UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CONSTANCE A. CONRAD Plaintiffs, v. ABBOTT LABORATORIES, INC. ACTAVIS MID-ATLANTIC, LLC. f/k/a Alpharma, Inc., BIOVAIL PHARMACEUTICALS, LLC, BLANSETT PHARMACAL COMPANY, INC., CYPRESS PHARMACEUTICALS, INC., DURAMED PHARMACEUTICALS, INC., E. CLAIBORNE ROBINS COMPANY, INC. FERNDALE LABORATORIES, INC., GOLDLINE LABORATORIES, INC., HEALTHPOINT, LTD., HAWTHORN PHARMACEUTICALS, INC., HI-TECH PHARMACAL COMPANY, INC., MEDPOINTE, INC., f/k/a Carter Wallace, Inc. MYLAN INC. f/k/a Mylan Laboratories, Inc. PAMLAB, LLC., f/k/a Pan American Laboratories, Inc., QUALITEST PHARMACEUTICALS, INC., RUGBY LABORATORIES, INC., SCIELE PHARMA, INC. f/k/a First Horizon Pharmaceutical Corp., SHIRE US, INC., TEVA PHARMACEUTICALS USA, INC., f/k/a Copley Pharmaceutical, Inc., THE HARVARD DRUG GROUP, LLC d/b/a Major Pharmaceuticals, UNITED RESEARCH LABORATORIES, INC., WARNER CHILCOTT CORPORATION WATSON LABORATORIES, INC. – FLORIDA f/k/a Andrx Pharmaceuticals, Inc. Defendants.	)	C.A. No. 02-CV-11738-RWZ **TENTH AMENDED FALSE CLAIMS ACT COMPLAINT** **Leave to File Granted July 26, 2011**

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I. Nature Of The Case

1. Constance A. Conrad ("Relator") brings this action on behalf of the United States of America ("United States") for treble damages and civil penalties arising from Defendants' violations of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). Defendants submitted false records or statements to the United States through the federal Center for Medicare and Medicaid Services ("CMS") and thereby caused false claims for payment to be made through state Medicaid programs for unapproved or ineffective drugs, or for products that are not drugs at all.

2. Medicaid provides prescription drug reimbursement only for statutorily defined "Covered Outpatient Drugs." "New Drugs" that the FDA has not approved are expressly excluded from the definition, as are non-drug items, like vitamins, minerals and other dietary supplements. The products sold to Medicaid which are identified in this Complaint are not approved by the FDA and have never been proven safe and effective. Nevertheless, Defendants reported false information to CMS regarding these products, representing that they met the definition of a Covered Outpatient Drug to make them ostensibly eligible for Medicaid reimbursement.

3. This false information corrupted CMS's list of Medicaid reimbursable drugs, caused claims for ineligible products to be submitted to state Medicaid programs, led state programs to pay for and in turn seek reimbursement from CMS for such ineligible drugs, and thereby caused CMS to pay false claims, all in violation of 31 U.S.C. §§ 3729(a)(1)(A) and (B).

4. The Defendants' FCA violations fall into four categories:

(i) knowingly submitting false information concerning "New Drugs" that have not been FDA approved, thereby causing false claims to be made;

(ii) knowingly submitting false information concerning drugs which have not been FDA approved, and which have been determined to be "Less Than Effective" for all indications, thereby causing false claims to be made;

(iii) knowingly submitting false information concerning dietary supplements, which are not drugs, thereby causing false claims to be made;

(iv) knowingly causing to be presented false claims by the submission of the false information described herein.

5. The Defendants' FCA violations caused the federal and state governments to pay well in excess of $500 million in false claims. This number represents only the amounts specifically identified in the body of the Complaint, and even those amounts do not encompass all of the years for which such false claims were paid.

6. But for Defendants' express misrepresentations that their products were Covered Outpatient Drugs and therefore Medicaid-eligible, the federal government and the states would not have paid untold millions in reimbursement claims and Defendants would not have had illegal access to the enormous Medicaid market.

7. The Defendants' unapproved drugs are not only ineligible for Medicaid coverage, their manufacture and sale violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), and subjects the Defendants to criminal penalties as well. *See* 21 U.S.C. § 331(d). Defendants' submission of them to Medicaid for coverage is therefore doubly reckless and brazen. For the purposes of clarity and brevity in this Complaint, Defendants' unapproved drugs are called "Illegal Drugs."

8. The Defendants' dietary supplements are not "drugs" by any definition, and as such do not even remotely satisfy the Covered Outpatient Drug criteria. Among other exclusionary markers, unless a product is legally required to carry a National Drug Code ("NDC") number, it is expressly excluded from the definition of a Covered Outpatient Drug. 42

U.S.C. §1396r-8(k)(3). Dietary Supplements are not required to carry an NDC, but as Medicaid's payment system identifies products by those NDC numbers, Defendants unilaterally created NDCs for their supplements and so reported them to CMS. Without these rogue NDCs, Defendants' Non-Drugs could never have infiltrated the Medicaid Drug Rebate Program. For the purposes of clarity and brevity in this Complaint, these dietary supplements are called "Non-Drugs."

