

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

----- X
THE PEOPLE OF THE STATE OF NEW YORK, :
by ELIOT SPITZER, Attorney General of the :
State of New York, :
:
Plaintiffs, :
:
- against - :
:
GLAXOSMITHKLINE, P.L.C., :
d/b/a/ GlaxoSmithKline, :
:
GLAXO WELLCOME, INC., :
d/b/a/ GlaxoSmithKline, :
:
SMITHKLINE BEECHAM CORPORATION, :
d/b/a/ GlaxoSmithKline, :
:
Defendants. :

COMPLAINT
Index No.

----- X
TO: THE SUPREME COURT OF THE STATE OF NEW YORK

The People of the State of New York, by their attorney, Eliot Spitzer, Attorney General of the State of New York, allege the following upon information and belief:

PRELIMINARY STATEMENT

1. GlaxoSmithKline, P.L.C., Glaxo Wellcome, Inc. and SmithKline Beecham Corporation (all doing business as GlaxoSmithKline and collectively “GSK”), a pharmaceutical manufacturer with net earnings for 2001 of over \$4.5 billion, makes fraudulent and deceptive misrepresentations that conceal the true average wholesale price of its drugs from consumers, government agencies, and drug price reporting services. Government health plans, such as Medicare, Medicaid and EPIC (Elderly Pharmaceutical Insurance Coverage Program), base reimbursement for covered drugs in large measure

on the average wholesale price. Consumers pay a coinsurance or copayment for drugs reimbursed by Medicare, Medicaid and EPIC. As a result of GSK's misrepresentations, doctors and other healthcare providers are improperly induced to prescribe GSK's drugs and government payers and consumers, including the elderly and the catastrophically ill, pay artificially inflated sums for chemotherapy and other drugs.

2. The Attorney General of the State of New York brings this action to stop GSK's illegal and deceptive actions and to obtain restitution for the consumers and state government agencies defrauded by GSK.

JURISDICTION AND PARTIES

3. Eliot Spitzer is the Attorney General of the State of New York. He is authorized: to institute all actions and proceedings in which the State is interested, N.Y. Executive Law § 63(1); to seek an order that enjoins repeated or persistent fraudulent or illegal business acts or practices and awards damages and restitution for such acts, N.Y. Executive Law § 63(12); to bring an action to enjoin deceptive acts or practices in the conduct of business and to obtain restitution and civil penalties, including additional civil penalties for fraud perpetrated against the elderly, N.Y. General Business Law ("GBL") §§ 349, 349-c, 350-d; and to recover treble damages for overpayments of public funds obtained by means of false statements or other fraudulent schemes, N.Y. Social Services Law § 145-b(2).

4. GlaxoSmithKline, P.L.C. is a public limited company organized under the laws of England and Wales. GlaxoSmithKline, P.L.C. was formed by the merger of Glaxo Wellcome, P.L.C. and SmithKline Beecham, P.L.C., both of which were organized under the laws of England and Wales. Glaxo Wellcome, Inc. is a North Carolina corporation, and SmithKline Beecham Corporation is a

Delaware corporation, both of which are wholly owned subsidiaries of GlaxoSmithKline, P.L.C. (Defendant GlaxoSmithKline, P.L.C. includes all of its predecessors and its past and current components, which are collectively referred to as “GSK.”) GSK regularly conducts business within the State of New York and derives substantial revenues from goods consumed in New York.

5. The Attorney General provided GSK with the pre-litigation notice required by GBL §§ 349(c) and 350-c, a copy of which is annexed as Exhibit A.

FACTUAL ALLEGATIONS

I. Government Health Plans

A. THE MEDICARE PROGRAM

6. Medicare is a health insurance program created by the federal government for the elderly and disabled. 42 U.S.C. §§ 1395, et seq. Individuals become eligible for Medicare health insurance benefits when they turn 65 years of age or become disabled. The vast majority of Medicare beneficiaries are 65 years of age or over. There are two major components of the Medicare Program: Part A and Part B.

7. Medicare Part A is financed by a dedicated federal payroll tax, premiums paid by beneficiaries and general federal tax revenues. It pays for inpatient hospital, skilled nursing, hospice and some home healthcare services for eligible recipients. 42 U.S.C. §§ 1395e through 1395i-5. Medicare Part A pays for prescription drugs only if they are administered on an inpatient basis in a hospital or similar setting.

