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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA EX REL. DR. PETER ROST Plaintiffs, v. PFIZER, INC., and PHARMACIA CORPORATION Defendants.	Docket No. 03-CV-11084-PBS The Honorable Patti B. Saris FIRST AMENDED COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT [31 U.S.C.§3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. §1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 et seq.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 et seq.]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. §175 et seq.]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 §5 et seq]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.];

) TENNESSEE MEDICAID FALSE CLAIMS
) ACT [Tenn. Code Ann. §71-5-181 et seq.];
)
) TEXAS MEDICAID FRAUD PREVENTION
) LAW [Tex. Hum. Res. Code Ann. §36.001 et
) seq.];
)
) VIRGINIA FRAUD AGAINST
) TAXPAYERS ACT [Va. Code Ann
) §8.01-216.1 et seq.]; and
)
) DISTRICT OF COLUMBIA
) PROCUREMENT REFORM AMENDMENT
) ACT [D.C. Stat. §2-308.14, formerly D.C.
) Code Ann. §1-1188.13 et seq.]
)
) NEW YORK FALSE CLAIMS ACT
) [McKinney's New York State Finance Law §
) 187 et seq.]
)
) JURY TRIAL DEMANDED
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Plaintiff/Relator, Dr. Peter Rost, submits this First Amended Complaint ("FAC") on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Massachusetts, the State of Nevada, the State of Tennessee, the State of Texas, the State of Virginia, the District of Columbia and the State of New York (collectively "the States and the District of Columbia"). The FAC against Defendants Pfizer, Inc. and Pharmacia Corporation (collectively the "Defendants"), is based upon personal knowledge, relevant documents, and information and belief.

I. PRELIMINARY STATEMENT

On June 3, 2003, Dr. Rost filed his Complaint under seal on behalf of the United States, whereby he alleged that the Defendants' off-label promotion of a dangerous human-growth hormone, called Genotropin, caused the submission of many false claims to the United States and various states in violation of the federal False Claims Act ("FCA") and similar state statutes.

On November 8, 2005, the Department of Justice unsealed the Complaint and, for the first time, allowed Dr. Rost to proceed to litigate this action without government intervention. Almost immediately, and before Dr. Rost even served his Complaint, the Defendants filed a Motion to Dismiss on the ground that the Court lacked subject matter jurisdiction and the Complaint lacked sufficient particularity.

On August 30, 2006, the District Court granted that part of the motion brought under Federal Rule of Civil Procedure 9(b) finding that the Complaint did not sufficiently allege fraud with particularly. The Court denied the motion on all other grounds including the Defendants' primary argument that Dr. Rost's Complaint was barred by the FCA's "public disclosure" bar.

Dr. Rost appealed that portion of the Order granting the Motion to Dismiss. On appeal all

issues raised and considered by this Court were reviewed.

On November 15, 2007, the First circuit affirmed the District Court's holding that Dr. Rost's claims were not barred by the public disclosure bar, and remanded the case after also finding that the District Court erred in not considering Dr. Rost's request to amend. *U.S. ex rel Rost v. Pfizer, Inc.*, 507 F.3d 720 (2007).

In this FCA, Dr. Rost incorporates new allegations in paragraphs 89 to 132, wherein he pleads, with particularly, evidence of more than 200 false claims submitted to the United States for reimbursement of off-label usage of Genotropin.

1. This is an action to recover damages and civil penalties on behalf of the United States of America, the states and the District of Columbia, arising from false and/or fraudulent records, statements, and claims made, used and caused to be made, used, or presented, by Pharmacia Corporation and its successor-in-interest, Pfizer, Inc. (collectively referred to hereafter as "Defendants"), and/or their agents, employees, and co-conspirators, in violation of the FCA, 31 U.S.C. §3729 *et seq.*, as amended, and the governing statutes of the States and the District of Columbia.

2. Beginning in approximately 1997, and continuing to the present date, Pharmacia illegally promoted a growth hormone medication - Genotropin - for off-label indications. Although the FDA has only approved the sale of Genotropin for a very limited number of medical conditions, primarily involving growth hormone deficiency in children and in adults, Pharmacia has mounted a national campaign over several years to promote Genotropin for numerous physical conditions far beyond the FDA-approved indications. As alleged below, Pharmacia's "off label" marketing of Genotropin promoted its use in a broad range of treatments,

from anti-aging in adults, to short stature in children unrelated to growth hormone deficiency. Pharmacia's improper marketing of Genotropin has been very profitable, transforming Genotropin into one of Pharmacia's fastest growing products. In the last four years, annual United States sales revenues for Genotropin more than tripled, reaching $150 million in 2002.

3. Pharmacia's success, however, was the result of marketing and promotional activities that are prohibited by federal law. As a direct result of Pharmacia's improper practices, approximately 60 percent of all adult sales of Genotropin are off-label, and approximately 25 percent of all pediatric sales of Genotropin are off-label. Translated into dollar terms, in 2002 alone, there were approximately $50 million in off-label sales of Genotropin. Total off-label sales of Genotropin since it was first marketed in 1995 amount to hundreds of millions of dollars. A significant portion of these sales were reimbursed by federal and state health insurance programs, including Medicaid, MediCal, CHIP, CHAMPUS/TRICARE, CHAMPVA and the Federal Employee Health Benefits Program. These programs have been caused to pay false or fraudulent claims, including but without limitation the claims identified in this FAC, for reimbursement of off-label uses of Genotropin that would not have been paid but for Pharmacia's illegal business practices.

4. The FCA was enacted during the Civil War, and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the

information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

5. The Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. The FCA defines "knowingly" to include acts commit with "actual knowledge," as well as acts committed "in deliberate ignorance" or in "reckless disregard" of their truth or falsity. Liability attaches when a defendant seeks, or causes others to seek, payment that is unwarranted from the Government.

6. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

7. As set forth below, Pharmacia's acts also constitute violations of the California False Claims Act, Cal. Govt Code §12650 et seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 *et seq*.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq*.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq*.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq*.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 *et seq*.;

the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 *et seq.*; and the District of Columbia Procurement Reform Amendment Act, D.C. Stat §2-308.14 *et seq*., formerly D.C. Code Ann. §§1-1188.13 *et seq.*; and, McKinney's New York State Finance Law §187 *et seq.*

8. Based on these provisions and through this action, Dr. Rost seeks to recover damages and civil penalties arising from Defendants' making or causing to be made false or fraudulent records, statements, and/or claims, in connection with Defendants' knowing off-label marketing of Genotropin. Although Defendants did not directly submit claims for Genotropin to federal and state health insurance programs, they acted knowingly, deliberately, and recklessly in their off-label marketing practices, and knew or should have known that those practices would cause the submission of false claims to these health insurance programs for prescriptions of Genotropin that were not eligible for program reimbursement.

II. PARTIES

9. Dr. Peter Rost is a resident of New Jersey. Dr. Rost was employed by Pharmacia in June 2001 as Vice President in charge of the Endocrine Care Unit, in Peapack, New Jersey. Dr. Rost is a physician and has worked in the pharmaceutical industry since 1992.

10. Defendant Pharmacia Corporation was, until April 2003, a Delaware corporation with a principal place of business in Peapack, New Jersey. In April 2003, Pharmacia was acquired by Pfizer, Inc. At all times material hereto, Pharmacia was principally engaged in the manufacture and sale of pharmaceuticals. In 2002, Pharmacia employed approximately 43,000 people worldwide; its sales were approximately $14 billion, and its before-tax profits were approximately $2.4 billion.

11. Prior to March 31, 2000, Pharmacia was known as Pharmacia & Upjohn, Inc.

("P&U"), a Delaware corporation with headquarters in Peapack, New Jersey. On March 31, 2000, P&U merged with Monsanto Company to create Pharmacia. References in this complaint to "Pharmacia" prior to March 31, 2000 refer to P&U.

12. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with a principal place of business in New York, New York. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals. In 2002, Pfizer employed approximately 120,000 people worldwide; its sales were approximately $32.4 billion; and its before-tax profits were approximately $9.9 billion. With the acquisition of Pharmacia in April 2003, Pfizer became the world's largest pharmaceutical company, with a combined workforce of approximately 160,000 people worldwide and total sales of approximately $46 billion. As a result of the acquisition of Pharmacia, Pfizer is responsible for all liabilities resulting from any acts or omissions of Pharmacia prior to the acquisition.

III. JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

14. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in, reside, or transact or have transacted business in the District of Massachusetts.

15. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the Defendants can be found in and transact or have transacted business in the District of Massachusetts. At all times relevant to this Complaint, Defendants regularly conducted substantial business within the District of Massachusetts, maintained employees and offices in Massachusetts, and made significant sales within Massachusetts. In addition, the statutory violations, as alleged herein, occurred in this district.

IV. BACKGROUND

16. Growth hormone in the human body is a protein produced by the pituitary gland, a small "master gland" located at the base of the brain. The pituitary gland not only controls physical growth, but also regulates other glands throughout the body that produce hormones such as testosterone and estrogen.

17. Scientists first began to learn the benefits of growth hormone (also known as "GH") by studying and treating children who did not grow normally. Researchers found that injecting children with ground-up pituitary glands taken from cadavers led to their normal growth and development. The process was limited, however, by the supply of pituitary glands, since ongoing therapy required the harvesting and pooling of glands from large numbers of cadavers. The solution was genetic engineering. The process of making synthetic human growth hormone involves inserting a gene into laboratory cell lines to produce the desired protein, growing huge numbers of these cells, then purifying out the protein they produce for subsequent human use. The insertion of genes into cells is known as recombinant gene technology.

18. The first version of recombinant human growth hormone (also known as rhGH) was made by Genentech, and approved for sale by the FDA in 1985. Today, rhGH is produced

and sold by five companies under a number of brand names: Genotropin manufactured by defendant Pharmacia; Humatrope manufactured by Eli Lilly and Company; Norditropin manufactured by NovoNordisk; Saizen manufactured by Serono; and Nutropin and Protropin manufactured by Genentech. The main distinction among them is that they are produced in different types of cell lines and have been evaluated in clinical trials for different indications. As explained in the following section on the "Applicable Law," the FDA allows a company to claim a label indication only if it has conducted trials for a specific condition with that version of rhGH.

19. Although recombinant technology solved the problem of availability, it did not solve the problem of cost. All brands of rhGH, including Genotropin, are extremely expensive -- from several thousand dollars per year for limited supplemental use, to about $35,000 per year for a child who completely lacks the protein. The high price tag (and high profit margin) involved in selling rhGH, and the potential off-label uses of rhGH, have provided strong incentives for unlawful off-label promotional activity by rhGH manufacturers.

20. Genotropin has been approved by the FDA for three indications in children, and one indication in adults.

21. Pediatric Indications. The FDA has approved Genotropin for use in children with the following indications (the dates of the FDA's approvals are listed in parentheses): treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (August 1995); treatment of pediatric patients who have growth failure due to Prader-Willi syndrome, a rare genetic disorder that causes short stature and other disabilities (June 2000); and treatment of growth failure in children born small for gestational age ("SGA")

who fail to manifest catch-up growth by age two (this is a specific diagnosis that refers to infants who have a birth weight or length that is more than two standard deviations below mean normal values) (July 2001). Other pediatric uses for Genotropin had not been approved by the FDA during the time Defendants' marketed that drug for such off-label uses. For example, using Genotropin to treat children who do not suffer from a growth hormone deficiency, but are merely growing at a lesser rate than their peers, is an off-label use. This off-label indication is also known as "idiopathic short stature," meaning essentially "just being short," i.e., short with no known medical cause.

22. Adult Indications. The FDA has approved only one indication for the use of Genotropin in the adult population: adult patients with growth hormone deficiency (November 1997). All other uses of Genotropin in the adult population are off-label.

23. As alleged below, notwithstanding its knowledge that it could not lawfully promote Genotropin for non-approved uses, Pharmacia adopted marketing strategies that led to numerous off-label and unapproved uses of Genotropin, from halting the aging process in adults to short stature in children without GH deficiency.

24. In the United States, Genotropin sales and marketing efforts are undertaken by Pharmacia's Endocrine Care Division. Dr. Rost was Vice President in charge of that Division after he joined Pharmacia in June 2001, and in that capacity he learned of the practices of Pharmacia complained of herein. Prior to June 2001, Sean McNicholas was Vice President in charge of Pharmacia's Endocrine Care Division.

25. During the most recent time period relevant to this complaint, the Senior Director for United States Marketing was Carl Worrell, who supervised Genotropin marketing and sales

activities in this country. Mr. Worrell was terminated from employment at Pharmacia in April 2002.

26. Pharmacia's Genotropin sales and marketing in the United States are organized by regions, and each region is organized into numerous sales districts. Pharmacia sales representatives receive incentive-based compensation that includes an annual salary, plus a bonus. An individual sales representative's bonus is determined by his/her performance in the relevant market and whether s/he satisfies or surpasses sales targets. Accordingly, the more Genotropin sold by a Pharmacia sales representative, the higher his or her compensation.

V. APPLICABLE LAW

A. The FDA Regulatory Scheme

27. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

28. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use for which the drug may be prescribed is called the "indication." The FDA will specify particular dosages determined to be safe and effective for each indication.

29. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§352, 355(d). An

example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

30. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those required for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

31. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

32. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional

materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

33. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

34. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses.

35. With regard to the first practice - disseminating written information - the FDAMA permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

36. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997

entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* The promotion of off-label drug uses at a CME program which is not "free from the supporting company's influence and bias" violates Congress' off-label marketing restrictions.

37. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, i.e., the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

38. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid and other federal health care programs.

39. Drugs not approved for such uses, including Genotropin, were are not subject to reimbursement by Medicaid or by state health care programs at the time of the Defendants' promotional campaign, including without limitation those states on whose behalf Dr. Rost has asserted causes of action.

40. During the time period of Defendants' promotional campaign, off-label claims for reimbursement for Genotropin from Medicaid or other federal or state insurers would, therefore, have constituted false claims.

1. The Medicaid Program

41. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

42. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id*. §1396r-8(k)(3). They do not include drugs use for a medical indication, which is not a medically accepted one. *Id.*

43. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or which is included in one of the drug compendia identified in the Medicaid statute. Id. §1396r-8(k)(6). During the time period relevant to this Complaint, the off-label uses of Genotropin promoted by Pharmacia were not eligible for reimbursement as medically accepted indications.

2. Other Federal Health Care Programs

44. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

45. CHAMPUS/TRICARE, administered by the United States Department of

Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, e.g.,TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

46. The Children's Health Insurance Program ("CHIP") is a partnership between states and the United States to provide medical insurance for eligible children. Up until 2007, this program provided insurance for children who did not qualify for Medicaid but who lack the economic means to afford private health insurance.

47. During the time period relevant to this Complaint, the off-label uses of Genotropin promoted by Pharmacia did not qualify for reimbursement under any of the various federal health care programs.

3. The Anti-Kickback Statute

48. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives

rise to overutilization or poor quality of care.

49. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, CHIP, or other federal health care program.

50. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company to a physician which has as one of its purposes inducement of the physician to write additional prescriptions for the company's pharmaceutical products.

51. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the improper practices cited by the Inspector General are drug companies' payments to physicians where the physician had offered no particular services of benefit to the drug company but the payment appeared to have been based on the volume of business the doctor could generate for the drug company. *Id.*

52. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. With regard to

Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In a number of states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

53. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

C. Criminal Penalties For Unauthorized Distribution of Growth Hormone

54. In recognition of the fact that illegal trafficking in human growth hormone was becoming larger in scope and presenting an ever-increasing health risk, Congress in 1990 imposed stringent criminal penalties for the illegal distribution of human growth hormone. Under the law in 2003, a manufacturer's unlawful distribution of human growth hormone is treated similarly to the unauthorized distribution of narcotics under the Controlled Substances Act. Specifically, Congress amended the FDCA to explicitly criminalize as a five-year felony the distribution and possession, with intent to distribute, of human growth hormone "for any use . . . other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services . . . and pursuant to the order of a physician . . . ." 21 U.S.C. §333(f). The maximum penalty is increased to 10 years

imprisonment if human growth hormone is unlawfully distributed to individuals under the age of 18. *Id.*

VI. ALLEGATIONS

A. Pharmacia's Marketing Strategy For Genotropin Was Driven By Lucrative Off-Label Markets

55. The market for approved on-label uses for Genotropin is very limited. In the adult population, there are fewer than 50,000 adults who have growth hormone deficiency, and only approximately 6,000 new cases are diagnosed each year. In the pediatric population, the number of children who have growth hormone deficiency, growth disturbance in connection with Prader Willi syndrome, or are identified as SGA is also relatively small. On the other hand, the market for the off-label uses of Genotropin - anti-aging and body image improvement for the adult population, and treatment of short stature unrelated to GH deficiency in children - is significant. Pharmacia knew that if these markets could be tapped, Pharmacia could substantially increase sales of Genotropin.

56. As described below, in response to these market realities, Pharmacia initiated a variety of practices designed to aggressively promote the off-label uses of Genotropin. The results were very successful, with Genotropin sales revenue roughly tripling between 1999 and 2003. With the support of off-label sales, Genotropin sales revenues rose from negligible revenues shortly after the drug was introduced in 1995, to $54 million in 1999, then to $69 million in 2000, and jumped to $115 million in 2001. In 2002, they increased again, to $150 million. In 2003, at the time of filing the original complaint in this action, Genotropin revenues were on track to exceed $170 million. As a direct result of Pharmacia's illegal practices, Federal

government health insurance programs, and their State counterparts, have been induced to pay claims for a significant portion of these prescriptions - claims that they would not have paid but for the practices complained of herein. Pharmacia's practices have caused damages to the U.S. Treasury and the affected States in the tens of millions of dollars.

B. Pharmacia Knew That A Large Percentage Of Its Genotropin Sales Were Off-Label

57. Pharmacia was well aware that its illegal marketing practices resulted in the extensive off-label use of Genotropin. Pharmacia maintains a computerized database that includes details of virtually every sale of Genotropin since its introduction in 1995. The data in the computer database comes primarily from Pharmacia's "Bridge Program." The Bridge Program provides comprehensive patient services that assist patients and families in a variety of ways, including giving free drugs until reimbursement is secured, assisting with insurance reimbursement and claims filing.

58. The Bridge Program database contains information on approximately 30,000 patients for whom Genotropin has been prescribed since the drug was first approved for marketing by the FDA. The information comes from the Statement of Medical Necessity ("SMN") that a physician must fill out for each new patient for whom Genotropin is prescribed. The information in the data base includes, inter alia, the date of the SMN, the primary and secondary diagnosis, the code for the prescribing doctor, and the dosage prescribed.

59. The Bridge Program data base reveals that approximately 60 percent of all adult sales of Genotropin, and approximately 25 percent of all pediatric sales, are off-label. The adult off-label sales are primarily for treatment of conditions associated with aging. The pediatric

off-label sales are primarily for treatment of children of short stature not due to GH deficiency and for treatment of children with Turner's syndrome, a rare chromosomal disorder of females characterized by short stature and the lack of sexual development at puberty. Pharmacia has not sought FDA approval to use Genotropin to treat any of these off-label indications.

60. During the time period relevant to this Complaint, the above information concerning the high percentage of off-label sales of Genotropin was available to, and known by, Pharmacia's management, who kept close track of sales performance in this area.

C. Dr. Rost Learned of Pharmacia's Aggressive Off-Label Promotion Of Genotropin Shortly After Joining The Company

61. When Dr. Rost joined Pharmacia in June 2001 as Vice President in charge of the Endocrine Care Division responsible for the marketing and sales of Genotropin, he became aware of sales and marketing activities that actively encouraged off-label sales. Sales representatives, largely unsupervised, were unilaterally signing contracts on behalf of Pharmacia offering doctors and distributors price discounts and rebates. The sales representatives had a significant financial incentive to promote Genotropin in this unrestrained manner, since their bonus was based on total number of new patients, regardless of whether the patients were prescribed Genotropin for off-label or on-label treatments.

62. In the course of integrating into his new position with Pharmacia, Dr. Rost also learned of the following practices, among others.

a. Although Pharmacia's formal policy forbade promotion of Genotropin for off-label uses, the company had communicated a different message to its sales force, namely: increase Genotropin sales whenever and wherever possible, whether off-label or on-label.

b. Several Genotropin sales representatives had been requested by their superiors at Pharmacia, including former Sales Director Trevor Burke, to conduct off-label promotion of Genotropin, and those who had refused to promote Genotropin for off-label uses had been forced out of the company.

c. A large "study program" directed by Pharmacia, called "KIGS/KIMS," was being used by Pharmacia (1) to financially reward physicians for prescribing Genotropin on and off-label and (2) to promote off-label uses of Genotropin.

d. Pharmacia encouraged its sales force to promote Genotropin to the community of doctors and distributors working in the anti-aging area, who prescribed Genotropin exclusively for off-label use, i.e., as a treatment for bodily conditions associated with aging. A number of financial incentives provided to these doctors and distributors are discussed below.

e. Pharmacia sales representatives promoted off-label uses of Genotropin in the pediatric population. The largest share of the pediatric off-label prescriptions are for treatment of children short for their age not due to GH deficiency and for treatment of children with Turner's syndrome. The FDA has not approved Genotropin for these purposes.

f. Sales representatives had offered doctors and pharmacists improper financial inducements to prescribe Genotropin. For example, after Pharmacia's National Sales Manager for Florida left the company in 2002, several physicians in the Florida area informed the newly appointed Sales Director that the former manager had given them direct payments as inducements to prescribe Genotropin.

g. Certain sales representatives had routinely filled out the Statement of Medical Necessity (SMN) required for each new patient. This practice is a direct violation of

federal regulations issued by the Center for Medicare and Medicaid (formerly the Health Care Financing Administration).

h. Pharmacia paid lucrative "consultant" fees which, in reality, were used to mask payments to individuals or companies for off-label promotion of Genotropin. Several of these practices are discussed in greater detail below.

D. Pharmacia's Marketing Practices Deliberately Promoted The Off-Label Uses of Genotropin

63. Beginning on a date unknown but estimated to be on or about 1997, Pharmacia's national marketing strategy for the Genotropin brand recognized that its off-label uses could provide potentially large gains in sales and revenues for the drug. Thereafter, Pharmacia's off-label promotion of Genotropin became extremely opportunistic, and targeted especially marketable areas of concern for individual health and quality of life - e.g., anti-aging and improving body image in adults; and targeting short stature unrelated to GH deficiency in children. In the United States, these areas represent multi-billion dollar markets every year.

64. Pharmacia's promotion and marketing of Genotropin's off-label uses took a variety of forms, including but not limited to those discussed below.

