

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA))	CRIMINAL NO. 01-CR-10350-DPW
)	
)	VIOLATION:
)	
V.)	18 U.S.C. §371
)	Conspiracy to Violate:
)	42 U.S.C. §§ 1320a-7b(b)(1) and (b)(2);
)	21 U.S.C. §§ 331(T) and 333(b)
)	
1.	ALAN MacKENZIE)	
2.	DONALD PATTON)	42 U.S.C. § 1320a-7b(b)
3.	W. DONALD MEEK)	Illegal Remuneration
4.	ERIC OTTERBEIN)	
5.	JANICE SWIRSKI)	21 U.S.C. § 333(b)
6.	RITA JOKIAHO)	Sale of Drug Samples
7.	CAREY SMITH)	
8.	MARK SMITH)	18 U.S.C. § 2
9.	HENRY VAN MOURIK)	
)	Aiding and Abetting
10.	DONNA TOM)	
11.	KIMBERLEE CHASE)	
12.	DAVID GUIDO)	
13.	JOHN ROMANO, M.D.)	
Defendants)	
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SUPERSEDING INDICTMENT

The Grand Jury charges that:

At all times material hereto, unless otherwise alleged:

TAP PHARMACEUTICAL PRODUCTS INC.

1. TAP Pharmaceutical Products Inc., hereinafter “TAP”, is a Delaware corporation with its principal place of business in Deerfield, Illinois. TAP’s shares are equally owned by Abbott Laboratories, Inc., an American corporation with a principal place of business in Abbott Park, Illinois, and Takeda Chemicals, Inc., a Japanese corporation with a principal place of business in Osaka, Japan. At various times during the 1990s, TAP was known as “TAP Pharmaceuticals Inc.” and “TAP Holdings Corporation.”

2. From in or about 1989 through the date of this Indictment, TAP sold a drug called Lupron in several different formulations, for among other things, treatment of prostate cancer. At times material hereto, TAP also sold another drug called Prevacid for treatment of conditions involving stomach acid. To induce physicians and others to purchase and prescribe Lupron instead of other drugs, and to induce hospitals, health maintenance organizations and other entities to place Lupron and Prevacid on their formularies and thereafter prescribe those drugs, the individuals charged in this Indictment who were in the 1990s employees of TAP, offered and gave, and aided and abetted offering and giving, to physicians and others money, free and nominally priced drugs, discounted prices on one drug to induce prescription of the other, free consulting services, money, educational grants, textbooks, and other things of value. The Medicare Program, the nation's health insurance program for the elderly, and the State Medicaid Programs, the nation's health insurance programs for the poor, which programs at all times relevant hereto paid for the cost of Lupron prescribed for thousands of beneficiaries of those

programs, and which paid for a part of the cost of Prevacid when prescribed to patients in hospitals, were harmed by this conduct and paid inflated prices for these drugs, in part to cover the cost of the kickbacks and other inducements.

THE TAP EMPLOYEE DEFENDANTS

3. The defendant **ALAN MacKENZIE** was a resident of Illinois and was employed by TAP from in or about November 1985 through on or about September 1998 in a number of positions, including Manager, Training and Development, Director, Sales Operations, and Vice President for Sales.

4. The defendant **DONALD PATTON** was a resident of Illinois and was employed by TAP in the 1990s and held a number of different positions, including Vice President for Sales and Vice President for Marketing.

5. The defendant **W. DONALD MEEK** was a resident of Illinois and was employed by TAP in the 1990s and held a number of different positions, including National Sales Director.

6. The defendant **ERIC OTTERBEIN** was a resident of Illinois and was employed by TAP in the 1990s and held a number of different management positions, including National Sales Director, East.

7. The defendant **JANICE SWIRSKI** was a resident of Massachusetts, and was employed by TAP from on or about May 1985 through on or about May 1998, as a National Account Manager.

8. The defendant **RITA JOKIAHO** was a resident of Massachusetts and was employed by TAP in the 1990s as a district manager, supervising sales representatives calling in

Maine, Massachusetts, Connecticut, Rhode Island and New Hampshire. **JOKIAHO** succeeded the defendant **KIMBERLEE CHASE** as a district manager.

9. The defendant **CAREY SMITH** was a resident of California and was employed by TAP in the 1990s and held a number of different positions, including district manager of hospital account executives calling upon hospitals in California, Arizona, Nevada, Oregon and Washington.

10. The defendant **MARK SMITH** was a resident of XXXX and was employed by TAP in the 1990s as a district manager supervising sales representatives calling in Ohio and Pennsylvania.

11. The defendant **HENRY VAN MOURIK** was a resident of California and was employed by TAP in the 1990s as a district manager supervising sales representatives calling in the San Francisco area.

12. The defendant **DONNA TOM** was a resident of New York. **TOM** was employed by TAP from on or about April 1989 through on or about December 1999. From in or about 1997 through on or about December 1999, she was a district manager supervising sales representatives calling in New York state.

13. The defendant **KIMBERLEE CHASE** was a resident of Massachusetts and was employed by TAP from on or about December 1990 through on or about July 1997. From in or about January 1995 through on or about July 1997, she was a district manager, supervising sales representatives calling in Maine, Massachusetts, Connecticut, Rhode Island and New Hampshire.

14. The defendant **DAVID GUIDO** was a resident of Connecticut and was employed by TAP from on or about December 1996 through and including at least 2000, at times as a

hospital account executive with responsibilities for calling on hospitals, and physicians working in hospitals, in Connecticut.

15. Together these twelve defendants, **MacKENZIE, PATTON, MEEK, OTTERBEIN, SWIRSKI, JOKIAHO, CAREY SMITH, MARK SMITH, CHASE, TOM, VAN MOURICK, and GUIDO** will be referred to in this indictment collectively as “the TAP Employee Defendants.”

THE PHYSICIAN DEFENDANT

DR. JOHN ROMANO

16. The defendant **JOHN ROMANO** was a urologist licensed to practice medicine in Massachusetts with a principal place of business in Plymouth, Massachusetts. **ROMANO** from time to time diagnosed and treated patients in his medical practice who were suffering from prostate cancer, most of which patients were insured by the Medicare Program.

RELEVANT CRIMES

17. At all times material to this Indictment, it was a crime, in violation of Title 42 U.S.C. section 1320a-7b(b), for an employee of a company engaged in the lawful distribution of drugs to knowingly and willfully offer and pay any remuneration, including any kickback, bribe or rebate, directly or indirectly, covertly or overtly, in cash or in kind, to any one to induce that person to order or to recommend the ordering of any drug for which payment was made in whole or in part by the Medicare or Medicaid Programs, or, after 1996, by any other federal health care program. At all times material to this Information, each of the TAP Employee Defendants charged in this Indictment knew of this prohibition.

18. At all times material to this Indictment, the Prescription Drug Marketing Act

provided in part as follows:

a.. Title 21 United States Code section 331(t) prohibited the sale, purchase and trade, and the offer to sell, purchase and trade, drug samples in violation of section 353(c) of that Act. Section 331(t) also prohibited causing such conduct.

b. Section 353(c) provided that no person may sell, purchase or trade or offer to sell, purchase or trade any drug sample. Section 353(c) applied to samples of a drug which was intended for human use but, because of it's toxicity, potential for harmful effect and method of use, and the collateral measure necessary for use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug and with written prescription of such practitioner. Section 353(c)(1) further provided that a sample of such a drug was a unit of drug not intended to be sold but intended to promote the sale of the drug. The drugs Lupron and Zoladex were drugs subject to the requirements of Section 353(c)(1) and the free samples of the drug Lupron provided to physicians by TAP sales representatives, as set forth in this Indictment, were drug samples within the meaning of Section 353(c)(1).

c. Section 353(c)(3) permitted a manufacturer of a drug to distribute samples of the drug through its sales representatives but only if a practitioner licensed to prescribe the drug made a written request for such samples, which request contained at least the following: the name, address and professional designation of the practitioner, the identity and quantity of the drug requested, the name of the manufacturer of the drug, the date of the request, and the practitioner's signature.

d. At all times material to this Information, each of the TAP Employee Defendants charged in this Indictment, as well as the defendant Romano, knew of these legal

requirements and prohibitions.

PRELIMINARY ALLEGATIONS

Prostate Cancer and Drug Treatments

19. The drugs Lupron and Zoladex are known as GnRH agonists and are used in the treatment of patients suffering from prostate cancer. Zoladex is manufactured and sold by another company, which company will be referred to in this Indictment as Company Y.

20. As a general medical matter, the hormone testosterone, naturally produced by men, promotes the growth and spread of prostate cancer. One treatment for advanced stage prostate cancer has been the suppression or elimination of testosterone in men suffering from that disease. Testosterone can be eliminated through the removal of the testicles by a surgical procedure called an orchiectomy. Alternatively, men's production of testosterone can be chemically suppressed through the administration of a GnRH agonist like Lupron or Zoladex. Patients whose prostate cancer was being treated with a GnRH agonist typically receive regular injections of the drug for the remainder of their lives.

21. TAP had approval from the Food and Drug Administration to sell Lupron for the treatment of advanced stage prostate cancer. Lupron was administered in liquid form to patients by intramuscular injection, typically in the buttocks or arm, by a physician or by a nurse under the supervision of a physician. At various times in the 1990s and continuing on to the present, Lupron was available in daily, one month, three month and four month doses. The one month dose was known as "Lupron 7.5 mg"; the three month dose as "Lupron 22.5 mg"; and the four month dose as "Lupron 30 mg."

22. TAP also had approval from the Food and Drug Administration to sell Lupron for

the purpose of treating endometriosis and fibroids in women. The most common dose form for this purpose was known as “Lupron 3.75 mg” and will be referred to in this Indictment in that manner or as “Lupron for the treatment of endometriosis in women.” Women treated for endometriosis are typically of child bearing years and not insured by the Medicare program.

23. Zoladex was administered in solid pellet form by injection under the skin of the patient’s abdomen, by a physician or by a nurse under the supervision of a physician. At various times in the 1990s and continuing on to the present, Zoladex was available in one month and three month doses.

24. At all times material hereto, a one-month dose of Zoladex was more than \$100 cheaper for a patient than a one-month dose of Lupron and a three-month dose of Zoladex was more than \$300 cheaper for a patient than a three-month dose of Lupron.

Prescription of Zoladex and Lupron

25. At all times material to this Indictment, Lupron and Zoladex were essentially identical in medical efficacy in the treatment of prostate cancer. At all times material to this Indictment and as regards the treatment of men suffering from advanced stage prostate cancer with a GnRH agonist:

- a. some doctors prescribed only Lupron;
- b. some doctors prescribed only Zoladex;
- c. some doctors prescribed Lupron to some patients and Zoladex to other patients;
- d. some doctors alternated prescription of those two drugs, sometimes on a monthly basis, to the same patient; and
- e. some doctors abruptly switched every patient in their medical practice from monthly or quarterly administration of one of the two drugs to the

other.

TAP Sales and Marketing

26. In order to effect sales of its drugs, TAP maintained a large and complex sales force to call upon different kinds of customers in different parts of the country.

a. Lupron sales representatives were responsible for making sales calls on physicians with specialties in, among other areas, urology and obstetrics and gynecology. They reported to and were supervised by “district managers” who in turn reported to and were supervised by “regional managers.” At times in the 1990s, the regional managers reported to the Vice President of Sales for TAP and to National Directors of Sales covering the eastern and western parts of the United States. The Vice President for Sales reported to TAP's President.

b. In addition to the Sales Department, TAP had a Marketing Department run by a Vice President of Marketing who reported to the President of TAP.

c. Lupron sales representatives and their managers were eligible for substantial bonuses, in addition to salary. Certain top managers, including all Vice Presidents, were eligible to receive stock options in the stock of Abbott Laboratories. In addition, TAP provided other sales incentives in the form of cash prizes, products and trips, including a trip known as the “Excalibur.” The Excalibur party was awarded annually to the top 30% of the TAP sales force and typically consisted of an all-expenses paid trip to a resort. At times in the 1990s, the annual budget for the Excalibur party exceeded \$4,000,000.

d. Medical marketing specialists were employed by TAP to work with Lupron sales representatives, in part for the purpose of providing things of value to physicians.

27. TAP employed specialty sales personnel to call upon institutional customers,

including hospitals and health maintenance organizations. From time to time in the 1990s, the titles of these positions, as well as their responsibilities, changed. “National account managers” or “NAMs” called upon large customers with nationwide business operations. “Managed care executives” or “MCEs” called upon managed care entities whose business was regional in scope. “Hospital account executives” or “HAEs” called upon hospitals and upon the doctors and executives working in those hospitals.

Government Payment for Lupron and Zoladex

The Medicare Program

28. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care principally for Americans over the age of sixty-five. At all times material hereto, injections of Lupron and Zoladex were covered Medicare Program benefits.

29. At all times relevant to this Indictment, the Department of Health and Human Services was an agency of the United States and was responsible for the funding, administration and supervision of the Medicare Program. The Health Care Financing Administration ("HCFA") was a division of that agency of the United States and was directly responsible for administration of the Medicare Program. HCFA, in discharging its responsibilities, contracted with private insurance companies, known as fiscal intermediaries and carriers, to receive, review, and pay appropriate claims for reimbursement for the provision of care to Medicare Program beneficiaries. Doctors who were providers to the Medicare Program could prescribe and administer, or oversee the administration, of a dose of Lupron or Zoladex to a Medicare Program beneficiary and submit a claim for payment for that injection to a Medicare carrier. Hospitals

who provided care to program beneficiaries as in-patients were paid amounts from the Medicare Program dependent upon the nature of the care provided to the program beneficiaries, such payments covered the cost of any drugs prescribed to the beneficiary while being treated as an in-patient.

