

**MDL No. 1456**  
**Master File No. 01-12257-PBS**  
**(Original Central District of California**  
**No. 03-CV-2238)**  
**Judge Patti B. Saris**  
**JURY TRIAL REQUESTED**

INGELHEIM PHARMACEUTICALS INC.;	)
BRISTOL-MYERS SQUIBB COMPANY	)
a/k/a BRISTOL-MYERS ONCOLOGY	)
DIVISION/HIV PRODUCTS; C.H.	)
BOEHRINGER SOHN	)
GRUNDSTUCKSVERWALTUNG GMBH &	)
CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.;	)
GENEVA PHARMACEUTICALS INC.;	)
GENSIA INC.; GENSIA SICOR, INC.;	)
GLAXO WELLCOME INC. f/k/a	)
BURROUGHS WELLCOME CO.;	)
GLAXOSMITHKLINE PLC; HOECHST	)
MARION ROUSSEL, INC.; IMMUNEX	)
CORP.; LIPHA, S.A.; McGAW, INC.;	)
MERCK KGaA; MYLAN LABORATORIES,	)
INC.; MYLAN PHARMACEUTICALS,	)
INC.; NOVARTIS AG; PHARMA	)
INVESTMENT, LTD.; ROXANE	)
LABORATORIES, INC.; SANDOZ, INC.;	)
SCHERING-PLOUGH CORP.; SICOR, INC.	)
f/k/a GENSIA PHARMACEUTICALS, INC.;	)
SMITHKLINE BEECHAM CORPORATION	)
d/b/a GLAXOSMITHKLINE; TEVA	)
PHARMACEUTICAL INDUSTRIES, LTD.;	)
WARRICK PHARMACEUTICALS CORP.;	)
Z.L.B. BEHRING,	)
	)
Defendants.	)
	)

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**FIRST AMENDED COMPLAINT IN INTERVENTION**  
**FOR MONEY DAMAGES AND CIVIL PENALTIES**  
**FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT**

(California Government Code, §§ 12650 *et seq.*)

## TABLE OF CONTENTS

I.	<u>INTRODUCTION AND OVERVIEW OF THE SCHEME</u> .....	1
II.	<u>THE PARTIES</u> .....	1
III.	<u>JURISDICTION &amp; VENUE</u> .....	10
IV.	<u>BACKGROUND OF HOW PRESCRIPTION DRUG CLAIMS ARE PAID UNDER MEDI-CAL</u> .....	10
A.	<u>HOW THE SYSTEM WORKS IN CALIFORNIA</u> .....	10
V.	<u>SUMMARY OF DEFENDANTS' FRAUDULENT SCHEME</u> .....	15
VI.	<u>THE ACTIONABLE CONDUCT OF DEFENDANTS</u> .....	17
A.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT ABBOTT</u> .....	17
B.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT ARMOUR-BEHRING</u> ...	19
C.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT BAXTER</u> .....	20
D.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT BEDFORD</u> .....	22
E.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT BRISTOL-MYERS</u> .....	23
F.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT DEY</u> .....	26
G.	<u>SPECIFIC ALLEGATIONS AS TO GENEVA/SANDOZ</u> .....	28
H.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT GLAXO</u> .....	30
I.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT HOECHST/AVENTIS</u> ...	33
J.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT IMMUNEX</u> .....	34
K.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT McGAW</u> .....	37
L.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT MYLAN</u> .....	38
M.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT NOVARTIS/SANDOZ</u> ..	40
N.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT ROXANE</u> .....	41
O.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT SICOR</u> .....	43
P.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT SMITHKLINE</u> .....	46
Q.	<u>SPECIFIC ALLEGATIONS AS TO DEFENDANT WARRICK</u> .....	52
VII.	<u>CALIFORNIA LAW VIOLATED BY DEFENDANTS</u> .....	54

VIII.	<u>CAUSES OF ACTION AND DAMAGES</u>	55
	<u>FIRST CAUSE OF ACTION</u>	55
	<u>SECOND CAUSE OF ACTION</u>	57
	<u>THIRD CAUSE OF ACTION</u>	58
	<u>FOURTH CAUSE OF ACTION</u>	59
	<u>FIFTH CAUSE OF ACTION</u>	61
IX.	<u>JURY DEMAND</u>	63
X.	<u>PRAYER FOR RELIEF</u>	63

Plaintiffs the STATE OF CALIFORNIA, by and through its Attorney General, Bill Lockyer, and VEN-A-CARE of the Florida Keys, by and through its principal officers and directors Zachary T. Bentley and T. Mark Jones, hereby allege as follows:

**I.**

**INTRODUCTION AND OVERVIEW OF THE SCHEME**

1. Defendants defrauded the Medicaid program of the STATE OF CALIFORNIA (known as “Medi-Cal”) by reporting excessively high and false prices for some of their prescription drugs with knowledge that Medi-Cal used these reported prices for establishing reimbursement to its Medi-Cal providers for these drugs. As a result, Medi-Cal sustained significant losses to its program by making reimbursement payments for the drugs at illegally excessive prices compared to the prices at which the Medi-Cal providers actually acquired the same drugs. This is a practice known in the industry as “creating a spread”. The spread is utilized by pharmaceutical companies to seize market share and thereby to fraudulently increase their profits. In this lawsuit, the Attorney General is demanding treble damages, civil penalties of up to \$10,000 for each false claim, and other relief provided by California’s *qui tam* law. The Qui Tam Plaintiff, VEN-A-CARE OF THE FLORIDA KEYS, INC. (“VAC” or “Relator”), originally provided information to the STATE OF CALIFORNIA which, along with information obtained by the STATE OF CALIFORNIA in the course of its independent investigation, is the basis for this action.

**II.**

**THE PARTIES**

2. The plaintiff in this action is the STATE OF CALIFORNIA (“State” or “California”) by and through the CALIFORNIA ATTORNEY GENERAL (“Attorney General”). At all times material to this action, the California Department of Health Services (“DHS”) was an agency of the State and administered the State’s Medi-Cal program, which paid benefits from a combination of State and Federal Government funds in an approximate 50/50 ratio. DHS provided Medi-Cal benefits to qualified recipients, which included payment of claims to providers for the Defendants’ prescription drugs specified in this First Amended Complaint in Intervention. These claims were paid based upon the false, inflated and illegal representations of

the cost of drug products made by Defendants.

3. The Qui Tam Plaintiff VEN-A-CARE OF THE FLORIDA KEYS, INC. (“Ven-A-Care” or “VAC”) is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. VAC originally filed this action. VAC is a pharmacy licensed to dispense prescription drugs and pharmaceutical products, such as the drugs specified in this First Amended Complaint in Intervention, including the Exhibits attached hereto. At all relevant times, VAC was a small infusion pharmacy and, for a significant period of time, a Medicaid provider in Florida. Prices available to VAC from Defendants for the pharmaceutical products in this First Amended Complaint in Intervention and the Exhibits attached hereto were available on a nationwide basis, including to California’s Medi-Cal providers. VAC’s drug acquisition costs, alleged in this First Amended Complaint in Intervention, are often higher than many of the other providers in the marketplace. VAC routinely acquired the drugs alleged herein through buying groups that are available to small pharmacies in the marketplace. Acquisition costs of large pharmacies would often be even lower, e.g., sometimes as much as 50% lower. Thus, VAC did not always receive the lowest prices available to certain volume purchasers. Accordingly, wherever VAC’s prices are used in this First Amended Complaint in Intervention or the Exhibits thereto to establish the generally and currently available drug prices in the market, they establish a minimum degree of falsity and damages.

4. Defendant ABBOTT LABORATORIES, INC. (“ABBOTT”) is a corporation organized under the laws of Illinois, with its principal offices located in the Abbott Park, Illinois. ABBOTT manufactures prescription medications for clinical distribution nationwide, and is one of the world’s largest pharmaceutical companies with reported annual revenues for the year 2003 of approximately \$19.68 billion and net earnings of \$ 2.75 billion. At all times material to this action, ABBOTT has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

5. Defendant ARMOUR PHARMACEUTICAL CO. (“ARMOUR”) is a corporation organized under the laws of Delaware, with its principal offices located in Phoenix, Arizona. At all times material to this action, ARMOUR has transacted business in California by, including

but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

6. In 2004 Defendant AVENTIS BEHRING, L.L.C. was acquired by C.S.L. LIMITED, a company headquartered in Melbourne, Australia, and thereafter C.S.L. LIMITED was known as Z.L.B. BEHRING. Defendant AVENTIS BEHRING, L.L.C. (formerly known as Centeon L.L.C. and referred to herein as “BEHRING”) is a limited liability company organized under the laws of Delaware, with its principal offices in King of Prussia, Pennsylvania. BEHRING was formed in 1996 through a joint venture of Defendant HOECHST MARION ROUSSEL, INC. and Rhone-Poulenc Rorer Pharmaceuticals, Inc. At all times material to this action, BEHRING has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California. For some of the time at issue in this First Amended Complaint in Intervention, Defendant ARMOUR was affiliated with Defendant BEHRING. BEHRING is ARMOUR’s successor-in-interest with respect to one or more of the specified drugs, and the allegations about the specified drugs of BEHRING and ARMOUR are presented together. The Defendants are collectively referred to as ARMOUR-BEHRING.

7. Defendant BAXTER HEALTHCARE CORP. (“BAXTER”) is a corporation organized under the laws of Delaware with its principal offices in Deerfield, Illinois. In 1997 BAXTER acquired Immuno International AG, a Swiss corporation, and is therefore its successor in interest. At all times material to this action, BAXTER transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

8. Defendant BOEHRINGER INGELHEIM CORP. and BOEHRINGER INGELHEIM PHARMACEUTICALS INC. are Nevada corporations with their principal place of business located in Ridgefield, Connecticut. BOEHRINGER is a United States subsidiary of Pharma Investment Limited of Burlington, Canada, which, in turn, is a division of C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG of Ingelheim, Germany, a German corporation with its principal United States offices in Ridgefield, Connecticut. Defendant BEN VENUE LABORATORIES, INC. (“BEN VENUE”) is a

corporation organized under the laws of Delaware, with its principal offices located in Bedford, Ohio. Defendant BEN VENUE was founded in 1938. In 1993, BEN VENUE created a separate division, called BEDFORD LABORATORIES (“BEDFORD”), to market and sell generic formulas. In December 1997, BEN VENUE was acquired by BOEHRINGER.

(BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BEN VENUE, and BEDFORD are collectively referred to herein as the “BEDFORD”).

At all times material to this action, BEDFORD transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

9. Defendant BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS (“BRISTOL-MYERS”) is a corporation organized under the laws of Delaware, with its principal offices located in New York, New York. At all times material to this action, BRISTOL-MYERS has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

10. Defendant DEY, L.P. (“DEY”) is a limited partnership organized under the laws of Delaware, with its principal offices located in Napa, California. Defendant DEY, INC., f /k/a Dey Laboratories, Inc., is a corporation organized under the laws of Delaware, with its principal offices located in Napa, California. DEY, INC. is the general partner of DEY, L.P. At all times material herein, all acts committed by or on behalf of DEY, INC. were also committed by or on behalf of DEY, L.P., together referred to as “DEY.” At all times material to this action, DEY has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California. Defendant EMD, INC. (“EMD”) is a corporation with headquarters in Durham, North Carolina, and is the sole shareholder of DEY. In 1998, DEY became a subsidiary of Defendant LIPHA S.A. based in Lyon, France. In 1991, Defendant MERCK KGaA acquired the majority share of LIPHA S.A. Defendant MERCK KGaA (“MERCK”) is a German company based in Darmstadt, Germany. To the extent that the acts of DEY referenced herein were performed by or attributable to EMD, LIPHA S.A., or MERCK, or



to any subsidiary or affiliate of any of these Defendants, then EMD, LIPHA S.A. or MERCK are therefore liable for such acts.

11. Defendant GENEVA PHARMACEUTICALS INC. ("GENEVA") was incorporated in 1991 under the laws of Colorado, with its principal offices in Plainsboro, New Jersey. On December 1, 2003, GENEVA was acquired by Defendant SANDOZ, INC. ("SANDOZ"), whose corporate headquarters are located in Princeton, New Jersey. In turn, SANDOZ is an affiliate of Defendant NOVARTIS AG ("NOVARTIS"), a Swiss corporation headquartered in Basel, Switzerland. Within the NOVARTIS family of companies, SANDOZ is a member of the Novartis Global Generics Sector whose headquarters are located in Vienna, Austria. The NOVARTIS family of companies, which now includes the Novartis Global Generics Sector, SANDOZ, and its predecessor GENEVA, had 2002 worldwide sales of \$20.9 billion and a net income of \$4.7 billion. GENEVA and its successor, SANDOZ, are hereinafter referred to as "GENEVA/SANDOZ". To the extent that the acts of GENEVA/SANDOZ referenced herein were performed by or attributable to NOVARTIS AG, Novartis Global Generics Sector, or to any subsidiary or affiliate of this defendant, then NOVARTIS AG, Novartis Global Generics Sector are therefore liable for such acts. At all times material to this civil action, GENEVA/SANDOZ has transacted business in California by its specified drugs being sold directly or indirectly through intermediaries, such as wholesalers, to purchasers within California.

