based on this incident, Person A became suspicious and asked Person B about the drugs in the gym bag. Person B told Person A that PATWARDHAN buys these drugs from India and Honduras because they are cheaper than the drugs authorized for use in the United States. Person B also said that Person B has seen PATWARDHAN use these drugs during his chemotherapy treatment of patients. Person B explained further that PATWARDHAN does not

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[3] Person D, a Nurse Practitioner employed by PATWARDHAN, has been interviewed in connection with the investigation. (See paragraph 13 of this affidavit.)

administer full dosages of drugs to his patients, and that he does not discard the partially used vials of these drugs but instead places them on a shelf inside his office and administers the unused portion to other patients. According to the labels on the vials themselves (which are discussed below in paragraph 11(e), many of the vials of unapproved drugs are single use dosages.

e) In February 2008, Person A saw Person F[4] walk from the File Storage Location to the Patient Examination Location while carrying a Nordstrom bag. Approximately 15 minutes later, Person B called Person A and told Person A that Person B had seen Person F carrying the Nordstrom bag into the chemotherapy laboratory, which is located in the Patient Examination Location.[5] During this phone conversation, Person B asked Person A to come to the chemotherapy laboratory. Person A complied with Person B's request. After Person A arrived at the chemotherapy laboratory, Person B showed Person A three smaller

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[4] Person F, a business manager employed by PATWARDHAN, has been interviewed in connection with the investigation. (See paragraph 17 of this affidavit.)

[5] According to Person A, the chemotherapy laboratory is where PATWARDHAN reconstitutes chemotherapy drugs (which involves, among other things, injecting the drug into a saline solution intravenous drip) and otherwise prepares chemotherapy treatments for patients.

Nordstrom gift boxes, one of which Person B opened in Person A's presence. Person B opened the gift box because PATWARDHAN told her to remove the drugs from the gift boxes and put the drugs in a refrigerator located in the chemotherapy laboratory. Person A saw approximately 40 vials of Farmorubicina. Since the labels of these vials of Farmorubicina were written in Spanish, Person A realized that they were not approved for use in the United States. The labels indicated that the drugs were manufactured in Italy.

11) On May 30, 2008 and again on June 16, 2008, I interviewed Person B, who told me the following:

a) Person B has worked for PATWARDHAN as a medical assistant for approximately eight years. Her duties include treating patients and monitoring patients during their chemotherapy treatments. In addition, she is responsible for placing newly obtained cancer drugs into a refrigerator located in the chemotherapy laboratory. Person B stated that PATWARDHAN treats approximately 35 cancer patients per week.

b) Person B stated that she has witnessed PATWARDHAN administer unapproved foreign drugs to his patients. She knew that they were unapproved because they

were not delivered in refrigerated containers via Federal Express or another widely recognized courier service, but instead arrived in unrefrigerated gym bags and other packages that concealed their contents. In addition, when PATWARDHAN prepares the drugs for use by injecting them into an intravenous drip, Person B has seen PATWARDHAN inject less than the required amount. She knows that he has injected less than the required amount because she is responsible for reading the patient file and writing on the saline drip bag the amount of the drug that PATWARDHAN prescribed for that particular treatment of that particular patient.

c) In February 2008, while performing her duties at the Patient Examination Location, Person B saw an open gym bag with approximately 300 vials of drugs and an invoice. Based on her review of the labels on the drugs as well as the invoice, Person B was able to determine that some of the drugs inside the gym bag were Docetax, 80mg, manufactured in India, and Pemnat, 500mg, manufactured in India. According to Person B, the gym bag was sitting in a treatment room referred to as "Room 5" at the Patient Examination Location, which is where PATWARDHAN often works. Person B used her cellular telephone camera to take

a picture of the invoice. This is the same photograph of the invoice that accompanied the original complaint, described above in paragraph 9. The invoice is dated February 3, 2008 and reflects the purchase of 100 vials of Docetax 80mg and 300 vials of two additional drugs, the names of which are illegible. Person B could not recall the names of these drugs with the illegible names. The invoice, which indicates that it was issued by Arihant Chemist, Swojas House, Near Hatti Ganpati, 1159, Sadashiv Peth, Pune, India, bears what appears to be the signature of PATWARDHAN.

d) In February 2008, PATWARDHAN ordered Person B to report to the chemotherapy laboratory inside the Patient Examination Location to inspect medicine he had purchased. In particular, PATWARDHAN told Person B to count the medicine to make sure he received what he had paid for. Person B went to the chemotherapy laboratory and saw a Nordstrom bag sitting on the counter. The Nordstrom bag contained three individually wrapped packages. Person B opened the packages and saw approximately 120 vials of Farmorubicina, a drug designed to treat cancer patients that is manufactured in Italy. Person B put the drugs in a refrigerator inside the chemotherapy laboratory. Since

approximately January or February 2004, Person B has been ordered by PATWARDHAN to put unapproved drugs that Person B believed were purchased in Honduras or India into the refrigerator on approximately 10 occasions.