30. At all times material hereto, most patients suffering from prostate cancer -- more than 75% -- were insured through the Medicare program and most of those patients -- more than 85% -- had supplemental insurance to cover the copayment for a drug like Lupron or Zoladex. Only a small percentage of such patients had no insurance coverage at all.

31. At all times material hereto in all states until May 1997, upon receipt of a claim form from a physician for the administration of Lupron, the Medicare carrier paid to the physician the lower of 80% of the billed charge contained on the Medicare claim form or 80% of the average wholesale price ("AWP") for Lupron as published in an industry publication called the Redbook. Beginning in or about May 1997, the Medicare Program in certain states, upon receipt of a claim form from a physician for an injection of Lupron, paid to the physician 80% of the billed charge for Lupron, or 80% of the published AWP for Zoladex, because the two drugs were medically efficaciously identical and because Zoladex was the least costly alternative drug treatment. At all times in all states, the physician was responsible for billing the patients for the remaining 20%.

32. At all times material hereto, TAP and its management, including the defendants **MacKENZIE**, and **PATTON** knew that TAP controlled the published AWP for Lupron and that TAP could at any time raise the AWP of Lupron and thus the maximum reimbursement by Medicare to physicians for an injection of Lupron, in all states prior to May 1997 and in many

states thereafter. At all times material hereto, TAP and its management determined to charge physicians less for Lupron than the maximum allowed by Medicare, and then to urge those physicians to bill Medicare at the maximum allowed by Medicare so that they would earn a profit from prescribing Lupron to their patients. The TAP Employee Defendants, as well as others employed by TAP, called this profit the physician's "Return to Practice."

33. Between 1992 and 1999, TAP raised the AWP for Lupron from \$418.78, more or less, to \$594.65, more or less. In that same time period and while TAP, through the conduct of **MacKENZIE**, **PATTON**, and others, was raising the price that Medicare paid for Lupron, TAP simultaneously reduced the average sales price to urologists. Management employees at TAP also established as the list price for urologists purchasing Lupron an amount equal to 80% of the AWP that TAP caused the Redbook to publish. TAP and its management employees did this to insure that urologists earned at least a 20% Return to Practice profit from prescribing Lupron.

34. To induce physicians to order Lupron and to order Lupron in greater quantities, TAP and its management, including the defendants **MacKENZIE** and **PATTON**, determined in or about 1991 to give free drug to physicians. It was the expectation of TAP and its management, including the defendants **MacKENZIE**, **PATTON**, **OTTERBEIN** and **MEEK**, that doctors receiving the free drug would prescribe that free drug, and would thereafter bill it, to their patients and their insurers, including the Medicare program, and thus receive money from Medicare and others for the prescription of that free product. Because TAP set the AWP for Lupron, these free samples ranged in value if billed from \$418.75 in 1992 to \$594.65 in 1999. Beginning on a date before 1995, and in part for these purposes, TAP routinely provided annually to each sales representative at least 80 one-month samples. TAP also made additional

free product available to district managers and sales representatives.

35. In or about 1993, TAP and its top management, including the defendant **MackENZIE**, were informed by a physician in a management position with the American Urology Association that urologists receiving free drug as volume discounts were using and billing the free drug and that TAP was accordingly putting urologists at risk of criminal prosecution. That physician asked TAP to stop providing free drug to urologists. As a result, beginning in or about 1993, TAP implemented a volume price discount program. In this program, TAP reduced the price it charged urologists as they increased the volume of drug ordered. TAP changed these volume price discounts over time, to give urologists a greater profit margin as an inducement to treat their patients' prostate cancer with Lupron instead of with Zoladex, or with Lupron instead of performing an orchiectomy.

36. In or about August, 1994, a national account manager informed management at TAP, including the defendant **MackENZIE**, that sales representatives in California were providing free samples to physicians contingent upon sales and in order to effect a lower than invoice price and that this conduct put TAP at risk.

37. In 1991, the Medicare Program paid to all providers for the prescription of Lupron, \$74 million, more or less, and for the prescription of Zoladex, \$7.5 million, more or less. By 1994, Medicare Program reimbursements for Lupron had quadrupled to \$295 million, more or less, and payment for Zoladex had increased to 36 million, more or less. In or about 1996, the Medicare program paid more than \$450,000,000 for the prescription of Lupron.

The Medicaid Program

38. At all times material hereto, the Medicaid Program was a health care insurance

program for the poor. The various State Medicaid Programs were funded in varying proportions by the federal government and by the particular states.

39. Title 42 U.S.C. section 1396r-8 required that in order for a manufacturer of a drug to receive payment from the various State Medicaid programs for prescription of its drug to Medicaid program beneficiaries, the manufacturer had to enter into a rebate agreement with the Secretary of Health and Human Services. In such a rebate agreement, the manufacturer had to promise to sell its drug to the Medicaid programs at its best price. That section further defined best price as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity.” The section also provided that “best price” includes “cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates” and does not include “prices that are merely nominal in amount.”

40. On or about February 26, 1991, TAP entered into a Rebate Agreement with the Secretary of Health and Human Services. In that agreement, TAP agreed to comply with the section 1396r-8 and further agreed as follows:

a. TAP agreed to charge the Medicaid Program its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary.

b. TAP agreed that it would determine its best price based upon its average manufacturer’s price, calculated as “Net Sales divided by numbers of unit sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements)” and that it would include in that calculation cash discounts and all other price

reductions “which reduce the actual price paid.”

c. TAP agreed that prices in “bundled sales” would be included in determining its best price and that TAP would allocate the discount in a bundled sale “proportionately to the dollar value of the units of each drug sold under the bundled arrangement.” TAP further agreed that bundled sales were sales involving the “packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.”

d. TAP agreed that best price would not take into account nominal prices, defined as prices that are less than 10% of the average manufacturer’s price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

41. After execution of this agreement, TAP reported its average manufacturer’s price in each quarter to the Medicaid Program, and reported in each quarter from 1991 through 2000, its best price for one month and three month doses of Lupron. From the first quarter of 1994 through the second quarter of 1997, TAP reported as its best price for Lupron 7.5 mg., \$298.53, and for Lupron 22.5 mg., \$895.59.

The HMO Marketplace and The Effect of Capitation

42. In the mid 1990s, increasing numbers of patients, including Medicare program beneficiaries, purchased their health insurance through health maintenance organizations (HMOs). These organizations, through their structure and in their agreements with physicians, imposed cost controls on medical expenses.

a. Some HMOs reimbursed physicians through so-called capitation

payments: a fixed dollar amount per member per month, without regard as a general matter to the cost of the actual care provided to each patient. Such capitation payments shifted the cost of providing the patient's care from the HMO to the physician, in part, to encourage the physician to provide necessary care to the HMO beneficiary in an efficient and cost effective manner.

b. From time to time, capitation contracts between physicians and HMOs had so-called "carve-out" provisions: specifically listed service or care exceptions to the capitation agreement. A typical capitation agreement with a carve-out provision for a certain service or item allowed for payment to the doctor of a fee for the "carved-out" service or item provided to a particular patient, in addition to the capitation payment for other services and care provided to that same patient.

43. TAP and its management knew that urologists who signed contracts with HMOs that did not have carve-outs for drugs used in the treatment of prostate cancer would have a financial disincentive to continue to prescribe the more expensive Lupron to their patients and would likely switch those patients to the cheaper and equally effective drug Zoladex.

Formularies

44. At times relevant hereto, some hospitals and health maintenance organizations maintained an approved listing of drug or pharmaceutical products, known as a formulary.

a. A hospital formulary was a list of drugs approved for use in that hospital, by physicians authorized to practice medicine and to treat patients at that institution. Having a drug on a hospital's formulary enhanced use of the product, and thus sales, at the institution, and continued prescription of that product to patients after their discharge from that institution.

b. An HMO's formulary was a list of drugs that a physician could prescribe

to a patient insured by that organization. Such HMOs often required physicians to prescribe to patients insured by the HMO drugs included on the formulary, or, where the doctor prescribed a drug not on the formulary, only reimbursed the physician for the amount specified for the comparable drug listed on the formulary.

45. At all times material hereto, certain large hospital institutions and HMOs had influential or bellwether formularies: formularies that (1) influenced physician prescribing patterns for patients other than patients in that institution or insured by that HMO; or (2) influenced other hospitals and HMOs in the selection of a drug for their own formularies. At all times material hereto, TAP and its management knew that having Lupron on the formulary of such a bellwether institution or HMO as an approved treatment for prostate cancer had a financial value to TAP beyond TAP's sales just to that institution or HMO.

TAP and Indigent Patients

46. At all times material to this indictment, TAP had a free drug program for indigent prostate cancer patients. To participate in this program, the patient had to demonstrate lack of insurance and an annual income less than \$24,000. Once admitted, TAP provided free drug to the patient's urologist. Between 1992 and 1999, TAP admitted very few patients into this program.

Prevacid

47. At all times material hereto, Prevacid was an oral, prescription drug used to treat a number of conditions involving stomach acid, including relieving heartburn and other symptoms of gastroesophageal reflux disease (GERD). TAP had approval from the Food and Drug Administration to sell Prevacid for these uses.

48. When prescribed by a doctor to a patient on an outpatient basis, the Medicare Program did not cover the cost of Prevacid. When provided to a Medicare Program beneficiary who was an in-patient in an acute care hospital, Prevacid was a covered Medicare Program benefit. The cost of providing Prevacid to a Medicare Program beneficiary who was an in-patient was included in the payment made to the hospital for treating that beneficiary. Acute care hospitals providing Prevacid to such Medicare Program beneficiaries included the cost of purchasing Prevacid from TAP on their annual cost report submitted by the hospital to the Medicare Program. In many state Medicaid programs, prescription of Prevacid was a covered benefit for Medicaid Program beneficiaries, without regard to whether the beneficiary was an in-patient or an out-patient.

49. At all times material hereto, TAP and its management knew and understood that once a doctor prescribed Prevacid to a patient in a hospital, prescription of Prevacid to that patient would most likely continue upon the patient's discharge. Accordingly, TAP and its employees knew and understood that, in order to enhance sales of Prevacid, it was important that hospitals include Prevacid on their formularies and that doctors treating patients in the hospital prescribed Prevacid to the patient before his or her discharge.

TAP and Sampling of Physicians

50. At all times material hereto, TAP, as required by the Prescription Drug Marketing Act, required each sales representative who gave a drug sample to a urologist: (a) to require the urologist personally to sign a multi-part form, called sample signature cards, acknowledging receipt of the drug sample; (b) to leave one part of that form with the physician and submit the remaining parts to a company hired by TAP to monitor use of drug samples; and (c) to account

on a regular basis for samples entrusted to the representative. TAP employed a company in Burlington, MA to receive and monitor these sample signature cards. That company routinely provided to TAP district managers and other TAP employees monthly reports regarding the number of samples that each sales representative reporting to those managers had distributed.

51. At all times material to this Information, the TAP Employee Defendants knew that the law imposed certain requirements on the distribution of samples of Lupron. At times material to this Indictment, Lupron sales representatives, including representatives reporting to the defendant **CHASE**, engaged in the following conduct:

- a. providing samples to a physician without a written request for the samples signed by that physician;
- b. providing samples to one physician and creating a false receipt showing distribution of the samples to a different physician who did not receive the samples;
- c. falsifying the identity of the sales representative who actually provided the samples to the physician.
- d. forging physician signatures to sample signature cards; and
- e. swapping samples between representatives, and thereafter submitting signature cards that falsely reflected the actual use of the samples.

Using Free Samples To Enhance Return to Practice Profits

52. At all times material to this Indictment, the TAP Employee Defendants knew and understood the following:

- a. that a doctor who purchased an injection of Lupron at a volume discount and thereafter billed that Lupron to Medicare and the patient at the published AWP would earn a substantial profit from billing that drug;
- b. that a urologist who received an injection of Lupron for free earned no profit from the receipt of that free dose, if he obeyed the Prescription Drug Marketing Act and did not bill the free dose to the patient or his insurer;

- c. that the vast majority of all patients had primary insurance through the Medicare Program and supplemental insurance through another insurance company;
- d. that doctors could get free Lupron for any indigent patients; and
- e. that because TAP's charge to a doctor for Lupron was less than the primary insurance reimbursement to the physician, a doctor who purchased Lupron from TAP would still profit from the prescription of Lupron even if a patient did not or could not pay the copayment.

Given these facts, at times when a TAP sales representative offered free samples to a physician that TAP employee intended, or was willfully blind to the fact that, the physician, contrary to the law, would administer that free drug to a patient and thereafter bill at least the patient's primary insurer, including the Medicare Program, for that free drug.

53. In or about December 1997, TAP and its employees became aware that the company was under investigation for its sales and marketing activities regarding the drug Lupron.

COUNT 1: 18 U.S.C. §371 (CONSPIRACY)

54. Paragraphs 1 through 53 of this Indictment are herein realleged and incorporated by reference.

55. From in or about 1992 through in or about 2000, in the District of Massachusetts, and in the District of Connecticut, the Northern District of Illinois, and elsewhere throughout the United States, the defendants

**ALAN MacKENZIE
DONALD PATTON
W. DONALD MEEK
ERIC OTTERBEIN
JANICE SWIRSKI
RITA JOKIAHO
CAREY SMITH
MARK SMITH
HENRY VAN MOURIK
DONNA TOM
KIMBERLEE CHASE and
DAVID GUIDO**

together with others known and unknown to the Grand Jury, did knowingly combine, conspire and agree:

a0 To defraud the Medicare and Medicaid programs of money and to thwart the operation and administration of those programs through deceit, craft and trickery through the distribution of free samples, sale of product at nominal value, gifts of money, provision of “consulting services”, payment of “administration fees”, forgiveness of debt, provision of "educational grants" and other things of value to physicians, health maintenance organizations and others with the intent that those things of value would influence and induce those customers to purchase, prescribe

and administer, or recommend the purchase and prescription of the drugs Lupron and Prevacid, in violation of 18 U.S.C. § 371;

b0 To knowingly and willfully offer and give remuneration, in cash and in kind, including kickbacks, bribes and rebates, directly and indirectly, and overtly and covertly, to physicians and other customers for purchasing and ordering and for recommending to patients and others that they purchase and order the drug Lupron and the drug Prevacid, for which drug payment was made in whole and in part by the Medicare and Medicaid and other federal health care programs, in violation of 42 U.S.C. §§ 1320a-7b(b)(1) and (b)(2); and

c0 To knowingly cause the sale of samples of the drug Lupron, which samples were not intended to be sold and which were drug samples intended for the promotion of the sale of the drug lupron, in violation of 21 U.S.C. § 333(b)(1)(B).

