



U.S. Department of Justice

Michael J. Sullivan
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse
1 Courthouse Way
Suite 9200
Boston, Massachusetts 02210

August 24, 2006

06-CR-10250-PBS

FILED
U.S. District Court
DSDC, Mass.
9/20/06
[Signature]

Brien T. O'Connor
Ropes & Gray
One International Place
Boston, MA 02110

Re: Side Letter Agreement with Schering-Plough Corporation

Dear Mr. O'Connor:

This letter ("Side Letter Agreement") will confirm that, in exchange for full performance of the Plea Agreement entered into by and among the United States of America, acting through the United States Attorney for the District of Massachusetts ("U.S. Attorney") and the Department of Justice (collectively referred to as "the United States") and your client, Schering Sales Corporation ("Schering Sales"), a copy of which plea agreement is attached hereto as Exhibit One, and in exchange for certain other promises made herein between and among the United States and your client, Schering-Plough Corporation ("Schering-Plough;" collectively, Schering-Plough Corporation and Schering Sales Corporation will be referred to as "Schering"), the United States and Schering-Plough Corporation hereby agree as follows:

a. No Criminal Prosecution of Schering-Plough Corporation

The United States hereby declines prosecution of Schering-Plough Corporation for conduct by or attributable to Schering-Plough Corporation that:

- (1) falls within the scope of the Information to which Schering Sales is pleading guilty;
- (2) was a subject of the grand jury investigation by the U.S. Attorney in Massachusetts including allegations that Schering:
 - (a) failed to report to HCFA the price at which it sold products to health maintenance organizations pursuant to private label, repackaging or relabeling agreements as the best price for those products;

- (b) directly or indirectly offered or paid remuneration, such as drug samples, clinical trial grants and other items or services of value, and marketed vial overfill to customers including but not limited to physicians, physician practice groups, patient care groups, pharmacy benefit managers, HMOs, hospitals, buying groups, wholesalers and/or distributors (and individuals operating by or on behalf of those entities) to induce these entities or individuals to recommend, prescribe and/or purchase Schering's oncology and hepatitis drugs;
 - (c) paid remuneration to managed care entities to obtain and keep the Claritin family of drugs and other drug business, including by the provision of nominally priced goods to managed care entities to evade best price reporting requirements regarding the Claritin family of drugs;
 - (d) promoted, marketed and sold oncology and hepatitis drugs in violation of the Food, Drug & Cosmetic Act;
 - (e) failed to disclose clinical data concerning Schering's oncology and hepatitis drug products;
 - (f) destroyed documents and engaged in other allegedly obstructive conduct; and
 - (g) engaged in bundling and the unlawful manipulation of drug pricing to evade Medicaid rebate liability or to improperly inflate drug reimbursements; or.
- (3) was known to the U.S. Attorney in Massachusetts prior to the date of execution of this letter in connection with the sales, marketing, pricing and promotion of Schering's drugs prior to July 1, 2005.

The United States does not decline criminal prosecution of Schering-Plough Corporation or any of Schering's related entities for any other conduct beyond that set forth above.

This Side Letter Agreement is not intended to and does not affect the criminal liability of any individual.

It is understood among the parties to this Side Letter Agreement that the United States' promise not to prosecute Schering-Plough Corporation is dependent upon and subject to Schering Sales Corporation fulfilling its material obligations in the Plea Agreement and the related Civil Settlement Agreement attached hereto as Exhibit Two. If Schering does not fulfill its material obligations in the Plea Agreement and the related Civil Settlement Agreement, Schering-Plough Corporation agrees to waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought

or pursued as of August 17, 2006.

b. Cooperation of Schering-Plough Corporation

Schering shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing federal grand jury investigation of its current and former officers, agents, and employees. Schering shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice. Schering shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity.

In addition, Schering shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing grand jury investigation, trial or other criminal proceeding in the District of Massachusetts, and that are not covered by the attorney-client privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) Schering is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) Schering is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) Schering is not required to waive any privilege or claim of work product protection except to the extent set forth in the succeeding paragraph.

Schering specifically agrees to waive any attorney-client privilege regarding the decision to provide nominally priced Claritin RediTabs to the HMO referenced in the Information in 2000, and to terminate that arrangement in 2001.