e) Person B gave me samples of some of the drugs that she has seen PATWARDHAN administering to his patients. She obtained these samples from inside PATWARDHAN's office at the Patient Examination Location, but she said that she also had seen these drugs inside PATWARDHAN's facility at the File Storage Location. The samples that Person B gave me include Docetax 80mg, manufactured in India by Cipla Ltd for the treatment of metastatic breast cancer; Pemnat 500mg, manufactured in India by Natco Pharma Limited for the treatment of lung cancer; Neupeg, manufactured in India by Intas Biopharmaceuticals LTD for the treatment of neutropenia, a side effect of cancer; Grafeel 1ml, manufactured in India by Dr. Reedy's Laboratories for the treatment of cancer patients suffering from chemotherapy induced neutropenia, Amgem manufactured in India by MacMohan Pharma limited for the treatment of cancer; and Farmorubicina, manufactured in Italy by Pharmacia Italia for the treatment of carcinoma.

12) On June 16, 2008, I interviewed Person G, who told me the following:

a) Person G is a receptionist/verification coordinator employed by PATWARDHAN and has been so employed since October 2007.

b) Person G became aware that PATWARDHAN was administering unapproved drugs to his cancer patients after she went to dinner with Person B and Person D in February 2008. Person G stated that Person B told her that PATWARDHAN was treating his patients with unapproved drugs from Honduras and India and was injecting less than the required amount, based upon the amount prescribed by PATWARDHAN for that particular treatment.

c) Person G stated that she was at the office located at the Patient Examination Location in June 2008, when she entered "Room 5" to retrieve medical gauze for her injured elbow. Upon entering "Room 5," while looking for medical gauze, she opened a cabinet and noticed a Reebok gym bag. Person G pulled the gym bag from an upper shelf, opened the bag, and noticed approximately 20 vials of drugs that were contained inside the gym bag. Person G stated that the vials looked exactly like the drugs used by PATWARDHAN for chemotherapy treatments, although she did

not explain the basis for that belief. Person G returned the gym bag and the drugs to the upper shelf of the cabinet and immediately told Person B what she had seen. Person B told Person G that the drugs she saw are unapproved drugs from India.

13) On June 26, 2008, I interviewed Person D, who told me the following:

a) Person D has been employed by PATWARDHAN as a Nurse Practitioner in his medical office since July 2007.

b) Person D first became aware of PATWARDHAN using unapproved drugs in February 2008, when she went to dinner with Person B and Person G, and Person B told her that PATWARDHAN is administering unapproved cancer drugs to his patients. Person B also told Person D that, when PATWARDHAN reconstitutes the drugs for use, he administers less than the recommended dosage to the patient in an effort to save money.

c) In February 2008, while Person D was inside the Patient Examination Location, she entered the chemotherapy laboratory and saw Person B standing over an open gym bag. Person B told Person D to look inside the gym bag. Person D saw approximately 100 vials of Docetax. In addition, she saw an invoice inside the gym bag. The

invoice was from Arihant Chemist located in India. Based on Person D's education, training, and experience as a nurse practitioner, she knew that the drugs were adulterated, based on the fact that they were contained inside a gym bag, and unapproved, due to the fact that they were from India. Shortly after the above-mentioned incident, Person D submitted her resignation to PATWARDHAN as a nurse practitioner.

14) On July 21, 2008, I telephoned Dr. Judith McMeekin of the FDA, Center for Drug Evaluation and Research (CDER), Office of Compliance. Also participating in the telephone conference was Karen Rothschild, Regulatory Counsel for the FDA. I asked them whether the following drugs obtained from PATWARDHAN's office were approved for treatment in the United States: (1) Docetax 80mg, manufactured in India by Cipla Ltd for the treatment of metastatic breast cancer; (2) Pemnat 500mg, manufactured in India by Natco Pharma Limited for the treatment of lung cancer; (3) Neupeg, manufactured in India by Intas Biopharmaceuticals LTD for the treatment of neutropenia, a side effect of cancer; (4) Grafeel 1ml, manufactured in India by Dr. Reedy's Laboratories for the treatment of cancer patients suffering from chemotherapy induced

neutropenia; (5) Amgem manufactured in India by MacMohan Pharma limited for the treatment of cancer; and (6) Farmorubicina, manufactured in Italy by Pharmacia Italia for the treatment of carcinoma. Karen Rothschild stated that all the drugs were unapproved for use or distribution within the United States. In addition, the drug Farmorubicina is misbranded because the label is in Spanish.