12. Defendant GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO. ("GLAXO") was, until on or about March 31, 2001, a corporation organized under the laws of North Carolina, with its principal offices in Research Triangle Park, North Carolina. On or about October 31, 1995, GLAXO merged with its subsidiary, GLAXO WELLCOME INC. f/k/a/ GLAXO INC. ("GWI"), a corporation organized under the laws of North Carolina, with its principal offices in Research Triangle Park, North Carolina. GLAXO assumed all obligations of GWI. GLAXO and GWI sometimes transacted business through their CERENEX Pharmaceutical Division. GLAXO is named herein as a Defendant from the beginning of the relevant time period until the present. On or about March 31, 2001, GLAXO merged into Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE

("SMITHKLINE"). SMITHKLINE assumed all obligations of GLAXO. SMITHKLINE is properly named as a Defendant herein from the beginning of the relevant time period until the present, as a successor by merger with respect to GLAXO, and immediately after that time period until the present, as a Defendant in its own right. SMITHKLINE and GLAXO either became owned by, became part of, or formed Defendant GLAXOSMITHKLINE PLC, a foreign holding corporation, ("GLAXOSMITHKLINE"), which is incorporated under British law. GLAXOSMITHKLINE is properly named as a Defendant herein from the beginning of the relevant time period until March 31, 2001, as a successor by merger or otherwise with respect to both GLAXO and SMITHKLINE, and immediately after that time period until the present, as a Defendant in its own right. At all times material to this action, GLAXO, SMITHKLINE, and GLAXOSMITHKLINE transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California. GLAXO, SMITHKLINE, and GLAXOSMITHKLINE are collectively referred to as the "GLAXO DEFENDANTS."

13. Defendant HOECHST MARION ROUSSEL, INC. ("HOECHST") was, until on or about December 15, 1999, a corporation organized under the laws of Delaware, with its principal offices in Kansas City, Missouri. On or about December 15, 1999, HOECHST merged with Rhone-Poulenc Rorer Pharmaceuticals, Inc. to form Defendant AVENTIS PHARMACEUTICALS, INC. ("AVENTIS"), a Delaware corporation, with its headquarters in Parsippany, New Jersey. AVENTIS is properly named as a Defendant herein from the beginning of the relevant time period until December 15, 1999, as a successor by merger with respect to HOECHST, and immediately after that time period until the present, as a Defendant in its own right. HOECHST and AVENTIS are collectively referred to as "HOECHST/AVENTIS." At all times material to this action, HOECHST/AVENTIS transacted business in California by, including but not limited to, selling and distributing their prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

14. Defendant IMMUNEX CORP. ("IMMUNEX") a wholly owned subsidiary of Defendant AMGEN, INC., is a corporation organized under the laws of Delaware, with its principal offices in Seattle, Washington. AMGEN, INC. is a Delaware corporation with its

principal place of business in Thousand Oaks, California. Defendant AMGEN acquired IMMUNEX on or about June of 2000. (IMMUNEX and AMGEN will be referred to collectively as "IMMUNEX"). At all times material to this action, IMMUNEX has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

15. Defendant McGAW, INC. ("McGAW") was a Delaware corporation with its principal offices in Irvine, California. In 1997, McGAW, INC. was acquired by Defendants B. BRAUN OF AMERICA, INC. and its wholly owned subsidiary, B. BRAUN MEDICAL, INC., both Pennsylvania corporations with their principal offices located in Bethlehem, Pennsylvania. Defendants B. BRAUN OF AMERICA, INC. and B. BRAUN MEDICAL, INC. are part of a global organization, B. Braun Melsungen AG of Germany. Defendants McGAW INC., B. BRAUN OF AMERICA, INC. and B. BRAUN MEDICAL, INC. are referred to herein collectively as "McGAW." At all times material to this action, McGAW transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

16. Defendant MYLAN LABORATORIES, INC. is a corporation organized under the laws of Pennsylvania, with its principal offices in Canonsburg, Pennsylvania. Defendant MYLAN PHARMACEUTICALS, INC. is a corporation organized under the laws of West Virginia, with its principal offices located in Morgantown, West Virginia. MYLAN PHARMACEUTICALS, INC. is a wholly owned subsidiary and division of MYLAN LABORATORIES, INC. and the two Defendants are referred to collectively herein as "MYLAN." At all times material to this action, MYLAN has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

17. Defendant NOVARTIS AG is the parent of SANDOZ, INC. ("NOVARTIS/SANDOZ"). SANDOZ, INC. is a corporation organized under the laws of Delaware, with its principal offices in New Jersey. At all times material to this action,

NOVARTIS/SANDOZ has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California. To the extent the acts of NOVARTIS/SANDOZ referenced herein were performed by or attributable to NOVARTIS AG, or to any subsidiary or affiliate of any of these Defendants, then NOVARTIS AG is therefore liable for such acts.

18. Defendant ROXANE LABORATORIES, INC. (“ROXANE”) is a corporation organized under the laws of Delaware, with its principal offices located in Columbus, Ohio, and is a subsidiary of Defendant BOEHRINGER. To the extent that the acts of ROXANE at issue herein were performed by or otherwise attributable to BOEHRINGER, or any subsidiary or affiliate of it, then judgment should be entered against BOEHRINGER where appropriate. At all times material to this action, ROXANE has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

19. Defendant SICOR, INC. f/k/a GENSLIA PHARMACEUTICALS, INC.; GENSLIA INC.; GENSLIA SICOR, INC.; (“SICOR”) is a corporation organized under the laws of Delaware with its principal offices in Irvine, California. SICOR was founded in 1986 to discover, develop, manufacture and market pharmaceutical products, mostly relating to cardiovascular diseases. In 1997, GENSLIA and Rakepoll Finance merged and the corporate name was changed to GENSLIA SICOR, INC. The focus of this new merger is specialty pharmaceuticals. In 1999, GENSLIA SICOR, INC. officially changed its name to SICOR, INC. In 2003, TEVA PHARMACEUTICALS, LTD. acquired SICOR, INC. (GENSLIA, GENSLIA PHARMACEUTICALS, INC., GENSLIA SICOR, INC., SICOR, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD. will be collectively referred to as “SICOR.”) At all times material to this action, SICOR has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California.

20. Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE (“SMITHKLINE”) is a corporation organized under the laws of

Pennsylvania, with its principal offices in Philadelphia, Pennsylvania. SMITHKLINE is named as a Defendant from the beginning of the relevant time period through the present. On or about March 31, 2001, SMITHKLINE and GLAXO either became owned by, became part of, or formed Defendant GLAXOSMITHKLINE. GLAXOSMITHKLINE is properly named as a Defendant herein from the beginning of the relevant time period until March 31, 2001, as a successor by merger or otherwise with respect to both GLAXO and SMITHKLINE, and immediately after that time period until the present, as a Defendant in its own right. At all times material to this action, SMITHKLINE and GLAXOSMITHKLINE have transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California. SMITHKLINE and GLAXOSMITHKLINE are referred to collectively herein as the "SMITHKLINE DEFENDANTS."

21. Defendant WARRICK PHARMACEUTICALS CORP. ("WARRICK") is a corporation organized under the laws of Delaware, and WARRICK states that the company's principal offices are located in Reno, Nevada. At all times material to this action, WARRICK has transacted business in California by, including but not limited to, selling and distributing its prescription drugs, including those identified in this First Amended Complaint in Intervention, to purchasers within California. WARRICK is the generic marketing subsidiary of Defendant SCHERING-PLOUGH CORP. SCHERING-PLOUGH CORP. is a corporation organized under the laws of New Jersey, with its principal offices located in Kenilworth, New Jersey. To the extent that the acts of WARRICK referenced herein were performed by or attributable to SCHERING-PLOUGH CORP., or to any subsidiary or affiliate of this Defendant, then SCHERING-PLOUGH CORP. is therefore liable for such acts.

22. At all times relevant to this First Amended Complaint in Intervention each Defendant's prescription drug products were sold to Medi-Cal providers who dispensed them to Medi-Cal beneficiaries, filed claims for payment and were thereafter reimbursed by the Medi-Cal program for their cost of the drug product.

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### **III.**

#### **JURISDICTION & VENUE**

23. Jurisdiction is founded upon the California False Claims Act, California Government Code § 12652. This case was originally filed under seal on July 28, 1998.

24. Defendants have regularly transacted business in California by selling their drugs directly or through others throughout California, including Los Angeles County. Defendants knew their drugs would be supplied to Medi-Cal recipients throughout California, including those residing in Los Angeles County.

25. The Qui Tam Plaintiff commenced this action pursuant to California Government Code § 12652, and accordingly the Qui Tam Plaintiff is entitled to proceed as a co-plaintiff with California in this action in which the Attorney General of California has intervened.

### **IV.**

#### **BACKGROUND OF HOW PRESCRIPTION DRUG CLAIMS ARE PAID UNDER MEDI-CAL**

##### **A. HOW THE SYSTEM WORKS IN CALIFORNIA**

26. California routinely provides prescription drug coverage as part of its Medi-Cal program for medical assistance to the poor, needy, elderly and disabled. Included in that coverage are payments for drug products, including both single source drug products (brand name drugs) and multi-source drug products (generally generic drugs), that are delivered to the patient either by Medi-Cal providers including pharmacies and physicians incident to their services.

27. Medi-Cal reimburses providers for drugs from most manufacturers at what is called the Cost of the Drug Product (CDP), which is the lowest of the drug's Estimated Acquisition Cost (EAC), Federal Allowable Cost (FAC), or Maximum Allowable Ingredient Cost (MAIC) for the Standard Package size, or the amount billed by the provider. EAC for a drug product is the Direct Price (DP) or Average Wholesale Price (AWP) minus a determined percentage. (Cal. Code Reg. Title 22, § 51513 et seq.).

28. DP was used for defendant ABBOTT until on or about December 1, 2002.

29. For certain limited pharmaceutical therapies for the treatment of hemophilia,

commonly known as blood factors, Medi-Cal at some times reimbursed based upon the provider's invoice cost. The Defendant manufacturers, further caused the pricing information reported to Medi-Cal to be false and misleading for their products by providing off invoice financial inducements such as free goods and cash payments.

30. Providers' acquisition costs of a Defendant's drug is referred to herein as the "market price" of that drug. The difference between a drug's market price and the drugs' CDP is referred to in the industry and herein as the "spread."

31. The California term FAC means the price established for a generic drug by the Centers for Medicare & Medicaid Services (CMS, formerly the Health Care Financing Administration (HCFA)) of the Federal Department of Health and Human Services which price is referred to as Federal Upper Limit (FUL) by CMS. CMS establishes the FUL for some generic drugs based on the lowest price reported by a manufacturer to the price reporting services for a particular drug type. FAC and FUL are used interchangeably throughout the complaint.

32. The AWP, DP, and FUL are published in various price reporting services (also known as "compendia"), such as First DataBank (FDB), a Division of the Hearst Corporation. Medi-Cal uses FDB. The prices used to determine a FUL are the lowest published prices in the price reporting compendia, which are then multiplied by 150%.

33. Medi-Cal drug reimbursement rates at all times relevant to this First Amended Complaint in Intervention have been based on price data as published by FDB or other price reporting services. FDB gets this pricing information from the manufacturers of the various drugs, and then distributes it on a national basis.

34. The manufacturers control the prices that are reported by FDB. For example, FDB asserts that all pricing information is supplied and verified by the products' manufacturers, and that there is no independent review of those prices for accuracy. Dey sued FDB and another drug price reporting service, Medi-Span, in a complaint regarding drug price publishing policies. DEY's complaint describes the longstanding arrangement of FDB accepting and reporting manufacturers' prices without question, and its importance to the manufacturers, as follows:

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In each case, until the events that have resulted in the present crisis, First DataBank has (except for some inadvertent errors) selected for listing in its published reports the AWP as suggested by Dey. For over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First DataBank as AWP for Dey products in its databases.

Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey's knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

Dey, L.P. v. First Databank, Inc. et al., Napa, California Superior Court Case No. 26-21019; DEY Complaint, Paragraphs 32 and 37. The DEY complaint also refers to the testimony of an FDB representative who *admits* that FDB always accepted the AWP's provided by the manufacturers. Id. at Paragraph 47.

35. During all relevant times covered by this First Amended Complaint in Intervention:

- (a) Medi-Cal contracted with a fiscal intermediary, Electronic Data Systems ("EDS"), to evaluate and process claims for payment.
- (b) EDS, on behalf of Medi-Cal, contracted with FDB to provide the requisite drug pricing information to establish provider reimbursements.
- (c) Medi-Cal has relied on FDB as its primary source of pricing data and has utilized reports of AWP, DP, and FUL supplied by FDB (which FULs are obtained from CMS) in setting providers' reimbursement amounts for Defendants' prescription drugs.
- (d) FDB reported AWP's, DP's, wholesale acquisition costs ("WACs") and FULs for the specified prescription drugs based on the price information provided by the Defendants for their respective drugs.
- (e) Medi-Cal paid for drugs under various delivery systems, including the following:
  - (i) Pharmacy; and,
  - (ii) Incident to a physician's service.