8. Medicare Part B is an optional program that provides coverage for some healthcare services not covered by Part A. 42 U.S.C. §§ 1395j through 1395w-4. Medicare Part B is supported

by government funds and premiums paid by eligible individuals who choose to participate in the program.

9. Medicare Part B pays for a few categories of prescription drugs administered outside a hospital setting, including those administered by injection or infusion by physicians and their staff in the doctor's office and other outpatient settings or by other specified healthcare providers at other sites (collectively "physician-administered drugs"); some orally administered anti-cancer chemotherapy drugs and anti-emetics, which control the vomiting and nausea caused by such chemotherapy agents; and drugs administered through durable medical equipment such as a nebulizer (collectively "Part B-covered" drugs). 42 U.S.C. §§ 1395k(a), 1395x(s)(2); 42 C.F.R. § 405.517. Anti-cancer chemotherapy drugs and anti-emetics are the dominant types of physician-administered drugs covered by Part B.

10. For drugs covered by Part B, the healthcare provider or pharmacist receives the lower of the charge the healthcare provider or pharmacist actually bills Medicare or 95 percent of the drug's average wholesale price. Medicare pays eighty percent of this amount, and the beneficiary is responsible for 20 percent as a coinsurance payment. 42 U.S.C. §§ 1395u(o), 1395l(a).

B. THE MEDICAID PROGRAM

11. The Medicaid Program is a program jointly funded by the federal, state and county government that is administered by the state. It pays for prescription drugs, whether administered by physicians or dispensed by pharmacies, as well as other healthcare services, for low income persons, including individuals who work and children in government custody as foster children. Medicaid recipients pay a copayment for covered drugs, the amount of which depends on the cost of the drugs.

12. Reimbursement to pharmacists for drugs dispensed under the Medicaid Program generally is limited to the lower of the “[e]stimated acquisition costs plus reasonable dispensing fees” or the “[p]roviders' usual and customary charges to the general public.” 42 C.F.R. § 447.331. In New York State, Social Services Law § 367-a defines “estimated acquisition cost” as “the average wholesale price of a prescription drug...as reported by the prescription drug pricing service used by the department, less ten percent thereof...” for drugs that have no Federal Upper Limit.¹

C. THE EPIC PROGRAM

13. EPIC is a voluntary New York State-funded and state-administered program that provides prescription drug coverage to lower income consumers who are 65 years of age or older and are not eligible for full Medicaid coverage. It covers prescription drugs dispensed by pharmacies. Individuals who choose to participate in the program must pay a fee or satisfy an annual deductible based on income, as well as a copayment for each drug purchase based on the price charged for the drug. A participant’s copayments for the year are subject to an upper limit based on the participant’s income.

14. For drugs for which no Federal Upper Limit has been established or that cannot be replaced by a generic for a particular patient, EPIC reimburses the dispensing pharmacy at the lower of 90 percent (95 percent before 2002) of average wholesale price or the pharmacy’s usual and customary charge to the general public. N.Y. Exec. Law § 547-j(1)(b).

¹A Federal Upper Limit limits the amount that a Medicaid Program can pay for some generic drugs. The “Federal Upper Limit” is defined at 42 C.F.R. § 447.332 as “150 percent of the published price for the least costly therapeutic equivalent.”

II. GSK's Fraud and Deception Improperly Increase the Cost of Drugs to Medicare Beneficiaries, Medicaid Recipients, EPIC Participants and the State of New York.

15. At least quarterly, GSK reports an amount as the wholesale acquisition cost (the price a wholesaler, distributor or other middleman pays GSK) for each of its prescription drugs by transmitting this information to national drug price publishing services (collectively "price reporting services"). The price reporting services add a standard markup to the wholesale acquisition cost GSK provides, and they report that amount as the drug's "average wholesale price" (the price a physician or pharmacist pays a middleman).

16. These average wholesale prices are reported in generally available compendia published by the price reporting services, other than *First DataBank*. *First DataBank*, which merged with and succeeded Medispan, Inc. (Medispan and *First DataBank, Inc.* are collectively referred to as "*First DataBank*"), reports these average wholesale prices in a computer file which it sends to the New York Department of Health.

17. Prior to the creation of GSK in 2001, its predecessor companies reported amounts to the price reporting services, using various labels, that either were average wholesale price or its equivalent, which the price reporting services reported as "average wholesale price," or were another measure of cost or price that the price reporting services used as the basis for determining the average wholesale price that they reported for GSK's drugs. (Throughout this complaint, the term "wholesale acquisition cost," when used to refer to the pricing/cost information GSK transmits to price reporting services, includes the measurements and terms GSK's predecessors and their and GSK's subsidiaries have used or continue to use for this purpose.)

