



**U.S. Department of Justice**

**Michael J. Sullivan**  
*United States Attorney  
District of Massachusetts*

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Main Reception: (617) 748-3100

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

March 27, 2007

Ethan M. Posner  
Covington & Burling  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004

Re: Side Letter Agreement with Pfizer Inc

Dear Mr. Posner:

This letter ("Side Letter Agreement") will confirm that, in exchange for full performance of the Plea Agreement entered into by the United States Attorney's Office for the District of Massachusetts ("USAO") and your client, Pharmacia & Upjohn Company, Inc., a copy of which is attached hereto as Exhibit A, and full performance of the Deferred Prosecution Agreement ("DPA") between the USAO and your client, Pharmacia & Upjohn Company, LLC, a copy of which is attached hereto as Exhibit B, and in exchange for certain other promises made herein between and among the USAO and your client, Pfizer Inc, including all of its direct and indirect subsidiaries (collectively "Pfizer Inc"), the United States and Pfizer Inc hereby agree as follows:

- a. No Criminal Prosecution of Pfizer Inc Regarding Genotropin Conduct Prior to May 11, 2004

The USAO hereby declines prosecution of Pfizer Inc and any of its direct or indirect subsidiaries for conduct by or attributable to Pfizer Inc and any of its direct or indirect subsidiaries that:

- (1) falls within the scope of the Information to which Pharmacia & Upjohn Company, Inc. is pleading guilty;
- (2) falls within the scope of the DPA and Information incorporated therein between the USAO and Pharmacia & Upjohn Company LLC (Exhibit B);

- (3) was the subject of the grand jury investigation by the USAO regarding allegations that Pharmacia & Upjohn Company, Inc., Pharmacia & Upjohn Company LLC, and other Pharmacia and/or Searle ("Pharmacia") entities that were subsequently acquired by Pfizer Inc:
  - (a) directly or indirectly offered or paid remuneration, to induce entities or individuals to recommend, prescribe and/or purchase Genotropin prior to May 11, 2004; and
  - (b) promoted, marketed, sold, and distributed Genotropin in violation of the Food, Drug & Cosmetic Act prior to May 11, 2004;
- (4) was known to the USAO concerning the promotion, marketing, sale, or distribution of Genotropin occurring prior to May 11, 2004.

The USAO does not decline criminal prosecution of Pfizer Inc or any of its direct or indirect subsidiaries 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 or other entity.

It is understood between the parties to this Side Letter Agreement that the USAO's promise, described above, not to prosecute Pfizer Inc and its direct and indirect subsidiaries is dependent upon and subject to: (1) Pharmacia & Upjohn Company, Inc. fulfilling its material obligations in the Plea Agreement; and (2) Pharmacia & Upjohn Company LLC fulfilling its material obligations in the Deferred Prosecution Agreement. If Pharmacia & Upjohn Company, Inc. does not fulfill its material obligations in the Plea Agreement, or if Pharmacia & Upjohn Company LLC does not fulfill its material obligations in the Deferred Prosecution Agreement, Pfizer Inc and its direct and indirect subsidiaries agree 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 the date of execution of this Side Letter Agreement.

b. Cooperation of Pfizer Inc

Pfizer Inc 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 regarding the promotion, marketing, sale or distribution of Genotropin. Pfizer Inc 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. Pfizer Inc 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, Pfizer Inc 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 regarding the promotion, marketing, sale or distribution of Genotropin, and that are not covered by the attorney-client privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) Pfizer Inc 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) Pfizer Inc is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) Pfizer Inc is not required to waive any privilege or claim of work product protection.

Moreover, Pfizer Inc. acknowledges that Pharmacia & Upjohn Company, Inc. expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the Information attached hereto as Exhibit A and is in fact guilty of that offense. Pfizer Inc. agrees that it will not make statements inconsistent with this explicit admission of guilt by Pharmacia & Upjohn Company, Inc. to the kickback crime charged in the Information. In addition, Pfizer Inc. further acknowledges that Pharmacia & Upjohn Company LLC expressly and unequivocally admits and accepts responsibility for its conduct and the conduct of its employees described in the Information attached as Appendix A of the DPA. Pfizer Inc. will not make any public statements contradicting anything set forth in Appendix A of the DPA.

c. Who Is Bound By Agreement

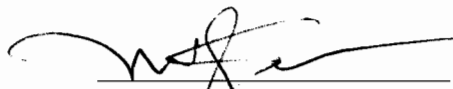
This letter agreement is binding upon the USAO and cannot and does not bind the Attorney General of the United States or any other federal, state or local prosecutive authorities.

d. Complete Agreement

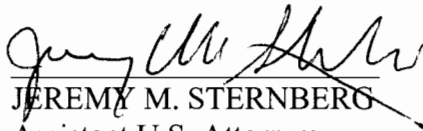
This Side Letter Agreement, the Plea Agreement with Pharmacia & Upjohn Company, Inc. and the Deferred Prosecution Agreement with Pharmacia & Upjohn LLC, are the complete and only agreements between the parties. No promises, agreements or conditions have been entered into other than those set forth or 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 USAO and Pfizer Inc. and you are duly authorized to enter into this agreement, please sign below and return the original of this letter to Assistant U.S. Attorney Jeremy M. Sternberg.

Very truly yours,



MICHAEL J. SULLIVAN  
United States Attorney  
District of Massachusetts




JEREMY M. STERNBERG  
Assistant U.S. Attorney  
District of Massachusetts


**ACKNOWLEDGMENT OF AGREEMENT**

The Board of Directors of Pfizer Inc. has been generally advised of the Plea Agreement with Pharmacia & Upjohn Company, Inc., the criminal Information charging Pharmacia & Upjohn Company, Inc., and the Deferred Prosecution Agreement with Pharmacia & Upjohn Company LLC, and has discussed this matter with its counsel. I acknowledge that this Side Letter Agreement accurately reflects the agreement entered into between the USAO and Pfizer Inc., and I am duly authorized to enter into this agreement on behalf of Pfizer Inc. I further acknowledge that no additional promises or representations have been made to Pfizer Inc. by the USAO in connection with the disposition of this matter other than as set forth in this Side Letter Agreement.

Dated:  
March 29, 2007

  
ALLEN P. WAXMAN  
Senior Vice President and General Counsel  
Pfizer Inc.

Dated: 3-29-07

  
ETHAN M. POSNER  
Covington & Burling  
Counsel for Pfizer Inc.

# EXHIBIT A



**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*

March 27, 2007

Ethan M. Posner  
Covington & Burling LLP  
1201 Pennsylvania Ave., N.W.  
Washington, D.C. 20004-2401

Re: United States v. Pharmacia & Upjohn Company, Inc.