OBJECTIVE OF THE CONSPIRACY

56 At all times material to this Indictment, TAP and the TAP Employee Defendants, as well as other TAP employees participating in this conspiracy who are not named in this Indictment, all of whom will be collectively referred to in this Indictment as “the TAP Conspirators”, knew and understood that Lupron was more expensive than the competing product Zoladex, that the two drugs were considered by most physicians to be medically efficaciously identical, and that some physicians, absent a financial inducement, would not prescribe Lupron because of its higher cost, both to the patients and to their insurers, including

the Medicare Program. The TAP Conspirators also knew and understood that most patients would follow the recommendation of their physician regarding the choice of treatment for their advanced stage prostate cancer. Many of the TAP Conspirators also knew and understood that the drug Prevacid faced competition from other drugs, including a drug called Prilosec, and that at times, the price of Prilosec was lower than the price at which TAP sold Prevacid. Given these things, the common goals and objectives of the participants in this conspiracy included the following.

a0 It was a common goal and objective of the TAP Conspirators in this conspiracy to provide remuneration, in cash and in kind, directly and indirectly, overtly and covertly, to urologists and other customers to overcome Lupron's price disadvantage and to induce physicians to prescribe and use Lupron and to continue to prescribe and use Lupron.

b0 It was a common goal and objective of the TAP Conspirators in this conspiracy to provide remuneration, in cash and in kind, directly and indirectly, overtly and covertly, to physicians and others employed by hospitals and by health maintenance organizations to induce and to reward them for placing on formulary TAP's drugs and for prescribing those drugs in lieu of alternative treatments.

c0 It was a common goal and objective of some of the TAP Conspirators to maintain high prices for TAP's drugs so as to maximize profits for TAP and to provide to TAP and its employees monies from which to provide inducements and rewards to physicians and other customers for prescribing its more expensive products and to provide monies with which to reward themselves on these induced sales.

d0 It was a common goal and objective of the TAP Conspirators to give free

samples and nominally priced drug to physicians for the referral of Medicare insured business, knowing and conspiring with the doctor that the doctor would either use the free samples or the nominally priced drug to reduce his overall expenses or that the doctor would “turn” the free samples and nominally priced drug into a cash kickback by prescribing them to persons insured by the Medicare Program and thereafter billing the Medicare Program for the free samples.

e0 It was a common goal and objective of TAP's sales employees participating in this conspiracy, including the defendants **SWIRSKI, JOKIAHO, CAREY SMITH, MARK SMITH, CHASE, VAN MOURICK, TOM, and GUIDO**, to seek to meet and exceed their sales targets and objectives in order to maximize the bonus paid to them by TAP and in order to be eligible for and to win sales prizes, including attendance at the annual Excalibur party. It was a common goal and objective of the TAP management employees participating in this conspiracy, including the defendant **MackENZIE, PATTON, MEEK, and OTTERBEIN** to maximize TAP's profits, increase the profit distributions to Abbott Laboratories and Takeda Chemicals, and to maximize their own income, as paid to them in salaries, bonuses, stock options in the stock of Abbott Laboratories, and other perks.

f0 It was a common goal and objective of the TAP Conspirators to use the funds of the Medicare and Medicaid Programs in part as TAP's checkbook for the payment of kickbacks, bribes and rebates to physicians and other customers.

**MANNER AND MEANS IN PROVIDING
FINANCIAL INDUCEMENTS TO CUSTOMERS**

Free and Nominally Priced Drug and Other Drug Discounts as Inducements

57 At all times material hereto, the TAP Conspirators provided Lupron for free to urologists as inducements to order and prescribe Lupron. The TAP Conspirators knew and

expected, or chose to be wilfully blind, that, in many instances in which they provided the free samples to urologists, those physicians would prescribe the free sample to their patients and thereafter convert the free samples into cash by billing the patients and their insurers for the free samples. In other instances, the TAP Conspirators knew and understood that the free samples aided a urologist financially by eliminating an expense in his practice – the cost of the product – and by improving his cash flow. Provision of free samples by the TAP Conspirators to physicians, and other related pricing inducements, occurred as follows:

- a0 **Free drug to induce new patient starts.**
- b0 **Free drug to induce patient conversions from Zoladex to Lupron.**
- c0 **Free drug to stop patient conversions from Lupron to Zoladex.**
- d0 **Free drug to cover patients without copayments:** TAP and its

employees knew and understood that some patients without supplemental insurance might not be able to afford or might not wish to pay to the doctor the high monthly copayment on a doctor's prescription of Lupron. To induce the physician to prescribe Lupron to such patients, the TAP Conspirators provided free drug samples to make up for the value of the potentially uncollectible patient copayments. In such instances, the TAP Conspirators knew and expected that the physician would administer the free drug and bill it to a patient's insurer, including Medicare.

- e0 **Free drug to cover lost volume discounts:** At times, sales representatives, seeking to meet a sales goal or to qualify for the Excalibur party, requested urologists to order Lupron "early": that is, to order in the representative's current bonus period product that the doctor would normally order in the subsequent time period. To induce the physician to place those early orders, and to make up for a potential lost volume discount on the

later order, sales representatives provided free samples in an amount whose value roughly equaled the expected value of the lost discount. The TAP Conspirators knew and expected that the urologists would administer the free samples and bill them to the patient and his insurer, including Medicare.

f0 Free drug to make the physician's total cash outlay for purchasing and prescribing Lupron equal to his total cash outlay for purchasing and prescribing Zoladex.

g0 Free drug for HMO patients: The TAP Conspirators offered and gave free samples to physicians who had some patients insured through an HMO with a capitated PMPM payment, in order to defray drug costs for those urologists and to induce those urologists to prescribe Lupron for their non-capitated, fee-for-service, patients.

h0 Free drug to pay off outstanding debt to TAP: The TAP Conspirators offered and gave free samples to physicians who were in debt to TAP on prior purchases. The TAP Conspirators provided these free samples to such urologists so that they could prescribe the free samples to the patient and bill the product to the patient's insurer, including Medicare, so that the urologists would have funds from which to pay off their outstanding debts.

i0 Free or Nominally Priced Drug: The TAP Conspirators offered and gave free or nominally priced drug to customers in order to obtain exclusive contracts or to effect a lower than invoice price for the Lupron sold to customers for the treatment of prostate cancer or for the Prevacid sold to the hospital or HMO customers. The TAP Conspirators engaged in this conduct in part in order to conceal from the Medicaid Program that it was in fact offering to another customer a price better than that offered to the Medicaid program.

j0 Price Discounts on Other Drugs in Exchange for Orders for Lupron

for Prostate Cancer: The TAP Conspirators offered discounts on the price of other drugs to hide a price discount on or to affect a lower overall price for, Lupron sold to that customer for treatment of prostate cancer. The TAP Conspirators engaged in this conduct in order to conceal from the Medicaid Program that it was in fact offering to another customer a price better than that offered to the Medicaid program.

Inducements called “Value Added Services”

58 The TAP Conspirators provided to physicians many other things of value to induce them to prescribe, to continue to prescribe, and to prescribe in greater quantities, Lupron. These inducements included the following:

a0 **Educational Grants:** The TAP Conspirators offered and gave so-called “educational grants” to urologists, hospitals, and health maintenance organizations, and to doctors and other individuals who held positions at such institutions which positions gave to those individuals the authority and ability to influence that institution's drug purchasing decisions, as an inducement and as a hidden discount to effect a lower but off-invoice price for that customer, for the purpose of concealing that lower price from the Medicaid Program.

(1) Under the label “educational grant” the TAP Conspirators provided money, sometimes in excess of \$50,000, to physicians and their employers, including hospitals and health maintenance organizations: to support marketing efforts, to finance parties, to pay for bar tabs at country club functions, to pay for golf outings, to pay for attendance at seminars and conferences of professional organizations, to purchase medical equipment, to pay for education for the physician’s office staff, to fund visiting professor preceptorships, and to use for any purpose "whatever."

(2) The TAP Conspirators knew and understood that they could not lawfully provide things of value, including educational grants, directly to employees of health maintenance organizations or hospitals which employees played a role in the decision-making process at those institutions whether Lupron or Prevacid would be on formulary. From time to time to circumvent this prohibition, TAP and its employees offered, in discussions with such employees, educational grants to the employer, with the understanding and expectation that the employee with whom the “institutional” grant was being discussed, would be able to obtain and receive the benefits of that grant as an inducement.

b0 **Free Consulting Services:** The TAP Conspirators offered and provided to urologists services from a health care consultant, for which services TAP paid. Such free consulting services included medical practice management advice, advice regarding practice mergers and advice regarding contract negotiations with HMOs. TAP routinely paid between \$5,000 and \$10,000 and on one occasion more than \$30,000, for such consulting services.

c0 **Payment of Administrative Fees:** The TAP Conspirators offered and paid so-called “administrative fees” to certain urologists as an inducement for the purchase of Lupron. These fees were based upon the sales volume of Lupron to that physician and were in effect off-invoice price rebates.

d0 **Free Trips and Conferences:** As a reward for Lupron customers and as an incentive to urologists prescribing Zoladex to convert their patients, the TAP Conspirators from time to time invited urologists to attend all-expenses paid weekend “conferences” at golf, ski and beach resorts as "consultants" to TAP. These events, called “TAP into the Future” programs, generally cost about \$200,000, or \$5,000, more or less, per attending urologist, and

included, at times, free lodging, meals and golf greens fees. Between 1995 and 1998, the TAP Conspirators held in excess of ten such events, at among other locations, the following: the Ritz-Carleton Aspen, Aspen, Colorado; the Scottsdale Princess, Scottsdale, Arizona; the Four Seasons Biltmore, Santa Barbara, California; and the South Seas Plantation, Captiva Island, Florida.

e0 **Employment as a “Consultant”:** As an inducement for Lupron purchases, the TAP Conspirators at times made payments to certain urologists as “consultants” under agreements in which TAP paid the urologist’s expenses in attending a conference without expecting to receive, or in fact receiving, any consulting services.

Unreported Price Discounts as Inducements

59 The TAP Conspirators, including the defendants **MackENZIE** and **PATTON**, provided price discounts to physicians as an inducement to purchase and prescribe Lupron, as opposed to any other treatment and conspired with physicians to insure that those discounts were not fully and adequately disclosed to the Medicare Program.

a0 The defendants **MackENZIE** and **PATTON**, together with other members of the conspiracy, provided volume discounts to physicians but deliberately chose not to tell those physicians to fully and accurately report those discounts to the Medicare and Medicaid programs.

b0 The defendants **MackENZIE** and **PATTON**, together with other members of the conspiracy, provided to TAP’s sales employees a computer program to demonstrate to a physician the profit, or “Return to Practice” the physician could make by prescribing Lupron and by billing the Medicare Program at the maximum allowed, the published average wholesale price.

c0 At times material hereto, the defendants **MacKENZIE** and **PATTON**, together with other members of the conspiracy, engaged in the following conduct designed to provide to physicians a price discount that TAP Conspirators intended not be fully and accurately reported to the Medicare and Medicaid programs:

(1) They raised the published average wholesale price of Lupron without raising the price that TAP charged urologists for Lupron for the sole purpose of increasing the profit spread between the urologists' cost for the drug and the maximum Medicare reimbursement to the doctor for prescribing the drug to a Medicare Program beneficiary.

(2) They raised the published average wholesale price to provide a greater return to practice to urologists who prescribed Lupron than could be earned through the prescription of Zoladex, provided that the physicians bill the Medicare Program at the maximum allowed. In this regard, in or about 1995 and while attending an Excalibur party in Hawaii, the defendants **MacKENZIE**, **PATTON** and others determined to raise the published AWP for Lupron, and thus the amount that the Medicare Program would pay for Lupron, solely because Company Y had raised the published AWP for Zoladex and had created a better spread for physicians at certain volume discounts.

(3) They urged urologists not to disclose to Medicare the prices TAP charged them for Lupron. In or about September, 1997, the defendant **MacKENZIE** told TAP's sales force to tell physicians that if doctors disclosed their invoice costs to the Medicare Program, that Program would take steps to reduce the maximum payment allowed for Lupron and thus reduce the physician's profit or Return to Practice. **MacKENZIE** further told the sales force to caution doctors not to discuss their price discounts with other physicians and instructed

TAP employees to tell urologists that “by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCFA then realizes that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amount you may charge.”

OVERT ACTS

In furtherance of the conspiracy, the defendants and other conspirators known and unknown to the United States Attorney committed overt acts in this district and elsewhere in the United States as set forth below in paragraphs 50 through 137.

60 In or about the spring, 1995, the defendant **ALAN MacKENZIE** informed a TAP employee that TAP hired outside attorneys “for purposes of keeping an eye on what HCFA was up to” but that those attorneys were not told the details about TAP’s marketing practices.