18. GSK knows of and relies on the price reporting services' use of the wholesale acquisition costs GSK provides to them in determining the average wholesale prices that they report.

A. MEDICARE

19. Medicare Part B imposes no legal duties on GSK, but GSK manipulates the Program's reimbursement system to defraud New York Medicare beneficiaries.

20. The "average wholesale price," as published in the price reporting services, is virtually the only information used to determine the amount Medicare will pay a New York Medicare provider or pharmacist for a Part B-covered drug. This has been true for over a decade, and GSK knows of and relies on this practice.

21. Both directly and through middlemen, GSK sells its Part B-covered drugs to physicians, other healthcare providers and pharmacists. GSK knows the prices middlemen pay for its drugs and the amount these middlemen charge providers and pharmacists for GSK's drugs.

22. The amount GSK transmits to the price reporting services as the wholesale acquisition cost of each of its Part B-covered drugs, which is the basis for the drug's reported average wholesale price, is greatly inflated and bears no relationship either to the price middlemen pay GSK or to the price physicians, other healthcare providers and pharmacists actually pay to purchase these drugs. GSK knowingly reports these false, misleading and deceptive amounts which it knows will be used to determine a false, misleading and deceptive average wholesale price.

23. Physicians, other healthcare providers and pharmacists are routinely reimbursed by Medicare for GSK's Part B-covered drugs in an amount equal to 95 percent of the drug's fraudulently inflated average wholesale price, and GSK is aware of this fact.

24. The difference between the amount a physician, other healthcare provider or pharmacist pays for a drug and the amount Medicare (or other healthcare program) reimburses for that drug is profit to the provider. These profits can be enormous when the provider selects one of GSK's drugs. In the pharmaceutical industry, this guaranteed profit is referred to as the "spread."

25. The following are examples of the spreads GSK created when, in providing information to the price reporting services, it misrepresented and concealed the wholesale acquisition cost, and therefore the average wholesale price, of its Part B-covered drugs: 72 percent for Albuterol sulfate (GSK's brand name is Ventolin[®]), in the form administered through a nebulizer to treat breathing difficulties caused by asthma, chronic bronchitis, emphysema, and other lung diseases; 25 percent for Granisetron HCl (SmithKline Beecham Corporation's brand name was Kytril[®]), an anti-emetic used to treat the nausea and vomiting caused by anticancer chemotherapy agents (GSK divested itself of all rights to Kytril[®] as a condition for the merger that created GSK); 15 percent for Vinorelbine Tartrate (GSK's brand name is Navelbine[®]), used to treat types of lung, breast and ovarian cancer; 11 percent for Topotecan (GSK's brand name is Hycamtin[®]), a chemotherapy agent used to treat ovarian cancer; and nine percent for Ondansetron HCl (GSK's brand name is Zofran[®]), which like Kytril[®] is an anti-emetic used in conjunction with anticancer chemotherapy. These spreads were calculated based on middlemen's catalog prices, but under terms negotiated with or on behalf of GSK, physicians, other healthcare providers and pharmacists actually pay middlemen far less than their catalog prices for some drugs. In just one year, the total overcharge to Medicare for GSK's Zofran[®], Navelbine[®] and Hycamtin[®] and for SmithKline Beecham's Kytril[®] was \$23.8 million.

26. GSK maintains or increases the sales volume for its Part B-covered drugs by actively marketing the spread to doctors and pharmacists. GSK encourages New York physicians, other New York healthcare providers and New York pharmacists to select GSK drugs by informing them of the amount of profit they can reap if they administer or dispense the Defendants' drugs, a profit the Defendants can guarantee the doctor or pharmacist because Medicare pays for the drugs based on GSK's deceptive reporting of the information used to calculate average wholesale price. GSK advises New York physicians, other New York healthcare providers and New York pharmacists about the availability of this artificially inflated and guaranteed profit.

27. GSK benefits from the fraudulent and deceptive misrepresentations it makes to the price reporting services that inflate its Part B-covered drugs' wholesale acquisition costs and consequently the value of their average wholesale prices.