36. The Defendants reported or caused to be reported false or misleading prices to



Medi-Cal by providing false or misleading price information including but not necessarily limited to AWP, Suggested Wholesale Price (“SWP”), CDP, WAC, DP, List Price and direct wholesale price to the compendia including FDB with knowledge that they in turn would utilize such false and misleading price information in determining the AWP and DP that were reported to Medi-Cal.

37. The claims which are the subject of this action were submitted to Medi-Cal for reimbursement for prescription drugs provided to Medi-Cal beneficiaries. Claims for each prescription are submitted on hard copy claim forms or through an electronic claims filing procedure using drug identification numbers known as National Drug Code (“NDC”) numbers. Claims for physicians’ services are submitted and paid using California-specific “X-Codes.”

38. Each Defendant, at a minimum, provided such pricing information at least annually to FDB for the express purpose of causing FDB to report such prices to Medi-Cal.

39. The number of pharmacy claims processed for Medi-Cal from July 1994 through March 2004 is as follows:

<b>Fiscal Year</b>	<b>Paid Claims</b>	<b>Denied Claims</b>	<b>Total Claims</b>
1994-1995	61,754,453	2,776,758	64,531,211
1995-1996	62,637,343	2,238,472	64,875,815
1996-1997	61,564,937	2,893,628	64,458,565
1997-1998	61,205,223	2,648,677	63,853,900
1998-1999	61,352,480	2,173,907	63,526,387
1999-2000	63,438,437	2,909,587	66,348,024
2000-2001	67,712,496	2,616,610	70,329,106
2001-2002	78,713,259	2,952,621	81,665,880
2002-2003	86,768,629	18,788,579	105,557,208
2003-03/2004	67,518,078	3,406,939	70,925,017
Totals	672,665,335	43,405,778	716,071,113

40. The number of pharmacy claims Medi-Cal received on average during the fiscal years from 1994 through March 2004 was approximately 1.37 million per week. The number of NDCs for which Medi-Cal processed the preceding claims has been reported at around 20,000 per year, and since 1991 through the present the number may have reached as many as 40,000

NDCs.

41. While neither directly investigating nor disclosing a fraud scheme, Myers and Stauffer LC, Certified Public Accountants, prepared “A Survey of Acquisition Costs of Pharmaceuticals in the State of California” (“Survey”) dated June 2002 for DHS (Exhibit L). The survey compared acquisition costs, based on a random sample of 2,010 pharmacies, to FUL, AWP and DP. The “Summary of Findings” stated, in part,

The significant findings of the study are as follows:

For the 272 pharmacies that provided invoices from external wholesalers, typical acquisition costs for single source drugs ranged from 82% to 84% of the AWP. The average acquisition cost was 82.8%, with a standard deviation of 1.2% . . . .

Of the sampled 1,000 single source drugs, 796 drug products were matched to one or more purchases. Of these 796 products, typical acquisition costs for single source drugs ranged from 79% to 84% of the AWP with an average acquisition cost of 81.7% of the AWP. The average actual drug acquisition cost is considerably less than the Department’s current ingredient cost allowance of AWP minus 5.0% (95% of the AWP).

For the pharmacies in the sample with external invoices, the average acquisition cost for single source drug products paid with a Direct Price (DP) was 94.5% of the DP, with a standard deviation of 2.3%.

The acquisition costs for multi-source drugs exhibited much greater variation, but averaged 56.6% of the AWP (mean weighted by Medi-Cal volume) for drugs without FUL prices. For multi-source drugs with FUL prices, the weighted average acquisition cost was 12.7% of the AWP and 38.7% of the FUL.

(Survey p. 4. Copy at Exhibit L. Also at Exhibit L are Exhibits 5 and 6 of the survey.) The study, therefore, found differentials between acquisition costs and the AWP or DP of single source drugs and even greater differentials between acquisition costs and the AWP or FUL of multi-source drugs. Note that the study was conducted to analyze the adequacy of pharmacy reimbursement rates and did not set out to investigate fraudulent drug pricing schemes perpetuated by drug manufactures. Nevertheless, the data reviewed in the study show significant differentials that underscore the allegations of fraud herein.

42. This case focuses on prescription drugs which were sold and/or distributed by Defendants, and for which Medi-Cal, through its fiscal agents, approved and paid claims to providers based on the false and inflated representations of prices knowingly reported or caused to be reported by Defendants. Defendants’ inflation of their reported prices caused many, if not

most, claims paid by Medi-Cal for Defendants' specified prescription drugs to be false claims. Defendants' inflation of their reported prices were misrepresentations which caused Medi-Cal to pay excessive reimbursements to providers who utilized Defendants' products.

**V.**

**SUMMARY OF DEFENDANTS' FRAUDULENT SCHEME**

43. The time period relevant to this First Amended Complaint in Intervention began on or before January 1994, and continues through to the present. During this time, Medi-Cal reimbursed health care providers and pharmacies for certain of Defendants' pharmaceutical products which were provided to Medi-Cal beneficiaries. Those reimbursements were based on prices that Defendants reported to FDB. Defendants caused the inflated Medi-Cal reimbursements by reporting false and excessive prices for their products to FDB. The difference between the providers' acquisition costs of the Defendants' drugs and reimbursement rates based on the Defendants' falsely reported cost information, is referred in the industry as the "spread."

44. Defendants competed with each other by inflating their spread. Defendants used the spread as an unlawful financial inducement to increase their market share and profits. Defendants' actual prices for drugs sold to providers, directly or through wholesalers, were much lower than the prices (AWP, DP, FUL, etc.) reported by Defendants and used by DHS for reimbursement. Defendants caused Medi-Cal to reimburse providers' claims for the specified prescription drugs at inflated amounts. At the same time, providers were able to purchase Defendants' drugs at materially lower prices than the prices Defendants reported, thus increasing the spread.

45. Defendants gave providers contract terms that decreased the price of prescription drugs, such as discounts, rebates, off-invoice pricing, free goods, charge backs, volume discounts, credit memos, "consulting" fees, debt forgiveness, educational and promotional grants, and other financial incentives given to providers. These price reductions financially benefitted providers, but were not reflected in the AWP's and other price quotes the Defendants reported to FDB, which formed the basis for reimbursements by Medi-Cal.

46. In October of 2000, the ranking member of the Congressional Ways and Means

Committee wrote a letter to ABBOTT's Chief Executive, describing the scheme as follows:

The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to . . . as "the spread." The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

*See*, October 31, 2000 letter from U.S. Representative Pete Stark to Miles White, Chief Executive Officer of ABBOTT (P007647-78 referenced in the Second Amended Master Consolidated Class Action Complaint ["SAMCCAC"] at p. 55, in MDL 1456, Case No. 01-CV-12257). Similar statements of Congressional concern were made in a letter from Rep. Stark in 2002 (BMSAWP/0011247), referenced in the Second Amended Master Consolidated Class Action Complaint ["SAMCCAC"] at p. 112, in MDL 1456, Case No. 01-CV-12257, (discussing incidents of intentional reporting of inflated prices and price manipulation for the purpose of increasing market share of certain drugs); and in a letter from Rep. Stark dated October 3, 2000 (P007613-P007632), referenced in the Second Amended Master Consolidated Class Action Complaint ["SAMCCAC"] at pp. 163-165, in MDL 1456, Case No. 01-CV-12257, (discussing marketing practices, including disparities between AWP and DP and other incentives to providers.)

47. As a result of their fraudulent scheme, Defendants and their customers have reaped hundreds of millions of dollars in illegal profits at the expense of California, and directly contributed to Medi-Cal's soaring cost of providing prescription drugs for California's needy, poor, elderly and disabled. During the period from 1997 through 2001, the number of Medi-Cal recipients fell by almost 15%, while Medi-Cal prescription drug costs doubled over that period, from \$1.55 billion in 1997 to \$3.11 billion in 2001.

48. Because FULs were based on reported prices, Defendants' reporting of inflated

prices corrupted the FULs and prevented California from gaining the full benefit of the FUL safeguard. The FUL pricing provided an upper limit on the pricing of certain drugs. However, if truthful prices had been reported, the FUL prices would have exceeded reimbursement based on many companies' reported prices and the FUL upper limit prices would not have been utilized for reimbursement. There remained significant spreads between the FUL prices and the prices that were generally and currently available to providers for the drugs that were reimbursed by Medi-Cal. For example, in April 2003 a 17 gram albuterol inhaler manufactured by WARRICK (NDC# 59930156001) was reimbursed by DHS at an FUL amount of \$0.88 per gram. In 2003, the wholesale cost of the inhaler, taken from contract documents, was approximately \$0.13 per gram. Using a FUL, DHS was reimbursing at 676% of the true wholesale cost for Albuterol, while pharmacies and physicians in California routinely purchased the drug for, at most, a small amount over the wholesale cost.

## **VI.**

### **THE ACTIONABLE CONDUCT OF DEFENDANTS**

49. The following Sections contain specific allegations about the individual Defendants. The specific allegations and the referenced Exhibits state the Plaintiffs' factual basis for claiming that the specific Defendants have knowingly reported or caused the reporting of false price representations to Medi-Cal. Specifically, the Plaintiffs have listed each drug at issue, specific industry insider price information available to Ven-A-Care, specific price information obtained in the Attorney General's investigation and the false prices that the specific Defendants knowingly caused to be reported. A comparison of the prices generally and currently available to industry insiders such as Ven-A-Care, with the prices reported to Medi-Cal, reveals that the reported prices were false and misleading. The Medi-Cal reimbursement system for the Defendants' drugs was based upon the reported prices and each Defendant knew this, yet caused the reporting of the false and misleading prices that they knew would be used by Medi-Cal to determine reimbursement amounts.

#### **A. SPECIFIC ALLEGATIONS AS TO DEFENDANT ABBOTT**

50. From on or after January 1, 1994, to the present, Defendant ABBOTT knowingly caused hundreds of thousands of false claims for reimbursement for ABBOTT's drug products

described herein to be presented to the Medi-Cal program for payment or approval. Defendant ABBOTT knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit A<sup>1/</sup>** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP's from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by ABBOTT included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false.

51. In the face of governmental scrutiny beginning in 1999, ABBOTT began to modify select pricing representation to FDB while continuing its efforts to have FDB report other inflated prices.

52. Pricing information for ABBOTT demonstrates significant spreads of its drugs. For example, in 1999 California paid \$0.1177 cents per unit of Sodium Chloride of 0.9% solution (NDC 00074710123). The contract price or price at which this product was sold to a Group Purchasing Organization (GPO) was \$0.0119 cents per unit. Medi-Cal paid 9.89 times more for this product than did a GPO acting on behalf of its member doctors and/or pharmacists. The reported DP for this product at the time was \$0.1177 cents per unit.

53. Documents produced by Defendant ABBOTT show that ABBOTT's marketing managers and representatives understood that their product would sell over their competitors whenever their product as compared to competitors' offered a higher spread between the actual market price on the one hand and the AWP and the Medi-Cal reimbursement amount on the other hand. ABBOTT's marketing managers and representatives understood that a higher spread in their product meant customers would make more money using their product.

54. The acts of Defendant ABBOTT in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

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1. Exhibits A-K and M-R are redacted, and the full exhibits will be filed under seal.

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified ABBOTT drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant ABBOTT's customers, and those acting in concert with them, to select Defendant ABBOTT's drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

55. The actions by defendant ABBOTT alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**B. SPECIFIC ALLEGATIONS AS TO DEFENDANT ARMOUR-BEHRING**

56. From on or after January 1, 1994, to the present, Defendant ARMOUR-BEHRING knowingly caused hundreds of false claims for reimbursement for ARMOUR-BEHRING's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant ARMOUR-BEHRING knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit B** herein. This Exhibit lists the drug products' NDC; label name; date; AWP; from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by ARMOUR-BEHRING included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false.

57. ARMOUR-BEHRING routinely compared and evaluated the acquisition cost prices reported to FDB and current Medicaid reimbursements for its competitors IVIG and hemophiliac products (blood factor). California's Medi-Cal program reimburses blood factor at acquisition cost plus 1% and ARMOUR-BEHRING through discounts to its customers not reflected on its invoices, caused the filing of claims which showed acquisition costs higher than they actually were resulting in the Medi-Cal Program reimbursing more than it should have. With regard to IVIG products delivered by physician assistance (known as X Codes) California's

Medi-Cal Program reimburses providers based on the prices reported to FDB by the Defendant and its competitors manufacturing similar products. ARMOUR-BEHRING and its competitors consistently monitored each others reported prices. The spread between Medi-Cal reimbursement and provider acquisition cost remained significantly high.