Schering-Plough Corporation acknowledges that Schering Sales Corporation expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the Information and is in fact guilty of that offense. Schering-Plough Corporation agrees that it will not make statements inconsistent with this explicit admission of guilt by Schering Sales Corporation to the crime charged in the Information.

c. Who Is Bound By Agreement

This letter agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys, except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of the Treasury.

It is expressly understood that this Side Letter Agreement will have no effect on state or local

prosecuting authorities, except as set forth in the settlement agreements between Schering-Plough Corporation and the various states.

d. Complete Agreement

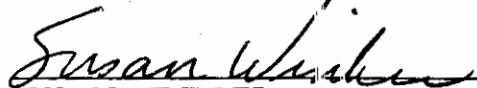
This Side Letter Agreement, the Plea Agreement with Schering Sales, the Civil Settlement Agreement, and the Corporate Integrity Agreement, are the complete and only agreements between the parties. No promises, agreements or conditions have been entered into other than those set forth or referred to in the above-identified documents. This agreement supersedes prior understandings, if any, of the parties, whether written or oral. This agreement cannot be modified other than in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the agreement entered into between the United States and Schering-Plough Corporation and its Board of Directors has authorized you to enter into this agreement, please sign below and return the original of this letter to Assistant U.S. Attorney Susan G. Winkler.

Very truly yours,



MICHAEL J. SULLIVAN
United States Attorney
District of Massachusetts



SUSAN WINKLER
Assistant U.S. Attorney
District of Massachusetts

ACKNOWLEDGMENT OF AGREEMENT

The Board of Directors of Schering-Plough Corporation has authorized me to execute this Side Letter Agreement and the Civil Settlement Agreement on behalf of Schering-Plough Corporation. The Board of Directors has been advised of the contents of this Side Letter Agreement, the Civil Settlement Agreement, the Plea Agreement with Schering Sales Corporation, the criminal Information charging Schering Sales Corporation, and the Corporate Integrity Agreement, and has discussed them fully with me. I am further authorized to acknowledge on behalf of Schering-Plough Corporation that these documents fully set forth the agreements made between Schering-Plough Corporation and the United States, and that no additional promises or representations have been made to Schering-Plough Corporation by any officials of the United States in connection with the disposition of this matter, other than those set forth in those documents.

Dated:

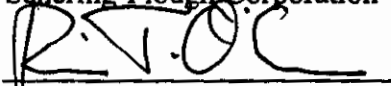
8/25/06



THOMAS J. SABATINO
Executive Vice President and General Counsel
Schering-Plough Corporation

Dated:

8/25/06



BRIEN T. O'CONNOR
Ropes & Gray
Counsel for Schering-Plough Corporation

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

<hr/>)	
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.)	
)	
<hr/>)	

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.”

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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 PRESCRIPTIONS

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

- 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.

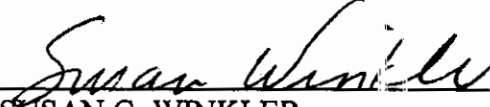
36. As a result of the false representations in the July 12, 2001 letter, **SCHERING SALES** and its co-conspirators caused the FDA, on or about August 2, 2001, to issue a letter that stated that the FDA considered the matter closed in light of the following affirmations contained in Schering's July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

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement ("Agreement") is entered into by the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the District of Massachusetts, and the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"); TRICARE Management Activity ("TMA")(formerly known as the Office of the Civilian Health and Medical Program of the Uniformed Services), a field activity of the Office of the Secretary of Defense, the United States Department of Defense; the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP"); Schering-Plough Corporation ("Schering"), a New Jersey Corporation with a principal place of business in Kenilworth, New Jersey, and its subsidiaries and divisions, including Schering Sales Corporation, through their authorized representatives. Collectively, all of the above shall be referred to as "the Parties."