B. MEDICAID

28. As GSK has known for years, the New York Medicaid Program reimburses pharmacist-dispensed drugs for which no Federal Upper Limit has been set exclusively on the basis of the average wholesale price reported in *First DataBank*. Thus, by reporting to *First DataBank* false and fraudulently inflated wholesale acquisition costs for its products, which GSK knows will be converted to average wholesale prices, GSK controls the reimbursement amount paid by Medicaid for these drugs, irrespective of any change in their market prices.

29. As a result, GSK deceptively causes the State to pay more for these drugs than is permitted by law.

30. GSK fraudulently creates and markets the spread on its drugs to New York pharmacists who are Medicaid providers. GSK does this to induce pharmacists to recommend

GSK drugs to Medicaid recipients and their physicians, to purchase more of its drugs, and to bill those drugs to Medicaid. GSK thereby offers reimbursement that it has enhanced through its fraudulent acts as the quid pro quo for recommending GSK drugs and, together with those providers who accept this offer, intentionally causes Medicaid to pay the falsely overstated prices. The amount of the spread on GSK's drugs has not been disclosed to the State and to Medicaid recipients who purchase such drugs, and it has not been reflected in claims for Medicaid reimbursement.

C. EPIC

31. The Department of Health sets reimbursement for drugs covered by EPIC using information from *First DataBank*. By reporting false and fraudulently inflated wholesale acquisition costs to *First DataBank*, which are the basis for its determination of average wholesale prices, GSK knowingly causes the EPIC Program to pay excessive amounts for covered drugs for which no Federal Upper Limit had been set.

32. GSK manipulates and markets the spread on its EPIC-covered drugs to New York pharmacies by informing them of the increased and guaranteed profits available for dispensing GSK's drugs. By doing this, GSK increases or maintains its sales of these drugs.

D. INJURY TO CONSUMERS AND THE STATE

33. New York Medicare beneficiaries, Medicaid recipients and EPIC participants spend far more than their statutory share of the unmanipulated average wholesale price of GSK's drugs. For example, in many cases the Medicare beneficiary's coinsurance payment is significantly greater than 20 percent of the bona fide average wholesale price.

34. GSK knows that Medicare beneficiaries are responsible for 20 percent of the amount Medicare allows for a Part B-covered drug and that Medicaid recipients and EPIC participants are responsible for a copayment based on the amount the government healthcare program allows for the purchased drug. GSK also knows that Medicare beneficiaries, Medicaid recipients and EPIC participants suffer significant economic injuries as a consequence of the Defendants' deceptive reporting of false wholesale acquisition costs as the basis for determining false average wholesale prices.

35. GSK's fraudulent misrepresentations that conceal the average wholesale price of its drugs deceive, and have the potential to deceive, New York Medicare beneficiaries, Medicaid recipients and EPIC participants into believing they are paying the legally permitted amount for the drugs covered by these government healthcare programs.

36. In New York, physicians have fiduciary obligations to their patients, including the duty to use their independent professional judgment in making treatment decisions and not to accept any consideration to alter that judgment. GSK creates and markets the spread on its prescription drugs to New York doctors without the consent or knowledge of their patients and with the intent to influence the physicians' choice of drugs to administer or prescribe to their patients.

37. Persons 65 years of age and older comprise the vast majority of Medicare beneficiaries, many Medicaid recipients and all of the EPIC participants, and GSK knows this. The nature and severity of the illnesses that require the use of drugs covered by Part B, Medicaid and EPIC, as well as the consumers' age, render the victims of the Defendants' fraud and deception especially vulnerable. Medicare beneficiaries, Medicaid recipients and EPIC participants who are

65 years of age or older have suffered economic damages as a result of GSK's fraud and deception.

38. GSK has knowingly made false statements and representations concerning the wholesale acquisition cost of its Medicaid- and EPIC-covered drugs on behalf of New York pharmacists, and has fraudulently engaged in marketing the spread on these drugs, resulting in the overpayment of public funds for GSK's prescription drugs covered by the New York Medicaid Program or EPIC.

FIRST CAUSE OF ACTION
DECEPTIVE ACTS AND PRACTICES

39. GBL § 349 provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York] are ... unlawful."

40. By engaging in the acts and practices described above, GSK has engaged in and continues to engage in deceptive business practices in violation of GBL § 349.

SECOND CAUSE OF ACTION
REPEATED AND PERSISTENT FRAUD

41. Executive Law § 63(12) makes "repeated fraudulent ... acts or ... persistent fraud ... in the carrying on, conducting or transaction of business" actionable by the Attorney General.