58. The acts of Defendant ARMOUR-BEHRING in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified ARMOUR-BEHRING drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant ARMOUR-BEHRING's customers, and those acting in concert with them, to select Defendant ARMOUR-BEHRING's drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

59. The actions by Defendant ARMOUR-BEHRING alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**C. SPECIFIC ALLEGATIONS AS TO DEFENDANT BAXTER**

60. From on or after January 1, 1994, to the present, Defendant BAXTER knowingly caused several thousand false claims for reimbursement for BAXTER's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant BAXTER knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit M**, pages 1-50, attached herein. The Defendant's drugs products, that are the subject of this complaint, are identified by their National Drug Code (labeler code) numbers 0338 and 0944. Pages 1-50 of the attached Exhibit, lists defendant's drug products for labeler code 0338 and provides the complete NDC; label name; date; AWP's from FDB; CDP; a market price per unit; and the source of that market price. With respect to Baxter's products, specified in Exhibit M, and in addition to the other pricing information used by Medi-Cal in setting reimbursement, Baxter periodically provided Medi-Cal with Average Manufacture Price ("AMP") information for certain of its



products under Labeler Code 0944. AMP represents a weighted average price of sales to the wholesale class of trade, and thus is a weighted average of a range of prices computed by Baxter. The California Attorney General's Office secured additional AMP information from Baxter in its investigation. Baxter's price representations to FDB were relied upon by the Medi-Cal Program to estimate acquisition costs based upon prices generally and currently available to purchasers. The prices represented by Baxter were materially inflated and in fact had no good faith relationship to the range of prices which comprised AMP. Accordingly, Defendant's own documents show that their immune globulin products, also known as IVIG products, (NDC numbers 009442620 -01,-02, -03 and -04) were reimbursed by the Medicaid Program at 2 to 3 times the Defendant's Average Manufacturer's Price (AMP) for the same product. *See Exhibit M*, pages 51-54. (Bates No. CA-BAX-09908, CA-BAX-09940, CA-BAX 09941, and CA-BAX-00840). The wrongful acts committed by BAXTER included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false.

61. Defendant BAXTER's sales managers instructed field representatives to be careful when presenting reimbursement scenarios to customers out of fear it might demonstrate that a competitor's product might be more profitable to the customer. *Exhibit M*, page 55, Bates No. CA-BAX-09920. Also, Baxter employees were provided with spread sheets that compared various manufacturers' AWP and WAC prices. *Exhibit M*, pages 55-56, Bates Nos. CA-BAX-09909 and CA-BAX-09908.

62. With regard to immune globulin and hemophiliac products (blood factor), BAXTER routinely compared and evaluated acquisition costs, prices reported to FDB and current Medicaid reimbursements for its competitors. *Exhibit M*, pages 51, 55, 56. California's Medi-Cal program reimburses blood factor at acquisition cost plus 1% and BAXTER through discounts to its customers, not reflected on its invoices, caused the filing of claims which showed higher than actual acquisition costs higher resulting in the Medi-Cal Program reimbursing more than it should have. *Exhibit M*, pages 57, 58, Bates Nos. CA-BAX-09485, CA-BAX-09486. With regard to IVIG products delivered by physician assistance (known as X-Codes),

California's Medi-Cal Program reimburses providers based on the price reported to FDB by the defendant and its competitors manufacturing similar products. BAXTER and its competitors consistently monitored each other's reported prices. The spread between medi-Cal reimbursement and provider acquisition costs remained significantly high.

63. The acts of Defendant BAXTER in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified BAXTER drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant BAXTER's customers, and those acting in concert with them, to select Defendant BAXTER's drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

64. The actions by Defendant BAXTER alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**D. SPECIFIC ALLEGATIONS AS TO DEFENDANT BEDFORD**

65. From January 1, 1994, to the present, BEDFORD knowingly caused thousands of false claims for reimbursement for BEDFORD's drug products described herein to be presented to the Medi-Cal program for payment or approval. BEDFORD knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendants' drugs including those specified in this Section and in **Exhibit N**, attached to the First Amended Complaint in Intervention and incorporated herein by reference. This Exhibit lists the drug products' NDC; label name; date; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by BEDFORD included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendants' drugs, and that providers would submit false claims for such reimbursements. The acts of BEDBORD in providing false and misleading price information to Medi-Cal include the following:

(a) BEDFORD controlled and set the AWP for its pharmaceutical products through direct communications with industry price reporting services. For example, a September 27, 1996 document entitled “*Red Book* Product Listing Verification” required BEDFORD to sign each page that contained a list of the BEDBORD’s products, NDC numbers, AWP, WACs and price effective dates.

66. According to BEDFORD’s own documents, the published AWP for its drugs were, in fact, higher than the actual prices provided to wholesalers. In response to government subpoenas, BEDFORD produced several price lists setting forth spreads between AWP and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists confirmed that BEDFORD consistently offered the above drugs and other solutions to its customers at prices significantly below the published AWP, and that the spread was of great importance to its customers.

67. BEDFORD’s scheme to inflate their reported AWP and market the resulting spread to increase the market share of drugs resulted in excessive overpayments by the State.

68. The acts of BEDFORD in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified BEDFORD drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce BEDFORD’s customers, and those acting in concert with them, to select BEDFORD’s drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

69. The actions by BEDFORD alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**E. SPECIFIC ALLEGATIONS AS TO DEFENDANT BRISTOL-MYERS**

70. From January 1, 1994, to the present, Defendant BRISTOL-MYERS knowingly caused thousands of false claims for reimbursement for BRISTOL-MYERS’ drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant BRISTOL-MYERS knowingly used or caused the use of false statements about the prices of its

drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit O** attached to the First Amended Complaint in Intervention and incorporated herein by reference. This Exhibit lists the drug products' NDC; label name; date; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by BRISTOL-MYERS included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and that providers would submit false claims for such reimbursements. BRISTOL-MYERS engaged in an ongoing deliberate scheme to inflate AWP. For example, in a letter dated February 27, 2001 to BRISTOL-MYERS, Rep. Stark outlined numerous examples of illegal practices by BRISTOL-MYERS. Referring to a letter from Denis Kaszuba, a senior pricing analyst at BRISTOL-MYERS, to Medi-Span, dated August 10, 1992, Rep. Stark noted:

Bristol has control over the AWP, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWP for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

71. BRISTOL-MYERS controlled and set the AWP for its pharmaceutical products through direct communications with industry price reporting services. A prime example is referenced in Rep. Stark's letter, above, where a senior BRISTOL-MYERS pricing analyst instructs Redbook that the "factor" used in determining BRISTOL-MYERS' AWP for its oncology products should be changed from 20.5% to 25%.

72. Other internal documents clearly indicate that BRISTOL-MYERS had direct

control over the spread between its stated wholesale price and the published AWP. A BRISTOL-MYERS inter-office memo dated September 9, 1992 noted the need for a mark up of the AWP over the stated wholesale price; specifically those items with a labeler code 0003 realized a 1.25 mark-up and those items with labeler code 00015 saw a 1.20 mark up.

73. BRISTOL-MYERS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BRISTOL-MYERS was aware of and tracked the prices and AWP's of its competitors in order to remain competitive. In an internal BRISTOL-MYERS memorandum, BRISTOL-MYERS identified its competitors who sell etoposide (Gensia, Pharmacia, ABBOTT , Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWP's.

74. BRISTOL-MYERS created AWP competitor analyses that tracked the AWP's of its competitors' relevant drugs, and used that data internally to propose suggested AWP's for BRISTOL-MYERS drugs. BRISTOL-MYERS believed the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BRISTOL-MYERS document, concerning its drug Vepesid (etoposide), BRISTOL-MYERS articulated that physicians could take advantage of the growing disparity between Vepesid's listed AWP price and the actual acquisition cost when obtaining reimbursement for etoposide purchases. BRISTOL-MYERS realized that if the acquisition price came too close to the list price, then physician's financial incentive for selecting BRISTOL-MYERS' brand was diminished greatly.

75. The published AWP's for the drugs manufactured by BRISTOL-MYERS were substantially higher than the actual prices listed by wholesalers. Internal BRISTOL-MYERS documents showed the AWP set by BRISTOL-MYERS for its drugs bore no relation to an *actual* wholesale price, and is greater than the highest price actually paid by providers.

76. The February 27, 2001 letter from Rep. Stark to BRISTOL-MYERS noted that "... the manipulated discrepancies between [BRISTOL-MYERS'] inflated AWP's and DP's versus their true costs are staggering. For example, in the 2000 edition of the Red Book, Bristol reported an AWP of \$1296.64 for . . . Vepesid (Etoposide) for injection . . . while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for \$70.00." The difference noted by Rep. Stark represents a 1,752% spread on Vepesid.

77. BRISTOL-MYERS internal documents reveal that in 1995, BRISTOL-MYERS set the Red Book AWP for Blenoxane at \$276.29. At the same time, BRISTOL-MYERS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only \$224.22. In 1996, BRISTOL-MYERS increased its reported AWP for Blenoxane to \$291.49, while continuing to sell the drug to oncologist for \$224.27. In 1997, BRISTOL-MYERS falsely reported that it had increased the AWP of Blenoxane to \$304.60, when in reality, BRISTOL-MYERS had lowered the price to oncologists to \$155.00. In 1998, BRISTOL-MYERS again reported a false AWP for Blenoxane of \$304.60 while further reducing the actual price to oncologists to \$140.00.

78. The acts of Defendant BRISTOL-MYERS in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified BRISTOL-MYERS drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant BRISTOL-MYERS' customers, and those acting in concert with them, to select Defendant BRISTOL-MYERS' drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

79. The actions by Defendant BRISTOL-MYERS alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

#### **F. SPECIFIC ALLEGATIONS AS TO DEFENDANT DEY**

80. From on or after January 1, 1994, to the present, Defendant DEY knowingly caused over one million false claims for reimbursement for DEY's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant DEY knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit C** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP's from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by DEY included, but were not limited to, knowingly making false representations to FDB with

knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false.

81. DEY had significant spreads on its drugs, for example, the Albuterol Inhaler (NDC 49502030317). In comparing a sampling of true wholesale prices of the inhaler to the published prices reimbursed by DHS, for third quarter 2000, 58% of the DHS price paid for the inhaler was spread. In other words, DHS' price reimbursed to providers for the inhaler is 241% of the contract price paid by providers for third quarter 2000. Contract prices were determined by documentation provided by Relators, Ven-a-Care (taken from prices to McKesson Servall group) and compared to DHS actual reimbursement prices for the same time periods. DEY's other NDCs have similar spreads between the contract prices and the prices reimbursed by DHS.

82. DEY's published WAC and AWP prices are fraudulent because DEY knew they bore no good faith relationship to any true prices in the marketplace. In various memos issued by DEY personnel it is clearly stated that the company goal is to compete with its drugs and gain market share by playing the spread game. DEY marketed its drugs by emphasizing to customers the spread profit that the customers will make by purchasing DEY's products at a discount and obtaining reimbursement at an amount based on the inflated AWP.

83. On May 30, 1995, DEY Marketing Director, Helen Burnham, issued a memo to Sales and Marketing which stated in part that "WAC is not representative of our published wholesale prices, but like AWP, is used for calculation of reimbursement." She went on to state: "Our updated WAC values are in line with the Warrick WAC values provided by First Data Bank and should level the playing field for Medicaid reimbursement." Helen Burnham has also stated that DEY's spread on the drug Metaproterenol between pharmacy direct price and AWP remains very competitive even with the reduction in AWP.

84. Robert P. Mozak, Executive Vice President of sales and marketing at DEY, has stated in regard to Albuterol pricing strategy that DEY should increase the spread in order to provide incentive to retail and chain providers. DEY has admitted that increasing spread for retail will provide DEY with the highest profit.

85. Rob Ellis, DEY Product Manager in the Marketing Department, has stated in

reference to Albuterol sales that an introductory offer will produce a larger spread than DEY currently offers, if the introductory discount is applied to the direct wholesale price.

86. DEY Sales Representative, Ross Uhl, has made reference to a pricing formula that spread equals AWP minus cost.

87. DEY directed and controlled its published AWP and WAC prices. DEY implemented the spread on its products through direct reporting of falsely inflated prices to the drug price reporting services. For example, on January 13, 1996, DEY sent a letter to FDB instructing FDB to update their database on Ipratropium Bromide AWP and WAC prices.

88. The acts of Defendant DEY in reporting false and misleading price information used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified DEY drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant DEY's customers, and those acting in concert with them, to select Defendant DEY's drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

89. The actions by Defendant DEY alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**G. SPECIFIC ALLEGATIONS AS TO DEFENDANT GENEVA/SANDOZ**

90. From on or after January 1, 1994, to the present, Defendant GENEVA/SANDOZ knowingly caused well over seven million false claims for reimbursement for GENEVA/SANDOZ's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant GENEVA/SANDOZ knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit D** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP's from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by GENEVA/SANDOZ included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these



reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false.

