

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA)	
)	
Plaintiff,)	
)	Criminal No.
v.)	
)	18 U.S.C. § 371
SCHERING SALES CORPORATION)	Conspiracy to Violate Title 18 U.S.C. § 1001
(A SUBSIDIARY OF SCHERING-)	
PLOUGH CORPORATION),)	
)	
Defendant.)	
)	
)	

INFORMATION

COUNT ONE: 18 U.S.C. § 371 (CONSPIRACY TO VIOLATE 18 U.S.C. § 1001)

The United States Attorney charges that:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

THE DEFENDANT

1. **SCHERING SALES CORPORATION** (“**SCHERING SALES**”) was a Delaware corporation with its principal place of business in Kenilworth, New Jersey. **SCHERING SALES** was a wholly-owned subsidiary of Schering Corporation, a New Jersey corporation, which in turn was a wholly-owned subsidiary of Schering-Plough Corporation, a New Jersey corporation. The shares of Schering-Plough Corporation were listed on the New York Stock Exchange and were publicly traded. Schering-Plough Corporation and its subsidiaries, including **SCHERING SALES**, will be referred to in this Information collectively as “Schering.”

2. Schering developed, manufactured, distributed and sold pharmaceutical products nationwide, including in the District of Massachusetts. **SCHERING SALES** marketed and sold drugs manufactured by Schering-Plough Corporation. **SCHERING SALES** employed a nationwide sales force which was divided among business units. One business unit was the oncology and biotechnology business unit (hereafter “OBBU”), which focused on sales of drugs in oncology and hepatitis. Another business unit was the managed care business unit, which focused on sales of drugs, including oncology and hepatitis drugs, to health maintenance organizations and other national accounts.

THE FEDERAL MEDICAID PROGRAM AND CLARITIN REDITABS

3. In 1965, Congress enacted Title XIX of the Social Security Act (“Medicaid” or the “Medicaid Program”) to expand the nation’s medical assistance program for the needy and medically needy aged, blind, disabled, and families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid Program was funded by both federal and state monies, collectively referred to as “Medicaid Funds,” with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b). Each State was permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the Department of Health and Human Services (“HHS”). 42 U.S.C. § 1396a. Among other forms of medical assistance, the States were permitted to provide medical assistance from the Medicaid Funds to eligible persons for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A), 1396d(a)(12).

4. HHS was an agency within the executive branch of the United States government and was responsible for the administration, supervision and funding of the federal Medicaid Program. The Health Care Financing Administration (“HCFA”), currently known as the Center

for Medicare and Medicaid Services (“CMS”), was a division of HHS and was directly responsible for administering the federal Medicaid Program, including review and approval of the individual State medical assistance plans.

5. In 1990, Congress enacted the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, to attempt to control exploding Medicaid drug costs. Under this program, each drug manufacturer voluntarily entered into an agreement with HCFA in which it agreed to pay rebates to the States based on the utilization of its drug products in exchange for having those drug products covered by the State plans and reimbursed through Medicaid Funds. 42 U.S.C. § 1396r-8(a)(1).

6. Under the Medicaid Rebate Program and the rebate agreement with HCFA, among other responsibilities, participating drug manufacturers, including Schering, were required:

- a. to report to HCFA on a quarterly basis the “best price” for single source and innovator multiple source drugs, defined as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, *health maintenance organization*, non-profit entity or governmental entity within the United States,” with certain specified statutory exclusions. 42 U.S.C. § 1396r-8(c)(1)(C)(i)(emphasis added)(hereafter referred to as “Best Price”);
- b. to determine best price by including, among other things, “*free goods that are contingent on any purchase requirement.*” 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I)(emphasis added); and

- c. to pay to each State plan a quarterly rebate with respect to single source and innovator multiple source drugs equal to the product of (a) the units of each dosage form and strength paid for under the State plan during the rebate period as reported by the state, and (b) the greater of (i) the difference between the average manufacturer price and the best price, or (ii) a minimum rebate percentage of the average manufacturer price. 42 U.S.C. § 1396r-8(c)(1)(A).

