AO 257 (Rev. 6/78)

DEFENDANT INFORMATION RELATIVE TO A CRIMINAL ACTION - IN U.S. DISTRICT COURT

BY: ☐ COMPLAINT ☐ INFORMATION ☒ INDICTMENT ☐ SUPERSEDING

Name of District Court, and/or Judge/Magistrate Location

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FILED
2008 MAR 18 P 12:42
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

OFFENSE CHARGED

See attached

E-filing

☐ Petty
☐ Minor
☐ Misde-meanor
☒ Felony

PENALTY: See attached

DEFENDANT - U.S

▶ W. SCOTT HARKONEN

DISTRICT COURT NUMBER

CR 08 0164 CRB

PROCEEDING

Name of Complaintant Agency, or Person (& Title, if any)

U.S. FOOD AND DRUG ADMINISTRATION

☐ person is awaiting trial in another Federal or State Court, give name of court

☐ this person/proceeding is transferred from another district per (circle one) FRCrp 20, 21, or 40. Show District

☐ this is a reprosecution of charges previously dismissed which were dismissed on motion of: ☐ U.S. ATTORNEY ☐ DEFENSE } SHOW DOCKET NO.

☐ this prosecution relates to a pending case involving this same defendant

☐ prior proceedings or appearance(s) before U.S. Magistrate regarding this defendant were recorded under } MAGISTRATE CASE NO.

DEFENDANT

IS *NOT* IN CUSTODY

Has not been arrested, pending outcome this proceeding.

1) ☒ If not detained give date any prior summons was served on above charges ▶

2) ☐ Is a Fugitive

3) ☐ Is on Bail or Release from (show District)

IS IN CUSTODY

4) ☐ On this charge

5) ☐ On another conviction } ☐ Federal ☐ State

6) ☐ Awaiting trial on other charges

If answer to (6) is "Yes", show name of institution

Has detainer been filed? ☐ Yes ☐ No } If "Yes" give date filed

DATE OF ARREST ▶ Month/Day/Year

Or... if Arresting Agency & Warrant were not

DATE TRANSFERRED TO U.S. CUSTODY ▶ Month/Day/Year

Name and Office of Person Furnishing Information on this form: Brian J. Stretch, Acting USA

☒ U.S. Attorney ☐ Other U.S. Agency

Name of Assistant U.S. Attorney (if assigned): IOANA PETROU

☐ This report amends AO 257 previously submitted

ADDITIONAL INFORMATION OR COMMENTS

PROCESS:

☒ SUMMONS ☐ NO PROCESS* ☐ WARRANT Bail Amount:

If Summons, complete following:

☒ Arraignment ☐ Initial Appearance

Defendant Address:

** Where defendant previously apprehended on complaint, no new summons or warrant needed, since Magistrate has scheduled arraignment*

Date/Time: 3/28/08 @ 9:30 am Before Judge: JOSEPH C. SPERO

Comments:

PENALTY SHEET ATTACHMENT **W. SCOTT HARKONEN**

OFFENSES:

COUNT ONE:

18 U.S.C. §1343 – WIRE FRAUD

18 U.S.C. § 2 – AIDING AND ABETTING

COUNT TWO:

21 U.S.C. §§ 331(K), 333(A)(2) AND 352(A) – DOING ACTS, WITH INTENT TO DEFRAUD AND MISLEAD, RESULTING IN DRUGS BEING MISBRANDED WHILE HELD FOR SALE FOLLOWING SHIPMENT IN INTERSTATE COMMERCE

PENALTIES:

COUNT ONE:

18 U.S.C. §1343 – 20 YEARS IMPRISONMENT, $250,000 FINE, 3 YEARS SUPERVISED RELEASE, $100 SPECIAL ASSESSMENT

COUNT TWO:

21 U.S.C. §§ 331(K), 333(A)(2) AND 352(A) – 3 YEARS IMPRISONMENT, ~~$10,000~~ $250,000 FINE, 1 YEAR SUPERVISED RELEASE, $100 SPECIAL ASSESSMENT

BRIAN J. STRETCH (CABN 163973)
Acting United States Attorney

E-filing

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

W. SCOTT HARKONEN,

Defendant.

CR 08 0164 CRB

No.