61 In or about August 1995, and at a meeting of the Lupron sales force, TAP management directed the sales force to forward to the defendant **ALAN MacKENZIE** any Zoladex free-good and return-to-practice profit proposals that had been provided to a Lupron customer. Also at that meeting, the TAP sales management discussed an expected launch by Company Y of a new product and expressed the concern that Company Y might offer free samples of that product to urologists, or might offer a discount on that product to induce doctors to switch Lupron patients to Zoladex notwithstanding that "incenting to use is also illegal." The defendant **HENRY VAN MOURIK** attended this meeting and informed his superior of these facts.

EDUCATIONAL GRANTS AS INDUCEMENTS

“Educational Grants” Offered to Tufts HMO

62 Tufts Associated Health Plans (“Tufts”) is a health maintenance organization with principal place of business in Waltham, Massachusetts. As an HMO, Tufts pays for, among other things, treatment provided by urologists for patients suffering from prostate cancer, including the cost of Lupron or Zoladex. Pursuant to its agreement with providers who treat

patients insured through Tufts, Tufts receives bills from the providers for the care rendered and makes payment to the providers pursuant to its agreements with the providers. Some of Tufts insured patients are Medicare Program beneficiaries.

63 At all times material hereto, the defendant **JANICE SWIRSKI** was the National Account Manager responsible for calling upon Tufts. The defendant **KIMBERLEE CHASE**, was the district manager in whose district Tufts had its principal places of business.

64 In or about the summer 1996, Tufts announced to its providers that effective January 1, 1997, and absent special circumstances, Tufts would not reimburse a physician who prescribed and administered Lupron to a patient, unless special authorization was obtained for the prescription of Lupron to that patient, and that Tufts would only reimburse for the prescription and administration of Zoladex. Principally in charge of this decision for Tufts was a physician who will be referred to in this Indictment as “the Tufts Medical Director.”

65 The TAP Conspirators knew and understood in 1996 that this decision by Tufts would result in a conversion of patients from Lupron to Zoladex. In order to “slow the Tufts Zoladex switches” while the contract issue with Tufts was under negotiation, a TAP employee provided to **CHASE** fifty “DM Discretionary 22.5 mg samples” to be used by **CHASE** to induce physicians not to switch Tufts patients.

66 In or about August 1996, the defendant **SWIRSKI** met with the Tufts Medical Director and told him that TAP could not reduce the price that it charged Tufts for Lupron because that would affect government pricing. **SWIRSKI** told the Tufts Medical Director that she and TAP had calculated that paying for Lupron for prostate cancer for Tufts-insured patients was about \$80,000 more expensive for Tufts than would be the cost of prescribing Zoladex to

those patients. **SWIRSKI** then offered to the Tufts Medical Director and to Tufts an educational grant of \$40,000 if Tufts would continue to pay for Lupron.

67 Between March and July 1997, **SWIRSKI** and **CHASE** met with the Tufts Medical Director and offered to him and to Tufts things of value in excess of \$65,000 in exchange for: (1) a decision by him reversing the Tufts' decision to reimburse Lupron at the same rate as Zoladex, and (2) the referral of almost all of Tufts' purchases of a GnRH agonist for the treatment of prostate cancer in men. These things of value included the following:

- a0 \$65,000, more or less, in the form of so-called educational grants; and
- b0 Hiding a lower price for doses of Lupron 7.5 mg (for treatment of prostate cancer in men) by selling Tufts Lupron 3.75 mg (for treatment of endometriosis and fibroids in women) at a substantially discounted price if Tufts were to purchase both drugs.

68 In making these offers to the Tufts and its medical director, **SWIRSKI** and **CHASE** told the Tufts Medical Director the following, among other things:

- a0 that TAP could not further discount the price of Lupron for prostate cancer because that would affect the prices charged to government programs and that was one of the reasons for providing the discount on prices of Lupron 3.75 mg;
- b0 that Tufts and the Tufts Medical Director could use the educational grant for any purpose whatsoever and that TAP would not take any steps to insure that the grant monies were in fact used for education;
- c0 that the contract for the sale of Lupron to Tufts and the agreement to provide education grants to Tufts had to be kept separate so that TAP did not have to discount its pricing to government health care programs; and
- d0 that while the education grants were being given in exchange for the referral of the Lupron for prostate cancer business, the agreement on the education grants could not be executed on the same day as the contract for the sale of Lupron and that it had to be a separate handshake agreement.

69 On or about April 2, 1997, **CHASE** and **SWIRSKI** met with the Tufts Medical

Director. In that meeting, **SWIRSKI** told the Tufts Medical Director that TAP could not discount the price for Lupron for prostate cancer because TAP had “government pricing to protect” but would reduce the overall price to Tufts by discounting the price for Lupron 3.75 mg for endometriosis and fibroids. **SWIRSKI** also offered the Tufts Medical Director education grants as a part of a “handshake agreement.”

70 On or about April 23, 1997, **CHASE** and **SWIRSKI** met with the Tufts Medical Director. In that meeting, **SWIRSKI** offered to the Tufts Medical Director \$60,000 in educational grants, \$20,000 per year for three years.

71 On or about June 3, 1997, **CHASE** and **SWIRSKI** met with the Tufts Medical Director. In that meeting, **SWIRSKI** told the Tufts Medical Director that the \$60,000 in education grants had to be a part of a “loose handshake” and that to get the \$60,000 in education grants the Tufts Medical Director had to send a letter each year to TAP asking for an “educational grant for whatever.” **SWIRSKI** also told the Tufts Medical Director that while the head of marketing for Lupron had “given the green light on this”, the “head of contracts” “wants nothing to know about” a grant because if it was attached “we’d probably have to discount” “our entire Medicaid business” and “that’s why it’s kept separate.” The three also discussed two physician groups that had been long time exclusive users of Zoladex and whether as a part of the agreement, the Tufts Medical Director would force those two groups to switch to Lupron as well. **SWIRSKI** and **CHASE** discussed how much it was worth to them and to TAP to have those two groups switch from Zoladex to Lupron. **SWIRSKI** stated that “because of this ego thing” “I’m telling you I’m willing to scrape up my dollars just to see it happen” even though “it’s gonna cost us more than what it would pay us back.”

72 On or about June 10 1997, **SWIRSKI** sent to the Tufts Medical Director a letter forwarding a copy of the proposed contract between Tufts and TAP and confirming a \$20,000 educational grant to be used “at your discretion.” **SWIRSKI** also told the Tufts Medical Director in that letter that she had “locate[d] an additional \$5,000 for conversion of the two targeted urology groups that we had discussed.”

Educational Grants and other Financial Inducements Paid to a Massachusetts Clinic

73 Clinic LF was a provider of health care to persons in Massachusetts and New Hampshire through numerous clinics and hospitals located in both of those states. Doctors treating patients in those clinics at times treated patients suffering from prostate cancer and from ailments for which the drug Prevacid could be prescribed. In the 1990s, Clinic LF entered into contracts with TAP for the purchase of the drug Lupron.

74 Clinic LF had operations in the sales territories of sales representatives who were supervised by the defendants **KIMBERLEE CHASE** and **RITA JOKIAHO**. Both **CHASE** and **JOKIAHO** knew and understood that any decision by Clinic LF to stop purchasing Lupron for use in its clinics and hospitals would negatively affect the performance of the TAP sales representatives reporting to them. Those managers also knew and understood that if Clinic LF continued to purchase Lupron, and if doctors treating patients in its clinics and hospitals prescribed more Lupron, they would benefit by those increased sales through sales bonuses.

75 TAP employee JR was a Managed Care Executive responsible for calling upon Clinic LF. She will be referred to in this indictment as MCE JR. TAP employee JW was a sales representative responsible for calling upon Clinic LF in 1997, 1998 and early 1999. JW reported first to the defendant **CHASE** and thereafter to the defendant **JOKIAHO**.

76 In 1997, and after Tufts had announced that it would no longer reimburse for Lupron, as described above in paragraphs 64 to 74, MCE JR and other TAP employees reported to their superiors that Company Y was getting "very aggressive" in selling Zoladex to Clinic LF. On or about March 15, 1997, MCE JR reported to her superior that TAP had "a very strong relationship here for over 5 years and our added value services have been above and beyond. This has been saving us from [Company Y] threats."

77 In or about July 20, 1997, MCE JR met with the Chief Executive Officer of Clinic LF to make sure that TAP had "his support in light of the [Company Y] blitz at the clinic." In that meeting, MCE JR discussed the "Grants and Support given to the clinic over the past 3 years" and the Clinic's CEO "bought off on it but told me I had to sell this to the clinic manager and pharmacy." Thereafter, MCE JR met with the clinic manager and the pharmacy director and "did a grant-added value service review for both and both agreed TAP has been extremely supportive in the Urology and GYN markets." MCE JR reported to her superior that those individuals told her that if TAP could save Clinic LF an additional \$100,000 through a "combination of straight pricing and grants-added value service" it would "keep them happy."

78 On or about September 29, 1997, MCE JR met with the Clinic's CEO and presented him a check for his "prostate cancer research lab" and reported to her superior that the timing in the delivery of the check was "perfect."

79 Sometime in or about the late summer and fall 1997, Clinic LF and TAP agreed to a contract renewal and TAP offered and gave to Clinic LF, as off-invoice inducements for the renewal of that contract and in order to reduce the overall contract price, 50 free one-month injections of Lupron. These injections were delivered in two sets of 25 samples, one in

November 1997 and the second in February 1998. To hide the delivery of 50 total samples to Clinic LF, Rep JW had five different physicians sign for quantities of between 5 and 7 samples on two different days in December 1997 and February 1998. Rep JW told the defendant **JOKIAHO** that on November 18, 1997 she dropped off "25 samples to Marsha at Pharmacy" but that on December 11 she got four doctors to sign for those samples, including a doctor who will be referred to in this indictment as Dr. JS.

80 On November 7, 1997, Rep. JW reported to **JOKIAHO** that MCE JR had given the Clinic CEO a \$2,000 grant but that he did not "want it going to clinic, he wants an Attending/Resident Holiday party at L'Esplaiier."

81 On or about November 21, 1997, Rep. JW reported to **JOKIAHO** that the holiday party for Clinic LF's CEO was on December 18 and that while she had "called around, everyone is booked except Grill 23."

82 On or about December 17, 1997, Rep JW recommended that Dr. JS be given a free trip to a ski or golf resort in 1998 in part to "increase his loyalty and utilization."

83 On or about January 23, 1998, Rep JW told the defendant **JOKIAHO** that she had started a contest at Clinic LF that offered a \$250 gift certificate as an inducement for the nurse or doctor who converted the most patients by the end of March 1998 from the 22.5 mg dose of Lupron to the 30 mg dose of Lupron. In response, **JOKIAHO** asked Rep JW if she had posted the poster in a location where the Zoladex representative "can get a hold of" it. **JOKIAHO** cautioned Rep JW that offering \$250 for switching patients from one dose form to the other can be considered bribing and that it was illegal so "please please please be cautious how excited we get on this program." **JOKIAHO** told Rep JW that she had "no problem you

getting creative as long as it doesn't put you or TAP in a difficult situation. But by the way let me know [who's] converted the most [patients] to the 4 month.!!!!!!!!!!!!!!!"

84 On or about March 20, 1998, the defendant **JOKIAHO** told Rep JW that she had spoken with Dr. JS and that he had told **JOKIAHO** that "his nurses are killing each other to get more [patients] on 4 month [because] of the competition you have. Sounds like this program is working for you."

85 In or about April, 1998, **JOKIAHO** and Rep JW met with the Clinic CEO, as well as the pharmacy director to discuss rumors that Clinic LF was considering switching to Zoladex. In those meetings, **JOKIAHO** and Rep JW presented to the pharmacy director "all the Value Added services we provided [Clinic LF] last 97." **JOKIAHO** and Rep JW made a similar presentation to the clinic manager, whose "jaw dropped to floor when he saw the report", and to Dr. JS, who stated: "Good job, this is all I wanted to see." Shortly after these meetings, **JOKIAHO** sent to Rep JW a letter praising her for her work at Clinic LF and making everyone aware of the monies that TAP had provided to the clinic: "specially when you add all other factors into formula, such as the commitment we have to the department over the years, your excellent work with the physicians, residents and nurses, the continued financial support, and lastly the 50 free kits we provided as part of the negotiation for the Lupron contract."

86 On or about June 19, 1998, Rep JW reported to **JOKIAHO** that in a meeting with the pharmacy director, he had told her that he did not want to incorporate the 50 free samples into the comparison between the cost for Lupron versus the cost for Zoladex because they were "not clean numbers" and that in the future he just wanted a "lower price and no free goods!!"

87 On or about June XX, the defendant **JOKIAHO** hired the pharmacy director of

Clinic LF to give a speech to her sales representatives and paid him \$500 for that one hour speech in part “to continue building our case” and to demonstrate to the pharmacy director and others at Clinic LF “why they should cont[inue] to work with TAP and not [Company Y] as their preferred company.”

88 On or about July 15, 1998, **JOKIAHO** sought money from other employees of TAP in order to provide \$15,000 to Clinic LF for a golf outing, stating that the “contribution to this institution [was] much more visible to administration in a time where [Company Y] continues to push for a switch and continues to try to take our business away” and that the money “will help us get a great return on our investment now as well as in the future.”