7. On or about February 28, 1991, Schering entered into a Medicaid rebate agreement with the Secretary of HHS. Under the rebate agreement Schering agreed, in pertinent part, that:

- a. “Best Price” . . . “shall be inclusive of cash discounts, *free goods*, volume discounts, and rebates.” *See* Rebate Agreement, Paragraph I(d)(emphasis added); and
- b. To report to the Secretary quarterly, . . . “in the case of Single Source and Innovator Multiple Source Drugs,” Schering’s “Best Price for all Covered Outpatient Drugs.”

8. As **SCHERING SALES** knew and understood, the purpose of the Medicaid Rebate Program was to ensure that Medicaid, the nation’s medical assistance program for the poor, received the lowest price available for its drugs to certain other purchasers, including specifically prices that Schering made available to HMOs.

9. Among other prescription drug products, **SCHERING SALES** marketed and sold loratadine rapidly dissolving tablets, a non-sedating antihistamine, marketed under the brand

name Claritin RediTabs (a form of Claritin which dissolves on the tongue.) Claritin was Schering's flagship product. Claritin RediTabs was a Single Source Drug for which, on a quarterly basis, Schering was required to report the Best Price to HCFA and to pay rebates to the State Medicaid programs, including the Medicaid program of the Commonwealth of Massachusetts.

THE FDA REGULATORY FRAMEWORK AND TEMODAR AND INTRON A

10. The United States Food and Drug Administration ("FDA") was an agency within the executive branch of the United States government and was responsible for, among other responsibilities, evaluating the safety and effectiveness of any new drug for human use before distribution in interstate commerce. See, 21 U.S.C. § 355. Under federal law, a "new drug" was any drug, with certain exceptions not relevant here, that was not generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling. See, 21 U.S.C. § 321(p).

11. The Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, among other things, governed the lawful interstate distribution of drugs for human use. See, 21 U.S.C. § 301 *et seq.* Before any new drug could be legally distributed in interstate commerce, the FDCA required a sponsor to submit a New Drug Application ("NDA") for the drug, and the FDA to approve the NDA. See, 21 U.S.C. § 355(a)

12. The FDCA required a drug manufacturer to submit to the FDA, as part of an NDA, proposed labeling for the proposed intended uses for the drug and specify, among other things, the conditions for therapeutic use. See, 21 U.S.C. § 355(b). The FDCA further required a sponsor to provide, to the satisfaction of the FDA, data generated in randomized and well-

controlled clinical trials demonstrating that the drug was safe and effective when used in accordance with the proposed labeling.

13. The FDCA prohibited the introduction into interstate commerce of any new drug, unless an approval of an NDA had been obtained. Only after the FDA reviewed the NDA, including the proposed labeling, and found sufficient evidence of safety and effectiveness to approve the NDA, was the sponsor permitted by law to promote and market the drug, and then only for the medical conditions of use specified in the approved labeling. Uses not approved by FDA, and not included in the drug's approved labeling, were known as "unapproved uses" or "off-label uses." See, 21 U.S.C. § 355.

14. **SCHERING SALES** marketed and sold certain oncology drugs including temozolomide, a chemotherapeutic agent, marketed under the brand name Temodar, and interferon alpha-2b (also known as interferon alfa-2b), marketed under the brand name Intron A.

15. In or about 1983, Schering submitted an NDA for approval of Intron A. Intron A was a new drug within the meaning of 21 U.S.C. § 321 (p) and 21 C.F.R. § 310.3 (h)(4) and (5). Since in or about 1986, the FDA approved Intron A for the treatment of various conditions, including but not limited to, chronic hepatitis B, chronic hepatitis C, AIDS-related Kaposi's sarcoma, hairy cell leukemia, malignant melanoma and follicular lymphoma. At no time during the period covered by this Information, did the FDA approve Intron A for use in superficial bladder cancer.

16. In or about 1998, Schering submitted an NDA for approval of a drug called Temodar for use in treatment of three forms of cancer: (a) refractory anaplastic astrocytoma (a type of brain tumor that was unresponsive to a first-line drug regimen of nitrosourea and

procarbazine), (b) recurrent glioblastoma multiforme (another type of brain tumor that was unresponsive to first-line therapy), and (c) metastatic malignant melanoma (melanoma that has metastasized to the brain). Temodar was a new drug within the meaning of 21 U.S.C. § 321 (p), and 21 C.F.R. § 310.3 (h)(4) and (5). The FDA considered Temodar under its accelerated approval procedures for new drugs for serious or life threatening illnesses. *See*, 21 C.F.R. § 314.510. In or about August 1999, the FDA approved Temodar for the treatment of refractory anaplastic astrocytoma, a disease suffered by about 4,000 patients a year. At no time during the period covered by this Information, did the FDA approve Temodar for use in newly diagnosed anaplastic astrocytomas, glioblastoma multiformes, metastatic melanoma, or brain metastases of other solid tumors.