1. The KIGS/KIMS "Study" Program: A Vehicle To Financially Reward Physicians For Prescribing Genotropin, And An Opportunity To Promote Off-Label Uses of Genotropin

65. One particularly large "study program" directed by Pharmacia, called "KIGS/KIMS," was used by Pharmacia both to financially reward physicians for prescribing Genotropin, and to promote off-label uses of Genotropin.

a. KIGS stands for "Kabi International Growth Study" administered by Pharmacia. (The title is derived from the name of the company that began the study, Kabi International, which was later acquired by Pharmacia.) KIGS is an international study of children and adolescents with growth disorders. The KIGS study collects information on the long-term safety and growth response of adolescents to Genotropin.

b. KIMS is a comparable study for adults with growth hormone deficiency. KIMS collects data on the long-term safety and efficacy of Genotropin used by adults with growth hormone deficiency.

66. Although the KIGS/KIMS studies took the form of clinical research programs, they were in fact used as marketing tools by Pharmacia to provide financial incentives and off-label promotional material to induce physicians to prescribe Genotropin for increasing numbers of patients.

67. Every physician who prescribes Genotropin for an adolescent or adult patient is given the opportunity to participate in the KIGS or KIMS studies, respectively. The participating physicians are called "investigators." The "investigators" practicing medicine in the United States are paid $200 for every patient enrolled in the "study," and $200 every year thereafter that the patient remains enrolled. "Investigators" outside of the United States generally are not paid for enrolling their patients in the study. The payments to the U.S. "investigators" do not reflect the value of services provided, as the physicians have no real investigational responsibilities, but merely provide a small amount of information about each patient. To keep a patient enrolled in the study, the physician is only required to update the information once a year, and for doing so is paid $200 for that patient each year. Each of these $200 payments constituted an inducement and

reward for the U.S. physician's prescribing of Genotropin.

68. Approximately 60 percent of all patients who use Genotropin are enrolled in the KIGS/KIMS study, which for many individual participating physicians represented an increase in income of approximately 5 to 25 percent. It is well-known in the pharmaceutical industry that pediatric endocrinologists (who treat hormone-related conditions in children) are among the lowest paid specialists. Indeed, as an internal Pharmacia marketing presentation entitled "Genotropin U.S. Brand Plan 2003," candidly stated: "Pediatric Endocrinology practices depend on funding from growth hormone manufacturers to survive." Pharmacia exploited this fact to influence the physicians' prescribing practices.

69. Pharmacia made, and continued to make, the $200 per-patient annual payments to all prescribing physicians participating in the KIGS/KIMS program in the United States, notwithstanding its knowledge that approximately 60 percent of the adult patients, and approximately 25 percent of the pediatric patients, are prescribed Genotropin for off-label uses. These payments, therefore, encourage physicians' off-label use of Genotropin.

70. Pharmacia also provides additional financial inducements for the United States physician "investigators." Each year since 1997, Pharmacia has sponsored an all-expenses-paid "National Meeting" of KIGS/KIMS "investigators," held at luxury resort locations in the United States and the Caribbean. Typically 600 to 800 U.S. physician "investigators" attend the meetings. Pharmacia pays their round-trip airfare, ground transportation, accommodations, meals and entertainment. Pharmacia also pays the expenses of an accompanying spouse, less a nominal contribution by the couple.

71. Pharmacia uses the KIGS/KIMS National Meetings as a vehicle to promote

Genotropin, including its off-label uses. The three-night/four-day event includes two days of presentations, and ample time to enjoy the resort. The presentations - offered by Pharmacia employees as well as outside speakers paid substantial honoraria by Pharmacia - include discussions relating to off-label uses of Genotropin. Pharmacia sales representatives also play an active role at the National Meetings, offering the attendees information about Pharmacia's products. All aspects of the meeting are designed, monitored, and approved by Pharmacia. It selects the speakers, and picks the presentation topics. It pays all costs relating to the event.

72. The KIGS/KIMS annual meeting constitutes a reward or kickback for the investigators' prescribing Genotropin to their patients.

73. The promotional purpose of the annual meeting is openly acknowledged within Pharmacia. For example, in an internal Pharmacia marketing presentation entitled, "Global Business Review [Re:] Genotropin," presented to company executives in 2002, the first item listed under "KIGS & KIMS Objectives" is: "Stimulate Long-term Sales Potential." And the first method listed to accomplish this objective is: "Secure relationship with key prescribers - Annual meetings." In other words, Pharmacia recognized that the chief purpose of the National Meetings was not scientific or educational, but to "secure" the business of "key prescribers" attending the meetings.

74. A typical KIGS/KIMS National Meeting was held in San Juan, Puerto Rico during the weekend of January 23-26, 2003. Over 600 U.S. physician-attendees were given round-trip airfare to Puerto Rico (worth approximately $800), three-nights accommodations (worth at least $500), ground transportation and free meals and entertainment (worth approximately $500). The value of the meeting was approximately $1,800 per physician, not including the amounts paid by

Pharmacia to cover the expenses of an accompanying spouse. In addition, Pharmacia paid the presenters' expenses and fees, as well as all of the administrative and facilities costs associated with the event. This National Meeting cost Pharmacia well in excess of a million dollars.

75. The 2003 meeting in Puerto Rico was not unique. Pharmacia sponsored similar National Meetings of KIGS/KIMS investigators at the following locations:

Location	**Date**
Miami, Florida	December 3-6, 1997
Laguna Niguel, California	December 3-6, 1998
Naples, Florida	December 9-11, 1999
Scottsdale, Arizona	November 9-12, 2000
Coronado Island, California	January 25-27, 2002

76. The combined total cost to Pharmacia for these meetings was several million dollars. Pharmacia expected to, and did, reap a return on its investment, in terms of increased Genotropin sales: Genotropin sales increased annually at an average of over 40 percent during this period of time.

2. Pharmacia Offered Financial And Other Incentives To Distributors And Doctors Working Exclusively In The Off-Label Anti-Aging Area

77. Since the early 1990's there has been a proliferation of "anti-aging" clinics and lay publications extolling the benefits of growth hormone in reversing or preventing the effects of aging. In addition, several Web sites have touted the cure-all benefits of various formulations of growth hormone. None of these growth hormone treatments have been scientifically shown to be effective in reversing or preventing aging, and none have been approved by the FDA as safe or effective for that purpose. Nevertheless, the lure of eternal youth and miracle cures has tempted many consumers to try the various growth hormone formulations pitched by these doctors, clinics

and distributors of growth hormone.

78. Pharmacia recognized the huge potential for profit in the anti-aging area. In fact, promotion of Genotropin in the anti-aging market was an explicit Pharmacia goal. For example, in an internal Pharmacia marketing presentation entitled, "Global Business Review [Re:] Genotropin," the following goal was stated: "Attempt to promote/distribute product [Genotropin] through alternative channels (such as the Internet) to focus on alternative indications (such as Healthy Aging)." In other words: promote Genotropin for off-label uses. In the same presentation and on the same power-point slide, it was also an announced Pharmacia goal to gain share in the Medicaid market.

79. Although Pharmacia knew that anti-aging proponents were prescribing and promoting Genotropin and other growth hormone drugs for off-label uses, Pharmacia actively encouraged and subsidized those efforts in a variety of ways. One way was through financial incentives. Specifically, Pharmacia offered anti-aging doctors and the distributors who supplied them with prescription drugs favorable contracts providing for price discounts on their Genotropin purchases and/or rebates for their Genotropin sales, knowing that they would be using Genotropin for off-label purposes.