Dear Mr. Posner:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts ("the U.S. Attorney"), and your client, Pharmacia & Upjohn Company, Inc., a Delaware Corporation ("Pharmacia"), in the above-captioned case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date Pharmacia shall waive indictment and shall plead guilty to the Information attached hereto as Exhibit A. The Information charges that Pharmacia knowingly and willfully offered inflated payments on a contract to induce another party to recommend purchasing or ordering Pharmacia's drug products in violation of 42 U.S.C. §1320a-7b(b)(2)(B). Pharmacia acknowledges and agrees that it is in fact guilty of that offense. Pharmacia agrees to waive venue, any applicable statutes of limitations, and any legal or procedural defects in the Information.

2. Penalties

With respect to its violation of 42 U.S.C. §1320a-7b(b)(2)(B), Pharmacia is subject to a maximum possible fine of \$500,000, twice the gross gain derived from the offense or twice the gross loss, whichever is greatest. See 18 U.S.C. §§3571(c) and (d). The gain from the offense is \$12,300,000, and thus the maximum possible fine is \$24,600,000.

Pharmacia may be sentenced to a term of probation of not less than one (1) year and not more than five (5) years. See 18 U.S.C. §3561(c)(1). Pharmacia shall also pay a special assessment of \$400. See 18 U.S.C. §3013(a)(2)(B).

3. Sentencing Guidelines

The parties agree that the following provisions of the United States Sentencing Guidelines (“U.S.S.G.”) apply to the sentencing of Pharmacia:

- a. The parties agree that the Guideline Manual in effect as of November 1, 2000, should be used in determining Pharmacia’s sentence. See U.S.S.G. §§1B1.11(a) and (b)(1);
- b. The parties agree that the base fine is \$12,300,000, which is the value of the unlawful payment. See U.S.S.G. §§8C2.3 and 2B4.1(c)(1)(A);
- c. Pursuant to U.S.S.G. §8C2.5, the culpability score is 8 as determined as follows:
  - (1) Base culpability score is five (5) pursuant to U.S.S.G. §8C2.5(a);
  - (2) Add four (4) points in that the unit of the organization within which the offense was committed had 1,000 or more employees, and an individual within the high-level personnel of the unit participated in or condoned the offense;
  - (3) Deduct one (1) point pursuant to U.S.S.G. §8C2.5(g)(3).
- d. Pursuant to U.S.S.G. §8C2.6, the appropriate multiplier range associated with a culpability score of 8 is 1.6 to 3.2.
- e. Thus, the Guideline Fine Range is \$19,680,000 to \$24,600,000. See 18 U.S.C. §§3571(c) and (d) (maximum fine is twice the gross gain or gross loss).
- f. The parties agree that (1) disgorgement pursuant to U.S.S.G. §8C2.9 is not necessary, (2) there is no basis for a downward departure or deviation under the U.S.S.G. and (3) a fine within the guideline range will result in a reasonable sentence taking into consideration all of the factors set forth in 18 U.S.C. §§3553(a), 3572.

The United States may, at its sole option, be released from its commitments under this Agreement, including but not limited to, its agreement regarding the appropriate disposition of this case, if at any time between its execution of this Agreement and sentencing, Pharmacia:

- (a) Fails to admit a complete factual basis for the plea;
- (b) Fails to truthfully admit its conduct in the offense of conviction;
- (c) Falsely denies, or frivolously contests, relevant conduct for which Pharmacia is accountable under U.S.S.G. § 1B1.3;

- (d) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Pharmacia is accountable under U.S.S.G. § 1B1.3;
- (e) Engages in acts which form a basis for finding that Pharmacia has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1;
- (f) Attempts to withdraw its plea.

Pharmacia expressly understands that it may not withdraw its plea of guilty, unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

#### 4. Agreed Disposition

The U.S. Attorney and Defendant agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the following is the appropriate disposition of this case:

- (a) a criminal fine in the amount of nineteen million, six-hundred and eighty thousand dollars (\$19,680,000: culpability score of 1.6 x \$12,300,000) to be paid within three business days of sentencing; and
- (b) a mandatory special assessment of \$400 pursuant to 18 U.S.C. §3013, which shall be paid to the Clerk of Court on or before the date of sentencing.

#### 5. Payment of Mandatory Special Assessment

Pharmacia agrees to pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

#### 6. Cooperation

Pharmacia shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing federal grand jury investigation of the conduct at issue in the Information. Pharmacia's cooperation shall include furnishing 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.

Notwithstanding any provision of this Agreement, Pharmacia is not required: (1) 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) to take any action against its officers, agents, or employees for following their attorney's advice; and (3) to waive any privilege or claim of work product protection.

7. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

8. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Pharmacia's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Pharmacia cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement. If the sentencing judge rejects this Agreement, this Agreement shall be null and void at the option of either the United States or Pharmacia.

Pharmacia may seek sentencing by the Court immediately following the Rule 11 plea hearing. The United States will not object to any request by Pharmacia that the Court sentence Pharmacia immediately following the Rule 11 plea hearing or prior to the completion of a Presentence Report. Pharmacia understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

9. Civil Liability

By entering into this Agreement, the United States does not compromise any civil liability, including but not limited to any tax liability, which Pharmacia may have incurred or may incur as a result of its conduct and its plea of guilty to the charges specified in paragraph one of this Agreement.

10. Waiver of Defenses

If Pharmacia's guilty plea is not accepted by the Court for whatever reason, or is later withdrawn for whatever reason, Pharmacia hereby waives and agrees it will not interpose, if charges are filed within six (6) months of the date on which such guilty plea is rejected or withdrawn, any defense to any charges brought against it which it might otherwise have for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that Pharmacia may already have for conduct occurring before August 26, 2000.

11. Breach of Agreement

If the U.S. Attorney determines that Pharmacia has failed to comply with any provision of this Agreement, the U.S. Attorney may, at his sole option, be released from his commitments under this Agreement in their entirety by notifying Pharmacia, through counsel or otherwise, in writing. The U.S. Attorney may also pursue all remedies available to him under the law, irrespective of whether he elects to be released from his commitments under this Agreement. Further, the U.S. Attorney may pursue any and all charges which have been, or are to be, dismissed pursuant to this Agreement. Pharmacia recognizes that no such breach by it of an obligation under this Agreement

shall give rise to grounds for withdrawal of its guilty plea. Pharmacia understands that, should it breach any provision of this agreement, the U.S. Attorney will have the right to use against Pharmacia before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by it, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation. In the event of a breach, Pharmacia, with respect to any charges which could have been brought as of March 23, 2007, hereby waives, and agrees it will not interpose, any defense to any additional charges brought against it which it might otherwise have for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that Pharmacia may already have for conduct occurring before August 26, 2000.