89 In or about September, 1998, **JOKIAHO** and Rep JW met with the CEO of Clinic LF and discussed “the value added services” as a reason why Clinic LF should purchase Lupron and not Zoladex for its patients. **JOKIAHO** demonstrated to the CEO that TAP had, through its “partnership” with the Clinic, provided the following monies to the Clinic in 1997 and 1998 as inducements to keep its business and to reduce off-invoice the price difference between Lupron and Zoladex:

(1)	Prostate cancer screening	\$1,500
(2)	Monthly journal club	\$2,500
(3)	Resident Textbooks	\$2,000
(4)	Board review	\$100
(5)	Graduation dinner sponsorship	\$5,000
(6)	Golf tournament (1997)	\$20,000
(7)	Golf tournament (1998)	\$18,000

(8)	Unrestricted grant	\$2,000
(9)	50 (7.5 mg) Lupron kits	\$15,250
(10)	Capsure prostate cancer database	\$2,500
(11)	Liver doctor visiting professor preceptorship (VPP)	\$2,500
(12)	Dr. Doug Rex Colon VPP	\$3,500
(13)	Ocean Edge CME Support (Liver DZ)	\$1,500
(14)	IM Waterville Yearly Conference	\$1,000
(15)	Dr. Fred Whitcomb Liver Center Donation	\$1,500
(16)	Textbooks	\$500
(17)	Dept. Educ. Function	\$2,000
(18)	Board Review Textbooks	\$500
	Total:	\$63,100

JOKIAHO reported to her supervisor at TAP that in response, the CEO at Clinic LF stated that “If you didn’t help us with all your \$\$\$ support, then we the institution would have to pay for this” and that he would make it clear to the clinic administrator to “find a way to give some money back” to the pharmacy director’s budget to keep him “at peace.” Following this meeting, Clinic LF continued its contract with TAP.

90 It was a part of the intent of the defendant **JOKIAHO** and other TAP employees, in offering and giving, and in approving the offer and giving, of educational grants and other things of value, to Clinic LF and to doctors and others employed by that Clinic, including the CEO, the pharmacy director, and the clinic's administrator, to induce that clinic and those individuals to continue to purchase the drug Lupron and to continue to recommend to their

patients and to other doctors at that institution, the prescription of Lupron for the treatment of prostate cancer.

“Educational Grants” to California Doctors and Institutions

91 Defendant **CAREY SMITH** was a manager of Hospital Account Executives and managed such TAP employees in, in part, Southern California.

a0 In her territory was County X, a county in California that operated numerous hospitals and clinics. and through those hospitals and clinics, provided health care to numerous persons, including persons insured by the Medicaid and Medicare Programs. Doctors treating patients in those hospitals and clinics at times treated patients suffering from prostate cancer and from ailments for which the drug Prevacid could be prescribed. At times in the 1990s, County X and hospitals and clinics that were a part of that county system, put Lupron and Prevacid on formulary and entered into contracts with TAP for the purchase of the both drugs. One of the hospitals in County X was Hospital XA.

b0 Hospital XA had urology, gynecology and gastroenterology departments and physicians practicing in those departments from time to time treated patients suffering from prostate cancer and from medical conditions for which Prevacid or a competing drug were prescribed. Like many institutions, Hospital XA had a formulary for drugs for use in the institution and the hospital included in its cost reports to the Medicare Program expenses for drugs sold to the Hospital by TAP, including Lupron and Prevacid.

c0 A second hospital in **CAREY SMITH's** territory in Southern California was Hospital W. That hospital had a gastroenterology and internal medicine departments and had a Pharmaceutical and Therapeutics Committee. That committee, the P & T committee,

among other things determined what drugs should be on the formulary for Hospital W. Prior to June 1997, the drug Prevacid was not on the formulary at Hospital W.

d0 In about June 1997, Hospital W added Prevacid to its formulary. Dr. G at Hospital W was at times material to this indictment head of the Gastro-Enterology Department at Hospital W.

92 The defendant **CAREY SMITH** became district manager of the HAEs that called in Southern California, in or about September 1997. At that time, Lupron and Prevacid were on the formulary for Hospital XA and County X, and Lupron and Prevacid were on the formulary for Hospital W. The County, Hospital XA and Hospital W were were purchasing Lupron and Prevacid from TAP, and doctors practicing in those institutions were prescribing those products to their patients. **CAREY SMITH** knew and understood that any decision by County X and Hospital XA, and by Hospital W, to take either Prevacid or Lupron off their formularies would negatively affect the performance of the TAP HAEs reporting to her. **CAREY SMITH** also knew and understood that if County X and Hospital XA, and Hospital W continued to purchase Lupron and Prevacid, and if doctors treating patients at those institutions prescribed more Lupron and Prevacid, **SMITH** and her HAEs would benefit by those increased sales through sales bonuses. One of the hospital account executives reporting to **CAREY SMITH** will be referred to in this indictment as "HAE SS."

Inducements to Hospital W

93. On or about the end of May, 1997, HAE SS met with Dr. G at Hospital W and gave to him a check for \$5,000. When she gave that check to Dr. G, HAE SS asked Dr. G, if, in return for the \$5,000 grant, he would appear before the P & T committee of Hospital W and

recommend that that committee put Prevacid on its formulary. Dr. G agreed to do so. In or about June, 1997, Dr. G did that, and also in that month, Hospital W put Prevacid on its formulary.

94. On or about June 6, 1997, HAE SS reported to her manager, the defendant CAREY SMITH's predecessor, that Hospital W had placed Prevacid on its formulary. On or about June 20, 1997, HAE SS reported to her manager that Dr. G had told her he had undertaken extensive efforts to make sure that Hospital W added Prevacid to its formulary and that he had "demanded that TAP financially supports [sic] the GI department by matching what [the competitor] contributes (\$30,000). His point was that [the competitor] has been contributing 30K every year and he took a big risk of losing [sic] that support by standing up for Prevacid and therefore TAP should also come up with 30K." HAE SS told her manager that she had told Dr. G she would do her best, but that he had responded: "You go back to your people to let them know that I have done my job to get your drug on, now it is time that you do your job to support me." HAE SS's manager responded by asking: "TO DATE, HOW MUCH \$\$\$ HAVE WE GIVEN [DR. G]?"

95. In or about August 8, 1997, HAE SS reported to her manager that Dr. G was "extremely angry" and "furious" that TAP had at that point provided to him only \$10,000 in grants, instead of \$30,000 as he had demanded and that if TAP did not give him additional grant monies, he would "bow out of the P & T and pull Prevacid out of the formulary at the next 6-month P & T review and anything that had to do with TAP and that we do not have the friendly relationship that he thought we had."

96. In or about September 1997, HAE SS told the defendant **CAREY SMITH** that several doctors at Hospital W were asking for "\$\$\$\$" including several urologists and that she had no more grant funds available in her budget and would not be funding these requests. **CAREY SMITH** told HAE SS that if "TAP wants to stay in the league with the big boys we need to have the funds to do so."

97. In or about September and October 1997, the defendant **CAREY SMITH** asked each HAE she supervised to provide to her an assessment of the grants given to hospitals in their territory by the competitor and then forwarded this information to her supervisor with a request for additional grant monies in order to remain competitive. When one HAE told her in or about September 26, 1997, that the competitor had given one customer more than \$130,000 and that she needed to "put more money into" the GI department at that hospital, the defendant **CAREY SMITH** responded that she would pass this information along and that she hoped it would "result in some relief."

98. On or about October 3, **CAREY SMITH** told HAE SS that she was "not out of funds anymore" and that **CAREY SMITH** had obtained for the district \$15,000 for additional educational grants. On about November 7, 1997, HAE SS told the defendant **CAREY SMITH** that she had delivered the additional the two checks to Dr. G for \$11,500 and that he was "grateful" and that she had asked him to post a plaque bearing TAP's name and displaying the month and the visiting professor's name so that TAP's grants would receive "recognition." **CAREY SMITH** responded that she liked "**the plaque idea**" and that that would be a "**constant reminder of TAPs support.**" HAE SS also told **CAREY SMITH** that three different urologists at Hospital

W were looking for \$12,500 to \$14,500 in grant support for three different prostate cancer conferences scheduled for early 1998; SMITH told her she had “passed this on...”

Inducements to the Department of Health Services, County X

99. On or about December 3, 1997, CAREY SMITH and other TAP employees met with employees of the department of health services of County X regarding a contract proposal for Prevacid. In that meeting, CAREY SMITH and the other TAP employees told County X that County X should purchase Prevacid from TAP in part because TAP had provided in 1997 \$44,291 in educational grants to hospitals and clinics in the County, including money for textbooks, "Hawaii Programs", awards to specific doctors, and physician education programs. CAREY SMITH also told employees of County X that TAP would, in addition to selling Prevacid to the County at the public health service price of \$1.80 per pill, sell the county certain quantities of Prevacid as "nominal goods" at \$0.26 per pill provided the County met specific market share requirements and that the nominally priced product would drop the actual price to the County below the public health service price.

100. On or about November 15, 1998, the defendant CAREY SMITH and other TAP employees presented to County X a contract proposal for the sale of Lupron to the hospitals and clinics in the County. In that proposal CAREY SMITH and the TAP employees told County X, in part to keep the County from switching its Lupron patients to Zoladex, that if the County switched to Zoladex that the County would lose the "TAP value-added services" and that the "Total Package" of TAP's support included education grants to the hospitals and clinics in the County, which grants had totaled in 1997 and 1998 \$21,535.18, more or less. At the end of the presentation, CAREY SMITH and the TAP employees asked the County to evaluate whether, in

light of all the money that TAP had given to the County in "value added services", the County would "really save money with Zoladex."

101. It was a part of the intent of the defendant **CAREY SMITH**, in offering and giving, and in approving the offer and giving, of educational grants to Dr. G, to other doctors at his hospital, to County X, to Hospital XA and to other doctors and hospitals in her territory, to offer and give, and to recommend the offering and giving of these things of value as an inducement to the those customers to continue to order and prescribe the drug Lupron and the drug Prevacid.

"Educational Grant" for Christmas Party for Urology Practice on Cape Cod:

102. On or about November 6, 1995, a sales representative reporting to the defendant **KIMBERLEE CHASE** sought approval to give a urology practice located on Cape Cod \$200 to support the practice's annual Christmas Party. Urologists in that practice had in the past prescribed Lupron to patients suffering from prostate cancer, some of which patients were insured by the Medicare Program. In requesting this money as an "educational grant" the sales representative stated that she would ask one of the doctors "to talk about Lupron and prostate cancer at the party to justify the donation, ha-ha."

103. The defendant **KIMBERLEE CHASE**, and others, approved this request for money and labeled the gift of cash to support the practice's Christmas Party an "educational grant."

104. It was a part of the intent of the defendant **CHASE** in approving the gift of money, to offer and give the money to the practice as an inducement to the practice to continue to order and prescribe the drug Lupron. Among other things provided to this practice from in or

about June 1995 through in or about June 1997 were the following: a fax machine; free consulting services; money for a holiday party; money for a newsletter; money for a patient satisfaction survey; tuition to attend an AUA managed care seminar; and golf.

Educational Grant to Urology Department at a New Haven Hospital

105. Practice D was a Department of Urology at a hospital in New Haven, Connecticut. It was a part of the practice of medicine at Practice D that urologists working in that practice from time to time diagnosed and treated patients suffering from prostate cancer. As a part of the treatment of some of those patients, urologists in Practice D prescribed for those patients Lupron and Zoladex. At all times material hereto, Practice D and the hospital at which that practice was based received more than \$10,000 in benefits from the Medicare Program and many of the patients being treated for prostate cancer in that Practice were insured by the Medicare Program.

106. From in or about January 1999 and into the year 2000, the defendant **DAVID GUIDO** was a Hospital Account Executive and had responsibilities with respect to Practice D.

107. In or about the fall, 1998, Practice D converted its patients on Zoladex to Lupron and began to purchase Lupron from TAP. Thereafter, in or about early 1999, Practice D failed to realize a certain volume price discount in purchasing Lupron.

108. In or about March 1999, the defendant **DAVID GUIDO** began soliciting funds from other TAP employees to provide an educational grant as an inducement to a urologist at Practice D to retain that practice's business. Defendant **DAVID GUIDO** informed other TAP employees that he had been told by the urologist that unless TAP made up for the lost discount, Practice D would stop ordering Lupron and would switch all of its patients back to Zoladex.

GUIDO told the other TAP employees that when he asked the urologist at Practice D “how TAP could make up for the miscommunication and how TAP could support the department and clinic” the urologist thereafter asked **GUIDO** for financial support for a conference that the Practice would be holding at the hospital in the fall 1999. In an effort to obtain funds from these other TAP employees so that he could provide this financial inducement to Practice D, **GUIDO** told these employees that Practice D had “threatened to convert back to Zoladex” because of the lost price discount, but that he was going to “remedy the situation” by the “technique” of “promising funding for the fall seminar.” **GUIDO** cautioned the other TAP employees not to copy or print the electronic communication because it made reference to this “technique.” In response to these solicitations for money, **GUIDO** received promises of funding from other TAP employees, including from the defendant **RITA JOKIAHO**.

109. On or about April 2, 1999, **GUIDO** forwarded to Practice D a check for \$2,000. On or about August 4, 1999, **GUIDO** forwarded to Practice D a check for \$5,000. On or about April 12, 2000, **GUIDO** forwarded to Practice D a check for \$3,000. In forwarding these checks it was at least one of **GUIDO**'s purposes to provide these funds as an inducement to the urologist at Practice D to continue to order and prescribe Lupron to patients in that practice.

Inducements to Doctors K, H and S in Defendant MARK SMITH's Territory

110. Doctors K, H and S were urologists practicing medicine in Ohio and Pennsylvania and were called upon by sales representatives supervised at times material to this Indictment by the defendant **MARK SMITH**. Each of these urologists from time to time treated patients suffering from prostate cancer, and each purchased Lupron from TAP and prescribed that drug to some of their patients, many of whom were insured by the Medicare Program.

Inducements to Dr. K

111. From time to time throughout the 1990s, TAP and its employees provided things of value to Dr. K as an inducement to get and keep his Lupron business and to keep him from switching his patients to Zoladex. Such inducements included employing Dr. K as a "consultant" to attend meetings of the American Urology Association, attendance at TAP into the Future programs at resort locations, and free product. In the 1990s, Dr. K received more than 300 injections of Lupron for free.