91. Pricing information for GENEVA/SANDOZ demonstrates significant spreads on its drugs. For instance, in comparing a sampling of wholesale prices obtained by the State for 2002 for Atenolol 25 mg. tablets (NDC 00781107801), to the prices at which that drug was reimbursed by DHS, i.e. CDP, 67% of the price paid by DHS was spread. The data supporting this statement is depicted on page 7 of Exhibit D, for the first and second quarters of 2002 ("20021", "20022".) The following three additional representative samples, also drawn from wholesale pricing data obtained by the State, further illustrate the substantial price differentials characterizing GENEVA/SANDOZ's drugs: (1) In 2001, DHS reimbursed on Desipramine 25 mg. tablets (NDC 00781197201) at \$0.07/tablet (weighted average), at a time when wholesale contract prices variously demonstrate that 43% and 57% of that reimbursement was spread (see Exhibit D, p. 25); (2) In 2002, DHS reimbursed on Haloperidol 10 mg. tablets (NDC 00781139701) at \$0.68/tablet (weighted average), when a survey of contract prices indicates that 72% of that reimbursement amount was spread (Exhibit D, p. 46); and (3) In 2001, DHS reimbursed on Chlorpromazine 100 mg. tablets (NDC 00781171801) at \$0.70/tablet (weighted average), when a survey of contract prices indicates that 68% of that reimbursement amount was spread (Exhibit D, p. 14).

92. The acts of GENEVA/SANDOZ in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified GENEVA/SANDOZ drugs in amounts that substantially exceeded the amounts that otherwise should have been paid according to law.

(b) Were knowingly committed in order to induce GENEVA/SANDOZ'S customers, and those acting in concert with them, to select GENEVA/SANDOZ'S drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

93. The actions by GENEVA/SANDOZ were a substantial factor in causing the damages that California has sustained as set forth below.

## **H. SPECIFIC ALLEGATIONS AS TO THE DEFENDANT GLAXO**

94. From on or after January 1, 1994, to the present, GLAXO DEFENDANTS knowingly caused over ten thousand false claims for reimbursement for GLAXO DEFENDANTS' drug products described herein to be presented to the Medi-Cal program for payment or approval. GLAXO DEFENDANTS knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendants' drugs including those specified in this Section and in **Exhibit Q**, attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP's from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by GLAXO DEFENDANTS included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendants' drugs, and which would cause the claims for such reimbursements to be false. GLAXO DEFENDANTS introduced Zofran in about 1991. The SMITHKLINE DEFENDANTS introduced a competitive drug named Kytril in about April 1994. A "Glaxo Memo" dated "10/25/1994" from Nancy Pekarek to Jim Dawson, Andy Hartsfield, Patti Pozella, and Rick Sluder on the subject of "Issue considerations on Zofran pricing strategies" stated, "Attached is a draft outlining the issues we discussed yesterday regarding Zofran pricing strategies. Please review for further discussion this afternoon." The attachment ("Attachment") was entitled "Zofran pricing recommendation considerations" and commenced:

If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:

- 1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran - perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?

If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.

- 2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do

we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in AWP? What argument can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government? How will this new pricing structure compare with costs in other countries?

3) Private insurers, out-of-pocket payers: . . .

*Other questions to consider:*

1. What percentage of our Zofran business in the clinical setting is subject to Medicaid reimbursements? If this proportion of the business is relatively small, why implement such a sweeping policy? Have we considered and tried other options for retaining market share short of a pricing strategy that will be seen as an exorbitant increase?

2. Both before and after the entrance of Kytril on the market, Glaxo's public position has been that the company would not compete on the basis of price, but rather continue to reinforce the message that Zofran provides therapeutic value in the marketplace. If we do try to explain the pricing rationale, we seem to be doing an about face. What does this say about the stability of our product, and the future of a company that has taken the public position that our future depends on the strength of newer products like Zofran?

3. How will SKB respond to Glaxo's new pricing policy? Are we igniting a price war? If SKB lowers their price again, how do we respond?

4. What kind of response can we expect from consumer advocates? How does Glaxo respond to those advocates?

5. How do we respond to critics' charges that this policy proves that the pharmaceutical companies are unfairly discriminating against independent pharmacies by offering discounts to different classes of trade as well as other issues in that debate?

6. Do we have plans to use this same strategy with regard to other Glaxo products?

7. Does this pricing policy, and similar policies implemented by other companies, provide evidence to reform advocates who support the establishment of government price review boards? Is the industry helping to moderate health care costs when it implements policies that increase the cost of pharmaceuticals to government?

95. CERENEX Pharmaceuticals ("CERENEX") is a Division of GLAXO that sold Zofran. In a CERENEX memo dated October 31, 1994, from David Cory to Steve Skolsky on the subject of "Pricing Committee Recommendation" the memo stated in part, "The attached position paper ["Memo"] outlines the planned recommendation for Zofran Injection in the clinic market segment at the November 4, 1994 Pricing Committee meeting." In the "Introduction" the Memo discussed the market share its competitor drug, Kytril, had achieved, and stated, in part, "The clinic contribution to the CIE market is currently 35% or approximately \$100MM in available antiemetic dollars per year. The Zofran pricing plan identifies 25% in cumulative Kytril unit sales as a trigger point at which time Glaxo Inc. would deliver a market response."

Under “Discussion,” the Memo continued, “Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP. The typical spread between the List Price and the AWP in the industry is either 16 2/3% or 20%. The majority of agents in the oncology market carry a 20% AWP.” The Memo noted that the clinic promotion of Kytril by GLAXO’s competitor, SMITHKLINE (“SKB”), “... has been based on a therapeutic equivalency campaign with significant reimbursement advantages in favor of Kytril. The current reimbursement spread favors Kytril at \$18.80 per single dose vial compared to Zofran at \$-0.89 [sic] per 32mg dose per patient.” Under “Recommendation,” the Memo said,

In order to balance the reimbursement spread which currently exists between Zofran and the market in which it competes, one of the two scenarios which follow are recommended:

*Recommendation #1*

4.5% price increase	\$178.97	to	\$187.02
Increase AWP	16 2/3%	to	20%
	\$214.76	to	\$233.78 (8.5%)
3% Wholesaler	\$187.02	to	\$172.92 (chargeback)
Rebate	\$172.92	to	\$167.31 (rebate)

In response to the two recommendations, the Memo stated, “SKB will likely have two options:” “Option 2: Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than \$52.00.” The Memo concluded, “Neither option appears advantageous for SKB.”

96. In an advertisement in The Network dated January/February 1996, the GLAXO DEFENDANTS marketed the spread between its product, Zofran, and its competitor’s product, Kytril. The advertisement stated, in part:

The RedBook AWP per 32 mg Zofran bag is \$196.76. An average purchase price per 32 mg bag is \$129.65 (your individual practice purchase price may be less). Therefore, the average reimbursement per patient is \$67.11. This reimbursement per patient compares favorably to the Zofran MDV (\$52.06) and Kytril (\$38.00).

97. In an spreadsheet entitled “Medicare part B Expenditures for Zofran Injection,” the GLAXO DEFENDANTS calculated that the increase to reimbursements that was “Attributable to AWP Increase” was \$1,747,011.21.

98. The acts of the GLAXO DEFENDANTS in reporting false and misleading price

information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified GLAXO DEFENDANTS' drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce the GLAXO DEFENDANTS' customers, and those acting in concert with them, to select the GLAXO DEFENDANTS' drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

99. The actions by the GLAXO DEFENDANTS alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**I. SPECIFIC ALLEGATIONS AS TO DEFENDANT HOECHST/AVENTIS**

100. From on or after January 1, 1994, to the present, Defendant HOECHST/AVENTIS knowingly caused over four thousand false claims for reimbursement for HOECHST/AVENTIS' drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant HOECHST/AVENTIS knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit E** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP; FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by HOECHST/AVENTIS included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false.

101. HOECHST/AVENTIS prepared a document entitled "Contracted Pricing - Oral" and "Anzemet Pricing - Oral" dated September 1997 in which it compared the price of its drug, Anzemet, with its competitors' drugs, Zofran and Kytril. Anzemet's price was stated as follows:

AWP	66.00
Reimb. (AWP-5%)	62.70
NWP	55.00
Distribution Pricing	39.70
SWP	38.54

GPO	
Tier I	49.50
% Discount	10%
Tier II	45.10
% Discount	18%
Tier III	39.70
% Discount	28%
Reimbursement	
Margin	
\$	23.00
%	58%

102. HOECHST/AVENTIS prepared a document entitled “Reimbursement Spreadsheet” in which HOECHST/AVENTIS concluded that the Annual Profits gained by a provider of \$89,229 per patient for using Anzemet was higher than the profits that could be earned by using its competitors’ drugs, Zofran and Kytril.

103. The acts of Defendant HOECHST/AVENTIS in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified HOECHST/AVENTIS drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant HOECHST/AVENTIS’ customers, and those acting in concert with them, to select Defendant HOECHST/AVENTIS’ drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

104. The actions by Defendant HOECHST/AVENTIS alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

#### **J. SPECIFIC ALLEGATIONS AS TO DEFENDANT IMMUNEX**

105. From on or after January 1, 1994, to the present, IMMUNEX knowingly caused over a thousand false claims for reimbursement for IMMUNEX’S drug products described herein to be presented to the Medi-Cal program for payment or approval. IMMUNEX knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendants’ drugs including those specified in this Section and in **Exhibit F**, attached herein. This Exhibit lists the drug products’ NDC; label name; date; AWP from FDB; CDP; a market

price per unit; and the source of that market price. The wrongful acts committed by IMMUNEX included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendants' drugs, and which would cause the claims for such reimbursements to be false.

106. The acts of defendant IMMUNEX in providing false and misleading price information to Medi-Cal include the following:

107. IMMUNEX's internal documents reveal that it understood how industry compendia defined and utilized AWP. In its internal documents, IMMUNEX identified Red Book's definition of AWP as the average wholesale price a retail hospital or pharmacy pays if it purchases the product from the wholesaler before any discount. Likewise, Immunex identified the Blue Book definition of AWP as representing an average price which a wholesaler would charge a pharmacy for a particular product.

108. IMMUNEX controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia. In 2000, in the midst of numerous government investigations concerning AWP manipulation, Immunex denied responsibility for controlling the published AWP for its products. For example, in an October 26, 2000 letter to Red Book, Immunex enclosed updated summaries of list pricing and package information for its products. IMMUNEX stated that it was not responsible for setting AWP nor did it approve AWP information for any of its products.

109. Previously, in a 1996 interview with Barron's magazine for an article entitled "Hooked On Drugs" dated June 10, 1996, an IMMUNEX spokesperson stated that "drug manufacturers have no control over the AWP published."

110. IMMUNEX's internal documents, however, establish that it controlled the AWP for all of its products. For example, in a January 12, 1996 letter to IMMUNEX, Red Book confirmed it received and entered IMMUNEX'S latest AWP price changes into the Red Book system. Furthermore, in a January 12, 1995 letter to Red Book it states that IMMUNEX enclosed a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC's all effective January 10, 1995. IMMUNEX requested that

Red Book update its databases accordingly. IMMUNEX also promised that its new copy of its Average Wholesale Price Product Pricing Guide would be sent to Red Book within a week.

111. The purpose of IMMUNEX's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of the State. Immunex understood that providers and intermediaries were reimbursed at AWP – and benefitted from a larger spread.

(a) In an internal document entitled “Health Care Policy Fast Facts,” created in 1995, IMMUNEX urged its sales personnel to remember Physician's offices use their own charge schedule for billing purposes, and get reimbursed at AWP, based on the published prices in the pricing databases.

(b) In a January 3, 2000 interoffice memo, IMMUNEX discussed the significant revenues to be made by providers which used its Leucovorin and Methotrexate products. Specifically, IMMUNEX stated that Leucovorin and Methotrexate represent significant revenue sources for the physician office or clinic. Due to the ‘spread’ (difference between acquisition cost and AWP), physicians have reaped substantial profits.

112. IMMUNEX performed an analysis of competitive AWP pricing and established a “Reimbursement Hotline” for a number of its products.

113. IMMUNEX, through its employees and agents, also provided free samples of its drugs to customers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from the State.

114. In response to government subpoenas, IMMUNEX produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

115. IMMUNEX's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State.



116. IMMUNEX deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, under the guise of “simplifying” its product listings, on June 3, 1994, IMMUNEX instructed the *Red Book* to “delete all references to Direct Price for all Immunex products, effective immediately” and confirmed that “only AWP (Average Wholesale Price) would be listed for [its] products.” IMMUNEX effectively hid the AWP spread from the State.

117. The acts of defendant IMMUNEX in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified drugs in amounts that substantially exceeded the amounts that otherwise should have been paid according to law.

(b) Were knowingly committed in order to induce defendant IMMUNEX’s customers, and those acting in concert with them, to select defendant IMMUNEX’s drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

118. The actions of defendant IMMUNEX alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**K. SPECIFIC ALLEGATIONS AS TO DEFENDANT McGAW**

119. From on or after January 1, 1994, to the present, Defendant McGAW knowingly caused hundreds of false claims for reimbursement for McGAW’s drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant McGAW knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant’s drugs, including those specified in this Section and in **Exhibit G** attached herein. This Exhibit lists the drug products’ NDC; label name; date; AWP’s from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by McGAW included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant’s drugs, and which would cause the claims for such

reimbursements to be false.