12. Corporate Authorization

Pharmacia's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached hereto. Pharmacia shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the Board of Directors of Pharmacia, affirming that the Board of Directors has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement or have been advised of the contents thereof; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Pharmacia to plead guilty to the charges specified in the Information; and (5) voted to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. Pharmacia agrees that either a duly authorized corporate officer for Pharmacia shall appear on behalf of Pharmacia and enter the guilty plea and will also appear for the imposition of the sentence.

13. Who Is Bound By Agreement

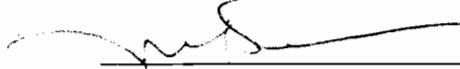
This Agreement is limited to the U.S. Attorney for the District of Massachusetts, and cannot and does not bind the Attorney General of the United States or any other federal, state or local prosecutive authorities.

14. Complete Agreement

This Agreement (along with the Side Letter dated March 27, 2007,) contains the complete and only agreement between the parties relating to the disposition of the conduct at issue in the Information. No promises, representations or agreements have been made other than those set forth in this letter and the Side Letter. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement can be modified or supplemented only in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the U.S. Attorney and Pharmacia, please have Defendant sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Jeremy M. Sternberg.

Very truly yours,



MICHAEL J. SULLIVAN  
United States Attorney  
District of Massachusetts

By: 

JEREMY M. STERNBERG  
Assistant U.S. Attorney  
District of Massachusetts

ACKNOWLEDGMENT OF PLEA AGREEMENT

The Board of Directors has authorized me to execute this Plea Agreement on behalf of Pharmacia & Upjohn Company, Inc. The Board has read this Plea Agreement, and the attached criminal information, or has been advised of the contents thereof, and has discussed them fully in consultation with Pharmacia's attorneys. I am further authorized to acknowledge on behalf of Pharmacia that these documents fully set forth Pharmacia's agreement with the United States, and that no additional promises or representations have been made to Pharmacia by any officials of the United States in connection with the disposition of this matter, other than those set forth in these documents.

Pharmacia & Upjohn Company, Inc.

*Meredith Davis*

By:  
Its: *Vice President and Secretary*

Date: *March 28, 2007*

\_\_\_\_\_  
Ethan M. Posner  
Covington & Burling  
Counsel for Pharmacia

Date: \_\_\_\_\_

ACKNOWLEDGMENT OF PLEA AGREEMENT

The Board of Directors has authorized me to execute this Plea Agreement on behalf of Pharmacia & Upjohn Company, Inc. The Board has read this Plea Agreement, and the attached criminal information, or has been advised of the contents thereof, and has discussed them fully in consultation with Pharmacia's attorneys. I am further authorized to acknowledge on behalf of Pharmacia that these documents fully set forth Pharmacia's agreement with the United States, and that no additional promises or representations have been made to Pharmacia by any officials of the United States in connection with the disposition of this matter, other than those set forth in these documents.

Pharmacia & Upjohn Company, Inc.

By: \_\_\_\_\_  
Its:

Date: \_\_\_\_\_



Ethan M. Posner  
Covington & Burling  
Counsel for Pharmacia

Date: 3/28/07

**UNANIMOUS WRITTEN CONSENT OF DIRECTORS  
OF PHARMACIA & UPJOHN COMPANY, INC.**

The undersigned, being all of the Directors of Pharmacia & Upjohn Company, Inc., a Delaware corporation (the "Company"), pursuant to the provisions of Section 141(f) of the General Corporation Law of the State of Delaware, waive notice of the time, place and purpose of Meeting of the Board of Directors of the Corporation, and hereby consent to and approve the following resolutions and each and every action affected thereby:

WHEREAS, the U.S. Attorney's Office in Boston, Massachusetts has been conducting an investigation into the Company's conduct alleging that the Company offered remuneration to recommend the purchasing of drug products, the "Anti-kickback Matter";

WHEREAS, the Company's legal counsel has been negotiating a resolution of the Anti-kickback Matter;

WHEREAS, the Company's legal counsel has reported to the board the terms and conditions of a proposed resolution of the Anti-kickback Matter;

NOW, THEREFORE, BE IT:

RESOLVED, that the Company, is hereby, authorized to enter into the Plea Agreement dated March [ ], 2007 between the United States Attorney for the District of Massachusetts and Pharmacia & Upjohn Company, Inc., the "Agreement".

FURTHER RESOLVED, that Heidi Chen, President & Treasurer or any other Officer of the Company are hereby authorized and directed to take all actions and deliver any agreements, certificates and documents and instruments with respect to or contemplated by the Agreement and matters set forth above, including, without limitation, the payment of all amounts, fees, costs and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the settlements contemplated hereby.

FURTHER RESOLVED, that any actions taken by the Officers of the Company prior to the adoption of these resolutions, that are within the authority conferred hereby, are hereby fully ratified, confirmed and approved as the act and deed of the Company.

\* \* \*

IN WITNESS WHEREOF, the undersigned Directors of the Company have executed this consent as of the 28<sup>th</sup> day of March, 2007.



Heidi Chen



Michael Diaco

# EXHIBIT A

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	CRIMINAL NO.
	)	
v.	)	VIOLATION:
	)	
PHARMACIA & UPJOHN	)	42 U.S.C. §1320a-7b(b)(2)(B)
COMPANY, INC.,	)	
	)	
Defendant.	)	
	)	

**INFORMATION**

The United States Attorney charges that:

**COUNT ONE: 42 U.S.C. §1320a-7b(b)(2)(B)**  
**(Offer of Payment of Kickbacks)**

At all times material hereto, unless otherwise alleged:

**The Defendant**

1. **PHARMACIA & UPJOHN COMPANY, INC. (“PHARMACIA”)** was a Delaware corporation, with a principal place of business in Kalamazoo, Michigan. **PHARMACIA** was a subsidiary of Pharmacia & Upjohn Company LLC, which was the successor to Pharmacia & Upjohn Company, a former subsidiary of Pharmacia Corporation, which during the relevant period of time (the year 2000) was a publicly traded company on the New York Stock Exchange. **PHARMACIA** and its corporate affiliates will be referred to in this Information as “**PHARMACIA.**”

2. **PHARMACIA** was engaged in, among other things, the development, manufacture, promotion, sale and interstate distribution of prescription drugs intended for human use in the United States. **PHARMACIA** distributed or directed the distribution of pharmaceutical drugs to

all fifty states and the District of Columbia.