II. PREAMBLE

A. WHEREAS, at all relevant times, Schering distributed, marketed and sold pharmaceutical products in the United States, including the following prescription drug products: (1) loratadine rapidly dissolving tablets, a non-sedating antihistamine, marketed under the brand name Claritin Redi-Tabs; (2) potassium chloride 20 meq, an electrolytic and water balance agent, marketed under the brand name K-Dur 20; (3) temozolomide, a chemotherapeutic agent, marketed under the brand name Temodar; (4) interferon alfa-2b, a biologic, marketed under the brand name Intron A; (5) pegylated interferon alfa-2b, a biologic, marketed under the brand name PEG-Intron; (6) interferon alfa-2b marketed together with ribavirin, a nucleoside analogue, under the brand name

Rebetron; and (7) pegylated interferon alfa-2b marketed together with ribavirin as PEG-Intron Combination Therapy (collectively, "the drugs"). Schering sold the drugs to various customers including, among others, health maintenance organizations ("HMOs"), hospitals, long term care providers, chain pharmacies, specialty pharmacies, and physicians. One of the HMOs to which Schering sold drugs was Kaiser Permanente Medical Care Program ("Kaiser").

B. WHEREAS, Schering Sales Corporation, a wholly owned subsidiary of Schering-Plough Corporation, has agreed to enter into a plea agreement with the United States Attorney for the District of Massachusetts (the "Plea Agreement"), under which, if the Plea Agreement is approved by the Court, Schering Sales Corporation will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an Information to be filed in United States of America v. Schering Sales Corporation (District of Massachusetts)(the "Criminal Action") that will allege that Schering Sales Corporation violated Title 18, United States Code, Section 371, by conspiring to make false statements in violation of Title 18, United States Code, Section 1001, to the Health Care Financing Administration ("HCFA") in connection with Schering's best price for Claritin Redi-Tabs for second quarter 1998 through fourth quarter 1999, and to the United States Food and Drug Administration ("FDA") in response to an inquiry by the FDA in July 2001 regarding Schering's off-label marketing activities.

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D. WHEREAS, at all material times, Schering participated in the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Rebate Program, Schering entered into a rebate agreement with HCFA, currently known as the Centers for Medicare and Medicaid Services (“CMS”), and Schering’s drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with HCFA, Schering generally agreed: (i) to report quarterly to HCFA its average manufacturer price and, for single source and innovator multiple source drugs, best price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and best price, or a minimum rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(1).

E. WHEREAS, at all material times, Schering participated in the Drug Pricing Program, 42 U.S.C. § 256b, which is part of the Public Health Service (“PHS”) Act, 42 U.S.C. §§ 201-300gg-92. As a participant in the Drug Pricing Program, Schering entered into an agreement with HHS in connection with the pricing of its drug products sold to entities such as AIDS drug purchasing assistance programs, community health centers, hemophilia treatment centers, and disproportionate

share hospitals, as defined in 42 U.S.C. § 256b(a)(4) (the “PHS entities”). Under the Drug Pricing Program and its agreement with HHS, Schering generally agreed that the amount that Schering required the PHS entities to pay for drug products would not exceed the average manufacturer price, as reported by Schering to HCFA in the previous calendar quarter, minus a specified rebate percentage that was derived in part from the Medicaid rebate paid by Schering in the preceding calendar quarter for each drug, as further described in 42 U.S.C. § 256b(a).

F. WHEREAS, Schering has entered into or will be entering into separate settlement agreements (hereinafter referred to as the “Medicaid State Settlement Agreements”) with the states which will be receiving settlement funds from Schering pursuant to Paragraph 1(B) below for the Covered Conduct described in Paragraph H below (hereinafter referred to as the “Medicaid Participating States”).

G. WHEREAS, the United States alleges that Schering caused to be submitted claims for payment for the drugs to the Medicaid Programs, established pursuant to or in connection with Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the “Medicaid Program”); and the United States further alleges that Schering caused to be submitted claims for payment for the drugs to the Medicare Program, established pursuant to Title XVIII of the Social Security Act, § 1395-1395ggg, which is administered by HHS; the TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services (“CHAMPUS”)), 10 U.S.C. §§ 1071-1106, which is administered by the Department of Defense through the TMA; the FEHBP, 5 U.S.C. §§ 8901-8914; and that Schering caused purchases of the drugs by the Department of Veterans’ Affairs (“DVA”).