17. Schering sold and marketed both Intron A and Temodar directly to physicians nationwide by the OBBU sales force of **SCHERING SALES**. That sales force also sometimes attended physician conferences where physicians with possible interest in Temodar or Intron A were expected to attend.

THE CONSPIRACY

18. From in or about early 1998 through in or about August 2001, the exact dates unknown, in the District of Massachusetts, and elsewhere throughout the United States, the defendant

SCHERING SALES CORPORATION

together with others known and unknown to the United States Attorney, did knowingly and willfully combine, conspire and agree to knowingly and willfully make materially false, fictitious and fraudulent statements and representations in matters occurring within the

jurisdiction of the executive branch of the United States government in violation of 18 U.S.C. § 1001.

19. The objective of the conspiracy to make false statements to agencies within the executive branch of the United States government was to enrich Schering and to protect and further its ability to keep monies to which it was not entitled.

MANNER AND MEANS

20. **SCHERING SALES** and its co-conspirators used the following manner and means, among others, in furtherance of the conspiracy:

a. It was a part of this conspiracy that **SCHERING SALES** and its co-conspirators knowingly and willfully made material false statements to HCFA regarding the Best Price of Claritin Reditabs by concealing the fact that Schering was providing to an HMO free drugs contingent on purchases of the drugs from Schering, thereby allowing Schering to retain approximately \$4,392,000 in monies which were owed in rebates to the state Medicaid programs and to which Schering was not entitled; and

b. It was further a part of the conspiracy that **SCHERING SALES** and its co-conspirators knowingly and willfully made material false statements to the FDA in order to avoid scrutiny by the FDA of Schering's off-label promotional activities regarding Temodar and Intron A, thereby allowing Schering to obtain approximately \$124,179,000 in before-tax profits which it otherwise would not have obtained.

OVERT ACTS

In furtherance of the conspiracy, and to effect the objects thereof, in the District of Massachusetts and elsewhere, **SCHERING SALES** and its co-conspirators, committed the following overt acts, among others:

False Statements Concerning The Claritin Reditabs "Sampling" Program

21. In or about January 1998, an employee of **SCHERING SALES** met with a representative of a particular large health maintenance organization ("HMO"), that maintained a widely known formulary and that had, effective in or about July 1997, removed Claritin from that formulary and replaced it with a less expensive non-sedating antihistamine. As a result of this meeting, **SCHERING SALES** learned that the HMO was willing to reestablish Claritin Reditabs on its formulary if the price was reduced to \$1.10 per Claritin Reditab, a price that **SCHERING SALES** knew and understood would set a new Best Price for the drug and would require Schering to pay increased Medicaid rebates to the state Medicaid programs.

22. In February 1998, **SCHERING SALES** and certain of its employees discussed several different proposals to provide the \$1.10 price for Claritin Reditabs to the HMO, all of which were designed to avoid reporting the new low price to HCFA and incurring the corresponding obligation to pay increased rebates to the state Medicaid programs. One of the proposals discussed was to ship sufficient trade size packages of Claritin Reditabs to the HMO for free as "samples" so that the blended price between the drug purchased by the HMO and the drug provided for free was \$1.10 per Reditab.

23. On or about February 18, 1998, **SCHERING SALES** obtained legal advice from outside counsel that a proposed Claritin Reditab "sampling" program to the HMO would not

affect Schering's Best Price reporting obligations. In obtaining this legal advice, **SCHERING SALES** failed to disclose the material fact that the "samples" of free drug provided would be contingent on the amount of drug purchased to reach a blended price of \$1.10 per RediTab.

24. In or about April 1998, **SCHERING SALES** and its co-conspirators caused a sufficient quantity of free trade size packages of Claritin RediTabs to be shipped to the HMO so that, when combined with the Claritin Reditabs purchased by the HMO, the blended price was \$1.10 per RediTab.