3. One of the pharmaceutical drugs promoted, sold and distributed interstate by **PHARMACIA** was a human growth hormone product called Genotropin.

4. The business unit within **PHARMACIA** that was responsible for the promotion, sale and distribution of Genotropin was the Endocrine Care Business Unit.

**The Bridge Program and the Selection of Company P**

5. For the drug Genotropin, **PHARMACIA** used outside vendors for distribution, patient assistance and insurance reimbursement. **PHARMACIA** called this outsourced program the Bridge Program. Proper administration of the Bridge Program was critical to the success of Genotropin.

6. In early 2000, **PHARMACIA** determined that it was dissatisfied with its then current vendor on the Bridge Program and announced that it was putting the contract for the administration of its Bridge Program out to bid. In early to mid-2000, **PHARMACIA** met with certain potentially interested bidders and provided a Request for Proposal to these entities for a three year contract.

7. In June of 2000, **PHARMACIA** received bids from three entities; Company P, a subsidiary of Company Q, and Company R.

8. After receiving those bids, in or about early July 2000, **PHARMACIA** rated the bids using over a dozen criteria, including understanding the Bridge Program and its needs, ability to deliver Bridge Program needs, cost competitiveness, quality systems, products and services, and responsiveness. **PHARMACIA**'s evaluation based on those criteria yielded a selection of

Company P. **PHARMACIA** evaluated Company P's bid as \$12 million less expensive, over a three year period, than the nearest competitor's bid.

9. In mid-July 2000, the Endocrine Care team of **PHARMACIA** recommended to **PHARMACIA**'s senior management that Company P be selected to manage the Bridge Program. That recommendation included the following statements:

A team of representatives from Pharmacia's Procurement, Auditing Services, Accounting, Distribution, Legal, Sales, Accounting and Marketing functions was composed to perform site visits and review RFP responses and presentations. Based on input from Marketing, Accounting, Distribution, Auditing Services and Procurement through their individual completion of the RFP evaluation form, and internal financial analysis of proposed program costs, collectively the team recommends [Company P] as Pharmacia's new Genotropin Bridge Program outsourcing partner.

Shortly thereafter, by telephone, **PHARMACIA** notified Company P that it had been awarded the Bridge Program.

#### **Formulary Opportunities at Company Q**

10. However, at or about the same time, **PHARMACIA** learned from Company Q of an opportunity to improve the formulary positioning and/or formulary ancillary relationships of **PHARMACIA** drug products at Company Q, one of the country's largest and most influential pharmacy benefit managers. Thereafter, **PHARMACIA** believed that Company Q was willing to recommend the purchasing or ordering of **PHARMACIA**'s drug products, some or all of which were drug products that were eligible for payment in whole or in part under a Federal health care program, in return for **PHARMACIA** awarding the Bridge Program contract to the subsidiary of Company Q which had previously submitted a bid rejected by **PHARMACIA**.

11. The basis for **PHARMACIA**'s belief, referred to above, included a July 13, 2000

conference call, initiated by Company Q, between employees of **PHARMACIA** and Company Q, during which employees of Company Q emphasized the interest of the subsidiary of Company Q in obtaining the Bridge Program contract and also described assistance that Company Q could provide with generating sales of **PHARMACIA**'s drug products.

12. A further basis for **PHARMACIA**'s belief, referred to above, included a meeting at **PHARMACIA**'s Skokie, Illinois offices on July 20, 2000, between employees of **PHARMACIA** and employees of Company Q. At this meeting, the participants discussed Company Q's bid for the Bridge Program, and the fact that **PHARMACIA** viewed the bid as substantially more expensive than the bid from Company P. The participants also discussed the assistance that Company Q could provide with generating sales of **PHARMACIA**'s drug products. A high level employee of Company Q also provided **PHARMACIA** with a private tutorial on Company Q's formulary bidding process.

13. Shortly thereafter, including on or about July 28, 2000 and July 31, 2000, **PHARMACIA** prepared financial analyses that showed that the anticipated financial benefits to **PHARMACIA** resulting from improved formulary positioning and formulary ancillary benefits from Company Q were worth millions of dollars in increased drug sales to **PHARMACIA**. One of these analyses noted that if the bids from Company P and the subsidiary of Company Q were analyzed on a stand alone basis, the choice would be Company P. However, this analysis noted that when factoring in the formulary positioning and formulary ancillary benefits that **PHARMACIA** expected it would obtain from Company Q if it awarded the Bridge Program to the subsidiary of Company Q, an award to the subsidiary of Company Q maximized the total

corporate value to **PHARMACIA**.

14. To assuage the Endocrine Care Business Unit that expected to incur more than \$12 million in excess costs over 3 years if the subsidiary of Company Q were awarded the Bridge Program, **PHARMACIA** promised the Endocrine Care Business Unit that another business unit within **PHARMACIA** that expected to benefit from the improved formulary positioning and formulary ancillary benefits would reimburse the Endocrine Care Business Unit for the excess costs associated with selecting the subsidiary of Company Q as opposed to Company P.

**The Offer of the Bridge Program to the Subsidiary of Company Q**

15. On or about August 1, 2000, **PHARMACIA** retracted the award of the Bridge Program contract to Company P, despite believing that Company P's bid price for the contract was millions of dollars lower, and the quality of services higher, than the bid presented by the subsidiary of Company Q.

16. **PHARMACIA** instead offered the Bridge Program contract to the subsidiary of Company Q to induce Company Q to provide improved formulary positioning and/or formulary ancillary benefits that **PHARMACIA** expected would increase its drug sales by millions of dollars.

17. On or about August 1, 2000, in the District of Massachusetts and elsewhere,

**PHARMACIA & UPJOHN COMPANY, INC.**

knowingly and willfully offered remuneration in the form of excess payments on a contract to administer the Bridge Program to a subsidiary of Company Q to induce Company Q to recommend purchasing or ordering **PHARMACIA**'s pharmaceutical products, which were

eligible for payment in whole or in part under a Federal health care program.

All in violation of 42 U.S.C. §1320a-7b(b)(2)(B).