80. Following is a list of some of the distributors who had Genotropin discount or rebate agreements with Pharmacia. Most of these distributors, as Pharmacia well knew, dealt exclusively with doctors prescribing Genotropin for anti-aging treatment:

Contracting Party	**Date Of Initial Contract**
Advance Paradigm Clinical Services, Inc., Baltimore, MD	December, 2000
CCMJ Pharmaceuticals, Scottsdale, Arizona	May, 2001

Curascript Pharmacy, Inc., Orlando, Florida	February, 2001
Heartwise Fitness Institute, Whittier, California	December 2000
Health Partners, Inc., Minneapolis, Minnesota	June, 1999
HealthTeam Northwest, Bothell, Washington	July, 1999
Hopewell Pharmacy, Inc., Hopewell, New Jersey	January, 2001
MedQuest, Inc., Midvale, Utah	February, 2000
Nova Factor, Inc., Memphis Tennessee	August, 2001
Pharma Health Infusion Services, Rochester, NY	December, 2000
Portland Professional Pharmacy, Portland, Maine	April, 2000
Pharmacy Plus Inc., Philadelphia, Pennsylvania	November 2000
Pharmaceutical Specialties, Inc., Athens, Georgia	July 1999
Renew Youth Centers, Atlanta, Georgia	August 2000
Vita RX, Jefferson, Louisiana	September 2001
Youthspan, Inc., Atlanta, Georgia	July, 2000

81. By providing these entities with Genotropin at below-market rates, Pharmacia subsidized and encouraged off-label sales and promotion of Genotropin.

82. Pharmacia also entered into similar contracts offering price discounts directly to doctors working exclusively in the anti-aging area, knowing that they would sell Genotropin to patients for off-label anti-aging treatment. At least 18 anti-aging doctors had such contracts with Pharmacia, including Dr. Jeffrey Bloom of Newport Beach, California (contract signed in December, 2000), and Dr. Richard Leconey of Houston, Texas (contract signed in October, 2000). The names of the other doctors will be found in the records of Pharmacia to which Dr.

Rost does not have access.

83. Pharmacia also encouraged Genotropin use for anti-aging treatment by paying $10,000 a month to Health Strategy Group, a company based in Toronto, Canada, to help train doctors in how to set up practices exclusively devoted to anti-aging treatment and also to help in speaker training of the same doctors in order for them to participate in Pharmacia's Speakers Program.

84. In mid-2002, Pharmacia canceled all of the above contracts and arrangements, following an internal Pharmacia investigation into the company's Genotropin marketing and sales practices.

3. Pharmacia Used "Consultant" Contracts To Funnel Payments For Off-Label Promotion of Genotropin

85. To evade prohibitions on manufacturer promotion of off-label uses of its prescription drugs, Pharmacia paid lucrative contracts to supposedly independent "consultants," who promoted the off-label uses of Genotropin. Under the fiction that these contractors were acting as consultants, Pharmacia generously subsidized off-label promotional activities.

86. For example, in April 2000, Pharmacia entered into a "Consulting Agreement" with Dr. William A. Abelove of Miami, Florida, in which Pharmacia agreed to pay Dr. Abelove $50,000 over an eight-month period. Dr. Abelove is the director of several "Longevity Centers" in Florida, and is a well-known advocate of the use of growth hormone for anti-aging treatment. The so-called "Consulting Contract" with Dr. Abelove was nothing more than a payment to Dr. Abelove in exchange for his promotion of the anti-aging uses of Genotropin and for prescribing Genotropin off-label to the patients in his "Longevity Centers."

87. In another example, Pharmacia paid Health Strategy Group, of Toronto, Canada, a monthly retainer of $10,000 to promote off-label uses of Genotropin in the anti-aging area. For example, Health Strategy Group generated marketing material for doctors promoting anti-aging uses of Genotropin, organized speakers training on this off-label topic, and, as noted above, even helped doctors set themselves up in business to target this market segment.

88. Dr. Rost is informed and believes that similar "consulting" arrangements existed with other doctors and companies. Dr. Rost cannot at this time identify those individuals or companies by name, as that information is contained in records within the exclusive possession of Pharmacia, to which Dr. Rost does not have access.

E. False Claims Submitted to Medicaid and CHIP

89. Hundreds, and possibly thousands, of false claims for off-label uses of Genotropin were submitted to (and reimbursed by) federal agencies as a result of the Defendants' illegal and wrongful wide-ranging, off-label promotional and marketing campaign.

90. The federal Medicaid and CHIP programs received submissions to (and reimbursed) more than 200 false claims for off-label uses of Genotropin from citizens living in the state of Indiana alone during the peak years of the Defendants' pervasive, off-label promotional activities.

91. Indiana provided Dr. Rost with detailed claims data from citizens of that state for drug claims submitted to (and reimbursed by) Medicaid and the CHIP programs.

92. Because Medicaid and CHIP are partnerships between the states and federal government, data for these programs is maintained by the individual states and claims are reimbursed jointly by the states and the United States.

93. The Medicaid and CHIP information that Dr. Rost obtained lists claims electronically submitted to these federal agencies (and to the state of Indiana) for individual patients, listed by an encrypted Random Identification Number ("RID").

94. For each patient, the data reveals: a) the drug for which medical providers submitted claims for reimbursement to Medicaid and/or CHIP; b) the medical diagnosis accompanying that claim; c) the diagnosis and dispensation dates for the drug; and d) the prescription dosage of that drug for which federal (and state) reimbursement was sought.

95. Claims submitted for Genotropin are listed via a National Drug Code ("NDC"). The NDC codes are based on the drug and the drug dosage, but the codes for Genotropin all begin with the numbers 001326.

96. The diagnostic codes submitted by the provider, which show whether the claim was for an off-label or on-label use, are listed on the website: http://www.icd9data.com.

97. The diagnostic code for short stature, without growth hormone deficiency, is 783.43. The code for "small for date" is 764.00. Both indications were never approved for use of Genotropin during the time period covered by this action. Claims for either would, therefore, be false off-label claims.

98. Using this data, one can readily match up and chart the claims submitted and reimbursed by Medicaid and CHIP for off-label usage of Genotropin by drug, by diagnosis and by dates.

99. A representative sample of this data is set forth below:

Encrypted RID	Diagnosis Date	Dispense Date	Diagnosis	NDC

7RS86BD7IU9DBDGRTW	11/6/2001	11/16/2001 12/16/2001 1/16/2002 3/1/2002	783.43 - short stature	13264681 - Genotropin 13.8 MG Cartridge
7RS86BD7IU9DBDGRTW	3/18/2002	4/1/2002 4/30/2002 5/30/2002 8/16/2002 11/1/2002	783.43 - short stature	13264681 - Genotropin 13.8 MG Cartridge

100. The data reveals which claims were for uses of Genotropin that were off-label and thereby false.

101. This data reveals that more than 200 claims were submitted to Medicaid and/or CHIP for off-label Genotropin usage, such as to correct "short stature," during the time period covered by Defendants' off-label marketing campaign.

102. A more complete summary chart listing the data for more than 200 false off-label claims is attached in Exhibit A, attached hereto.

103. The 200- plus Medicaid and CHIP claims are from just one state, Indiana, whose population is slightly more than over 2percent of the population of the United States.

F. Additional Evidence of the Submission of False Claims to Federal and State Health Care Programs

1. Defendants Admitted Their Fraudulent Scheme to the Government through the OIG Voluntary Disclosure Program

104. In his original Complaint, Dr. Rost alleged that Defendants' promotion of Genotropin for off-label usage led to the submission of claims to federal and state agencies, which are the largest insurers paying for drugs in the United States.

105. In moving to dismiss the Complaint, Pfizer argued unsuccessfully that Dr. Rost's action should be barred because Pfizer disclosed identical information to certain government officials a few days before Dr. Rost had done.

106. Pfizer attached correspondence to its Motion to Dismiss in which Pfizer admitted that Pharmacia bribed doctors and engaged in a wide-range of other activities to illegally market and promote the off-label use of Genotropin.

107. Moreover, Pfizer represented in this attached correspondence that it entered a Department of Health and Human Services Office of Inspector General ("OIG") Voluntary Disclosure Program to disclose the Defendants' off-label promotion of Genotropin.

108. To participate in this OIG program, a party must present detailed information about the fraudulent scheme within its organization. 63 Fed. Reg. 58, 399 at 58,401-402 (Oct. 30, 1998). Significantly, a requirement for entry is that the applicant describe with "sufficient particularity" the documents and records that reveal the illicit practice the applicant is disclosing. 63 Fed.Reg. 58,399 at 58,402.