112. Sometime in or about 1998, Dr. K demanded additional inducements from TAP in the form or guise of additional consulting payments. The defendant **MARK SMITH**, together with a sales representative reporting to him, sought approval for these inducements from other individuals within TAP, including from the defendant **DONALD PATTON**. Because TAP was then under federal investigation, certain TAP employees questioned Dr. K's past employment as a "consultant" and asked the sales representative reporting to **MARK SMITH** whether Dr. K had ever "formally presented any 'consulting report' to TAP after he had been to the AUA or TAP into the Future" or had TAP "just been paying his expenses to attend these programs and has not requested any feedback from him." That representative responded that to his knowledge Dr. K had not "formally reported back to TAP's marketing department on any consulting trip that he has attended" but that Dr. K had "provide[d] value to TAP in other ways including consistent ordering of Lupron Depot since well before I was running the account in 1997." the defendant **MARK SMITH** told the representative that Dr. K could request to be a "site for clinical trials." Thereafter, an employee within TAP determined to not approve the hiring of Dr. K as a consultant.

113. Later in 1998, and after that employee had transferred to a new position within TAP, **MARK SMITH** and the representative sought once again for approval to make payments to Dr. K as consulting payments in order to keep him from switching the treatment of his patients from Lupron to Zoladex. At that point in time, Dr. K was one of the single largest physician purchasers of Lupron in the country and was the largest account under **MARK SMITH's** supervision. **MARK SMITH** knew and understood that the loss of Dr. K's business meant a reduction of sales bonuses for him.

114. On or about November 17, 1998, the defendant **MARK SMITH** and the representative met with Dr. K to discuss his financial demands. After that meeting, the representative recommended to **MARK SMITH** that TAP provide to Dr. K, in order to keep him from switching his patients to Zoladex, two dinner programs for primary care physicians, at a cost of \$4,000 per program and \$2,000 in "honoraria" for Dr. K and one of his partners, and two consulting trips in 1999 "and a VIP trip to Chicago slated for December 1998", among other things. Also in or about November 1998, the representative wrote to **MARK SMITH** in his monthly activity report that the "Chicago VIP trip ... should ultimately decide what will happen with this account" and that "[w]e must ensure that he maintains 250 patients a month on Lupron in order to receive all of the Incentives that we propose."

115. In or about November 1998, the defendant **MARK SMITH** forwarded to his superior a "history" of the relationship with Dr. K. **MARK SMITH** indicated in that history that Dr. K had threatened to switch to Zoladex and that he had demanded, to keep him from switching, numerous things of value including 120 day invoicing, as opposed to 90 day invoicing offered to all other doctors; employing him and his partner for four consulting programs;

sponsoring 4 speaker programs for him, to be paid for by TAP; and paying a “credit” to Dr. K if his payments from HMOs were lower than the payments he had received in the past, thus guaranteeing him a certain level of profit. **MARK SMITH** also stated that Dr. K had complained that TAP had stopped providing to him free good and that Company Y had offered to send him on "4 consulting trips in 1999."

116. In or about December 1998, TAP invited Dr. K to a meeting in Illinois, for which trip, TAP paid for Dr. K's expenses. In or about the time of that meeting with numerous TAP employees, including the defendants **DONALD PATTON**, and **MARK SMITH**, TAP offered and agreed to employ Dr. K as a consultant in 1999, and to make payments to him, in order to keep him from switching his prescriptions to his patients from Lupron to Zoladex.

Inducements to Dr. H

117. In or about October 1997, Dr. H told the defendant **MARK SMITH** and a sales representative reporting to **SMITH** that he would switch his patients from Zoladex to Lupron in return for free samples. Thereafter, and over the next year and with the defendant **MARK SMITH**'s approval, the sales representative provided to Dr. H more than 65 free samples of Lupron. In return, Dr. H converted numerous patients from treatment with Zoladex to treatment with Lupron.

118. In providing and approving the things of value to these three physicians, the defendant **MARK SMITH** intended to induce the purchase of the drug Lupron from those three physicians, and intended to induce those physicians to continue to recommend to their patients that they treat their prostate cancer with the drug Lupron.

Inducements to Dr. S

119. At times material to this Indictment, Dr. S prescribed both Lupron and Zoladex to patients he was treating who were suffering from prostate cancer, facts known to the defendant **MARK SMITH** and to a sales representative that he was supervising who had sales responsibility for Dr. S. In order to induce Dr. S to switch his patients from Zoladex to Lupron, the sales representative, with the defendant **MARK SMITH's** approval, gave him numerous things of value, including monies for golf outings in 1997, 1998 and 1999. That representative reported to the defendant **MARK SMITH** that Dr. S had told her that while "he has been a longstanding loyal Lupron customer for years and feels one good deed deserves another" and that while "he would not be shallow enough to switch to Zoladex based upon a few extra dollars" TAP needed to be aware of "his needs," that other companies were "holding large golf outings and providing things etc. that TAP has never offered" and that he would do "what he feels necessary with his Lupron business if TAP does not agree to provide what other companies offer generously." With defendant **MARK SMITH's** approval, TAP thereafter provided to the doctor \$1,950 for a golf tournament.

FREE SAMPLES TO GET OR KEEP BUSINESS

Free Samples Given to DR. JACOB ZAMSTEIN

120. Jacob Zamstein, M.D. (hereinafter referred to as Zamstein) was a physician licensed to practice medicine in the state of Connecticut, with a practice located in Bloomfield and a specialty in urology. At all times material hereto, it was a part of Dr. Zamstein's practice of medicine to diagnose and treat patients suffering from prostate cancer. Beginning as early as 1992, Dr. Zamstein purchased Lupron from TAP and prescribed that drug to some of his patients, many of whom were insured by the Medicare Program.

121. From in or about May 1995 through in or about August 1997, a sales representative who will be referred to in this Indictment as “Rep. JK” called upon Dr. Zamstein. At times during that period, JK reported to the defendant **KIMBERLEE CHASE**.

122. Beginning in or about 1993 and continuing into 1997, the sales representatives calling upon Dr. Jacob Zamstein provided to him 95, more or less, free one-month samples of the drug Lupron, or approximately \$35,000 in free drug. These representatives, including Rep. JK, offered and gave these free samples to Dr. Zamstein as an inducement to get and keep his business and with the expectation that he would prescribe and administer these free samples to patients insured by the Medicare Program and other insurance companies and thereafter submit claims to those insurers and be paid for the prescription of these free dosages. The defendant **KIMBERLEE CHASE** knew and approved of this conduct.

123. In or about May, 1995, TAP sales employees offered and provided to Dr. Zamstein, as a reward for his past purchases of Lupron and as an inducement to him to continue to recommend Lupron to his patients, attendance at a TAP into the Future weekend program at the South Seas Plantation on Captiva Island, in Florida.

124. In or about April, 1996, TAP sales employees offered and provided to Dr. Zamstein, as a reward for his past purchases of Lupron and as an inducement to him to continue to recommend Lupron to his patients, free consulting services regarding managed care issues from a consultant paid for by TAP.

Free Samples Given to DR. JOSEPH SPINELLA

125. Dr. Joseph Spinella was a urologist with a principal place of business in Bristol, CT. Dr. Spinella, from time to time in the 1990s, treated patients suffering from prostate cancer,

many of whom were insured through the Medicare program. For many of those patients, Dr. Spinella prescribed a GnRH agonist.

126. From in or about May 1995 through in or about August 1997, Rep. JK called upon Dr. Spinella as a TAP sales representative. At times during that time period, Rep. JK reported to the defendant **KIMBERLEE CHASE**.

127. In or about 1995, and because of a disagreement regarding the amount that he owed TAP on purchases of Lupron, Dr. Spinella switched all of his patients from Lupron to Zoladex. In or about August 1995, an employee of Dr. Spinella told Rep. JK that Dr. Spinella had ceased prescribing Lupron to 26 patients, more or less, and had begun prescribing Zoladex to those patients. Rep. JK reported this to the defendant **CHASE**.

128. On or about August 24, 1995, Rep. JK, in an attempt to get Dr. Spinella to switch his patients back to Lupron, left at Dr. Spinella's office a document demonstrating to the doctor that the profits that he could earn through TAP's Return to Practice program from the prescription of Lupron and the billing of it to the Medicare Program at the maximum allowed charge exceeded by as much as \$7,000 per year those profits that he could earn from the prescription of Zoladex.

129. On or about October 26, 1995, Dr. Spinella informed a TAP employee that he understood that he could earn a greater profit by prescribing Lupron but that he also wanted free goods in exchange for switching his patients back to Lupron from Zoladex.

130. On or about November 17, 1995, Dr. Spinella told Rep. JK that he then had thirty patients, more or less, on Zoladex and that for every free one-month dose of Lupron that he received, Dr. Spinella would switch one patient from Zoladex to Lupron. Both Dr. Spinella and

JK knew, understood, and expected that, upon receipt of these free one-month doses, Dr. Spinella would administer them to patients insured by, among other entities, the Medicare program and that he would bill that program in order to turn the free one-month doses of Lupron into cash and that that cash, paid by the Medicare Program and others, including Dr. Spinella's patients, would be the kickback and bribe paid by TAP and Rep. JK to Dr. Spinella in exchange for his referral of business to TAP. On or about that date, Rep. JK agreed to provide thirty one-month samples to Dr. Spinella to induce him to prescribe Lupron and not Zoladex to his prostate cancer patients.

131. On or about November 22, 1995, Rep. JK delivered to Dr. Spinella twenty free one-month doses of Lupron.

132. On or about December 5, 1995, Rep. JK delivered to Dr. Spinella ten free one-month doses of Lupron.

133. From on and after November 22, 1995, Dr. Spinella administered the free one-month doses of Lupron to patients insured by the Medicare Program and others, billed the Medicare Program, other insurers, and his patients for those one-month doses, and received in payment from that Program, various insurers, and his patients \$15,000, more or less, as a kickback and bribe for prescribing Lupron to those patients. From and after November 22, 1995, Dr. Spinella switched his thirty patients from Zoladex to Lupron, as he had promised.

Free Samples Offered to a Brockton Urologist

134. Dr. B was a urologist with a principal place of business in Brockton, Massachusetts. Dr. B from time to time in the 1990s diagnosed and treated patients suffering from prostate cancer, many of whom were insured by the Medicare Program. As a part of the

treatment of some of those patients, and beginning as early as 1992, Dr. B prescribed Lupron.

135. At all times relevant hereto and until she terminated her employment with TAP, the defendant **CHASE** supervised a TAP sales representatives who will be referred to in this Indictment as Rep. K. At all times material hereto, Rep. K called upon Dr. B.

136. In or about the end of 1996, Dr. B began to fall in arrears in paying his bill for Lupron to TAP. In that same time period, Dr. B also began to be concerned about the high cost of Lupron, both for him and his patients, in comparison with the cost of Zoladex. Then and thereafter in 1997, Dr. B communicated both of these concerns to Rep. K and to **CHASE**.

137. In or about March, 1997, Dr. B told Rep. K that he intended, because of the high cost of Lupron and the large outstanding debt that he had to TAP, to switch his patients to Zoladex. In order to stop Dr. B from converting his patients to Zoladex, Rep. K and the defendant **CHASE** met with Dr. B and Dr. B's office manager and offered to give to him 15 three month injections of Lupron for free. On or about March 27, 1997, **CHASE** caused to be delivered to Dr. B those 15 three month injections. **CHASE** and Rep. K thereafter offered those injections to Dr. B for free if he would cancel his order for Zoladex. **CHASE** and the sales representative offered these samples to Dr. B as an inducement for the continued referral of his prostate cancer patients and to keep him from converting those patients to Zoladex.

Free Samples Given to Dr. JOHN ROMANO

138. The defendant **DR. JOHN ROMANO** was a urologist with a principal place of business in the Plymouth, Massachusetts area. It was a part of **ROMANO's** practice of medicine that he from time to time diagnosed and treated patients suffering from prostate cancer. Beginning as early as 1992, **ROMANO** prescribed for some of those patients Lupron and

Zoladex, many of whom were insured by the Medicare Program.

139. From in or about early 1993 through in or about the end of 1998, Rep. K called upon **ROMANO**.

140. In or about 1993, Rep. K met with **ROMANO** in a sales call as a part of a continuing effort to convince him to switch his patients from Zoladex to Lupron. In that conversation, and after he offered to switch his patients, **ROMANO** asked Rep. K for free samples. Rep. K agreed to give **ROMANO** free samples. Rep. K intended the samples to be an inducement to **ROMANO** to insure that he would in fact switch his business from Zoladex to Lupron and thereafter keep his patients on Lupron. Rep. K agreed to provide to **ROMANO** six one-month injections of Lupron each quarter of each year, so long as he continued to purchase and prescribe Lupron. At all times material hereto, Rep. K told her district managers, including the defendant **CHASE**, that she was routinely provided samples to **ROMANO** and that she was doing so because he had agreed to convert his Zoladex patients to Lupron.

141. Beginning in or about March 1993 and continuing to in or about January 1999, Rep. K provided to the defendant **DR. JOHN ROMANO** one hundred and forty-seven one-month doses of Lupron, more or less, for free. **ROMANO** administered the free one-month doses of Lupron to patients insured by the Medicare Program and others, billed the Medicare Program, other insurers, and his patients for those one-month doses, and received in payment from that Program, various insurers, and his patients \$70,000, more or less, as an inducement for the prescription and administration of Lupron to those Medicare beneficiaries.

142. In or about the end of 1998, Rep. K informed her district manager that **ROMANO** was putting new patients on Zoladex, instead of Lupron. Rep. K further informed

her district manager that because of her deal with **ROMANO**, that if he did not switch those new patients to Lupron, she was going to stop giving him free samples.