MICHAEL J. SULLIVAN  
UNITED STATES ATTORNEY

By:

\_\_\_\_\_  
Jeremy M. Sternberg  
Susan G. Winkler  
Assistant U.S. Attorneys

# EXHIBIT B



**U.S. Department of Justice**

**Michael J. Sullivan**  
*United States Attorney*  
*District of Massachusetts*

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Main Reception: (617) 748-3100

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

March 27, 2007

Ethan M. Posner  
Covington & Burling LLP  
1201 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004-2401

Re: Pharmacia & Upjohn Company LLC

Dear Mr. Posner:

This letter sets forth the agreement ( the "Agreement") between the United States Attorney's Office for the District of Massachusetts ("USAO") and your client, Pharmacia & Upjohn Company LLC (hereafter, "Pharmacia").

WHEREAS, in April 2003, Pfizer, Inc. ("Pfizer") acquired Pharmacia Corporation and its subsidiary Pharmacia & Upjohn Company, which it subsequently converted to Pharmacia & Upjohn Company LLC;

WHEREAS, in May 2003, one month after its acquisition of Pharmacia & Upjohn Company, Pfizer initiated a self-disclosure of the conduct that is the subject of this Agreement to the Office of Inspector General for the Department of Health and Human Services ("OIG-HHS"), to the United States Food and Drug Administration ("FDA"), and to the United States Department of Justice;

WHEREAS, thereafter, the USAO conducted a criminal investigation regarding the conduct disclosed by Pfizer, to wit, allegations that Pharmacia promoted, sold, and distributed the human growth hormone drug Genotropin in violation of the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 321 *et seq.*, by promoting, selling, and distributing Genotropin for anti-aging, cosmetic use or athletic performance enhancement (the "Subject Matter"). As a result of its investigation, the USAO informed Pharmacia that the USAO has determined that there is sufficient basis to seek an indictment of Pharmacia for violations of federal criminal law, specifically and without limitation, for distribution of an unapproved new drug in interstate commerce, with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

WHEREAS, Pharmacia has represented to the USAO that it has discontinued any promotion and knowing sale and distribution of Genotropin for anti-aging, cosmetic use, or athletic performance enhancement by Pharmacia and its subsidiaries, parents, affiliates, agents, employees and contractors;

WHEREAS, on May 11, 2004, Pfizer entered a five-year Corporate Integrity Agreement ("CIA") with the OIG-HHS. The CIA applies to Pfizer and Pharmacia and requires those entities to undertake various compliance obligations designed to ensure compliance with Federal health care program and FDA requirements. Among other provisions, the CIA includes "Specific Training" obligations that require all remaining employees of Pharmacia affiliates in "Promotional and Product Services Related Functions" (as defined in the CIA), to receive annual training concerning all applicable FDA requirements regarding the proper methods for selling, marketing, promoting, and advertising the relevant drug products and disseminating information about off-label uses of those products, including without limitation the requirements of the FDCA and FDA regulations. In the course of this Specific Training, Pharmacia represents it has conducted training with reference to 21 U.S.C. §§331(a), 331(d), 333(a), 333(e) and 355, and provided clear instruction that human growth hormone is not FDA approved for any anti-aging, cosmetic or athletic performance enhancement use, and may not be promoted, sold or distributed for those uses. The HHS-OIG monitors compliance with the CIA obligations and enforces any breaches in accordance with the remedies set forth in the CIA.

WHEREAS, the USAO has determined that an indictment of Pharmacia may cause undue harm to innocent individuals including Pharmacia's current employees and shareholders and those of affiliated entities, including Pfizer which, within one month of its acquisition of Pharmacia, made a full self-disclosure of the conduct at issue to the various federal agencies described above.

NOW, THEREFORE, the USAO and Pharmacia agree as follows:

1. This agreement shall be in effect for thirty-six (36) months from the date of its execution.
2. Pharmacia admits to and accepts responsibility for its conduct and the conduct of its employees described in the Information attached hereto as Appendix A, and agrees that the conduct was unlawful. Pharmacia agrees that facts in Appendix A (paragraphs 1-4 and 10-18) are accurate in their entirety and Pharmacia agrees not to contradict the facts stated therein.
3. Pharmacia agrees that, if it violates any terms of this Agreement, the USAO may file the attached criminal Information in the United States District Court for the District of Massachusetts charging Pharmacia with violation of 21 U.S.C. §§331(d), 333(a)(2), and 355(a). As set forth more completely below, Pharmacia waives any rights it may have to proceed by way of indictment, and further waives any and all rights it may have under applicable statutes of limitation or

other legal, equitable or constitutional limitations that may limit the period of time during which the USAO may seek an indictment or other charging document (such as a complaint or other information) for the offense covered by the Information.

4. Pharmacia does not endorse, ratify, or condone illegal conduct and has taken steps to prevent such conduct from occurring in the future.
5. During the term of this Agreement, Pharmacia agrees to cooperate fully with the USAO, and, as directed by the USAO, with any other federal, state or foreign law enforcement or regulatory agency regarding the Subject Matter. The duty to cooperate includes an affirmative duty of full and truthful disclosure. Pharmacia shall truthfully disclose to the USAO all non-privileged information respecting the activities of Pharmacia and its present and former directors, officers, employees, agents, attorneys, parents, affiliates and subsidiaries relating to Subject Matter about which the USAO may inquire, or which Pharmacia reasonably believes is material to the investigation by the USAO. Pharmacia agrees that its cooperation concerning the Subject Matter shall include, but is not limited to, the following:
  - (a) assembling, organizing and producing, or taking reasonable steps to effectuate the production of, on request from the USAO, all documents, records, or other tangible evidence related to the investigation in Pharmacia's possession, custody or control in such reasonable format that the USAO requests;
  - (b) using its reasonable best efforts to make available its present or former directors, officers, employees, agents, affiliates and subsidiaries to provide information and/or testimony related to the investigation of the Subject Matter as requested, including sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities. Cooperation under this sub-paragraph will include identification of witnesses who, to Pharmacia's knowledge, may have material information regarding the investigation of the Subject Matter.
  - (c) providing testimony and other information deemed necessary by the USAO or the court to establish the original location, authenticity, or other evidentiary foundation to admit into evidence documents in any criminal case or other proceeding as requested by the USAO;
  - (d) maintaining Pharmacia as a lawfully organized entity for purposes of this Agreement during the time this Agreement is in effect; and
  - (e) complying with any agreements between (or binding) Pharmacia and any

governmental agency as long as such agreements remain in effect.