109. A strong inference, based on Pfizer admissions, is that the Defendants' off-label

promotion of Genotropin led to the submission of false claims to federal and state health care programs in violation of the FCA.

110. Another strong inference is that the Defendants made false statements to illegally promote Genotropin for off-label usage, which caused false claims.

111. The Defendants made these inferences even stronger when, in seeking the dismissal of Dr. Rost's Complaint, they represented that their participation in the OIG Voluntary Disclosure Program enabled them to disclose all "key elements" of Dr. Rost's action to "appropriate" public officials prior to his filing of a complaint. A key element of Dr. Rost's Complaint is that the off-label promotion of Genotropin led to the submission of false claims to Federal health care programs in violation of the FCA.

112. In the attachments to its Motion to Dismiss, Pfizer redacted large sections of the materials that it had previously sent to the OIG relating to off-label prescriptions of Genotropin reimbursed by federal health care programs. It is reasonable to infer that the redacted material related to off-label claims for Genotropin submitted to these agencies, and that such information would have been highly pertinent to the Defendants' application and likely to be known by the Defendants, who were closely monitoring insurance claims' information for at least 30,000 Genotropin patients at the time.

2. Defendants Pled Guilty to A Felony, Entered A Deferred Prosecution Program and Paid Fines Totaling $34.7 Million, All In Relation to Their Off-Label Promotion and Sale of Genotropin

113. After Dr. Rost's Complaint was filed, the United States Attorney's Office for the District of Massachusetts initiated a criminal investigation. Dr. Rost testified before the grand

jury.

114. The Defendants, facing criminal charges that they illegally promoted Genotropin for off-label uses and offered kickbacks in connection with their promotional activity, entered into an agreement with the Department of Justice under which they agreed to pay $34.7 million in fines.

115. On April 2, 2007, while this case was still pending in the First Circuit Court of Appeal, the United States Attorney's Office for the District of Massachusetts announced that it would be entering into a deferred prosecution agreement with Pharmacia & Upjohn, LLC arising out of the illegal promotion of its human growth hormone product, Genotropin, for the off-label uses relating to anti-aging, cosmetic, and athletic power enhancement.

116. At the same time, the U.S. Attorney's Office filed criminal charges against Pharmacia and Upjohn Company, Inc., as a Pfizer subsidiary, charging these entities with one count of offering a kickback in connection with their outsourcing contract for the administration and distribution of its human growth hormone Genotropin.

117. This felony charge related to the Bridge Program database that the Defendants used to monitor 30,000 Genotropin patients, including scrupulously tracking and recording their insurance claims and reimbursement information.

118. On April 26, 2007, the parties agreed to the terms set forth in a Deferred Prosecution Agreement, and Pharmacia was fined $15 million dollars for the illegal promotion of Genotropin, and Pharmacia & Upjohn, Inc. as a subsidiary of Pfizer, pled guilty to one count of offering a kickback to a pharmacy benefit manager for which these entities paid a criminal fine of $19.7 million.

119. Because of this criminal conviction, Pharmacia & Upjohn, Inc. was permanently excluded from participation in all federal health care programs.

120. The Deferred Prosecution Agreement states that the United States Attorneys' Office for the District of Massachusetts "conducted a criminal investigation regarding the conduct disclosed by Pfizer, to wit, the allegations that Pharmacia promoted, sold, and distributed the human growth hormone drug Genotropin in violation of the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 321 *et seq*., by promoting, selling, and distributing Genotropin for anti-aging, cosmetic use or athletic performance enhancement (the 'Subject Matter')."

121. As a result of its investigation, the U.S. Attorney's Office informed Pharmacia that it had determined that there was sufficient basis for that office to indict Pharmacia for federal crimes, specifically and without limitation, for distribution of an unapproved new drug in interstate commerce, with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

122. As part of this agreement, Pfizer admitted that the Defendants engaged in the unlawful promotion of Genotropin for off-label uses and that "there is a sufficient basis to seek an indictment of Pharmacia for violations of federal criminal law." Significantly, Defendants also specifically admitted that "Pharmacia made misleading representations about the effectiveness of Genotropin as an anti-aging medication."

123. Although this agreement did not discuss the Defendants' off-label promotion of Genotropin for pediatric uses, it is a reasonable inference, given Defendants' common and pervasive off-label promotional scheme of Genotropin and the high percentage of off-label

pediatric sales and revenue, that they also made similar, if not identical, false statements to promote the off-label pediatric sales of Genotropin.

124. In addition, Pfizer agreed that the business unit within Pharmacia that was responsible for the promotion, sale, and distribution of Genotropin was the Endocrine Care Business Unit. Dr. Rost was a Vice President, Marketing, Endocrine Care.[1]

125. Pfizer also admitted that Genotropin was sold and promoted for unapproved uses, and that Pharmacia earned hundreds of millions of dollars in gross revenue from selling Genotropin for unapproved uses.

126. In the Deferred Prosecution Agreement and related documents, Defendants do not deny that their conduct caused off-label claims to be submitted. It is a reasonable inference that: a) both the United States and the Defendants would have ascertained this information before coming to settlement terms; and b) that Defendants would have denied that the claims were submitted for off-label usage if that were the case.

127. These inferences are made even stronger by two additional facts. First, the wording of the Deferred Prosecution Agreement indicates that the Defendants had access to this information. Second, as mentioned above, the Defendants had monitored and maintained records, including insurance submission and reimbursement records, for 30,000 Genotropin patients in their Bridge Program database, many of whom used Genotropin for off-label purposes. Based on such information, the Defendants presumably had, and still have, detailed, if not complete, information at their disposal concerning the submission to federal and state governmental agencies of claims for off-label uses of Genotropin.

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[1] Dr. Rost has never been accused of participating in any way in any of the illegal conduct described in this Amended Complaint

128. Additionally, in this litigation, and in a related wrongful termination action that Dr. Rost has been litigating against Pfizer since December 12, 2005, which is currently pending in the Southern District of New York, the Defendants also have never denied their knowledge of claims submitted to federal and state agencies for the off-label usage of Genotropin while the Defendants engaged in a massive promotional and marketing campaign to promote such off-label usage.

3. Statistical Evidence of Claims

129. Defendants sold hundreds of millions of dollars worth of Genotropin, and generated more than $300 million in sales from 2000 to 2002 alone, the majority of which was sold for off-label uses.

Year	2000	2001	2002
U.S. Genotropin Sales in millions	$69	$115	$147

130. According to documents that Dr. Rost obtained while serving as a Vice President in charge of the Endocrine Sales Unit, pediatric sales of Genotropin accounted for between 85percent and 90percent of all U.S. Genotropin sales. Dr. Rost also determined, while employed by the Defendants, that the information contained in the Defendants' Bridge database indicates that approximately 25percent to 30percent of the pediatric usage of Genotropin was for off-label indications not approved by the FDA.

131. Despite such heavy pediatric usage, the FDA had only approved Genotropin for very limited pediatric uses in the years covered by this action. These limited usages related to growth problems due to certain pituitary problems.

132. Nationwide, approximately, 10 percent of all U.S. prescriptions are reimbursed by

federally-funded Medicaid.

Year	1999	2000	2001	2002	2003
Percentage of Prescriptions Reimbursed by Medicaid	9.44%	9.84%	10.19%	10.7%	11.64%

Count I

False Claims Act 31 U.S.C. §§3729(a)(1) and (a)(2)

133. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

134. This is a claim for treble damages and penalties of each false claim and each false statement under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

135. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

136. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

137. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label or illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

138. Dr. Rost cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate

entities, across the United States, and over many years. Dr. Rost has no control over or dealings with such entities and has no access to the records in their possession.

139. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

140. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid many thousands of claims, amounting to many hundreds of millions of dollars, for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by Defendants.