25. From in or about March 1998 through in or about September 1999, **SCHERING SALES** and its co-conspirators caused false documentation to be created that indicated that the free goods shipped to the HMO were samples requested by the HMO, despite the fact that **SCHERING SALES** and its co-conspirators knew and understood that the HMO did not allow its physicians to receive samples except in very limited quantities; that the HMO refused to sign any agreement for free drug that contained the word "samples;" that Schering shipped full trade packs of Claritin RediTabs to the HMO; that Schering shipped the free drug to the same HMO warehouses as it shipped the purchased drug; that the HMO distributed the free drug within its pharmacies no differently than the purchased drug; that the physicians did not receive the free drug for use as "samples" despite the fact that certain physicians at the HMO signed "sample request forms" prepared by Schering, each of which requested several thousand samples to be sent to the HMO warehouse; and that the HMO entered the blended price of \$1.10 per RediTab into its accounting systems for all Claritin RediTabs whether purchased from Schering or provided by Schering to the HMO for free.

26. From at least February 1999 through in or about July 1999, **SCHERING SALES** and its co-conspirators prevented an internal audit team at Schering from auditing the “sampling” program at the HMO in accord with Schering’s normal audit procedures by frustrating the scheduling of an on-site visit to determine how the “samples” were handled by the customer. In or about August 1999, the internal audit team raised concerns about the “sampling” program to management.

27. In or about September 1999, after a decision was made to terminate the program, **SCHERING SALES** and its co-conspirators caused a final calculation to be made of the amount of free drug required to be provided to the HMO contingent on the amount of drug purchased by the HMO to reach the blended \$1.10 price for Claritin RediTabs for the remainder of 1999 for each of the HMO’s regions of operation, and caused a final shipment of free drug to be made to each of the HMO’s regional warehouses.

28. In or about October 1999, after the “sampling” program was terminated, **SCHERING SALES** obtained a written legal opinion from outside counsel that confirmed the earlier legal conclusion provided that the “sampling” program did not impact Schering’s best price reporting obligations “because the provision of these drug samples to [the HMO] by the Company [was] not contingent on any purchase requirements,” although, as **SCHERING SALES** knew and understood, the free drug was in fact provided contingent on purchase requirements to obtain the \$1.10 blended price. This written legal opinion, finalized in October 1999, bore a date of February 18, 1998, thereby falsely indicating that the legal analysis contained therein was provided to **SCHERING SALES** before the free goods were shipped to the HMO, despite the fact that the opinion referenced a letter to the HMO not written until

March 1998, incorporated by reference a kickback analysis from a compliance binder that was not completed before the fall of 1998, and purported to be authored by two attorneys, one of whom did not even join the law firm until months later.

29. In each quarter from second quarter 1998 through fourth quarter 1999, inclusive, **SCHERING SALES** and its co-conspirators caused materially false statements to be submitted to HCFA regarding the Best Price for Claritin Reditabs that failed to include the \$1.10 price for Claritin Reditabs that was being provided to the HMO in the calculation of Best Price.

30. In each quarter from second quarter 1998 through fourth quarter 1999, inclusive, **SCHERING SALES** and its co-conspirators caused Schering to underpay rebates owed to the state Medicaid programs and retain approximately \$4,392,000 in monies to which it was not entitled, in that Schering failed to include the \$1.10 price for Claritin Reditabs in the calculation of the Best Price that was being utilized to determine the amount of rebate owed.

False Statements Concerning Schering's Off-label Marketing of Oncology Drugs

31. On or about June 29, 2001, **SCHERING SALES** and various co-conspirators received a copy of, or learned of, an untitled letter dated June 28, 2001, that Schering received from the Division of Drug Marketing, Advertising, and Communications ("DDMAC") of the FDA concerning a May 2001 commercial exhibit hall booth that Schering maintained and staffed with representatives of the OBBU sales force at the 37th American Society of Clinical Oncology ("ASCO") Annual Meeting, held in San Francisco, California. This letter notified Schering that DDMAC had "identified promotional activities that [were] in violation of the Federal Food Drug and Cosmetic Act (Act) and its implementing regulations," and explained that Schering gave "false or misleading efficacy information about Temodar to visitors at the commercial exhibit

hall both” at the ASCO meeting and that “Schering also promoted Temodar for the unapproved use in first line therapy of anaplastic astrocytoma.” DDMAC requested that Schering “immediately cease making such violative statements and any other promotional activities or materials for Temodar that make the same or similar claims or presentations.” The letter requested Schering submit a written response to the FDA on or before July 13, 2001, and provide the date on which “this and other similarly violative materials were discontinued.”