VIOLATIONS:

18 U.S.C. §1343 - Wire Fraud;
18 U.S.C. § 2 - Aiding and Abetting;
21 U.S.C. §§ 331(k), 333(a)(2) and 352(a) - Doing acts, with intent to defraud and mislead, resulting in drugs being misbranded while held for sale following shipment in interstate commerce

SAN FRANCISCO VENUE

INDICTMENT

The Grand Jury charges:

INTRODUCTORY ALLEGATIONS

At times relevant to this Indictment:

1. InterMune, Inc. ("InterMune"), was a Delaware corporation that developed, marketed and sold drugs for lung and liver diseases. InterMune's drugs were biopharmaceuticals, which are drugs based on chemicals that the human body produces

naturally. From in or about February 1998 through in or about May 2000, InterMune's principal place of business was in Palo Alto, California. From in or about June 2000 through in or about June 2001, InterMune's principal place of business was in Burlingame, California. In June 2001, InterMune moved its principal place of business to Brisbane, California.

2. From April 1999 through March 2000, InterMune was a private corporation without any publicly traded stock. In March 2000, InterMune became a publicly traded company on the New York Stock Exchange and started selling shares of its stock to the public.

3. InterMune marketed and sold a drug called "interferon gamma-1b" under the brand name "Actimmune." Actimmune was a drug regulated and approved by the United States Food and Drug Administration ("FDA") , the federal agency charged with enforcing the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA").

4. Actimmune was approved by the FDA to treat chronic granulomatous disease in or about 1990, as well as approved to treat severe, malignant osteopetrosis in or about 2000. Both of these diseases are rare disorders that primarily affect children.

5. InterMune marketed and sold Actimmune to treat a disease called idiopathic pulmonary fibrosis ("IPF"). IPF is a fatal disease that affects mainly middle-aged people. IPF causes a person's lungs to fill up gradually with fibrotic scar tissue, which eventually prevents the lungs from working and deprives the victim of the ability to breathe.

6. Treating IPF was not an FDA-approved use of Actimmune. The FDA-approved label for a drug states all of the diseases that FDA has approved the drug to treat. An "off-label" use of a drug is the use of a drug to treat a disease for which FDA has not approved the drug and that is not on the drug's FDA-approved label.

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7. InterMune's sales from 2000 through 2003 were as follows:

	2000	2001	2002	2003
Actimmune:	$11,201,000	36,320,000	105,802,000	141,402,000
Other products:	-0-	3,631,000	6,163,000	12,736,000
Total sales:	$11,201,000	39,950,000	111,965,000	154,138,000

8. The vast majority of InterMune's sales of Actimmune were for the unapproved, off-label use of treating IPF.

9. The cost of Actimmune for one IPF patient for one year was approximately $50,000.

10. Actimmune was manufactured by Genentech, Inc., located in South San Francisco, California, and by subsidiaries of Boehringer Ingelheim, located in Europe. Actimmune was shipped from these manufacturers to InterMune's contract distributor, Cardinal SPS, formerly known as CORD Logistics, a subsidiary of Cardinal Health, Inc., located in Dublin, Ohio. Actimmune was shipped from Cardinal SPS' warehouse in La Vergne, Tennessee, to secondary distributors and pharmacies throughout the United States. These secondary distributors and pharmacies in turn shipped Actimmune to retail locations for distribution to patients, or directly to patients, throughout the United States, including, but not limited to, San Francisco, California.

The Defendant

11. Defendant W. SCOTT HARKONEN ("HARKONEN") was the Chief Executive Officer of InterMune from February 1998 through at least June 30, 2003. HARKONEN was also a member of InterMune's Board of Directors from February 1998 through September 2003. He directed all aspects of InterMune's operations, including, but not limited to, research, marketing, and investor relations. HARKONEN was a medical doctor and was licensed to practice medicine in California.

12. HARKONEN, along with others both known and unknown to the Grand Jury, was responsible for the marketing, distribution, and sale of Actimmune.

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FDA Regulation and Approval of Actimmune

13. The FDCA prohibited the doing of any act with respect to a drug, if the act was done while the drug was held for sale after shipment in interstate commerce and resulted in the drug being misbranded. A drug was misbranded if its labeling was false or misleading in any respect. Labeling included any written, printed, or graphic matter that accompanied a drug, and would further include materials disseminated by or on behalf of a drug manufacturer or distributor that are descriptive of a drug.

Studies of Actimmune as a Treatment for IPF

14. In October 1999, the results of an Austrian study of 18 patients was published in the New England Journal of Medicine ("the Ziesche study"). The Ziesche study stated that interferon gamma-1b had anti-fibrotic properties and that the lung function of the 9 patients who received interferon gamma-1b improved. It also stated that a larger, more scientifically controlled study was needed to test whether the results of the Ziesche study were valid.