15) On July 28, 2008, I again interviewed Person B, via telephone conference. During the conversation, Person B told me that, on or about July 1, 2008, while she was present at the Patient Examination Location, Person G told her that she had seen PATWARDHAN's former orthodontist carrying a gym bag while walking into "Room 5" of the Patient Examination Location. Later that day, Person B entered the same room, opened a drawer on the top shelf, and pulled out a gym bag. Upon opening the gym bag, she saw that it contained approximately 50 vials of Gemcigab, which, according to the labels on the vials, were manufactured in India.

16) On July 30, 2008, Special Agents from the OCI/FDA and U.S. Immigration and Customs Enforcement ("ICE") executed federal search warrants on the Patient Examination

Location and the File Storage Location, respectively. During the execution of these search warrants, OCI/FDA SA Gary Collins found inside the Patient Examination Location 27 vials of unapproved Docetax, which is used to treat breast cancer, one vial of unapproved Grafeel, which is used to treat cancer patients suffering from chemotherapy induced neutropenia, and one vial of unapproved Zildox, which is used to treat colorectal cancer. SA Collins did not find any packaging materials or instructions for any of these drugs.

17) On July 30, 2008, OCI/FDA SA William Leitner, ICE SA Raul Fernandez, and I interviewed Person F and she told us the following:

a) Person F was born in Honduras and has worked for PATWARDHAN since 1973, starting out as an office manager. Her present position is as business manager.

b) Person F was aware that PATWARDHAN was either personally bringing into the United States unapproved Oncology medicines from India or causing the entry of unapproved Oncology drugs through Honduras since 2004. In 2004, PATWARDHAN approached Person F about finding out how she could get Procrit (a drug used to treat anemia) into the United States from Honduras. Person F

found out that Procrit was not available in Honduras and advised PATWARDHAN accordingly.

c) Beginning in 2004, at the request of PATWARDHAN, Person F brought Zoladex (used in the treatment of endometriosis) that was manufactured by the "Corporacion Mandofer" in Honduras into the United States. Person F brought Zoladex into the United States on three occasions, from 2004 to 2005.

d) Starting in 2005 and up until February 7, 2008, Person F purchased Rituxan (a cancer medication that interferes with the growth of cancer cells and slows their growth/spread in the body) from "Fariter" (a primary drug distributor) in Honduras. Person F reported that she bought Rituxan three times per year and each time bought between 10 and 15 vials of the drug.

e) To quantify the cost of what PATWARDHAN was spending on the unapproved medications, Person F reviewed an invoice from March 2006, which indicated that PATWARDHAN paid $17,000.00 for the purchase of the following drugs in the quantities indicated:

i) Rituxan (four vials);

ii) Taxotere (one vial);

iii) Camptosar (six vials);

iv) Eloxatin (eight vials); and

v) Gemzar (amount not annotated).

Person F stated that the savings to PATWARDHAN was between $150.00 and $200.00 per vial.

f) Since she has known PATWARDHAN, he has travelled to India between three and four times per year. Person F said that during the last six or seven years, PATWARDHAN has been bringing unapproved oncology medications from India into the United States. Person F said that she has wired funds to "Arihant Chemist," a pharmaceutical wholesale company in India.

g) PATWARDHAN communicated with Arihant on what medications he would pick up during his travels. Person F did not see PATWARDHAN bring the unapproved medications into the medical offices. PATWARDHAN would tell Person F that he had provided the unapproved Oncology medications to his medical assistants after arriving in the United States from India. PATWARDHAN provided the invoices to Person F for accounting purposes.

h) PATWARDHAN smuggled the following unapproved medications into the United States from India. Each of these drugs are Oncology medications, except for Zofran, which I understand blocks the actions of chemicals in the

body that can trigger nausea/vomiting that may be caused by surgery or medicines to treat cancer:

i) Eloxatin;

ii) Neupogen;

iii) Taxotere;

iv) Rituxan;

v) Gemzar; and

vi) Zofran.

i) Person F was aware that Person H[6] went to the Philippines on one occasion in 2008 and returned with 12 vials of Zofran. Person H paid $600.00 for the Zofran which she purchased using her personal credit card. Person F reimbursed Person H from office funds for Person H's expenditure. Person F believed that PATWARDHAN asked Person H to bring back into the United States the unapproved Zofran from the Philippines.

j) In March 2008, Person F was told by Person I (a back-office assistant employed by PATWARDHAN) that two other employees of PATWARDHAN, Person B and Person A, had been taking photographs of the unapproved Oncology medications that PATWARDHAN had brought into the United

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[6] Person H, a Nurse Practitioner employed by PATWARDHAN, has been interviewed in connection with the investigation. (See paragraph 19 of this affidavit.)