120. McGAW produced a number of documents showing it understood that to compete, its products needed to offer customers the highest spread between cost and AWP. Documents show McGaw discussed how their spread could be more competitive if they increased AWP and sold to customers at contract price rather than list price. Other documents express concerns whether the practice of achieving highest spread between cost and AWP was ethical or not.

121. The acts of Defendant McGAW in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified McGAW drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant McGAW's customers, and those acting in concert with them, to select Defendant McGAW's drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

122. The actions by Defendant McGAW alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**L. SPECIFIC ALLEGATIONS AS TO DEFENDANT MYLAN**

123. From on or after January 1, 1994, to the present, Defendant MYLAN knowingly caused well over seven million false claims for reimbursement for MYLAN's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant MYLAN knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit H** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP's from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by MYLAN included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement

amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false. MYLAN has reported and continues to report an inflated AWP and WAC, which in turn affect Federal Upper Limit prices and cause over-reimbursement of their drugs by California.

124. MYLAN has significant spreads on its drugs, for example, in 2001 for Atenolol 50 Mg tablets. In comparing wholesale prices offered to Relator for the Atenolol 50 Mg tablets to the prices reimbursed by DHS, 98% of the DHS price paid for the solution is spread. In other words, DHS' price reimbursed to providers for Atenolol 50 Mg tablets is 4235% of the contract price paid by providers. MYLAN's other NDCs have similar spreads between the contract prices and the prices reimbursed by DHS.

125. MYLAN markets the spread in its drug pricing in order to improve market share. MYLAN actively markets its product based upon the spread between its generally unpublished WAC prices and its published AWP prices. MYLAN adds discounts and rebates in its pricing as an additional marketing incentive. In setting its pricing, MYLAN also compares the spread offered on its products to the spreads on products of other drug manufacturers. In reviewing the appeal of its pricing of drug product to its customers MYLAN focuses on the spread that the drug product provides the customer.

126. One of MYLAN's marketing goals is to maximize reimbursement profitability for providers and, therefore, maximize distribution of MYLAN's product and maximize MYLAN's net profitability. In an attempt to maximize reimbursement profitability for providers, MYLAN focuses on reimbursement criteria of individual state medicaid programs. MYLAN seeks to avoid pricing its drugs at the lowest AWP price amongst its competitors knowing that for certain drugs Medicare laws require payment at the lowest AWP. MYLAN, therefore, seeks to artificially keep its AWP prices inflated in order to maintain higher reimbursement for particular generics and to maintain significant spreads on the drugs.

127. The acts of Defendant MYLAN in reporting false and misleading price information used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified MYLAN drugs in amounts that substantially exceeded the amounts that should

have been paid according to law.

(b) Were knowingly committed in order to induce Defendant MYLAN's customers, and those acting in concert with them, to select Defendant MYLAN's drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

128. The actions by Defendant MYLAN alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**M. SPECIFIC ALLEGATIONS AS TO DEFENDANT NOVARTIS/SANDOZ**

129. From on or after January 1, 1994, to the present, Defendant NOVARTIS/SANDOZ knowingly caused thousands of false claims for reimbursement for NOVARTIS/SANDOZ drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant NOVARTIS/SANDOZ knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit I** herein. This Exhibit lists the drug products' NDC; label name; date; AWP from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by NOVARTIS/SANDOZ included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false.

130. NOVARTIS/SANDOZ routinely compared and evaluated the acquisition cost prices reported to FDB and current Medicaid reimbursements for its competitors IVIG and hemophiliac products (blood factor). California's Medi-Cal program reimburses blood factor at acquisition cost plus 1% and NOVARTIS/SANDOZ through discounts to its customers not reflected on its invoices, caused the filing of claims which showed acquisition costs higher than they actually were resulting in the Medi-Cal Program reimbursing more than it should have. With regard to IVIG products delivered by physician assistance (known as X Codes), California's Medi-Cal Program reimburses providers based on the prices reported to FDB by Defendant and its competitors manufacturing similar products. NOVARTIS/SANDOZ and its

competitors consistently monitored each others reported prices. The spread between Medi-Cal reimbursement and provider acquisition cost remained significantly high.

131. The acts of Defendant NOVARTIS/SANDOZ in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified NOVARTIS/SANDOZ drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant NOVARTIS/SANDOZ's customers, and those acting in concert with them, to select Defendant NOVARTIS/SANDOZ's drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

132. The actions by Defendant NOVARTIS/SANDOZ alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**N. SPECIFIC ALLEGATIONS AS TO DEFENDANT ROXANE**

133. From on or after January 1, 1994, to the present, Defendant ROXANE knowingly caused over five million false claims for reimbursement for ROXANE's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant ROXANE knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit J** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP's from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by ROXANE included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false. ROXANE has reported and continues to report an inflated AWP and WAC which in turn affect Federal Upper Limit prices and cause over-reimbursement of their drugs by California.

134. ROXANE has admitted that it has no rigid formula for determining AWP. In

responding to a questionnaire put forth by one of its wholesalers ROXANE stated in regard to the process for determining AWP: that it does not have a fixed rule or formula for pricing its products and that of the most common AWP pricing seen in the generic industry follows a rule of thumb of setting AWP at brand AWP less approximately 10% at the time of launch.

ROXANE stated that it sets pricing based upon market conditions and competition. In the same document the wholesaler also asked who was ultimately responsible for establishing the AWP and managing it on an ongoing basis. ROXANE responded that its pricing decisions are approved by the President and COO. No response was given to the question if ROXANE had ever adjusted AWP downward.

135. ROXANE has significant spreads on its drugs, for example for Ipratropium Bromide Solution (NDC 00054840211). In comparing wholesale prices offered to Relator for the Ipratropium Bromide Solution to the prices reimbursed by DHS, for third quarter 2001, approximately 70% of the DHS price paid for the solution is spread. In other words, DHS' price reimbursed to providers for Ipratropium Bromide Solution is 327% of the contract price paid by providers. ROXANE's other dosages have similar spreads between the contract prices and the prices reimbursed by DHS.

136. ROXANE marketed the spread in its drug pricing in order to improve market share. On April 9, 1996 a memo was faxed by a ROXANE Consultant to ROXANE's Product Manager for Ipratropium Bromide UDV. The memo discussed the initial marketing strategy for Ipratropium Bromide and stated that pricing of the IBUDV will follow the traditional parameters of a generic product. Specifically, AWP will be brand less 10%, or \$44.06 for the 25 count package; WAC will be AWP less 40%, or \$26.44 for the 25 count package. The memo stated that this type of price structure used for a generic launch and is to create an attractive spread between WAC and AWP, encouraging accounts to convert from brand names to the generic product as quickly as possible. The memo also stated that the rapid conversion is necessary in order to protect ROXANE's position in the market after generic competitors enter the market. The memo also stated that in a multi-source product launch, one of the most important keys to success is conversion from the brand to the first to market generic, as early as possible during the period of exclusivity. The memo stated that this is done through enticing the accounts with an

increased spread between WAC and AWP.

137. ROXANE was aware that its customers sought pricing based on false AWP prices and higher spreads between AWP and contract prices. A document that was in the possession of ROXANE and prepared by a drug purchasing organizations for bidding by Drug Manufacturers, states that contract pricing will be evaluated on lowest price and/or best spread between AWP and the contract price for multisource products.

138. The false price representations, as they were reported by Defendant ROXANE to the State via FDB, affected the price paid by DHS directly through the FDB prices and also through falsely inflated FUL.

139. The acts of Defendant ROXANE in reporting false and misleading price information used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified ROXANE drugs in amounts that substantially exceeded the amounts that otherwise should have been paid.

(b) Were knowingly committed in order to induce Defendant ROXANE's customers, and those acting in concert with them, to select Defendant ROXANE's drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

140. The actions by Defendant ROXANE alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**O. SPECIFIC ALLEGATIONS AS TO DEFENDANT SICOR**

141. From January 1, 1994, to the present, SICOR knowingly caused thousands of false claims for reimbursement for SICOR's drug products described herein to be presented to the Medi-Cal program for payment or approval. SICOR knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendants' drugs including those specified in this Section and in **Exhibit P**, attached to the First Amended Complaint in Intervention and incorporated herein by reference. This Exhibit lists the drug products' NDC; label name; date; CDP; a market price per unit; and the source of that market price. The wrongful acts committed

by SICOR included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendants’ drugs, and that providers would submit false claims for such reimbursements. SICOR had controlled and set the AWP for its pharmaceutical products through direct communications with industry price reporting services. For example, by letter dated February 21, 1994, Defendant SICOR advised Medi-Span of the impending launch of its new product called “Etoposide” and included specific guidelines for establishing GENSLA’s AWP for Etoposide. Simultaneously, SICOR sent a second letter to Medi-Span stating detailed information for their product and the AWP that Medi-Span should use:

<b>Etoposide Injection</b>				
<b>NDC#</b>	<b>Product Description</b>	<b>Vial Size</b>	<b>List Price</b>	<b>AWP</b>
0703-5643-01	20MG/ML (100MG)	5ML	\$105.16	\$131.30
0703-5646-01	20MG/ML (500MG)	25ML	\$483.74	\$638.76

142. Moreover, SICOR told its sales force to rely on the AWP information contained in the industry price reporting services when marketing to customers. For example, a memorandum dated April 6, 1994 to “Field Sales Force” regarding AWP provided up-to-the-minute printouts of GENSLA’s product and AWP information for SICOR directly from Medi-Span’s computer file. This information was more accurate than the information used by GENSLA’s customers. The printout identified the AWP and also provided the WAC and DP.

143. SICOR actively monitored the reported AWP’s of its competitors. This effort was done to determine the “correct” pricing when a drug entered the marketplace. In other words, SICOR wanted to ensure its reported AWP was the highest among its competitors to ensure its generic brand was prescribed most by oncologists seeking the greatest financial benefit gained by the enormous spread, and in turn, SICOR would reap the largest market share.

144. For example, for Doxorubicin, SICOR created charts identifying the competitors, their prices and the AWP. In this case, the 200mg size of Doxorubicin the identified “Market Price” was \$266.00; while SICOR competitors’ [Adria] AWP was \$946.94. Defendant GENSLA’s AWP for the same drug was \$966.14. Further evidence of this practice is highlighted



in internal SICOR documents. In a SICOR spreadsheet finalized in 1996, a survey of all the Red Book prices for Etoposide and Doxorubicin showed that SICOR consistently had the absolutely highest reported AWP, and in turn the largest spread, when compared to all other manufacturers competing in the marketplace.

145. SICOR engaged in an ongoing deliberate scheme to inflate AWP, and its scheme worked. For example, by letter dated September 25, 2000, to the HCFA administrator, the Chairman of the Commerce Committee revealed that: “[I]n 1998, a health care provider could buy Gensia’s Etoposide for \$14.00, while the AWP used to determine Medicare reimbursement was \$141.97.”

146. SICOR’s marketing strategies further demonstrate its fraudulent practices. In a marketing document prepared by SICOR and obtained by the government in its investigation, SICOR stated:

Concentrate field reps on the top 40 AIDS hospitals using a \$54.00 price in conjunction with a 10% free goods program to mask the final price. Provides the account with an effective price of \$48.60 per vial.

*See*, letter dated September 28, 2000 from U.S. Rep. Pete Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America.

147. Further, SICOR did not hesitate to directly market the spread to its clients. For example, in a flyer or advertisement “To All MHA Members”, SICOR advertises Doxorubicin listing the contract price, the AWP and the actual dollar spread each end-user would reap by ordering the drug. SICOR spelled out in black-and-white, side-by-side, the price the end-user paid and the price reimbursed by the Government, so every physician could see what dollars went directly into their pocket, because SICOR knew that marketing the spread was in its best interests. Realizing this, one customer of SICOR, Opticare, sent a memorandum to all its offices (with a copy to GENSIA) stating: “Gensia’s products offer a significant spread between AWP and contract price. This spread may be attractive, when a payor’s reimbursements is based on AWP and the drug is not MAC’d.”

148. According to the SICOR’s own documents, the published AWP for its drugs were higher than the actual prices provided to wholesalers. In response to government

subpoenas, SICOR produced numerous price lists setting forth spreads between AWP and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that SICOR has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

149. In addition to marketing the spread, SICOR utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing “off-invoice” inducements, such as free goods, SICOR provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

150. As set forth above, SICOR’s scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs and its use of other “off invoice” rebates and financial inducements to its customers has resulted in excessive overpayments by the State. The acts of SICOR in reporting false and misleading price information used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified SICOR drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce SICOR’s customers, and those acting in concert with them, to select SICOR’s drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

151. The actions by SICOR alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

**P. SPECIFIC ALLEGATIONS AS TO DEFENDANT SMITHKLINE**

152. From on or after January 1, 1994, to the present, SMITHKLINE DEFENDANTS knowingly caused over ten thousand false claims for reimbursement for SMITHKLINE DEFENDANTS’ drug products described herein to be presented to the Medi-Cal program for payment or approval. SMITHKLINE DEFENDANTS knowingly used or caused the use of false

statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendants' drugs including those specified in this Section and in **Exhibit R**, attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by SMITHKLINE DEFENDANTS included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendants' drugs, and which would cause the claims for such reimbursements to be false. In connection with reporting a false inflated AWP of \$166.00 for SMITHKLINE's drug Kytril, SMITHKLINE implemented a plan to offer deep discounts to the oncology supply houses which supplied Kytril to physicians and clinics. On or about February 9, 1994, SMITHKLINE employee Elizabeth Posner sent an internal memorandum to Howard Pien regarding the WAC prices for Kytril. The memorandum recommended that SMITHKLINE provide Kytril to the oncology supply houses (such as Florida Infusion, OTN, or Oncology Supply) at a 16 2/3% discount off WAC or free goods equivalent in order to create a profit incentive. In fact, SMITHKLINE did create a standard discount to all oncology supply houses based on profit received from Medicare and Medicaid reimbursement.