Free Samples Given to Urology Practice at Boston Hospital

143. Practice U was group practice of urologists based at a Boston hospital. It was a part of the practice of medicine at Practice U that urologists in that practice from time to time diagnosed and treated patients suffering from prostate cancer and prescribed to some of those patients, Lupron and Zoladex. Many of those patients were insured by the Medicare Program.

144. At all times relevant hereto and until she terminated her employment with TAP, the defendant **KIMBERLEE CHASE** supervised Rep. K, the TAP sales representatives calling upon Practice U.

145. In or about the summer 1995, a urologist at that practice solicited offers from sales representatives from both Company Y and TAP. Rep. K and the defendant **KIMBERLEE CHASE** met with that urologist in or about July 1995. At that meeting and in a written proposal provided to that urologist, Rep. K and the defendant **CHASE** acknowledged that Practice U had to spend more cash up-front in purchasing Lupron instead of Zoladex. To make up for the difference in this cash outlay and to induce and encourage urologists in Practice U to continue to purchase and prescribe Lupron, **CHASE** and Rep. K offered free samples to Practice U.

146. Beginning in or about the summer 1995 and continuing through in or about 1998, Rep. K gave to the practice more than 111 one-month doses of Lupron for free, on or about the dates indicated in the following chart. These one hundred eleven samples, more or less, were given for free to Practice U as an inducement to get and keep its business. That practice thereafter prescribed and administered these free dosages to patients insured by the Medicare

Program and other insurance companies and submitted claims to those insurers and the patients for the prescription of these free dosages to turn those samples into a cash kickback and rebate.

Free Samples Given to Urology Practice in San Francisco

147. Dr. SF was a urologist with a principal place of business in the San Francisco area in California. Dr. SF from time to time in the 1990s diagnosed and treated patients suffering from prostate cancer, many of whom were insured by the Medicare Program. As a part of the treatment of some of those patients, and beginning as early as 1993, Dr. SF prescribed Lupron.

148. At all times relevant hereto and until he terminated his employment with TAP, the defendant **HENRY VAN MOURIK** supervised sales representatives who called upon Dr. SF.

149. Dr. SF informed the sales representatives calling upon Dr. SF, who so informed **VAN MOURIK**, that he would switch his business and prescribe Zoladex to his patients suffering from prostate cancer if TAP and its employees did not provide him for financial incentives than were being provide to him by Company Y.

150. In order to prevent Dr. SF from switching his patients to Zoladex, and as an inducement to him to continue to purchase Lupron and to prescribe that drug to his patients, many of whom were insured by the Medicare Program, the defendant **VAN MOURIK** authorized the sales representatives calling upon Dr. SF to give to him free samples of Lupron. At times, **VAN MOURIK** approved giving Dr. SF ten free samples in exchange for each order by him of more than 100 one-month injections of Lupron, and at times, **VAN MOURIK** contacted TAP's corporate headquarters to obtain those free samples for Dr. SF.

151. Beginning in or about July 1994 and continuing through in or about December 1997, sales representatives reporting to **VAN MOURIK** gave to Dr. SF more than 85 one-month

doses of Lupron for free, on or about the dates indicated in the following chart.

Date	Quantity
7/1/94	10
1/27/95	10
7/22/95	10
11/20/95	10
8/9/96	10
4/16/97	15
12/11/97	20

These eighty-five samples, more or less, were given by sales representatives reporting to **VAN MOURIK** for free to Dr. SF as an inducement to get and keep his business. That doctor thereafter prescribed and administered these free dosages to patients insured by the Medicare Program and other insurance companies and submitted claims to those insurers and the patients for the prescription of these free dosages to turn those samples into a cash kickback and rebate.

Free Samples Given to DR. F

152. Doctor F was a urologist with offices in Natick, Framingham and Marlboro, Massachusetts. From time to time throughout the 1990s, Dr. F employed other urologists in his medical practice, which practice will be called in this indictment "Practice N."

153. Urologists working in Practice N from time to time diagnosed and treated patients suffering from prostate cancer, many of whom were insured by the Medicare Program. As a part of the treatment of some of those patients, urologists in Practice N prescribed for those patients the drug Lupron.

154. From in or about August, 1994 through in or about August 1995, a TAP sales representative gave to Practice N eleven samples of one-month injections of the drug Lupron. In or about August, 1995, sales responsibility at TAP for the account of Dr. F and Practice N was transferred from that sales representative to Rep. CK.

155. At times relevant hereto, the defendant **KIMBERLEE CHASE** supervised Rep. CK.

156. Beginning in or about August, 1995, and continuing into August 1997, Rep. CK gave to Dr. F and other physicians employed by him 90 one-month injections of Lupron 7.5 mg, more or less, for free. It was part of Rep. CK's intent in providing these samples to induce Dr. F and his practice to continue to order Lupron and to continue to prescribe Lupron to the patients in that practice. That practice thereafter prescribed and administered these free dosages to patients insured by the Medicare Program and other insurance companies and submitted claims to those insurers and the patients for the prescription of these free dosages. It was a part of Dr. F's intent to solicit and receive these samples in return for purchasing and ordering the drug Lupron, and for recommending it to the patients of Practice N. It was also a part of Dr. F's intent to thereafter use and bill some of the free samples, and cause bills for some of the free samples to be submitted, to the Medicare Program in order to convert the samples into cash as a kickback and rebate to him for his purchases from TAP.

157. In or about the summer, 1997, Dr. F solicited from Rep. CK computer software program in exchange for purchasing and ordering the drug Lupron for, and for recommending that drug to, patients of Practice N.

Free Samples Given to Dr. Joel Olstein

158. Dr. Joel Olstein was a urologist with offices in Lewiston, Maine and from time to time in the 1990s diagnosed and treated patients suffering from prostate cancer, many of whom were insured by the Medicare Program. As a part of the treatment of some of those patients, Dr. Olstein prescribed for those patients the drug Lupron.

159. At times relevant hereto in 1995, 1996 and 1997, the defendant **KIMBERLEE CHASE** supervised the sales representatives who called upon Dr. Joel Olstein.

160. Beginning in or about 1994 and continuing into 1997, the sales representatives calling upon Dr. Joel Olstein provided to him 79 free one-month samples of the drug Lupron, or approximately \$38,000 in free drug. It was part of the sales representatives intent, and that of their manager **KIMBERLEE CHASE** in providing these samples to induce Dr. Olstein to continue to order Lupron and to continue to prescribe Lupron to the patients in that practice. Dr. Olstein thereafter prescribed and administered these free dosages to patients insured by the Medicare Program and other insurance companies and submitted claims to those insurers and the patients for the prescription of these free dosages.

Free Drug Given to Brooklyn Urologist

161. Dr. BU was a urologist licensed to practice medicine in the state of New York with offices in Brooklyn, New York.

162. Dr. BU from time to time diagnosed and treated patients suffering from prostate

cancer, many of whom were insured by the Medicare Program. As a part of the treatment of some of those patients, Dr. BU prescribed for those patients the drug Lupron and the drug Zoladex.

163. At times relevant hereto, the defendant **DONNA TOM** supervised the TAP sales representatives calling upon Dr. BU. The representative who called upon Dr. BU in 1997 and 1998 will be referred to in this indictment as Rep. KP.

164. On or about May 3, 1997, Dr. BU told Rep. KP that he had thirty patients on Zoladex and that he would switch his patients to Lupron if the TAP sales representative would give him free drug. Rep. KP told Dr. BU that she would give him 10 free kits for the initial switch of his patients from Zoladex to Lupron and five thereafter with every order. When Rep. KP informed **DONNA TOM** of the doctor's solicitation, **TOM** told her to show the doctor the "new RTP that will come with our price increase." **TOM** also told Rep. KP to "[l]et him simmer knowing that Lupron is where the money is."

165. On or about March 26, 1998, Rep. KP informed the defendant **TOM** in her Weekly Activity Report that Dr. BU would order more Lupron if TAP would give him more samples. Rep. KB informed **TOM** that she told Dr. BU's office manager that the doctor was "taking" a risk "accepting samples and billing for it" but that the office manager "didn't see it as a problem."

166. Beginning on or about June 19, 1997 and continuing thereafter until December 1998, Rep. KP with the knowledge and approval of the defendant **TOM** gave to Dr. BU 47 samples, more or less. It was part of **TOM's** intent in authorizing and approving offering and giving these samples to Dr. BU to induce him to order Lupron and to switch his Zoladex patients

to Lupron. That practice thereafter prescribed and administered these free dosages to patients insured by the Medicare Program and other insurance companies and submitted claims to those insurers and the patients for the prescription of these free dosages.

FORGIVING DEBT TO KEEP BUSINESS

Forgiveness of Debt Given to Dr. QM

167. Dr. QM was a urologist with a principal place of business in the Boston, Massachusetts area. It was a part of QM's practice of medicine that he from time to time diagnosed and treated patients suffering from prostate cancer. Beginning as early as 1993, QM prescribed for some of those patients Lupron, many of whom were insured by the Medicare Program.

168. At times relevant hereto, Dr. H was a urologist with a principal place of business in Hingham, Massachusetts. Dr. H, from time to time, diagnosed and treated patients suffering from prostate cancer, and beginning as early as 1992, Dr. H prescribed for those patients, Lupron. In or about December, 1995, Dr. H retired from the practice of medicine and sold his practice to QM.

169. At all times relevant hereto and until she terminated her employment with TAP, the defendant **KIMBERLEE CHASE** supervised Rep. K, the TAP sales representatives calling upon Dr. QM and on Dr. H.

170. In or about March to June, 1995, Dr. QM received free samples of Zoladex from Company Y as an inducement to convert his patients from Lupron to Zoladex. As a result Dr. QM, as early as June 1995 began to treat some of his patients suffering from prostate cancer with Zoladex instead of Lupron. Dr. QM administered the free samples that he received from

Company Y to some of his patients and thereafter billed those patients and their insurance companies for the prescription of those free samples.

171. At all times material hereto in the summer of 1995, the defendant **KIMBERLEE CHASE** and Rep. K knew and were aware that Dr. QM had switched his patients to Zoladex and had stopped using Lupron. In or about August 1995, Rep. K and another TAP employee met with Dr. QM and, in part, demonstrated to him, in an effort to get him to switch his patients back, that his annual Return to Practice from Lupron was at least \$4,600 better than the profit he could make off reselling Zoladex to his patients.

172. Sometime in or about the fall, 1995, Dr. QM ordered a quantity of Lupron and began again to treat some patients with Lupron. After receiving that shipment of Lupron in or about October 1995, Dr. QM continued to treat some of his patients with Zoladex.

173. From some time in or about the fall 1995 through in or about December 1995, Dr. QM negotiated with Dr. H for the purchase of his medical practice. Dr. H was then in arrears in paying his bills to TAP.

174. In or about November, 1995, TAP referred the collection of Dr. H's outstanding debt to Abbott Credit. In that month, Abbott Credit wrote a letter to Dr. H notifying him that he owed TAP \$24,446.48 and that the matter had been referred to it for collection. At all times material hereto, the defendant **CHASE** was aware of those collection efforts.

175. In or about early December, 1995, and as a part of the sale of Dr. H's medical practice, Dr. QM agreed to indemnify and hold Dr. H harmless for any liabilities for payments due to TAP in excess of \$30,000. On or about December 5, 1995, Dr. H's office informed Abbott Collection that Dr. QM was responsible for Dr. H's debt to TAP.

176. On or about December 13, 1995, Dr. QM informed **CHASE** that he wanted TAP to write off Dr. H's debt. Between that date and January 2, 1996, **CHASE** and Dr. QM, together with other TAP employees, negotiated Dr. QM's payment of Dr. H's debt and agreed that, in exchange for the continued referral of Dr. QM's business to TAP, and the referral of any patients not yet on Lupron, TAP would write off or waive \$11,000 of the debt.

177. On or about January 5, 1996, Abbott Collection confirmed in writing to Dr. QM that he had "verbally committed to Ms. Chase that in consideration for TAP's settlement of the outstanding debt, you have agreed to switch all of your patients to Lupron Depot. In return, the balance of your account with TAP will be reduced from \$24,446.48 to \$13,000." On or about January 24, 1996, Dr. QM signed that letter acknowledging this deal.

178. After December 5, 1995 and through January 16, 1996, Dr. QM switched ten patients, more or less, from treatment with Zoladex to treatment with Lupron, all of whom were insured by the Medicare Program. The defendant **CHASE** and other TAP employees intended to provide the forgiveness of approximately \$11,000 in Dr. H's debt as an inducement to Dr. QM for the continued prescription of Lupron to his patients.

Forgiveness of Debt to Fall River Urology Practice

179. Practice FR was a medical practice of urologists with a principal place of business in Fall, River, Massachusetts. Urologists working in Practice FR from time to time diagnosed and treated patients suffering from prostate cancer, many of whom were insured by the Medicare Program. As a part of the treatment of some of those patients, urologists in Practice FR from time to time prescribed for those patients Lupron.

180. At all times relevant hereto, the defendant **KIMBERLEE CHASE** supervised the

TAP sales representatives calling upon Practice FR.

181. In or about late 1995 and early 1996, Practice FR fell in arrears on paying its bills to TAP for Lupron that the practice had purchased. Practice FR at that point had an outstanding debt to TAP well in excess of \$70,000. In or about February 1996, that practice threatened that, if TAP did not forgive the debt that the practice owed to TAP, the practice would convert all of its patients from Lupron to Zoladex.

182. On or about February 2, 1996, the defendant **CHASE** informed a middle manager at TAP in Deerfield, Illinois by memorandum that Practice FR “threatened to send all of their patients to the oncology clinic at the hospital who uses Zoladex.” **CHASE** further informed that middle manager that her district had just lost a customer due to credit problems and “could not afford to lose this account.” **CHASE** recommended that TAP forgive \$4,535.82 that Practice FR owed to TAP as an inducement to the practice to keep it from converting its patients to Zoladex.