States from India. Person F stated that she told PATWARDHAN about this development and that PATWARDHAN spoke with Person B and Person A about it.

k) In March 2008, PATWARDHAN asked Person J (a Medical Doctor who does not work in PATWARDHAN's office) to bring unapproved Oncology medications from India into the United States. Person F said that Person J returned with Docetaxel and Zolfran. Docetaxel is a chemotherapy medication used mainly for the treatment of breast, ovarian and non-small cell lung cancer. Person F stated that Person J returned with approximately $21,000.00 worth of unapproved medications from India. Person F sent wire transfers to Arihant Chemist for the invoice for this sale. Person F said that she wrote a check to Person J to reimburse her for her travel expenses and the cost of the unapproved medications.

18) On July 30, 2008, SA Leitner, ICE SA Fernandez, and I interviewed PATWARDHAN. During the interview, PATWARDHAN told us that he has been personally bringing into the United States unapproved oncology medicines from India for "quite some time." PATWARDHAN could not provide a specific time frame for these activities. PATWARDHAN further stated that he has traveled to India on at least a

dozen occasions, bringing back into the United States unapproved oncology medications in either his suitcase or a gym bag. PATWARDHAN said that, under his authority, he has had another person bring unapproved oncology medications into the United States from Honduras.

19) On July 30, 2008, SA Leitner, ICE SA Fernandez, and I interviewed Person H and she told us the following:

a) Person H has been employed by PATWARDHAN since 2004. She currently works as a Nurse Practitioner for PATWARDHAN.

b) Person H first became aware of PATWARDHAN using unapproved drugs shortly after she began working for him. She saw PATWARDHAN arrive at the office carrying gym bags of unapproved drugs from India. She also saw PATWARDHAN order Person B to put the drugs away and to count the drugs to ensure that PATWARDHAN received what he had paid for.

c) In 2005, while vacationing with her family in Canada, Person H was asked by PATWARDHAN to purchase unapproved cancer medicine for use in his practice. Person H told PATWARDHAN that she would try to purchase the cancer medication. However, she did not purchase the medication because she was scared that she would be caught by law

enforcement if she attempted to bring the medications into the United States. After this incident, PATWARDHAN asked Person H to bring back cancer medications from foreign countries several times but she refused.

d) In April 2008, Person H was vacationing in the Philippines when PATWARDHAN asked her to purchase unapproved cancer medications from the Philippines and bring them back into the United States. Person H purchased Decadron, used to treat blood, hormone and immune system disorders, and Zofran, used to prevent nausea and vomiting associated with cancer patients. Person H brought these drugs into the United States in her suitcase and did not declare them to U.S. Customs officials upon her arrival in the United States. She gave them to PATWARDHAN after arriving in the United States. After she delivered the drugs to PATWARDHAN, she was reimbursed for the purchase of the drugs by Person F.

e) In 2004, Person H became aware that PATWARDHAN was diluting dosages of cancer drugs and then administering the dosages to his patients. While performing her duties as a Nurse Practitioner, Person H was ordered by PATWARDHAN to give half the required dosage of Procrit, used to treat anemia in cancer patients, to one of

her patients. Person H stated that she waited until PATWARDHAN left and then she administered the full dosage to her patient. Person H stated that she saw PATWARDHAN dilute the Procrit medication on two or three occasions. Person H stated that she witnessed PATWARDHAN dilute the dosages of cancer medications a total of approximately 20 to 30 times. When asked how many times PATWARDHAN diluted cancer medications to less than recommended dosages and gave the diluted drug to patients, Person H stated that she thought he did so every Tuesday and Thursday since Person H started working for PATWARDHAN in 2004.[7]

20) Based upon the foregoing facts, and upon my training and experience, I believe there is probable cause to believe that VINOD CHANDRASHEKM PATWARDHAN, M.D. violated the following sections of the United States Code: Title 21, United States Code, Sections 331(a), 352(f)(1), and 333(a)(2) (introducing or delivering for introduction

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[7] I have been told by several people, including PATWARDHAN, that PATWARDHAN only provides chemotherapy treatments on Tuesdays and Thursdays.

into interstate commerce any drug that is misbranded due to lack of adequate directions for use, with the intent to defraud or mislead).

William M. Crawford
Special Agent
Food & Drug Administration

Sworn to and subscribed before me this 19 day of August, 2008

OSWALD PARADA

THE HONORABLE OSWALD PARADA
United States Magistrate Judge