153. In a power point presentation on or about February 28, 1994, prior to the launch of the Kytril 1mg vial by SMITHKLINE, the "Price Strategy" for the Kytril launch was "AWP is high enough to provide an attractive reimbursement margin for customers" and "Moderate list price advantage disguises true customer acquisition cost advantage." SMITHKLINE employees created numerous comparisons of reimbursement of SMITHKLINE's Kytril and GLAXO's Zofran and distributed them to induce the physicians to purchase Kytril over Zofran, based on the profit or kickback they would receive in the form of higher reimbursement from Medicare and Medicaid funds. For example, a SMITHKLINE drug salesman named Heidi Haas ("HAAS") gave a health care provider in the Denville, New Jersey area promotional literature entitled "Cost v. Profit" between March 11, 1994, and February 6, 1995. SMITHKLINE's handout advocated that the physician use two SMITHKLINE 1 mg vials of Kytril on three patients and bill Medicare for three vials of Kytril. SMITHKLINE's handout further showed

that the profit received by prescribing physicians for use of its drug Kytril on three patients was \$163.20 and the profit received if its competitor GLAXO's Zofran was used was \$108.00. HAAS also distributed handouts with a detailed analysis of how its physician customers should pool vials of Kytril to obtain the most profit. On or about March 18, 1994, Horace Cook, Director of Trade Operations at SMITHKLINE, represented to Medical Economics Data (Red Book) employee, Lynne Handler ("HANDLER"), a false inflated AWP for SMITHKLINE's drug Kytril of \$166.00, when Kytril's true price to SMITHKLINE's customers was approximately \$112.75, as stated in Florida Infusion's catalog (an insider publication not available to the Government). COOK obtained HANDLER's signature on a document reporting the AWP for Kytril of \$166.00 and distributed the document to various persons including, but not limited to, health care providers making claims under Medicare Part B and various States' Medicaid programs.

154. In a chart created by SMITHKLINE for Kytril oncology supply house margins for April of 1994, the oncology supply house cost was 12% lower than WAC, creating a profit margin of 29.6% from Medicare reimbursement. The "Margin" was calculated on the chart by dividing the difference between AWP and Cost by AWP.

155. During that same time period, SMITHKLINE also offered a "special 8% added discount" which increased the profit received from Medicare to 35.2%.

156. On or about April 15, 1994, Peg Skelly ("SKELLY"), a SMITHKLINE employee, sent a letter to Jenie DeKneff, an official of the Texas Department of Health, wherein SKELLY represented for purposes of Texas Medicaid vendor reimbursement a false inflated AWP for Kytril, of \$166.00 when the price actually charged to SMITHKLINE's customers was \$112.75.

157. Another example of SMITHKLINE promoting the pooling of vials is, on or about October 17, 1994, Tom McClean, an employee of SMITHKLINE, prepared a memo entitled "Kytril Profit Model" and distributed it to other SMITHKLINE employees. The memo was also distributed to at least one health care provider in the Brunswick, Georgia area between October 17, 1994 and February 6, 1995. The memo compared the Medicare and Medicaid reimbursement for Kytril and Zofran, promoted pooling the 1mg single dose vials of Kytril, and

set out a format to market Kytril based upon the spread, the amount of the kickback SMITHKLINE caused to be paid from Government funds to SMITHKLINE's customers, the health care providers. The memo stated that, when using .7mg of 1 mg vial of Kytril, the average dose when pooling vials, the physician received \$81.00 of profit, because the AWP for a 1 mg vial of Kytril was \$166.00 and the actual cost of Kytril when pooling 1 mg vials was an average of \$85.00. McClean's claim, that costs go down and, therefore, profits to SMITHKLINE's customers go up as a result of pooling, was only true if the physician billed Medicare for full 1 mg vials when only .7 mg of 1 mg vials were used. For example, using two 1 mg vials for three patients and billing Medicare for three full 1 mg vials.

158. In a memorandum regarding the Zofran "price increase" dated January 11, 1995, from SMITHKLINE employee Dick Van Thiel ("Van Thiel") to SMITHKLINE employees Jerry Karabelas and Howard Pien, SMITHKLINE's Van Thiel reported, "I believe Glaxo is trying to provide oncology supply houses the same margins SB offers." VAN THIEL further stated that GLAXO raised its "price" or AWP, but offered a 14% rebate to all non-hospital customers, therefore providing a profit of \$52.75 per 32mg dose and a 28% margin to the doctor, whereas Kytril provided a profit of \$49.40 per 1mg dose and a 30% profit margin to the doctor. As a result, VAN THIEL concluded:

This new Glaxo strategy allows an oncologist to make more money by using Zofran due to higher price but allows a lesser margin than Kytril by 2%.

I believe the Zofran price increase and across the board discount for oncology supply houses that match our margins is a clear signal that Glaxo does not want to compete on price but is willing to lower price to meet our margins with oncology supply houses.

159. A SMITHKLINE memorandum dated February 25, 1995, showed that, after GLAXO increased the AWP of Zofran, the profit per vial was \$66.03, whereas the profit per vial for Kytril was \$47.05. However, SMITHKLINE's analysis further calculated the profit per dose. The profit per dose of Zofran was \$52.82 and the profit per dose of Kytril was \$70.84. The calculation of profit per dose was based on a dose of .8 mg with 1mg full vial reimbursed, while the remainder of the vial was to be "pooled" by the physician.

160. In an email dated March 25, 1995, from SMITHKLINE employee William

Chrencik to SMITHKLINE employee Robert Turner regarding the importance of reimbursement factors in the clinic setting, Chrencik concluded:

1. If an oncologist uses Kytril he makes money.
2. However, if an oncologist uses Zofran he loses money.  
Therefore, there is a positive profit impact to the clinic when Kytril is utilized.

161. SMITHKLINE knew that the prices it reported to Red Book, First Data Bank, the Texas Department of Health, and others were used to set Medicare and Medicaid reimbursement. In an internal report entitled “Kytril Market Situation Analysis” created on or about May 17, 1995, a SMITHKLINE employee stated:

Medicare currently reimburses physicians the average wholesaler price (AWP) for chemotherapeutic agents administered in the office or clinic. Because AWP is set by the manufacturer and often does not reflect actual market prices (wholesaler prices are normally much lower), profit-seeking physicians have a strong incentive to use whichever agents offer the greatest spread between actual cost and AWP.

162. SMITHKLINE created computer software programs based on the concept that a physician can “make money” if he uses Kytril and will “lose money” if he uses Zofran and distributed the programs to its sales personnel for use in physicians’ offices. SMITHKLINE designed the programs “to calculate total profits that can be achieved by using Kytril instead of Zofran.” The program calculated the “Differences in Reimbursement” between Kytril and Zofran, the “Total Reimbursement” per day and per year, the cost per day and per year, and the “Difference By Switching to Kytril Per Year.” Furthermore, the program was able to calculate “profit” based on the percentage of Medicare and/or Medicaid patients the physician treated. SMITHKLINE entered into rebate agreements with physicians groups such as PRN which provided for payments of kickbacks. On or about October 16, 1995, David Lichtenstein, Senior Contract Manager, and Jerry Ghastin, Account Manager, both employees of SMITHKLINE, offered to Bob Whren, Executive Vice President of Physicians Reliance Network (“PRN”) to pay a rebate of \$11.60 per vial of SMITHKLINE’s Kytril purchased in exchange for the condition that PRN maintain and market Kytril as the preferred oral and injectable anti-emetic. Bob Whren on behalf of PRN accepted SMITHKLINE’s offer and SMITHKLINE’s financial incentives on October 25, 1995, and SMITHKLINE’s David Lichtenstein and Jerry Ghastin also

signed the SMITHKLINE/PRN letter agreement on October 31, 1995. On or about April 4, 1996, SMITHKLINE's Jerry Ghastin prepared a utilization report for PRN, comparing PRN's utilization of SMITHKLINE's Kytril, versus its competitor GLAXO's Zofran. The report showed that SMITHKLINE's financial inducements dramatically increased utilization of SMITHKLINE's Kytril and at that time Kytril had 82.14% of the patient market share.

163. Although the true price of SMITHKLINE's drug Kytril was decreasing in the market place, as evidenced by SMITHKLINE's increase of the rebate paid to its customers who prescribed Kytril and the guaranteed price of \$102.00, SMITHKLINE represented to the Government that the price for Kytril was increasing, by reporting a false inflated AWP of \$173.95 on or about March of 1996.

164. Van Thiel and other SMITHKLINE employees strategized, analyzed, and implemented the fraud scheme to provide larger and larger kickbacks to the physicians to induce more sales of Kytril. In response to GLAXO's false inflation of Zofran's AWP to \$244.43 on March 7, 1996, SMITHKLINE reported a new false inflated AWP for Kytril of \$173.95 on or about March 26, 1996.

165. Van Thiel and SMITHKLINE employee Rich Francovitch analyzed the AWP increases in a power point presentation on or about June 6, 1996. The power point presentation showed calculations of "profit" for both Kytril and Zofran as a result of the increases. The power point also shows that the "profit" or kickback was being paid for by Medicare funds. SMITHKLINE actively encouraged physicians to dose Kytril based upon weight and then to pool the vials of Kytril to receive greater reimbursement. In a report entitled "Kytril Situation Analysis 1996," under the heading "Opportunities/Threats" a SMITHKLINE employee stated:

Physicians are not taking advantage of *Kytril's* full economic benefit because a large percentage of them are still giving an entire 1mg vial to each patient rather than dosing based on weight. SB is encouraging weight-based dosing - a move that could save customers 20-30%, and offset the effects of Zofran down-dosing. By lowering *Kytril's* effective cost per dose, SB expects to increase total usage, offsetting the 20%-30% reduction in dose. . . .

166. In a letter agreement dated on or about June 26, 1996, SMITHKLINE's David Lichtenstein and Jerry Ghastin offered to amend the SMITHKLINE/PRN Kytril Agreement

dated October 16, 1995 effective July 1, 1996, by increasing PRN's rebate to \$20.46 per vial and guaranteeing a net price of \$102.00 for SMITHKLINE's drug Kytril. The terms of the agreement were accepted by PRN's Bob Whren on July 8, 1996. PRN received rebates from SMITHKLINE for the third quarter of 1996 totaling \$235,658.28 and for the fourth quarter of 1996 totaling \$276,946.56.

167. The SMITHKLINE prepared a document entitled "ORAL ANTI-EMETICS COVERAGE EFFECTIVE 1/1/98" showing the difference in reimbursements when using its drug, Kytril, as compared to its competitor's drug, Zofran. SMITHKLINE's calculations for both drugs were based on each drug's AWP. SMITHKLINE concluded, "All parties, the payer, patient and the physician are better off using Kytril Tablets."

168. The acts of the SMITHKLINE DEFENDANTS in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified SMITHKLINE DEFENDANTS' drugs in amounts that substantially exceeded the amounts that otherwise should have been paid according to law.

(b) Were knowingly committed in order to induce the SMITHKLINE DEFENDANTS' customers, and those acting in concert with them, to select the SMITHKLINE DEFENDANTS' drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.

169. The actions by the SMITHKLINE DEFENDANTS were a substantial factor in causing the damages that California has sustained as set forth below.

**Q. SPECIFIC ALLEGATIONS AS TO DEFENDANT WARRICK**

170. From on or after January 1, 1994, to the present, Defendant WARRICK knowingly caused over four million false claims for reimbursement for WARRICK's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant WARRICK knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit K** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWP; from FDB;



CDP; a market price per unit; and the source of that market price. The wrongful acts committed by WARRICK included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false. WARRICK has reported and continues to report an inflated AWP and WAC which in turn affect Federal Upper Limit prices and cause over-reimbursement of their drugs California. WARRICK has taken the position in this litigation that they initially reported an AWP at ten to twenty percent below the equivalent brand product's AWP, and that AWP remained constant over time. With respect to WARRICK's drugs, however, there has been a decline in real wholesale prices as the generic drugs remain on the market over time. This decline in price has not been passed on to the consumer or to California by WARRICK.