15. In October 2000, InterMune began a Phase III clinical trial, named the GIPF-001 trial, to evaluate Actimmune's effect on the progression of IPF. In August 2002, the results of the GIPF-001 trial failed to show that Actimmune was effective in treating IPF.

16. On August 16, 2002, HARKONEN and others known to the Grand Jury, received the data from the GIPF-001 Phase III trial. After receiving the data showing that the GIPF-001 Phase III trial had failed, HARKONEN directed that InterMune employees conduct additional analyses of the mortality data that involved breaking the patient population into subgroups that had not been specified in the trial. This after-the-fact subgroup analysis suggested a survival trend for patients whose IPF was described by InterMune as "mild to moderate."

17. On August 27, 2002, HARKONEN and a small number of other InterMune employees, whose identities are known to the Grand Jury, spoke with the medical review staff at FDA about the results of the GIPF-001 Phase III trial and the additional analyses

of the mortality data. FDA medical review staff advised that the GIPF-001 Phase III trial data were inconclusive, that it would not be enough to get FDA approval for Actimmune to treat IPF, and that further study would be needed to determine whether Actimmune was effective for treating IPF.

18. Thereafter, HARKONEN and others at InterMune began discussions with FDA regarding the design of another trial of Actimmune to treat IPF. The main purpose of this study, known as the "INSPIRE" trial, was to find out if Actimmune helped patients with mild to moderate IPF live longer. InterMune began to enroll patients in the INSPIRE trial in December 2003.

19. On or about March 5, 2007, InterMune notified FDA and the public that it was discontinuing the INSPIRE trial because the IPF patients did not benefit from Actimmune.

Marketing of Actimmune to Treat IPF

20. Commencing in or about October, 2000, and continuing thereafter, HARKONEN, and others known and unknown to the Grand Jury, promoted and caused the promotion by InterMune of Actimmune as a safe and effective treatment for IPF, an intended use for which Actimmune had not been approved as safe and effective by FDA, in order to sell more Actimmune and to generate revenues and profits from sales of Actimmune for InterMune.

21. Commencing in or about October, 2000, and continuing thereafter, HARKONEN, and others known and unknown to the Grand Jury, established, and directed that InterMune establish, sales goals for Actimmune and hired, trained, and directed sales representatives at InterMune to call on doctors known as pulmonologists, who treat patients with lung diseases, to market and sell Actimmune to treat IPF in order to meet those sales goals. HARKONEN, and others known and unknown to the Grand Jury, devised plans to provide incentives and rewards to InterMune's sales representatives based upon the number of Actimmune prescriptions written by the doctors they called on

for the purpose of motivating the sales representatives to advocate that doctors prescribe Actimmune to treat IPF.

Scheme to Defraud

22. Beginning at a time unknown, but no later than August 16, 2002, and continuing through on or about June 30, 2003, in the Northern District of California and elsewhere, the defendant,

W. SCOTT HARKONEN,

did knowingly and intentionally devise a scheme and artifice to defraud, and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, well knowing that the pretenses, representations, and statements were materially false when made, in order to induce doctors to prescribe, and patients to take, Actimmune to treat IPF.

23. It was part of the scheme to defraud that HARKONEN, and others known and unknown to the Grand Jury, caused the general public media and InterMune's sales force to communicate information about the GIPF-001 Phase III trial results that falsely portrayed Actimmune as an effective treatment for IPF by helping IPF patients live longer.

a. On August 28, 2002, InterMune publicly announced the results of the GIPF-001 Phase III clinical trial of Actimmune for the treatment of IPF in the form of a press release. HARKONEN wrote the headline and byline and controlled the content of the entire press release. The press release contained false and misleading information regarding Actimmune and falsely portrayed the results of the GIPF-001 Phase III trial as establishing that Actimmune helped IPF patients live longer. The headline stated that "InterMune Announces Phase III Data Demonstrating Survival Benefit of

Actimmune in IPF," with the subheading "Reduces Mortality by 70% in Patients With Mild to Moderate Disease."

b. On or about August 28, 2002, HARKONEN caused the press release to be posted on InterMune's own website, hosted by a company located in San Francisco, and caused the press release to be sent to a wire service located in New York for release to news outlets nationwide.

c. On August 28, 2002, HARKONEN provided T-shirts regarding the GIPF-001 Phase III trial results to InterMune employees, including members of the sales force, at a party held by HARKONEN to celebrate the announcement of the trial results. These T-shirts were prepared at the direction of HARKONEN. The front of the T-shirts stated "ACTIMMUNE GIPF-001 IPF." The back of the T-shirts depicted a vial with an Actimmune label and stated, "FEEL BETTER LIVE LONGER."