6. Pharmacia will not, through its present or future directors, officers, employees, agents, attorneys, parents, affiliates, or subsidiaries, make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting anything set forth in Appendix A. Any such contradictory public statement by Pharmacia, its present or future directors, officers, employees, agents, attorneys, parents, affiliates or subsidiaries shall constitute a breach of this Agreement, and Pharmacia shall therefore be subject to prosecution on the Information attached to this Agreement.
7. The decision as to whether any public statement by any such person contradicting a statement contained in Appendix A will be imputed to Pharmacia for the purpose of determining whether Pharmacia has breached this Agreement shall be at the sole reasonable discretion of the USAO. Upon the USAO's reaching a determination that such a contradictory statement has been made by Pharmacia, the USAO shall so notify Pharmacia in writing and Pharmacia may avoid a breach of this Agreement by publicly repudiating such statement within five (5) days after written notification by the USAO. This paragraph is not intended to apply to any statement made by any individual in the course of any criminal, regulatory, or civil matter initiated by the USAO against such individual, unless such individual is speaking on behalf of Pharmacia. Consistent with Pharmacia's obligation not to make a contradictory public statement, Pharmacia may take good faith positions in litigation involving any private party.
8. In light of Pfizer's self-disclosure and Pharmacia's remedial actions to date and its willingness to (a) acknowledge responsibility for its behavior; (b) cooperate with the USAO and other governmental agencies regarding the Subject Matter; and (c) demonstrate its future good conduct and full compliance with the FDCA, the USAO agrees that if Pharmacia is in full compliance with all of its obligations under this Agreement, the USAO will not prosecute Pharmacia on the attached Information or in connection with the Subject Matter.
9. Upon execution of this Agreement, Pharmacia shall pay as a monetary penalty the amount of fifteen million dollars (\$15,000,000) to the United States Treasury. This payment is a material term of this Agreement. Failure to make payment within forty-eight (48) hours of receipt of written payment instructions from the USAO following execution of this Agreement renders the Agreement null and void.
10. For the term of this Agreement, should the USAO in its sole reasonable discretion, determine that Pharmacia (a) has knowingly and willfully given false, incomplete or misleading information under this Agreement; (b) engaged in conduct subsequent to the execution of this Agreement that constitutes a federal

crime; or (c) has otherwise knowingly breached any provision of this Agreement (these three circumstances, (a), (b) and (c), are collectively referred to herein as "Breach"), Pharmacia shall, in the USAO's sole reasonable discretion, thereafter be subject to prosecution(s) for any federal criminal violations, including, without limitation, the Information. Moreover, with respect to any prosecutions relating to the Subject Matter that are not time-barred as of the date of this Agreement by the applicable statute of limitations (or any other legal, equitable or constitutional basis upon which a prosecution may be time-barred), Pharmacia agrees that the applicable statute of limitations period (or any other legal, equitable or constitutional basis for barring prosecution based on the passage of time), shall be tolled for a period of time equal to the term of this Agreement, and the period of time previously tolled by letter agreement dated February 6, 2007. Pharmacia's agreement herein tolling the statute of limitations (and any other legal, equitable or constitutional basis for barring prosecution based on the passage of time) is knowing and voluntary and in express reliance on the advice of counsel.

11. The decision as to whether conduct and statements of any individual will be imputed to Pharmacia for the purpose of determining whether Pharmacia has committed a Breach shall be in the sole reasonable discretion of the USAO.
12. Should the USAO determine that Pharmacia has committed a Breach, the USAO shall provide written notice to Pharmacia of the alleged breach and provide Pharmacia with a two-week period in which to make a presentation to the USAO to demonstrate (a) that no Breach has occurred, (b) that the Breach is not a knowing breach, or (c) that the Breach has been cured. The parties hereto expressly understand and agree that should Pharmacia fail to make a presentation to the USAO within a two-week period, it shall be conclusively presumed, at the USAO's option, that Pharmacia has committed a Breach. In the event of a Breach that results in a prosecution of Pharmacia, such a prosecution may be premised upon any information provided by or on behalf of Pharmacia to the USAO at any time, unless otherwise agreed when the information was provided.
13. Pharmacia agrees that in the event that the USAO, in its sole reasonable discretion, determines that Pharmacia has committed a Breach: (a) Pharmacia will not contest the filing of the Information nor the admissibility into evidence of the facts set forth in the Information (paragraphs 1-4, 10-18) as binding admissions of Pharmacia; (b) Pharmacia will not contradict the contents of the Information; (c) all statements made by or on behalf of Pharmacia and any employee (current or former), or any testimony given by Pharmacia and any employee (current or former) before a grand jury or elsewhere, and any leads derived from such statements and testimony, shall be admissible in evidence against Pharmacia if proffered by the USAO in any criminal proceedings brought by the USAO against Pharmacia; (d) Pharmacia shall not assert any claim under the U.S. Constitution, the rules of evidence, common law or any other legal or

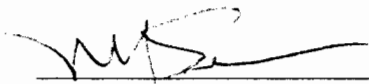
equitable principle, that statements made by or on behalf of Pharmacia prior to or subsequent to this Agreement, or any leads therefrom, should be suppressed; and (e) Pharmacia shall not assert that the conduct set forth in the Information fails to provide a sufficient factual or legal basis to support the charge set forth in the Information.

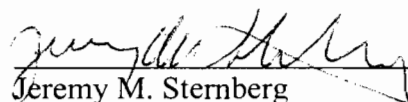
14. Pharmacia agrees that the consequences for a Breach as set forth in this Agreement, including without limitation, those set forth in paragraph 3 of this Agreement, are remedies to which the USAO is entitled in the event of a Breach and shall survive in the event of a Breach. Pharmacia further agrees that the USAO's remedies for a Breach are not limited to those set forth in this Agreement. Pharmacia further agrees that in the event of a Breach, Pharmacia shall nevertheless be bound by its waivers of any legal, equitable or constitutional rights set forth in this Agreement, including, without limitation, its waivers in paragraphs 3, 13 and 16 of this Agreement, and those provisions shall survive even in the event of a Breach.
15. Pharmacia agrees that if it sells or merges all or substantially all of the business operations as they exist as of the date of this Agreement, it shall include in any contract for sale or merger a provision binding the purchaser/successor to the obligations described in this Agreement.
16. Pharmacia shall waive any rights it may have to a speedy trial pursuant to the Fifth or Sixth Amendments to the United States Constitution, 18 U.S.C. §3161, Federal Rule of Criminal Procedure 48(b), any applicable local rule of the United States District Court for the District of Massachusetts, or any other applicable legal or equitable principle.
17. The parties understand and acknowledge that this Agreement is binding on Pharmacia and the USAO, but specifically does not bind any other federal agencies, or any state or local law enforcement or licensing authorities, although the USAO will bring the cooperation of Pharmacia and its compliance with its other obligations under this Agreement to the attention of state and local law enforcement or licensing authorities, if requested by Pharmacia or its attorneys.
18. Nothing in this Agreement restricts in any way the ability of the USAO from proceeding against any individual or entity not a party to this Agreement.
19. This Agreement expires thirty-six (36) months from the Effective Date; provided that if on the Effective Date the USAO or any other federal law enforcement or regulatory agency with which the USAO has directed Pharmacia to cooperate is then conducting any investigation, prosecution or proceeding relating to this investigation, then this Agreement shall expire on the date that any such investigation, prosecution or proceeding is finally terminated, as determined by

the governmental department or agency conducting the investigation, prosecution or proceeding. Between thirty (30) and sixty (60) calendar days before the expiration of this Agreement, Pharmacia shall submit to the USAO a written certification that Pharmacia is in compliance with this Agreement.