42. By engaging in the acts and practices described above, GSK has engaged in and continues to engage in repeated fraudulent acts or persistent fraud in violation of Executive Law § 63(12).

THIRD CAUSE OF ACTION
REPEATED AND PERSISTENT ILLEGAL CONDUCT:
COMMERCIAL BRIBERY

43. Penal Law § 180.00 provides that “a person is guilty of commercial bribing in the second degree when he confers, or offers or agrees to confer, any benefit upon any ... fiduciary without the consent of the latter’s ... principal, with intent to influence his conduct in relation to his ... principal’s affairs.”

44. By engaging in the acts and practices described above, GSK has engaged in and continues to engage in commercial bribing in the second degree in violation of New York Penal Law § 180.00.

45. Defendants' violations of Penal Law § 180.00 constitute repeated and persistent illegal conduct in violation of Executive Law § 63(12).

FOURTH CAUSE OF ACTION
REPEATED AND PERSISTENT ILLEGAL CONDUCT:
MEDICAID KICKBACKS AND FRAUD

46. The Regulations of the New York Department of Health, 18 N.Y.C.R.R. § 515.2(b)(5) provide that, “[u]nless the discount or reduction in price is disclosed to the client and the department and reflected in a claim,” an “Unacceptable Practice” within the New York Medicaid Program is committed by “offering or paying either directly or indirectly any payment (including any kickback, bribe, ... rebate or discount), whether in cash or in kind, in return for purchasing, ... ordering or recommending any medical care, services or supplies for which payment is claimed under the program.”

47. By engaging in the acts and practices described above, GSK has engaged in and continues to engage in Unacceptable Practices within the New York Medicaid Program as defined at 18 N.Y.C.R.R. § 515.2(b)(5).

48. Defendants' violations of 18 N.Y.C.R.R. § 515.2(b)(5) constitute repeated and persistent illegal conduct in violation of Executive Law § 63(12).

FIFTH CAUSE OF ACTION
REPEATED AND PERSISTENT ILLEGAL CONDUCT:
OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS

49. Social Services Law § 145-b provides that “[i]t shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for ... supplies furnished ... pursuant to” the Medicaid Program or EPIC.

50. By engaging in the acts and practices described above, GSK has knowingly made false statements and representations or engaged in a fraudulent scheme on behalf of New York pharmacists, resulting in the overpayment of public funds for GSK’s prescription drugs covered by the New York Medicaid Program or EPIC in violation of Social Services Law § 145-b.

51. Defendants' violations of Social Services Law § 145-b constitute repeated and persistent illegal conduct in violation of Executive Law § 63(12).

PRAYER FOR RELIEF

WHEREFORE, the People of the State of New York respectfully request that a judgment and order be entered that:

- A. Permanently enjoins GSK from engaging in the deceptive, fraudulent and unlawful practices alleged herein;
- B. Directs GSK to pay restitution and damages to all aggrieved consumers, including those not known at the time the order is entered;
- C. Directs GSK to pay a civil penalty of \$500 to the State of New York pursuant to GBL § 350-d for each instance of a deceptive or unlawful act or practice that violates GBL Article 22-A;
- D. Directs GSK to pay an additional civil penalty of \$10,000 to the State of New York pursuant to GBL § 349-c for fraud committed against the elderly;
- E. Directs GSK to pay restitution and damages to the State of New York based on GSK's fraudulent, deceptive and illegal practices, for the economic injuries suffered by the New York Medicaid and EPIC programs;
- F. Directs GSK to pay to the State of New York damages equal to three times the amount by which the State or any political subdivision, based on GSK's false statement or representation or other fraudulent scheme, overpaid public funds for GSK's prescription drugs under the New York Medicaid or EPIC program;
- G. Awards Plaintiffs costs, including additional costs in the amount of \$2,000 pursuant to C.P.L.R. § 8303(a)(6); and
- H. Grants all other relief that is just and proper.

Dated: New York, New York
February 13, 2003

Respectfully submitted,

ELIOT SPITZER
Attorney General of the
State of New York
Attorney for Plaintiffs
By:

Rose E. Firestein
Assistant Attorney General
Bureau of Consumer Frauds and Protection
120 Broadway, 3rd Floor
New York, New York 10271
(212) 416-8306

MATTHEW BARBARO
CAROL BEYERS
PATRICK LUPINETTI
DAVID SHARPE
SHIRLEY STARK

Assistant Attorneys General
of Counsel