H. WHEREAS, the United States contends that it has certain civil claims against Schering under the False Claims Act, 31 U.S.C. §§ 3729-33, the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b, other federal statutes, and/or common law doctrines as specified in Paragraph 2 below for engaging in the following conduct:

(i) The United States contends that, from Second Quarter 1998 through Fourth Quarter 1999, Schering knowingly and willfully misreported its best price to HCFA and underpaid its Medicaid rebates for Claritin Reditabs by omitting from its determination of best price the free Claritin Reditabs contingent on future purchases that were provided to Kaiser to effectuate an agreed-upon lower price;

(ii) The United States contends that, from First Quarter 2000 through Fourth Quarter 2001, Schering knowingly misreported its best price to HCFA and underpaid its Medicaid rebates for Claritin Reditabs by omitting from its determination of best price deeply discounted Claritin Reditabs that were provided to Kaiser to effectuate an agreed-upon lower price;

(iii) The United States contends that, from Fourth Quarter 1995 through Fourth Quarter 2000, Schering knowingly misreported its best price to HCFA and underpaid its Medicaid rebates for K-Dur 20 by omitting from its determination of best price the price of K-Dur 20 that was private labeled for Kaiser;

(iv) The United States contends that, from Fourth Quarter 1998 through Second Quarter 2002, Schering overcharged the PHS entities for Claritin Reditabs; and from Second Quarter 1996 through Second Quarter 2001, Schering overcharged the PHS entities for K-Dur, as a result of Schering's misreporting of its best prices as described in Preamble Paragraphs H (i), (ii) and (iii), above;

(v) The United States contends that, as part of Schering's sales and marketing practices for PEG-Intron, Rebetrone, and PEG-Intron Combination Therapy for patients with Hepatitis C from January 1999 through December 2002, Schering knowingly and willfully offered and paid illegal remuneration to induce physicians to start patients on drug therapy for Hepatitis C in violation of 42 U.S.C. §1320a-7b(b)(2) through three improper sales and marketing programs: the ReCAP Program, which paid physicians up to \$500 for each patient begun on drug therapy for Hepatitis C; the Physician Assistants ("PA") Fellowship Program, which placed Schering-funded physician assistants in busy physician practices; and Low Quintile Advisory Board programs, which paid physicians for attendance at Schering-sponsored events. Furthermore, the Government contends that during this time period, Schering knowingly caused the submission of false or fraudulent claims to the Medicaid and TRICARE Programs for PEG-Intron, Rebetrone, and PEG-Intron Combination Therapy, and caused the DVA to purchase PEG-Intron, Rebetrone, and PEG-Intron Combination Therapy by providing physicians with illegal remuneration through these three programs to induce them to prescribe these drugs to patients;

(vi) The United States contends that, as part of Schering's sales and marketing practices for Temodar, from September 1999 through December 2003, Schering knowingly and willfully offered and paid various forms of illegal remuneration to physicians and physicians' practices to induce utilization of Temodar for brain tumors and brain metastases, including, for example, improper preceptorships, advisory boards, entertainment, and placement of clinical studies in violation of 42 U.S.C. §1320a-7b(b)(2). Furthermore, the Government contends that, during this time period, Schering knowingly caused the submission of false or fraudulent claims for Temodar to the Medicaid and TRICARE Programs and caused the DVA to purchase Temodar by providing

physicians and physicians' practices with illegal remuneration to induce them to prescribe Temodar for patients;

(vii) The United States contends that, during the period September 1999 through December 2003, Schering knowingly promoted the sale and use of Temodar for brain metastases and certain brain tumors (including, specifically, newly-diagnosed anaplastic astrocytomas and a certain subset of glioblastoma multiformes), uses for which the Food and Drug Administration ("FDA") had not approved Temodar; i.e., Schering promoted Temodar for "unapproved" or "off-label" uses. The Government further contends that such off-label marketing violated the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331 (a) and (d). The United States further contends that the use of Temodar for brain metastases during this time period, and the use of Temodar for certain brain tumors during the portion of this time period prior to 2002, were not medically-accepted indications, as defined in 42 U.S.C. § 1396r-8(k)(6), and that certain State Medicaid Programs could not reimburse these uses. The Government further contends that Schering knowingly caused the submission of false or fraudulent claims for Temodar to the TRICARE, FEHBP, and Medicaid programs for non-reimbursable uses, and caused the DVA to purchase Temodar dispensed to patients for unapproved indications; and

(viii) The United States contends that, as part of Schering's sales and marketing practices for Intron A for superficial bladder cancer from September 1999 through December 2003, Schering knowingly and willfully offered and paid various forms of illegal remuneration to physicians and physicians' practices to induce the utilization of Intron A for superficial bladder cancer including, for example, improper preceptorships, advisory boards, entertainment, and placement of clinical studies in violation of 42 U.S.C. § 1320a-7b(b)(2), and encouragement of

improper billing by physicians of Intron A vial overfill and free drugs. The Government further contends that Schering promoted Intron A for superficial bladder cancer although Schering did not have approval from the FDA for use in that indication. Furthermore, the Government contends that, during this time period, Schering knowingly caused the submission of false or fraudulent claims to the Medicaid, Medicare, and TRICARE Programs for Intron A and caused the DVA to purchase Intron A by inducing physicians to prescribe it to patients with superficial bladder cancer by providing them with such illegal remuneration.