20. Pharmacia and the USAO agree that this Agreement, including Appendix A, shall be made available to the public.
21. Pharmacia warrants and represents that its Board of Managers has duly authorized, in a specific resolution, the execution and delivery of this Agreement by Pharmacia, and that the person signing the Agreement has authority to bind Pharmacia. Pharmacia further agrees that it will deliver on or before March 30, 2007 a copy of the requisite corporate resolution authorizing it to enter into this Agreement.
22. This Agreement (including Appendix A and the Side Letter dated March 27, 2007) constitutes the entire agreement, and supersedes all other prior agreements or understandings, both oral and written, among the parties with respect to the subject matter hereof.
23. This Agreement may not be modified except in writing signed by the parties.
24. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same agreement. The exchange of copies of this Agreement and of signature pages by facsimile or electronic transmission shall constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by facsimile or electronic transmission shall be deemed to be their original signatures for all purposes.

25. Pharmacia agrees that should a dispute between Pharmacia and the USAO arise as to the meaning of any provision of this Agreement, any ambiguities as to the terms of this Agreement shall be construed in favor of the USAO.

  
MICHAEL J. SULLIVAN  
United States Attorney

  
Jeremy M. Sternberg  
Assistant U.S. Attorney

Pharmacia & Upjohn Company LLC

By: \_\_\_\_\_  
Its: \_\_\_\_\_

\_\_\_\_\_  
Ethan M. Posner  
Counsel to Pharmacia & Upjohn Company LLC

25. Pharmacia agrees that should a dispute between Pharmacia and the USAO arise as to the meaning of any provision of this Agreement, any ambiguities as to the terms of this Agreement shall be construed in favor of the USAO.

MICHAEL J. SULLIVAN  
United States Attorney

Jeremy M. Sternberg  
Assistant U.S. Attorney

Pharmacia & Upjohn Company LLC

By: Cathy E. Wesel  
Its: Senior Corp Counsel

Ethan M. Posner

Ethan M. Posner  
Counsel to Pharmacia & Upjohn Company LLC

John J. Sullivan

**UNANIMOUS WRITTEN CONSENT OF MANAGERS  
OF  
PHARMACIA & UPJOHN COMPANY LLC**

The undersigned, being all of the managers of Pharmacia & Upjohn Company LLC, a Delaware limited liability company (the "Company"), hereby consent in writing to the adoption of the following resolutions:

WHEREAS, the U.S. Attorney's Office in Boston, Massachusetts has been conducting an investigation into the Company's promotion of Genotropin, alleging that the Company violated the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 321 et seq.; based on certain sales and marketing practices concerning Genotropin, the "Genotropin Matters";

WHEREAS, the Company's legal counsel has been negotiating a resolution of the Genotropin Matters;

WHEREAS, the Company's legal counsel has reported to the board the terms and conditions of a proposed resolution of the Genotropin Matters;

NOW, THEREFORE, BE IT:

RESOLVED, that the Company, is hereby, authorized to enter into the Agreement dated March [ ], 2007 between the United States Attorney for the District of Massachusetts and Pharmacia & Upjohn Company LLC, the "Agreement".

FURTHER RESOLVED, that Carlton E. Wessel, as our representative or any other Officer of the Company are hereby authorized and directed to take all actions and deliver any agreements, certificates and documents and instruments with respect to or contemplated by the Agreement and matters set forth above, including, without limitation, the payment of all amounts, fees, costs and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the settlements contemplated hereby.

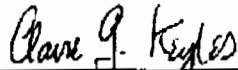
FURTHER RESOLVED, that any actions taken by the Officers of the Company prior to the adoption of these resolutions, that are within the authority conferred hereby, are hereby fully ratified, confirmed and approved as the act and deed of the Company.


[signature pages to follow]

\* \* \* \*

The actions taken by this Managers' Consent shall have the same force and effect as if taken at a special meeting of the Managers of the Company, duly called and constituted. This Written Consent of the Managers may be executed in any number of counterparts with the same effect as if all signatories hereto had signed the same document. All counterparts shall be construed together and shall constitute one document. Facsimile signature of this Written Consent may be substituted for an original signature and shall have the same effect as if the signatory had submitted the original thereof.

IN WITNESS WHEREOF, the undersigned Manager of the Company have executed this consent as of the 29<sup>th</sup> day of March, 2007.

  
\_\_\_\_\_  
Claire G. Keyes

  
\_\_\_\_\_  
Kathleen R. O'Connell

  
\_\_\_\_\_  
Charles F. Racburn

# EXHIBIT A

**Appendix A**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	CRIMINAL NO.
	)	
v.	)	
	)	
	)	
PHARMACIA & UPJOHN	)	VIOLATIONS:
COMPANY LLC	)	21 U.S.C. §§ 331(d), 333(a)(2), 355(a)
	)	
Defendant.	)	
	)	

**INFORMATION**

The United States Attorney charges that:

**COUNT ONE: 21 U.S.C. §§331(d), 333(a)(2) and 355(a)**  
**(DISTRIBUTION OF AN UNAPPROVED NEW DRUG)**

At all times material hereto, unless otherwise alleged:

**The Defendant**

1. **PHARMACIA & UPJOHN COMPANY LLC** (“**PHARMACIA**”) was a Delaware limited liability company with a principal place of business in Kalamazoo, Michigan.

**PHARMACIA** was the successor to Pharmacia & Upjohn Company which was a subsidiary of Pharmacia Corporation, which during the relevant period of time (January 1, 2000 through March 2003) was a publicly traded company on the New York Stock Exchange. **PHARMACIA** and its corporate predecessors and affiliates will be referred to in this Information as “**PHARMACIA.**”

2. **PHARMACIA** was engaged in, among other things, the development, manufacture,

promotion, sale and interstate distribution of prescription drugs intended for human use in the United States. **PHARMACIA** distributed or directed the distribution of pharmaceutical drugs to all fifty states and the District of Columbia.