32. At the time of the receipt of the FDA letter, as **SCHERING SALES** and its co-conspirators knew and understood, the OBBU sales force, at the direction of home office, was engaged in the widespread marketing of Intron A for superficial bladder cancer and Temodar for conditions other than refractory anaplastic astrocytoma. Among other actions taken by Schering’s home office to ensure that the OBBU sales force aggressively pursued sales of Intron A and Temodar for unapproved uses were the following: the sales force was trained to seek off-label sales through training classes, ride-alongs with managers, district meetings, teleconferences, and sales meetings; the marketing department provided the sales force a plan of action that targeted off-label sales; the sales force was provided with clean copies of “for your information only” scientific articles and abstracts from headquarters to use with physicians; the sales force was required to create business plans that emphasized detailed promotional goals to obtain off-label sales; the sales force was evaluated and richly compensated, in large measure, by their success in achieving sales in unapproved uses; the sales force was provided with substantial budgets for advisory boards, speakers, entertainment, and preceptorships to assist in obtaining off-label sales. **SCHERING SALES** and its co-conspirators knew and understood the sales

representatives would be done with their week's work "at noon on Monday" if they did not promote Temodar and Intron A for unapproved uses.

33. On or about June 29, 2001, certain employees of **SCHERING SALES** met to determine how to respond to the FDA's untitled letter of June 2, 2001.

34. On or about July 12, 2001, **SCHERING SALES** and its co-conspirators knowingly and willfully caused a written response to be submitted to the FDA that falsely stated that the statements identified in the FDA's letter were "an isolated incident" and "certainly inconsistent with the direction provided by the home office," despite the fact that **SCHERING SALES** and its co-conspirators knew and were directing the OBBU sales force to engage in widespread off-label marketing of Intron A for superficial bladder cancer and Temodar for conditions other than refractory anaplastic astrocytoma.

35. No later than on or about July 12, 2001, **SCHERING SALES** and its co-conspirators caused to be included in the written response to the FDA false assurances designed to lull the FDA into believing that effective remedial action had been taken in order to avoid further FDA scrutiny of Schering's promotional activity. Among other things, **SCHERING SALES** and various co-conspirators caused Schering to falsely state in writing to the FDA that Schering and its employees would only market Temodar according to its labeled indications and that an electronic message was that day being sent to all Schering Temodar sales representatives regarding the "importance of appropriate and accurate promotion" and that the sales force was being "reminded that they may only discuss the approved indication for this product." At the time, **SCHERING SALES** and its co-conspirators well knew that the electronic message was

not designed to deter such discussions because it would be substantially overridden by the training, incentives, and support to promote off-label uses of the drug.

36. As a result of the false representations in the July 12, 2001 letter, **SCHERING SALES** and its co-conspirators caused the FDA, on or about August 2, 2001, to issue a letter that stated that the FDA considered the matter closed in light of the following affirmations contained in Schering's July 12, 2001 letter:

- * "The statements made by your representative in this matter are an isolated incident and are not consistent with the direction provided by the Schering home office."
- * "Schering sent an electronic mail message on July 12, 2001, to all Schering Temodar sales representatives to reinforce the importance of appropriate and accurate promotion and highlight issues discussed in DDMAC's June 28, 2001, untitled letter, and to instruct them that they may only discuss the approved indication for Temodar."

37. As a result of the false statements to the FDA to avoid scrutiny of the ongoing off-label promotional activities directed by home office, **SCHERING SALES** and its co-conspirators caused Schering to obtain, between July 2001 and December 2003, approximately \$124,179,000 in before-tax profits to which it was not entitled.

All in violation of Title 18, United States Code, Section 371.

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS



SUSAN G. WINKLER
JEREMY STERNBERG
ASSISTANT U.S. ATTORNEYS

Dated: August 29, 2006