Schering's conduct as described in the Information in the Federal Criminal Action and Preamble Paragraph H is hereafter referred to as the "Covered Conduct."

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I. WHEREAS, HHS-OIG contends that it has certain administrative claims against Schering, as specified in Paragraphs 4 and 5 below, for engaging in the Covered Conduct.

J. WHEREAS, this Agreement is neither an admission of facts or liability by Schering, with the exception of such admissions as Schering Sales Corporation makes in connection with a guilty plea to the Information referenced in Paragraph B above, nor a concession by the Government that its claims are not well founded.

K. WHEREAS, to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Schering agrees to pay to the United States, the Medicaid Participating States, and the PHS entities, collectively, the sum of two hundred fifty-five million twenty-five thousand, eighty nine dollars and sixty cents (\$255,025,089.60), plus interest in an amount of 4.292% per annum on the Federal Settlement Amount and Medicaid State Settlement Amount as further set forth in subparagraphs A and B below (\$29,527 per day) from July 27, 2005 and continuing until and including the day before complete payment is made (the "Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States and the Participating States on the Effective Date of this Agreement. This debt is to be discharged by payments to the United States and the Medicaid Participating States, under the following conditions:

A. Schering shall pay to the United States the sum of one hundred fifty-nine million five hundred two thousand dollars (\$159,502,000), plus interest in an amount of 4.292% per annum (\$18,756 per day) from July 27, 2005, and continuing until and including the day before complete payment is made (the "Federal Settlement Amount").

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B. Schering shall pay to the Medicaid Participating States the sum of ninety-one million, six hundred two thousand dollars (\$91,602,000), plus interest in an amount of 4.292% per annum (\$10,771 per day) from July 27, 2005, until and including the day before complete payment is paid (the "Medicaid State Settlement Amount") under the terms and conditions of the Medicaid State Settlement Agreements. This Medicaid State Settlement Amount shall be paid into an interest bearing account as set forth in the Medicaid State Settlement Agreements no later than seven

business days after Schering receives written payment instructions from the National Association of Medicaid Fraud Control Units' Settlement Team for the Medicaid Participating States and following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Schering's attorneys, or (2) the District Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence. The Medicaid State Settlement Amount shall be paid to the Medicaid Participating States from the account following execution of the Medicaid State Settlement Agreements with all the Medicaid Participating States, or at any earlier date as otherwise agreed in writing between Schering and the National Association of Medicaid Fraud Control Units' Settlement Team.

C. Schering shall pay to the PHS entities the sum of three million nine hundred twenty-one thousand eighty nine dollars and sixty cents (\$3,921,089.60) (the "PHS Settlement Amount"). Schering agrees to present for review and audit the underlying calculations used to determine the correct price(s) for the PHS entities during the relevant time periods. Schering agrees that if it is determined that Schering owes any additional amounts to any PHS entity, based upon the allegations in the Covered Conduct, Schering agrees to pay any additional amount required to make that entity whole. The PHS Settlement Amount shall be paid by Schering to each affected PHS entity by check within sixty (60) days following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Schering's attorneys, or (2) the District Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence.

D. If Schering Sales Corporation's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph B is not accepted by

the District Court or that Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Schering. If either the United States or Schering exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five business days of the District Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Schering will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories to any civil or administrative claims, actions or proceedings which are brought by the United States within 90 calendar days of notification to all other Parties of that rescission, except to the extent such defenses were available before February 5, 2003.