3. One of the pharmaceutical drugs promoted, sold and distributed interstate by **PHARMACIA** was a human growth hormone product called Genotropin.

4. The business unit within **PHARMACIA** that was responsible for the promotion, sale and distribution of Genotropin was the Endocrine Care Business Unit.

#### **Regulatory Background**

5. The Federal Food, Drug & Cosmetic Act (“FDCA”), among other things, governed the interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at §355, the FDCA, and its implementing regulations, required, with certain exceptions not relevant here, that before a new drug could legally be distributed in interstate commerce, a sponsor of a new drug product was required to submit a New Drug Application (“NDA”) for consideration and approval by the United States Food and Drug Administration (“FDA”).

6. The FDCA required, at 21 U.S.C. §355, that the sponsor of an NDA submit to the FDA, as part of the NDA, labeling for all proposed intended uses for the drug which included, among other things, the conditions for therapeutic use. The NDA was also required to provide, to the satisfaction of the FDA, data generated in randomized and well-controlled clinical trials that demonstrated that the drug was safe and effective when used in accordance with the proposed labeling.

7. The FDCA, at 21 U.S.C. §§331(d) and 355(a), prohibited the introduction into interstate commerce of any new drug before approval of an NDA. Only after the NDA, including the proposed labeling, was reviewed and approved by the FDA, was the sponsor permitted by law to promote and market the drug, and only for the medical conditions of use specified in the approved labeling, for which use the FDA found sufficient evidence of safety and efficacy. Uses not approved by the FDA and not included in the drug's approved labeling, were known as "unapproved" or "off-label uses."

8. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor was required to file a new NDA, or amend the existing NDA by submitting evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug was safe and effective for the newly proposed therapeutic use or uses. Only upon thereafter receiving approval from the FDA could the sponsor label or promote the drug for the new intended use or uses.

9. The FDCA, at 21 U.S.C. §§331(d), 333(a), and 355, prohibited the distribution in interstate commerce of an unapproved new drug.

#### **Approved and Unapproved Uses of Genotropin**

10. In or about 1995, **PHARMACIA** submitted an NDA for approval of a drug called Genotropin (also known by its active chemical ingredient, somatropin recombinant), which was a new drug within the meaning of 21 U.S.C. §321(p). In that NDA, **PHARMACIA** sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as long term

treatment of children with growth failure due to inadequate secretion of endogenous growth hormone. On or about August 24, 1995, the FDA approved Genotropin for that specific use only. In response to supplemental NDAs, the FDA approved the use of Genotropin for other growth-related diseases, including long term replacement therapy in adults with growth hormone deficiency as demonstrated by an appropriate diagnostic test; treatment of pediatric patients with Prader-Willi Syndrome; and long term treatment of growth failure in children born small for gestational age who fail to manifest catch-up growth by two years of age. These approved uses for Genotropin will be referred to throughout this Information as the "Approved Uses."

11. At all times relevant to this Information, **PHARMACIA** did not seek approval from the FDA of any other uses and did not submit information in its NDA which demonstrated the safety and efficacy of Genotropin for any uses other than the Approved Uses. Accordingly, Genotropin was not approved for any use or condition other than the Approved Uses. Further, Genotropin was not exempt, pursuant to 21 U.S.C. §355(i), from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

12. As described herein, from at least January of 2000 through March of 2003, unapproved uses for Genotropin included athletic performance, cosmetic appearance and anti-aging. These unapproved uses for Genotropin will be collectively referred to herein as the "Unapproved Uses."

### PHARMACIA's Promotion Of Genotropin For Unapproved Uses

13. During the period January 1, 2000 through March 31, 2003, certain of **PHARMACIA's** strategic plans, business plans and other sales and marketing planning documents for Genotropin included objectives, strategies and tactics designed to increase the sale of Genotropin for Unapproved Uses. The most prominent of those Unapproved Uses was anti-aging. Some of the reasons that individuals took Genotropin for anti-aging had nothing to do with any medical condition, but instead were to obtain better skin tone, better skin elasticity, better general appearance, and better ability to lift more weights at the gym, among other things.

14. At all times relevant to this Information, certain **PHARMACIA** employees recognized that a sizable portion of its adult Genotropin sales were for Unapproved Uses and took steps to maintain and expand these sales. These steps included development of tactical plans to disseminate information to doctors on the value of growth hormone to combat the effects of aging.

15. **PHARMACIA** implemented a sales and marketing plan designed to increase Genotropin sales to the anti-aging market, including:

- a. directing its Genotropin sales representatives to make sales calls on anti-aging physician specialists;
- b. compensating its sales representatives for sales made to anti-aging physician specialists, as with other physician specialists;
- c. entering into "direct-buy" or "independent physician accounts," with physicians who treated patients for anti-aging, some of whom had widely advertised anti-aging practices;
- d. providing discounted Genotropin to an anti-aging physician for his own patient supply; and

- e. entering into a consulting contract with a physician who was a known proponent of growth hormone for anti-aging.

16. During the detailing visits by certain **PHARMACIA** sales representatives to anti-aging doctors and clinics, **PHARMACIA** made misleading representations about the effectiveness of Genotropin as an anti-aging medication. During some of these detailing visits, **PHARMACIA** sales representatives provided written materials to doctors regarding Genotropin as an anti-aging medication.

17. **PHARMACIA** knew it was illegal to promote Genotropin for Unapproved Uses such as anti-aging.

18. **PHARMACIA** earned millions of dollars in gross revenue from selling Genotropin for various Unapproved Uses. In most, if not all, instances, patients taking Genotropin for anti-aging, cosmetic appearance and athletic performance enhancement, paid for the Genotropin out-of-pocket without reimbursement from any public or private third-party payors.

19. From in or about January 1, 2000 through in or about March 31, 2003, in the District of Massachusetts, and elsewhere throughout the United States, the defendant

**PHARMACIA & UPJOHN COMPANY LLC**

did, with intent to defraud and mislead, introduce and cause the introduction into interstate commerce, into Massachusetts and elsewhere, quantities of Genotropin, a new drug within the meaning of 21 U.S.C. §321(p), which drug was intended for use for anti-aging treatment and

other Unapproved Uses, without the FDA approval required by 21 U.S.C. §355.

All in violation of 21 U.S.C. §§331(d), 333(a)(2) and 355(a).

MICHAEL J. SULLIVAN  
UNITED STATES ATTORNEY

By: \_\_\_\_\_

Jeremy M. Sternberg  
Susan G. Winkler  
Assistant U.S. Attorneys