d. On or about August 27, 2002, and with the knowledge and approval of HARKONEN, InterMune hired a marketing research firm to find out whether the upcoming August 28, 2002 press release would have an impact on the doctors' decision to prescribe Actimmune for IPF. On or about September 11, 2002, the research firm provided InterMune a report stating that the survey had found that the August 28, 2002 press release had a positive impact on pulmonologists and increased their likelihood to use Actimmune to treat IPF.

e. On August 28, 2002, InterMune's Vice President of Pulmonary Marketing, whose identity is known to the Grand Jury, forwarded to InterMune's sales representatives an email

containing information regarding Actimmune. Attached to this email were: (1) a document identified as "Phase III Communications" instructing the sales representatives how to speak with doctors about the August 28, 2002 press release, and (2) a copy of that press release. The "Phase III Communications" document contained "Frequently Asked Questions" and a page that stated at its top: "Top-line results from the Phase III Actimmune trial are as follows."

24. It was an essential part of the scheme to defraud that the information in the press release be conveyed to pharmacies that sold Actimmune and to patients and doctors. In furtherance of the scheme to defraud, HARKONEN, and others known and unknown to the Grand Jury, assisted and caused the dissemination by a specialty pharmacy in Florida of information to patients and doctors that portrayed Actimmune as an effective treatment for IPF in order to induce doctors to prescribe, and patients to take, Actimmune for IPF.

a. From in or around September 2002 to in or around October 2002, the same specialty pharmacy distributed a letter to Actimmune patients, which was sent with their Actimmune prescriptions. The letter contained information about Actimmune and stated, "On August 28, 2002, InterMune, Inc. announced that preliminary data from its Phase III clinical trial of Actimmune (Interferon gamma-1b) injection for the treatment of [IPF] showed a statistically significant reduction in mortality by 70% in patients with mild to moderate IPF. Interferon gamma-1b is the first treatment ever to show any meaningful impact in this disease in clinical trials. These results indicate that Actimmune should be used early in the

course of treatment of this disease in order to realize the most favorable long-term survival benefit."

b. Between on or about September 26, 2002, through on or about October 16, 2002, the same speciality pharmacy sent the press release with a cover sheet highlighting information in the press release to over 2,000 pulmonologists via fax blast.

COUNT ONE: (18 United States Code § 1343 – Wire Fraud; 18 United States Code § 2 – Aiding and Abetting)

25. Paragraphs 1 through 24 of this Indictment are realleged and incorporated by reference as if fully set forth herein.

26. On or about August 27, 2002, in the Northern District of California and elsewhere, having devised and intending to devise a scheme and artifice to defraud by means of materially false and fraudulent pretenses, representations and promises, the defendant,

W. SCOTT HARKONEN,

did, in furtherance of such scheme and artifice to defraud, knowingly transmit, and cause to be transmitted, the following wire communication in interstate commerce from the Northern District of California to a location outside of the State of California: a press release entitled "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," with the subheading "Reduces Mortality by 70% in Patients With Mild to Moderate Disease," which contained materially false and misleading information regarding Actimmune and falsely portrayed the results of the GIPF-001 Phase III trial as establishing that Actimmune reduced mortality in patients with IPF, all in violation of Title 18, United States Code, Sections 1343 and 2.

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COUNT TWO: (21 United States Code §§ 331(k), 333(a)(2) and 352(a) – Doing acts, with intent to defraud and mislead, resulting in drugs being misbranded while held for sale after shipment in interstate commerce; 18 United States Code § 2 – Aiding and Abetting)

27. Paragraphs 1 through 24 of this Indictment are hereby realleged and incorporated by reference as if fully set forth herein.

28. On or about August 28, 2002, and continuing thereafter through on or about June 2003, in the Northern District of California and elsewhere, the defendant,

W. SCOTT HARKONEN,

did, with the intent to defraud and mislead, disseminate and cause the dissemination of false and misleading information regarding Actimmune, thereby causing Actimmune to be misbranded while it was held for sale at retail locations throughout the United States, following shipment in interstate commerce, all in violation of Title 21, United States Code, Sections 331(k), 333(a)(2), and 352(a) and Title 18, United States Code, Section 2.

DATED: 03/18/08

A TRUE BILL.

FOREPERSON

BRIAN J. STRETCH
Acting United States Attorney

BRIAN J. STRETCH

(Approved as to form: AUSA PETROU

Sondra Mills and Allan Gordus, Trial Attorneys
U.S. Department of Justice, Office of Consumer Litigation