2. Subject to the exceptions in Paragraphs 3, 4, 6 and 7 below, and in consideration of the obligations of Schering set forth in this Agreement, conditioned upon Schering's payment in full of the Settlement Amount, subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), and subject to the acceptance by the United States District Court for the District of Massachusetts of Schering Sales Corporation's guilty plea described in Preamble Paragraph B, the United States, on behalf of itself, and its officers, agents, agencies, and departments, agrees to release Schering, its predecessors, and its current and former parents, affiliates, divisions, subsidiaries, successors and assigns, and their current and former directors, officers, and employees, from any civil or administrative monetary claim that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-33; the Food Drug and Cosmetic Act, 21 U.S.C. §§ 331(a), 331(d) and 332; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; the Medicaid Rebate Statute, 42

U.S.C. § 1396r-8; the Drug Pricing Program, 42 U.S.C. § 256b; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision applicable to federally-funded programs in this Agreement for which the Civil Division, Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, 0.45(d)(1995); and common law claims for fraud, unjust enrichment, payment by mistake, or disgorgement for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the United States specifically does not release any person or entity from any of the following claims or liabilities: (a) any criminal, civil, or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal liability; (c) any liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Schering; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Schering, its predecessors, subsidiaries, and affiliates, who receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement.

4. In consideration of the obligations of Schering set forth in this Agreement, and the Corporate Integrity Agreement and Addendum thereto (collectively, "CIA"), conditioned on Schering's payment in full of the Settlement Amount, and subject to Paragraph 15 below (concerning

bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Schering, and except for Schering Sales Corporation, its predecessors, and its current or former parents, affiliates, divisions, subsidiaries, successors, and assigns, under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks or other prohibited activities), for the Covered Conduct, except as reserved in Paragraph 3 above, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Schering from the Medicare, Medicaid, or other Federal health care program under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 3 above.

5. In compromise and settlement of the rights of OIG-HHS to exclude Schering Sales Corporation pursuant to 42 U.S.C. § 1320a-7(a)(1)(mandatory exclusion for a criminal offense related to the delivery of an item or service under Medicare or Medicaid) based on the Plea Agreement described in Paragraph II.B. above, and pursuant to 42 U.S.C. § 1320a-7(b)(7) based on the Covered Conduct described in Paragraph II.H above, Schering Sales Corporation agrees to be permanently excluded under these statutory provisions from Medicare, Medicaid, and all other Federal health care programs as defined in 42 U.S.C. § 1320a-7b(f). Such exclusion shall have national effect and shall also apply to all other federal procurement and nonprocurement programs. Federal health care programs shall not pay Schering Sales Corporation or anyone else for items or

services, including administrative and management services, furnished, ordered, or prescribed by Schering Sales Corporation in any capacity while Schering Sales Corporation is excluded. This payment prohibition applies to Schering Sales Corporation and anyone who employs or contracts with Schering Sales Corporation. The exclusion applies regardless of who submits the claims or other request for payment. Schering Sales Corporation shall not submit or cause to be submitted to any Federal health care program any claim or request for payment for items or services, including administrative and management services, furnished, ordered, or prescribed by Schering Sales Corporation during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution and imposition of civil monetary penalties and assessments. Schering Sales Corporation further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for goods or services furnished, ordered, or prescribed to such beneficiaries or sponsors during the exclusion. Schering Sales Corporation waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court. Schering Sales Corporation has been excluded since October 20, 2005, and the exclusion, as set forth in this Paragraph, shall continue permanently hereafter.

6. In consideration of the obligations of Schering set forth in this Agreement, conditioned upon Schering's full payment of the Settlement Amount, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from the TRICARE Program against Schering, its predecessors, its current or former parents, affiliates, divisions, subsidiaries, successors and assigns, and their current and former directors, officers, and

employees, under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 3 above, and as reserved in this Paragraph. TMA expressly reserves its authority under 32 C.F.R. § 199.9(f)(1)(i)(A) and (f)(1)(i)(B) based upon the Covered Conduct, and under 32 C.F.R. § 199.9(f)(1)(iii) if any entity is excluded by OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 3, above.

7. In consideration of the obligations of Schering set forth in this Agreement, conditioned upon Schering's full payment of the Settlement Amount, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking debarment from FEHBP against Schering, its predecessors, its current or former parents, affiliates, divisions, subsidiaries, successors and assigns, and their current and former directors, officers, and employees, under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 for the Covered Conduct, except as reserved in Paragraph 3 above, and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 3, above.

8. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

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10. Schering waives and shall not assert any defense it may have to criminal prosecution or administrative action relating to the Covered Conduct, which defense may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

11. In consideration of the obligations of the United States set forth in this Agreement, Schering, on behalf of itself and its predecessors, its current and former parents, affiliates, divisions, subsidiaries, successors and assigns fully and finally releases, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Schering has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the United States' investigation and prosecution of [Redacted], the Federal Criminal Action, and the Covered Conduct.

12. The Settlement Amount that Schering must pay pursuant to Paragraph 1 above will

not be decreased as a result of the denial of claims for payment now being withheld from payment by any State or Federal payer, related to the Covered Conduct; and, if applicable, Schering agrees not to resubmit to any State and Federal payer any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

13. Schering agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation (“FAR”), 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Schering, its predecessors, parents, divisions, subsidiaries, or affiliates, and its present or former officers, directors, employees, and agents in connection with: (1) the matters covered by this Agreement and the related Plea Agreement; (2) the United States’ audit and civil and criminal investigation relating to matters covered by this Agreement; (3) Schering’s investigation, defense, and any corrective actions undertaken in response to the United States’ civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys’ fees); (4) the negotiation and performance of this Agreement, the Plea Agreement, and the Medicaid State Settlement Agreement; (5) the payments made to the United States or any State pursuant to this Agreement, the Plea Agreement, or the Medicaid State Settlement Agreement and Release and any payments that Schering may make [Redacted]; and (6) the negotiation of and obligations undertaken pursuant to the CIA to: (a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (b) prepare and submit reports to the OIG-HHS, are unallowable costs on Government contracts

with DVA and other agencies and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP. However, nothing in this Paragraph affects the status of costs that are not allowable based on any other authority applicable to Schering. (All costs described or set forth in this Paragraph are hereafter, "Unallowable Costs").

b. Future Treatment of Unallowable Costs: If applicable, these Unallowable Costs shall be separately estimated and accounted for by Schering and Schering shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Schering, its predecessors, divisions, subsidiaries, or affiliates to Medicare, Medicaid, TRICARE, FEHBP or DVA.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Schering further agrees that within 60 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DVA, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Schering, its predecessors, parents, divisions, subsidiaries, or affiliates and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Schering agrees that the United States, at a minimum, shall be entitled to recoup from Schering any overpayment, plus applicable interest and penalties, as a result of the inclusion of such Unallowable Costs on previously-submitted cost

reports, information reports, cost statements, or requests for payment. Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Schering or its parents, divisions, subsidiaries or affiliates on the effect of inclusion of Unallowable Costs on Schering or its divisions, subsidiaries or affiliates' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or re-examine the Unallowable Costs described in this Paragraph.

14. Schering agrees that it shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors. Schering waives any causes of action against these beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims for payment covered by this Agreement.

15. Schering expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Schering within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

16. In the event Schering commences, or another party commences, within 91 days of the

Effective Date of this Agreement or any payment made hereunder, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Schering's debts, or seeking to adjudicate Schering as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Schering or for all or any substantial part of Schering's assets, Schering agrees as follows:

a. Schering's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Schering shall not argue or otherwise take the position in any such case, proceeding or action that: (i) Schering's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) Schering was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Schering.

b. If Schering's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases provided in this Agreement, and bring any civil and/or administrative claim, action or proceeding against Schering for the claims that would otherwise be covered by the releases provided in this Agreement. If the United States chooses to do so, Schering agrees that for purposes only of any claims, actions or proceeding referenced in this first clause of this Paragraph (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Schering from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding

described in the first clause of this Paragraph, and that Schering shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) Schering shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceedings which are brought by the United States within 90 calendar days of written notification to Schering that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before February 5, 2003; and (iii) the United States and the Participating States have a valid claim against Schering in the amount of two hundred fifty-five million twenty five thousand eighty nine dollars and sixty cents (\$255,025,089.60) plus applicable multipliers and penalties and they may pursue their claims, inter alia, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action or proceeding; and

c. Schering acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

17. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.

18. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the amounts paid hereunder for purposes of the Internal Revenue laws, Title 26 of the United States Code.

19. Each party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts

[Redacted]

except that disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

21. [Redacted]

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22. The undersigned Schering and Schering Sales Corporation signatories represent and warrant that they are authorized by their respective Board of Directors to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the United States through their respective agencies and departments.