Count II

California False Claims Act

Cal Govt Code §12651(a)(1) and (2)

141. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

142. This is a claim for treble damages and penalties under the California False Claims Act.

143. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

144. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

California State Government to approve and pay such false and fraudulent claims.

145. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

146. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

147. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count III

Delaware False Claims And Reporting Act

6 Del C. §1201(a)(1) and (2)

148. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

149. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

150. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

151. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

Delaware State Government to approve and pay such false and fraudulent claims.

152. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

153. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

154. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count IV

Florida False Claims Act

Fla. Stat. Ann. §68.082(2)

155. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

156. This is a claim for treble damages and penalties under the Florida False Claims Act.

157. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

158. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

Florida State Government to approve and pay such false and fraudulent claims.

159. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

160. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

161. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count V

Hawaii False Claims Act

Haw. Rev. Stat. §661-21(a)

162. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

163. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

164. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

165. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

Hawaii State Government to approve and pay such false and fraudulent claims.

166. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

167. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

168. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count VI

Illinois Whistleblower Reward And Protection Act

740 Ill. Comp. Stat. §175/3(a)(1), (2)

169. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

170. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

171. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

172. By virtue of the acts described above, Pharmacia knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois

State Government to approve and pay such false and fraudulent claims.

173. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

174. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

175. The State of Illinois is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count VII

Massachusetts False Claims Law

Mass. Gen. Laws ch. 12 §5B(1), (2)

176. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

177. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

178. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

179. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

Massachusetts State Government to approve and pay such false and fraudulent claims.

180. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

181. By reason of the Defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

182. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count VIII

Nevada False Claims Act

Nev. Rev. Stat. Ann. §357.040(1)(a), (b)

(amended by 2007 Nevada Laws Ch. 454 (S.B. 529)

183. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

184. This is a claim for treble damages and penalties under the Nevada False Claims Act.

185. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

186. By virtue of the acts described above, Defendants knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

187. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

188. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

189. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count IX

Tennessee Medicaid False Claims Act

Tenn. Code Ann. §71-5-182(a)(1)

190. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

191. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

192. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

193. By virtue of the acts described above, Defendants knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

194. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

195. By reason of the Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

196. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count X

Texas Medicaid Fraud Prevention Law

Tex. Hum. Res. Code Ann. §36.002

197. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

198. This is a claim for double damages and penalties under the Texas Medicaid Fraud Prevention Law.

199. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

200. By virtue of the acts described above, Defendants knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

201. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used Defendants' illegal off-label marketing practices and illegal inducements.

202. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

203. The State of Texas is entitled to the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XI

Virginia Fraud Against Taxpayers Act

Va. Code Ann. §8.01-216.3(a)(1), (2)

204. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

205. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

206. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

207. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

Virginia State Government to approve and pay such false and fraudulent claims.

208. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

209. By reason of the Defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

210. The State of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XII

District of Columbia Procurement Reform Amendment Act

D.C. Stat. §2-308 .14

(formerly D.C. Code Ann. §1-1188.14(a)(1), (2))

211. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

212. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

213. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

214. By virtue of the acts described above, Defendants knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

215. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

216. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

217. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XIII

New York State False Claims Act

New York State Fin. Law § 189

218. Dr. Rost realleges and incorporates by reference the allegations contained in paragraphs 1 through 132.

219. This is a claim for treble damages and penalties under the New York State False Claims Act, which applies retroactively.

220. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the state of New York payment or approval.

221. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

state of New York to approve and pay such false and fraudulent claims.

222. The state of New York, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

223. By reason of the Defendants' acts, the state of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

224. The state of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Prayer

WHEREFORE, Dr. Rost prays for judgment against the Defendants as follows:

1. that Defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the state statutes set forth above;

2. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of Cal. Govt. Code §12651(a);

4. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 6 Del. C. §1201(a);

5. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not mor than $10,000 for each violation of Fla. Stat. Ann. §68.082(2);

6. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

7. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

8. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

9. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions,

plus a civil penalty of not less than $2,000 and not more than $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1)(a), (b);

10. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of not less than $2,500 and not more than $10,000 for each violation of Tenn. Code Ann. §71-5-182(a)(1);

11. that this Court enter judgment against Defendants in an amount equal to two times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

12. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of Va. Code Ann. §8.01-216.3(a)(1), (2);

13. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more $10,000 for each violation of D.C. Stat. Ann. §2-308.14, formerly D.C. Code Ann. §1-1188.14(a)(1), (2);

14. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages that state of New York has sustained because of Defendants' actions, plus a civil penalty of not less than $6,000 and not more than $12,000 for each violation of New York State Finance Law § 189;

15. that Dr. Rost be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

16. that Dr. Rost be awarded all costs of this action, including attorneys' fees and expenses; and

17. that Dr. Rost recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Dr. Rost hereby demands a trial by jury.

Dated: January 17, 2008

Respectfully submitted,

By: /s/ Mark I. Labaton

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EXHIBIT A

SUMMARY OF CLAIMS DATA

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 1 [7RS3KOOWH92JSWA10D]	6/17/2003	Short Stature (783.43)		
			7/8/2003	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			8/8/2003	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			9/12/2003	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			10/8/2003	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			11/5/2003	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			12/31/2003	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			1/28/2004	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			2/26/2004	00013265302 = GENOTROPIN MINIQUICK - 1 MG
			4/9/2004	00013265402 = GENOTROPIN MINIQUICK - 1.2 MG
			5/6/2004	00013265402 = GENOTROPIN MINIQUICK - 1.2 MG
			6/21/2004	00013265402 = GENOTROPIN MINIQUICK - 1.2 MG
			9/1/2004	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			9/30/2004	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			11/2/2004	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			3/14/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			4/11/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			5/6/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			6/8/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			7/18/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			8/17/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			10/10/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			11/14/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			12/15/2005	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG
			1/19/2006	00013265702 = GENOTROPIN MINIQUICK - 1.8 MG

Patient: This information is from the Encrypted RID number.
Diagnosis Date and Diagnosis: These show the diagnosis for the patient and the date the diagnosis was made.
NCD Code: This code identifies the drug and the drug dosage.

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 2 [7RS3KV2HSOUISWA10D]	7/17/2002	Short Stature (783.43)		
			7/31/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			8/29/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	9/13/2002	Short Stature (783.43)		
			9/26/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			10/28/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	11/18/2002	Short Stature (783.43)		
			11/21/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	2/17/2003	Short Stature (783.43)		
			2/17/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			3/10/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			4/16/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			5/19/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			6/9/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			7/14/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			8/15/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	8/18/2003	Short Stature (783.43)		
			9/5/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			10/13/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			11/10/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			12/8/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			1/5/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			2/9/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			3/8/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			4/12/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			5/7/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			6/14/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 3	1/10/2002	Short Stature (783.43)		
[7RS4NUIOPPV4ACFTVY]	4/24/2002	Short Stature (783.43)		
	7/18/2002	Short Stature (783.43)		
			7/18/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	8/14/2002	Short Stature (783.43)		
			9/12/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			10/4/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	10/23/2002	Short Stature (783.43)		
			11/14/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			12/26/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			1/30/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			2/27/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			3/27/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	4/9/2003	Short Stature (783.43)		
			5/1/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	5/29/2003	Short Stature (783.43)		
			5/29/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			7/10/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			8/28/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			9/25/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	10/31/2003	Short Stature (783.43)		
	11/6/2003	Short Stature (783.43)		
			11/6/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			12/18/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			1/15/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			2/27/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	4/1/2004	Short Stature (783.43)		
			4/1/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			5/20/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			6/10/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			7/1/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 4	8/31/2001	Short Stature (783.43)		
[7RS86BC4V6RCY1DWYA]			9/19/2001	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	11/2/2001	Short Stature (783.43)		
			11/5/2001	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			12/4/2001	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			3/8/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			4/24/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
	5/17/2002	Short Stature (783.43)		
			6/6/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			7/10/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			8/28/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			10/10/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			11/13/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			12/12/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			1/15/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			2/12/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			3/12/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			5/14/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
Patient No. 5	9/18/2001	Short Stature (783.43)		
[7RS86BD7IU9DBDGRTW]	11/6/2001	Short Stature (783.43)		
			11/16/2001	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			12/16/2001	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			1/16/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			3/1/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
	3/18/2002	Short Stature (783.43)		
			4/1/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			4/30/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			5/30/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			8/16/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			11/1/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 6	7/19/2002	Short Stature (783.43)		
[7RSD5B46V2GQUYB91C]			1/15/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			2/14/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			3/10/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			4/25/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			5/22/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			6/30/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			7/31/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			9/23/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			10/23/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			12/1/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			12/31/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			1/14/2004	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			2/18/2004	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
Patient No. 7	5/8/2001	Short Stature (783.43)		
[7RSD5TNV1FIYMQTFG7]			7/1/2001	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			7/31/2001	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			8/21/2001	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			9/18/2001	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
	10/3/2002	Short Stature (783.43)		
			10/18/2001	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			10/6/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			10/29/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			11/30/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			12/10/2002	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			1/13/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			2/10/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			3/12/2003	00013264681 = GENOTROPIN 13.8 MG CARTRIDG