171. One of WARRICK's customers asked WARRICK if they could be released from contractual obligations to deal with invoices containing arbitrary, artificially inflated and false price information which served no legitimate business purpose and which caused unnecessary, costly and meaningless bookkeeping and accounting work to be done. Instead, the customer asked to receive invoices in the future which more accurately represented the actual transactions reflected by the respective invoices.

172. WARRICK had significant spreads on its drugs, for example the Albuterol Inhaler (NDC 59930156001). In comparing wholesale prices of the inhaler in second quarter 2001 to the price reimbursed by DHS, up to 71% of the DHS price paid for the inhaler is spread. In other words DHS' price paid to the provider for the WARRICK inhaler is 351% of the contract price paid by providers.

173. SCHERING-PLOUGH CORP. (WARRICK's parent company) attempted to gain market share by increasing the spread between reported price and actual price for its drugs. Parent company SCHERING-PLOUGH CORP. has admitted that its goal is to increase utilization and expand sales. SCHERING-PLOUGH CORP. and WARRICK were motivated to dominate the generic market through pricing flexibility in marketing new generic drugs. SCHERING-PLOUGH CORP. has admitted that it could reduce fraud by lowering the AWP on their products.

174. The Defendants WARRICK and SCHERING-PLOUGH CORP. entered into specific agreements and contracts with one or more telemarketing companies, including TMS (a/k/a Access Worldwide) a company located in Florida, but doing business by making telephonic contacts in California. As part of telephone sales pitches, telemarketers would advertise and promote WARRICK and SCHERING-PLOUGH CORP. products in part by marketing the spread and urging purchases of these products based upon the large and profitable spread between the net price the pharmacies would pay for the drugs and the high reimbursement amount those pharmacies would receive, known as the “profit message” and/or Return on Investment (“ROI”), among other phrases.

175. The acts of Defendant WARRICK in reporting false and misleading price information used by Medi-Cal in setting reimbursement amounts:

(a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified WARRICK drugs in amounts that substantially exceeded the amounts that should have been paid according to law.

(b) Were knowingly committed in order to induce Defendant WARRICK’s customers, and those acting in concert with them, to select Defendant WARRICK’s drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

176. The actions by Defendant WARRICK were a substantial factor in causing the damages that California has sustained as set forth below.

## **VII.**

### **CALIFORNIA LAW VIOLATED BY DEFENDANTS**

177. At all times relevant and material to this action, each Defendant “knew” or acted “knowingly,” which terms are defined in California Government Code section 12650, subdivision (b)(2), in causing the making, presenting, or submission of false claims. In that respect, each Defendant acted:

- (a) With actual knowledge of the information; or
- (b) In deliberate ignorance of the truth or falsity of the information; or
- (c) With reckless disregard of the truth or falsity of the information.

178. At all times relevant and material to this action, each Defendant “caused” the making, presenting, or submitting of false claims, as that term is defined in California Government Code section 12651, in causing:

(a) The presentation of false claims for payment or approval by Medi-Cal; and,

(b) The making and using of false statements and/or records for the purpose of getting false claims approved or paid by Medi-Cal. At all times relevant and material hereto, each Defendant knew that its conduct would cause Medi-Cal to pay claims for the specified prescription drugs in amounts exceeding that contemplated by applicable law.

179. Each Defendant “knowingly” reported or caused to be reported false and inflated AWP, DP, and WACs to FDB, Red Book, and the other pricing services by systematically concealing or otherwise failing to report decreases in the prices of the specified prescription drugs.

180. At all times relevant and material hereto, each Defendant knew that its conduct was in violation of California Welfare and Institutions Code section 14107.2, which prohibits receiving remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind in return for the purchasing, ordering, or arranging for or recommending the purchasing, or ordering of any goods, service or merchandise for which payment may be made, in whole or in part, under the Medi-Cal Program.

## **VIII.**

### **CAUSES OF ACTION AND DAMAGES**

#### **FIRST CAUSE OF ACTION**

#### **CALIFORNIA FALSE CLAIMS ACT, CAUSING PRESENTATION OF FALSE CLAIMS TO CALIFORNIA**

##### **California Government Code section 12651, subdivision (a)(1)**

181. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.

182. At all times relevant and material to this First Amended Complaint in

Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSLIA INC.; GENSLIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSLIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] caused false claims for payment or approval, in the form of false Medi-Cal Cost information for the drugs specified herein to be presented to officers or employees of the State. As a result, the State paid out as reimbursement to the Medi-Cal providers of the specified prescription drugs sums of money grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

183. Defendants' conduct violated Government Code section 12651, subdivision (a)(1) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

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## **SECOND CAUSE OF ACTION**

### **CALIFORNIA FALSE CLAIMS ACT, CAUSING FALSE RECORDS OR STATEMENTS TO BE MADE OR USED TO GET FALSE CLAIMS PAID OR APPROVED BY CALIFORNIA**

#### **California Government Code section 12651, subdivision (a)(2)**

184. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.

185. At all times relevant to this First Amended Complaint in Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSLA INC.; GENSLA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSLA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] caused false records or statements to be made or used to get false claims to be paid or approved by the State, in that Defendants caused false records or statements of the Medi-Cal Cost of Defendants' specified prescription drugs to be used by the State to pay or approve claims presented by the providers and suppliers of Defendants' specified prescription drugs. These paid or approved claims were

grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

186. Defendants' conduct violated Government Code section 12651, subdivision (a)(2) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

### **THIRD CAUSE OF ACTION**

#### **CALIFORNIA FALSE CLAIMS ACT, BENEFICIARIES OF INADVERTENT SUBMISSIONS OF FALSE CLAIMS TO CALIFORNIA, SUBSEQUENTLY DISCOVER THE FALSITY OF THE CLAIMS, AND FAIL TO DISCLOSE THE FALSE CLAIMS TO CALIFORNIA WITHIN REASONABLE TIME AFTER DISCOVERY OF THE FALSE CLAIMS**

##### **California Government Code section 12651, subdivision (a)(8)**

187. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.

188. At all times relevant to this First Amended Complaint in Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSLA INC.; GENSLA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSLA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES,

LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] were beneficiaries of inadvertent submissions of false claims to the State, subsequently discovered the falsity of the claims, and failed to disclose the false claims to the State within reasonable times after discovery of the false claims. On learning that Medi-Cal was paying inflated reimbursement amounts based upon the Defendants' falsely inflated reports of price and costs, and thereby paying false claims for the Defendants' drugs, the Defendants failed to disclose the false claims to the state within a reasonable time after discovery of the false claims. The Defendants' failure to disclose to the State, as required by Section 12651(a)(8), caused great financial loss to the State.

189. Defendants' conduct violated Government Code section 12651, subdivision (a)(8) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

#### **FOURTH CAUSE OF ACTION**

##### **CALIFORNIA FALSE CLAIMS ACT, CAUSING PRESENTATION OF FALSE CLAIMS; ILLEGAL REMUNERATION**

##### **California Government Code section 12651, subdivision (a)(1)**

190. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.

191. At all times relevant to this First Amended Complaint in Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME

CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSLIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knew that the prices charged to their customers for the specified pharmaceuticals were significantly reduced in amount from the prices and costs represented by the Defendants and upon which the Defendants knew Medi-Cal claims would be approved and paid. Accordingly, the Defendants have each knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from Medi-Cal to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the drugs named herein, and other drugs, for which the Defendants knew that payment would be made, in whole or in part, by Medi-Cal. Such financial inducement is specifically prohibited by California Welfare and Institutions Code section 14107.2. These paid or approved claims were grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

192. The Defendants knew that Medi-Cal would not pay or approve claims for the drugs named herein, and other drugs, if it were disclosed to Medi-Cal that said claims were for amounts that included remuneration prohibited by California Welfare and Institutions Code section 14107.2.

193. The Defendants also knew that their customers, in presenting claims for the drugs named herein and other drugs to Medi-Cal, would not and did not disclose that the claim amounts included the remuneration prohibited by California Welfare and Institutions Code section 14107.2.

194. The Defendants' knowing [as defined in California Government Code section 12650, subdivision (b)(2)] and willful actions in arranging for their customers to receive



remuneration prohibited by California Welfare and Institutions Code section 14107.2, in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, the claims for the drugs named herein, and other drugs, to be false claims and caused the claims to be presented to Medi-Cal for payment and approval in violation of California Government Code section 12651, subdivision (a)(1).

195. Defendants' conduct violated Government Code section 12651, subdivision (a)(1) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

#### **FIFTH CAUSE OF ACTION**

#### **CALIFORNIA FALSE CLAIMS ACT, CAUSING FALSE RECORDS OR STATEMENTS TO BE MADE OR USED TO GET FALSE CLAIMS PAID OR APPROVED BY CALIFORNIA; ILLEGAL REMUNERATION California Government Code section 12651, subdivision (a)(2)**

196. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.

197. At all times relevant to this First Amended Complaint in Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.;

ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSLIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knew that the prices charged to their customers for the drugs named herein, and other drugs, were significantly reduced in amount from the prices and costs represented by the Defendants and upon which the Defendants knew Medi-Cal claims would be approved and paid. Accordingly, the Defendants have each knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from Medi-Cal to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the drugs named herein, and other drugs, for which the Defendants knew that payment would be made, in whole or in part, by Medi-Cal. Such financial inducement is specifically prohibited by California Welfare and Institutions Code section 14107.2. These paid or approved claims were grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

198. The Defendants knew that Medi-Cal would not pay or approve claims for the drugs named herein, and other drugs, if it were disclosed to Medi-Cal that said claims were for amounts that included remuneration prohibited by California Welfare and Institutions Code section 14107.2.

199. The Defendants also knew that their customers, in presenting claims for the drugs named herein, and other drugs, to Medi-Cal, would not and did not disclose that the claim amounts included the remuneration prohibited by California Welfare and Institutions Code section 14107.2.

200. The Defendants' knowing [as defined in California Government Code section 12650, subdivision (b)(2)] and willful actions in arranging for their customers to receive remuneration prohibited by California Welfare and Institutions Code section 14107.2, in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused false records or

statements to be made and used to get false claims paid or approved by the State for the drugs named herein, and other drugs. The Defendants' actions herein caused said false records or statements to be made and used as prohibited by California Government Code section 12651, subdivision (a)(2).

201. Defendants' conduct violated Government Code section 12651, subdivision (a)(2) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

## **IX.**

### **JURY DEMAND**

202. The State and Qui Tam Plaintiff respectfully request a trial by jury as to all issues so triable.

## **X.**

### **PRAYER FOR RELIEF**

WHEREFORE, the State and the Qui Tam Plaintiff demand:

1. That judgment be entered in their favor and against Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a

GENSIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, with judgment to be entered against said Defendants, and each of them, for the amount of damages to Medi-Cal arising from claims for their specified prescription drugs and all other drugs as to which said Defendants engaged in substantially similar misconduct:

(a) On the First Cause of Action (California False Claims Act; Causing Presentation of False Claims to California) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:

- (i) Triple the amount of the State's damages;
- (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
- (iii) Recovery of costs, attorneys' fees and expenses;
- (iv) Such other and further relief as the Court deems just and proper.

(b) On the Second Cause of Action (California False Claims Act; Causing False Records or Statements To Be Made or Used To Get False Claims Paid or Approved By California) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:

- (i) Triple the amount of the State's damages;
- (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
- (iii) Recovery of costs, attorneys' fees and expenses;
- (iv) Such other and further relief as the Court deems just and proper.

(c) On the Third Cause of Action (California False Claims Act; Beneficiaries of Inadvertent Submissions of False Claims to California, Subsequently Discover the Falsity of the Claims, and Fail to Disclose the False Claims to California Within Reasonable Time after Discovery of the False Claims) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:

- (i) Triple the amount of the State's damages;

- (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
- (iii) Recovery of costs, attorneys' fees and expenses;
- (iv) Such other and further relief as the Court deems just and proper.

(d) On the Fourth Cause of Action (California False Claims Act; Causing Presentation of False Claims; Illegal Remuneration) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:

- (i) Triple the amount of the State's damages;
- (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
- (iii) Recovery of costs, attorneys' fees and expenses;
- (iv) Such other and further relief as the Court deems just and proper.

(e) On the Fifth Cause of Action (Causing False Records or Statements to Be Made or Used to Get False Claims Paid or Approved by California; Illegal Remuneration) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:

- (i) Triple the amount of the State's damages;
- (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
- (iii) Recovery of costs, attorneys' fees and expenses;
- (iv) Such other and further relief as the Court deems just and proper.

2. Further, the Qui Tam Plaintiff, on its behalf, requests that it receive such maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the State, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Qui Tam Plaintiff requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

Dated: August 24, 2005

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of the State of California

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On Behalf of the Qui Tam Plaintiff

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### CERTIFICATE OF SERVICE

I, BRIAN V. FRANKEL, hereby certify that on August 24, 2005, I caused a true and correct copy of the foregoing, **FIRST AMENDED COMPLAINT IN INTERVENTION FOR MONEY DAMAGES AND CIVIL PENALTIES FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT, WITH EXHIBITS A THROUGH R (all Exhibits except L are redacted)**, to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to Verilaw Technologies for posting and notification to all parties.

Dated: August 24, 2005



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