23. The "Effective Date" of this Agreement shall be on the date of signature of the last

signatory to the Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

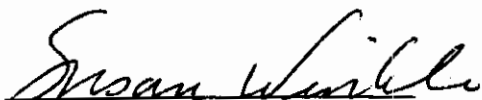
24. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

25. This Agreement shall not be amended except by written consent of the Parties, except that only Schering and OIG-HHS must agree in writing to modification of the CIA, without the consent of any other party to this Agreement or the Plea Agreement.

26. Schering hereby consents to the disclosure of this Agreement and information about this Agreement by the United States to the public.

27. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement

UNITED STATES OF AMERICA

By: 
SUSAN WINKLER
JENNIFER BOAL
GREGG SHAPIRO
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

Dated: 8/29/06

By: _____
ANDY J. MAO
Trial Attorney, Civil Division
United States Department of Justice

Dated:

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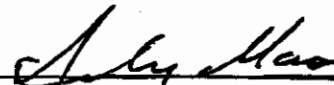
UNITED STATES OF AMERICA

By:

SUSAN WINKLER
JENNIFER BOAL
GREGG SHAPIRO
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

Dated:

By:

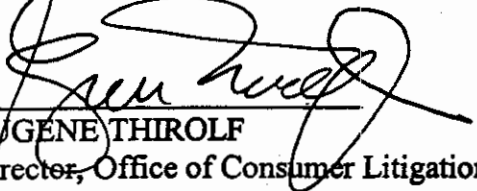


ANDY J. MAO
Trial Attorney, Civil Division
United States Department of Justice

Dated:

8/28/06

By:



EUGENE THIROLF
Director, Office of Consumer Litigation
United States Department of Justice

Dated:

8/23/2006

By:

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

Dated:

By:

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

Dated:

By:

KATHLEEN McGETTIGAN
Deputy Associate Director
Center for Retirement & Insurance Services
United States Office of Personnel Management

Dated:


By:

J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

Dated:

By: _____
EUGENE THIROLF
Director, Office of Consumer Litigation
United States Department of Justice

Dated:

By: 

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

Dated: 8/25/06

By: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

Dated:

By: _____
KATHLEEN McGETTIGAN
Deputy Associate Director
Center for Retirement & Insurance Services
United States Office of Personnel Management

Dated:

By: _____
J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

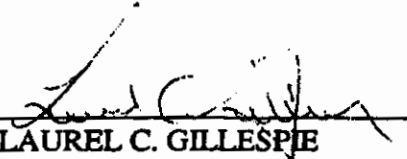
Dated:

By: _____
EUGENE THIROLF
Director, Office of Consumer Litigation
United States Department of Justice

Dated:

By: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

Dated:

By: 
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

Dated: 15 Aug 2006

By: _____
KATHLEEN McGETTIGAN
Deputy Associate Director
Center for Retirement & Insurance Services
United States Office of Personnel Management

Dated:

By: _____
J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

Dated:

Schering-Plough Corporation - Civil Settlement Agreement

By: _____
EUGENE THIROLF
Director, Office of Consumer Litigation
United States Department of Justice

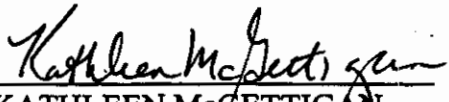
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By: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

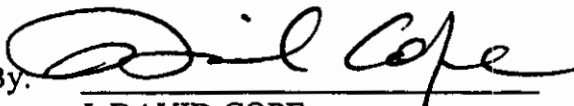
Dated:

By: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

Dated:


By: 
KATHLEEN McGETTIGAN
Deputy Associate Director
Center for Retirement & Insurance Services
United States Office of Personnel Management

Dated: 8/24/06


By: 
J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

Dated: 8/24/06

SCHERING-PLOUGH CORPORATION

By: 
THOMAS J. SABATINO
Executive Vice President and General Counsel
Schering-Plough Corporation

Dated: 8/25/06


By: 
BRIEN O'CONNOR
JOAN MCPHEE
JOSHUA LEVY
Ropes & Gray
Counsel to Schering-Plough Corporation

Dated: 8/25/06

SCHERING SALES CORPORATION

By: 
BRENT SAUNDERS
President
Schering Sales Corporation

Dated: 8/25/06

By: 
BRIEN O'CONNOR
JOAN MCPHEE
JOSHUA LEVY
Ropes & Gray
Counsel to Schering Sales Corporation

Dated: 8/25/06