183. On or about June 19, 1996, the sales representative handling this account informed **CHASE** that two of the doctors at the practice were “fed up” with TAP and wanted “to stop using Lupron and start fresh with Zoladex.” The sales representative informed **CHASE** the account was “too valuable to lose” and that to “keep the business and continue the relationship” TAP should forgive an additional \$8,596 in debt that the account owed TAP.

184. In or about June and July 1996, **CHASE** and others at TAP approved forgiving an additional \$8,596 in debt that Practice FR owed TAP as an inducement to the practice to continue to order Lupron and prescribe that drug to their patients.

185. On or about November 8, 1996, the sales representative informed Practice FR that TAP had “agreed to a credit in the full amount of \$8,596.”

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

COUNTS 2 and 3: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

186. Paragraphs 1-53 and 179-185 of this Indictment are herein realleged and incorporated by reference.

187. On or about the dates listed below, in the District of Massachusetts, the defendant

KIMBERLEE CHASE

did knowingly and willfully offer and pay remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Practice FR and to physicians employed by that practice, to induce them to purchase, order, arrange for and recommend to their patients suffering from prostate cancer that those patients purchase and order the drug Lupron as a treatment for their prostate cancer, payment of which drug may be made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
2	2/7/96	Practice FR, Fall River, MA	forgiveness of debt in the amount of \$4,335.24
3	11/8/96	Practice FR, Fall River, MA	forgiveness of debt in the

			amount of \$8,596
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All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

COUNTS 4-28: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

188. Paragraphs 1-53 and 143-151 of this Indictment are herein realleged and incorporated by reference.

189. On or about the dates indicated below, in the District of Massachusetts, the defendant

KIMBERLEE CHASE

did knowingly and willfully offer and pay remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Practice U, and to physicians employed at that practice, to induce them to purchase, order, arrange for and recommend to their patients suffering from prostate cancer that those patients purchase and order the drug Lupron as a treatment for their prostate cancer, payment of which drug may be made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
4	4/11/96	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg
5	5/8/96	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg
6	5/13/96	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
7	5/25/96	Practice U, Hospital, Boston MA	four free samples of Lupron 3.75 mg and one free sample of Lupron 7.5 mg
8	6/5/96	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg

Count	Date	Person	Remuneration
9	6/12/96	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
10	7/11/96	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
11	8/26/96	Practice U, Hospital, Boston MA	six free samples of Lupron 7.5 mg
12	9/4/96	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
13	10/8/96	Practice U, Hospital, Boston MA	six free samples of Lupron 7.5 mg
14	10/17/96	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
15	11/13/96	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg
16	12/17/96	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
17	1/13/97	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg
18	1/24/97	Practice U, Hospital, Boston MA	three free samples of Lupron 7.5 mg
19	2/3/97	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
20	2/18/97	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg
21	3/6/97	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg
22	3/13/97	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg
23	4/3/97	Practice U, Hospital, Boston MA	two free samples of Lupron 7.5 mg
24	4/18/97	Practice U, Hospital, Boston MA	three free samples of Lupron 7.5 mg

Count	Date	Person	Remuneration
25	5/9/97	Practice U, Hospital, Boston MA	three free samples of Lupron 7.5 mg
26	5/14/97	Practice U, Hospital, Boston MA	three free samples of Lupron 7.5 mg
27	5/28/97	Practice U, Hospital, Boston MA	three free samples of Lupron 7.5 mg
28	7/16/97	Practice U, Hospital, Boston MA	one free sample of Lupron 7.5 mg

All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

COUNTS 29-31: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

190. Paragraphs 1-53 and 62-72 of this Indictment are herein realleged and incorporated by reference.

191. On or about the dates indicated below, in the District of Massachusetts, the defendants

**KIMBERLEE CHASE and
JANICE SWIRSKI**

did knowingly and willfully offer remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Tufts HMO and the Tufts Medical Director to induce them to purchase, order, arrange for and recommend to their patients suffering from prostate cancer that those patients purchase and order the drug Lupron as a treatment for their prostate cancer, payment of which drug may be made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
29	April 2, 1997	Tufts HMO and the Tufts Medical Director	a discounted price of \$210 on the sale of Lupron 3.75 mg and an educational grant of about \$40,000
30	6/3/97	Tufts HMO and the Tufts Medical Director	a discounted price of \$210 on the sale of Lupron 3.75 mg and an educational grant of \$60,000 to be paid over three years
31	6/10/97	Tufts HMO and the Tufts Medical Director	a discounted price of \$210 on the sale of Lupron 3.75 mg and an educational

Count	Date	Person	Remuneration
			grant of \$65,000 to be paid over three years

All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

COUNTS 32-37: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

192. Paragraphs 1-53 and 138-142 of this Indictment are herein realleged and incorporated by reference.

193. On or about the dates indicated below, in the District of Massachusetts, the defendant

KIMBERLEE CHASE

did knowingly and willfully offer and pay remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Dr. John Romano to induce that person to purchase, order, arrange for and recommend to his patients suffering from prostate cancer that those patients purchase and order the drug Lupron as a treatment for their prostate cancer, payment of which drug may be made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
32	4/12/96	Dr. John Romano, Plymouth, MA	six free samples of Lupron 7.5 mg
33	7/8/96	Dr. John Romano, Plymouth, MA	six free samples of Lupron 7.5 mg
34	10/11/96	Dr. John Romano, Plymouth, MA	six free samples of Lupron 7.5 mg
35	1/13/97	Dr. John Romano, Plymouth, MA	six free samples of Lupron 7.5 mg
36	4/21/97	Dr. John Romano, Plymouth, MA	six free samples of Lupron 7.5 mg

Count	Date	Person	Remuneration
37	7/15/97	Dr. John Romano, Plymouth, MA	six free samples of Lupron 7.5 mg

All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

COUNT 38: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

194. Paragraphs 1-53 and 134-137 of this Indictment are herein realleged and incorporated by reference.

195. On or about the date indicated below, in the District of Massachusetts, the defendant

KIMBERLEE CHASE

did knowingly and willfully offer and pay remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Dr. B to induce him to purchase, order, arrange for and recommend to his patients suffering from prostate cancer that those patients purchase and order, the drug Lupron as a treatment for their prostate cancer, payment of which drug may be made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
38	4/1//97	Dr. B, Brockton, MA	offer of fifteen free samples of Lupron 22.5 mg.

All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

COUNTS 39-56: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

196. Paragraphs 1-53 and 152-157 of this Indictment are herein realleged and incorporated by reference.

197. On or about the dates indicated below, in the District of Massachusetts, the defendants

KIMBERLEE CHASE

did knowingly and willfully offer and pay remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Dr. F and to physicians employed in Practice N, to induce Dr. F to purchase, order, arrange for and to recommend to patients being treated by him and physicians employed by him, which patients were suffering from prostate cancer, that those patients purchase and order, the drug Lupron as a treatment for their prostate cancer, payment of which drug may be made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
39	5/21/96	Dr. F and the physicians employed in Practice N	three free samples of Lupron 7.5 mg
40	6/14/96	Dr. F and the physicians employed in Practice N	three free samples of Lupron 7.5 mg
41	7/18/96	Dr. F and the physicians employed in Practice N	three free samples of Lupron 7.5 mg
42	8/19/96	Dr. F and the physicians employed in Practice N	four free samples of Lupron 7.5 mg
43	9/30/96	Dr. F and the physicians employed in Practice N	five free samples of Lupron 7.5 mg
44	10/2/96	Dr. F and the physicians	two free samples of

Count	Date	Person	Remuneration
		employed in Practice N	Lupron 7.5 mg
45	11/1/96	Dr. F and the physicians employed in Practice N	two free samples of Lupron 7.5 mg
46	11/6/96	Dr. F and the physicians employed in Practice N	two free samples of Lupron 7.5 mg
47	12/13/96	Dr. F and the physicians employed in Practice N	three free samples of Lupron 7.5 mg
48	12/27/96	Dr. F and the physicians employed in Practice N	three free samples of Lupron 7.5 mg
49	4/1/97	Dr. F and the physicians employed in Practice N	four free samples of Lupron 7.5 mg
50	4/23/97	Dr. F and the physicians employed in Practice N	four free samples of Lupron 7.5 mg
51	5/30/97	Dr. F and the physicians employed in Practice N	three free samples of Lupron 7.5 mg
52	6/27/97	Dr. F and the physicians employed in Practice N	six free samples of Lupron 7.5 mg
53	7/14/97	Dr. F and the physicians employed in Practice N	five free samples of Lupron 7.5 mg
54	8/26/97	Dr. F and the physicians employed in Practice N	five free samples of Lupron 7.5 mg
55	9/8/97	Dr. F and the physicians employed in Practice N	four free samples of Lupron 7.5 mg
56	9/30/97	Dr. F and the physicians employed in Practice N	five free samples of Lupron 7.5 mg

All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

COUNT 57: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

198. Paragraphs 1-53 and 167-178 of this Indictment are herein realleged and incorporated by reference.

199. On or about the dates indicated below, in the District of Massachusetts, the defendant

KIMBERLEE CHASE

did knowingly and willfully offer and pay remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Dr. QM to induce him to purchase, order, arrange for and recommend to his patients suffering from prostate cancer that those patients purchase and order the drug Lupron as a treatment for their prostate cancer, payment of which drug may be made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
57	December 1995 and January 1996	Dr. QM	forgiveness of \$11,646.48 of debt

All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

COUNT 58: 21 U.S.C. § 333(b)(1)(B) (Selling Drug Samples)

200. Paragraphs 1-53 and 138-142 of this Indictment are herein realleged and incorporated by reference.

201. From in or about March 1993 through in or about December 1998, in the District of Massachusetts, the defendant

JOHN ROMANO, M.D.

did knowingly sell to patients suffering from prostate cancer 147 samples, more or less, of the drug Lupron, which samples were not intended to be sold and which were drug samples intended for the promotion of the sale of the drug lupron.

All in violation of Title 21 United States Code, sections 333(b)(1)(B) and 353(c)(1).

COUNTS 59-63: 18 U.S.C. Section 2: (Aiding and Abetting and Selling Drug Samples)

202. Paragraphs 1-53, 120-124, 138-146, and 152-160 of this Indictment are herein realleged and incorporated by reference.

203. From in or about January 1995 through in or about July 1997 in the District of Massachusetts, the defendant

KIMBERLEE CHASE

did knowingly aid and abet and cause the sale to patients suffering from prostate cancer of samples of the drug Lupron, which samples were not intended to be sold and which were drug samples intended for the promotion of the sale of the drug lupron, all as set forth below:

Count	Samples	Time Period	Physician
59	66	January 1995 through July 1997	John Romano
60	79	January 1995 through July 1997	Joel Olstein
61	71	June 1995 through July 1997	Practice U
62	47	May 1995 through July 1997	Jacob Zamstein
63	76	August 1995 through July 1997	Dr. F and Practice N

All in violation of Title 18 United States Code, section 2 and Title 21 United States Code, sections 333(b)(1)(B) and 353(c)(1).

COUNT 64: 18 U.S.C. §371 (Conspiracy to Sell Drug Samples)

204. Paragraphs 1-53 and 138-142 of this Indictment are herein realleged and incorporated by reference.

205. From in or about March 1993 through in or about December 1998, in the District of Massachusetts, the defendants

**JOHN ROMANO, M.D. and
KIMBERLEE CHASE**

together with Rep. K and others known and unknown to the grand jury, did knowingly combine, conspire and agree, in violation of Title 21 United States Code sections 333(b)(1)(B) and 353(c)(1), to sell to patients suffering from prostate cancer 147 samples, more or less, of the drug Lupron, which samples were not intended to be sold and which were drug samples within the meaning of Section 353(c)(1).

All in violation of Title 21 United States Code, section 371.

COUNTS 65-73: 42 U.S.C. § 1320a-7b (ILLEGAL REMUNERATION)

206. Paragraphs 1-53 and 73-90 of this Indictment are herein realleged and incorporated by reference.

207. On or about the dates indicated below, in the District of Massachusetts, the defendant

RITA JOKIAHO

did knowingly and willfully offer and pay remuneration, including kickbacks, bribes and rebates, directly and indirectly, overtly and covertly, in cash and in kind, as set forth below, to Practice LF, and to physicians and others employed at that Clinic, to induce them to purchase, order, arrange for and recommend to patients being treated at the Clinic and at all locations run by that Clinic who were suffering from prostate cancer that those patients treat their cancer with the drug Lupron, payment of which drug was made in whole and in part under the Medicare Program, a federal health care program, and did aid and abet such conduct:

Count	Date	Person	Remuneration
65	November 1997	Clinic LF	25 free samples of Lupron 7.5 mg
66	February 1998	Clinic LF	25 free samples of Lupron 7.5 mg
67	September 23, 1998	Clinic LF	\$15,000 for Golf
68	November- December 1997	Clinic LF	Approximately \$2,000 for Christmas Party
69	May 7, 1998	Clinic LF	\$2,774.97 for Visiting Professor Preceptorship
70	June 8, 1998	Clinic LF	\$1,500
			\$1,500 for Liver Center

Count	Date	Person	Remuneration
71	April 14, 1998	Clinic LF	Donation
72	August 11, 1997	Clinic LF	\$1,800 Celtics Night Celebrity Table
73	June 1998	Clinic LF	\$500 to Clinic Pharmacy Director

All in violation of Title 42 U.S.C. §§ 1320a-7b(b)(2)(B) and 18 U.S.C. section 2.

A TRUE BILL

FOREPERSON OF THE GRAND JURY

ASSISTANT U.S. ATTORNEY

DISTRICT OF MASSACHUSETTS
July 16, 2002

Returned into the District Court by the Grand Jurors and filed.

DEPUTY CLERK