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 8	9/25/2003	Short Stature (783.43)		
[7RSIQ9HMPIMPVZ0ZA0]	9/29/2003	Short Stature (783.43)		
	2/25/2004	Short Stature (783.43)		
	8/11/2004	Short Stature (783.43)		
	9/13/2004	Short Stature (783.43)		
	11/8/2004	Short Stature (783.43)		
	2/9/2005	Short Stature (783.43)		
			3/8/2005	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			4/6/2005	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			5/6/2005	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
			6/6/2005	00013264681 = GENOTROPIN 13.8 MG CARTRIDG
Patient No. 9	11/24/2003	Short Stature (783.43)		
[7RSIQ9HMWGJ6ILPHIK]			12/29/2003	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			1/23/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			2/27/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			3/19/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			4/23/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			7/6/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			7/23/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			10/22/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDG
			1/13/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			2/15/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			2/24/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			3/4/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			3/14/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			3/21/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			3/29/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			4/12/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			4/21/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			4/26/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			5/3/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			5/9/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			5/17/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			5/31/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			6/16/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			7/6/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			7/13/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG
			8/1/2005	00013265802 = GENOTROPIN MINIQUICK 2 MG

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 10	5/16/2001	Short Stature (783.43)		
[7RSIQGPX1B36PT9BCE]	6/28/2001	Short Stature (783.43)		
	1/30/2002	Short Stature (783.43)		
			3/7/2002	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
			4/4/2002	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
			5/1/2002	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
			5/29/2002	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
Patient No. 11	9/15/2004	Short Stature (783.43)		
[7RSIQTEI6IM9HJS84I]	9/27/2004	Short Stature (783.43)		
	10/27/2004	Short Stature (783.43)		
			11/18/2004	00013261694 = GENOTROPIN 5.8 MG CARTRIDGE
			12/16/2004	00013261694 = GENOTROPIN 5.8 MG CARTRIDGE
	1/27/2005	Short Stature (783.43)		
			2/1/2005	00013261694 = GENOTROPIN 5.8 MG CARTRIDGE
			3/8/2005	00013261694 = GENOTROPIN 5.8 MG CARTRIDGE
			4/11/2005	00013261694 = GENOTROPIN 5.8 MG CARTRIDGE
	4/25/2005	Short Stature (783.43)		
Patient No. 12	11/19/2004	Short Stature (783.43)		
[7RSJSVFJWJOTEG5MOR]			11/19/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			12/18/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			1/15/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
	2/12/2005	Short Stature (783.43)		
			2/12/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			6/17/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
	7/15/2005	Short Stature (783.43)		
			7/15/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			8/26/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
Patient No. 13	10/12/2004	Short Stature (783.43)		
[7RSLU20GMY0CD8J6NQ]	12/8/2004	Short Stature (783.43)		
	12/13/2004	Short Stature (783.43)		
			2/3/2005	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
	2/11/2005	Short Stature (783.43)		
			2/25/2005	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
			3/23/2005	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
			4/14/2005	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE
			5/9/2005	00013262681 = GENOTROPIN 5.8 MG CARTRIDGE

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 14	5/21/2001	Short Stature (783.43)		
[7RSLUV5PWD4NGIKLMP]			7/26/2001	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			8/20/2001	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			8/30/2001	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
	11/19/2001	Short Stature (783.43)		
	3/21/2002	Short Stature (783.43)		
			3/21/2002	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
Patient No. 15	10/30/2002	Short Stature (783.43)		
[7RSMW2EIUMSFTX0ZA0]			1/14/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			2/12/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			3/11/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
	8/27/2004	Short Stature (783.43)		
			9/21/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			10/14/2004	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
	1/3/2005	Short Stature (783.43)		
			1/20/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			2/17/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			3/10/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			4/15/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			6/2/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			7/5/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			8/24/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE
			9/21/2005	00013264694 = GENOTROPIN 13.8 MG CARTRIDGE

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 16	12/13/2001	Short Stature (783.43)		
[7RSMWA35XKPDBDHPRU]	7/3/2002	Short Stature (783.43)		
	7/5/2002	Short Stature (783.43)		
			7/5/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			8/5/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	9/3/2002	Short Stature (783.43)		
			9/3/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			10/7/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			11/4/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			11/5/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	12/2/2002	Short Stature (783.43)		
			12/4/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			12/19/2002	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	1/6/2003	Short Stature (783.43)		
			1/6/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			1/21/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			2/3/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			2/18/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	3/3/2003	Short Stature (783.43)		
			3/3/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			3/17/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			4/14/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			4/21/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			5/9/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	6/2/2003	Short Stature (783.43)		
			6/2/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			7/7/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			8/4/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	9/5/2003	Short Stature (783.43)		
			9/5/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			10/7/2003	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	1/5/2004	Short Stature (783.43)		
			1/5/2004	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			2/6/2004	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			3/1/2004	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	3/29/2004	Short Stature (783.43)		
			3/29/2004	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
	5/13/2005	Short Stature (783.43)		
			5/13/2005	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE
			6/7/2005	00013262694 = GENOTROPIN 5.8 MG CARTRIDGE

Patient	Diagnosis Date	Diagnosis (Code)	Dispense Date	NCD Code (Drug and Dosage)
Patient No. 17	4/6/2001	Short Stature (783.43)		
[7RSMWBC4PIMYHJPHIK]	2/15/2002	Short Stature (783.43)		
	3/8/2002	Short Stature (783.43)		
	6/21/2002	Short Stature (783.43)		
			11/12/2002	00013265002 = GENOTROPIN MINIQUICK 0.4 MG
			12/9/2002	00013265002 = GENOTROPIN MINIQUICK 0.4 MG
			1/9/2003	00013265002 = GENOTROPIN MINIQUICK 0.4 MG
			2/4/2003	00013265002 = GENOTROPIN MINIQUICK 0.4 MG
	2/21/2003	Short Stature (783.43)		
			3/11/2003	00013265102 = GENOTROPIN MINIQUICK 0.6 MG
			4/10/2003	00013265102 = GENOTROPIN MINIQUICK 0.6 MG
			5/8/2003	00013265102 = GENOTROPIN MINIQUICK 0.6 MG
			6/2/2003	00013265102 = GENOTROPIN MINIQUICK 0.6 MG
	10/17/2003	Short Stature (783.43)		
			10/28/2003	00013265102 = GENOTROPIN MINIQUICK 0.6 MG