9. The Defendants knew that the Illegal Drugs and Non-Drugs that are the subject of this Complaint were not Medicaid eligible Covered Outpatient Drugs. The Defendants also knew that CMS would rely on their representations in creating the Medicaid eligible prescription drug list it maintains, and that their products' inclusion as Covered Outpatient Drugs on that list would result in the submission and payment of false claims. So Defendants misrepresented their products to make them appear eligible.

10. This *qui tam* also seeks to recover losses caused by false claims submitted to other federally funded healthcare programs, including but not limited to Medicare, Tricare, Veterans Administration and Federal Employees Health Benefit. These additional claims for damages are limited to the Defendant: HEALTHPOINT (Xenaderm product only). For instance, Healthpoint, the manufacturer of Xenaderm (HEALTHPOINT) represented this product to be a Medicare Covered Outpatient Drug when submitting documentation to become eligible for Medicare Part D. As a result of Medicare's reliance upon these false representations, this drug was mistakenly covered under Medicare Part D from January 1, 2006 until Medicare discovered the deception.

11. Each Defendant's liability is premised upon a single, simple element – the knowing submission to CMS of false information, which misidentified unapproved drugs and dietary supplements which defendants manufactured and sold, as Covered Outpatient Drugs.

II. Federal Jurisdiction and Venue

12. The acts proscribed by 31 U.S.C. § 3729, *et seq*., and complained of herein occurred in the District of Massachusetts and elsewhere. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732(a), as well as under 28 U.S.C. § 1345.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this District and one or more of the acts proscribed by 31 U.S.C. § 3729 occurred in this District.

14. The allegations contained in this action have not been the subject of a public disclosure pursuant to § 3730(e)(4)(A) of the FCA.

III. The Parties

15. The United States funds the provision of medical care, including pharmaceutical products, for eligible individuals through government healthcare programs such as Medicaid, Medicare, TRICARE, and other agencies and programs (hereinafter "Government Healthcare Programs"), acting through CMS.

16. Relator, Constance A. Conrad, is a resident of the state of Pennsylvania. Ms. Conrad has over 30 years experience in the federal healthcare programs field.

17. The Defendants are drug manufacturers, distributors, and labelers. For brevity, when not referred to herein as "Defendants", they are simply called "manufacturers". The Defendants named in this Complaint shall include any successor (by merger, operation of law or otherwise) or assigns of such entity.

18. All Defendants engaged in the business of manufacturing, marketing, distributing and/or selling Illegal Drugs or Non-Drugs, a substantial portion of which ultimately were paid for by government healthcare programs throughout the United States. These Illegal Drugs or

Non-Drugs include, but are not limited to the Illegal Drugs and Non-Drugs identified in this Complaint. At all material times, all Defendants transacted substantial business with the Commonwealth of Massachusetts, including business unrelated to the Illegal Drugs or Non-Drugs and misrepresentations made to government healthcare programs described in this complaint.

A. Abbott Laboratories, Inc. ("ABBOTT") is an Illinois Corporation with its principal place of business in Abbott Park, IL.

B. Actavis Mid-Atlantic LLC ("ACTAVIS"), f/k/a Alpharma Pharmaceutical, Inc., is a Delaware Limited Liability Company with its principal place of business in Morristown, NJ.

C. Biovail Pharmaceuticals, LLC ("BIOVAIL"), f,k/a Biovail Pharmaceuticals, Inc., is a Delaware Limited Liability Company with its principal place of business in Bridgewater, NJ. It is a subsidiary of Biovail Corporation, Canada.

D. Blansett Pharmacal Company Inc. ("BLANSETT") is an Arkansas Corporation with its principal place of business in North Little Rock, AR.

E. Cypress Pharmaceuticals, Inc. ("CYPRESS") is a Mississippi Corporation with its principal place of business in Madison, MS.

F. Duramed Pharmaceuticals Inc. ("DURAMED") is a Delaware Corporation with its principal place of business in Ohio. Duramed is a subsidiary of Barr Pharmaceuticals, Inc., a Delaware Corporation (Barr is a subsidiary of TEVA).

G. E. Claiborne Robins Company, Inc. ("Robins") is a Virginia Corporation with its principal business at 9878 Maryland Drive, Richmond, VA 23233. During all periods relevant to the Complaint, Robins did business as ECR Pharmaceuticals.

H. Ferndale Laboratories, Inc. ("FERNDALE") is a Michigan Corporation with its principal place of business in Ferndale, MI.

I. Goldline Laboratories, Inc. ("GOLDLINE"), a division of Ivax Corporation, which is a subsidiary of Teva Pharmaceutical Industries, Ltd., is a Florida Corporation with its principal place of business in Miami, FL.

J. Healthpoint, Ltd. ("HEALTHPOINT"), a subsidiary of DFB Pharmaceuticals, is a Texas Corporation with its principal place of business in Fort Worth, TX.

K. Hawthorn Pharmaceuticals, Inc. ("HAWTHORN") is a Mississippi Corporation with its principal place of business in Madison, MS.

L. Hi-Tech Pharmacal Company, Inc. ("HI-TECH") is a Delaware Corporation with its principal place of business in Amityville, NY.

M. Medpointe, Inc. ("MEDPOINTE"), n/k/a Medpointe Pharmaceuticals, Corporation, a subsidiary of MEDA AB, (purchased in August 2007), is a Delaware Corporation with its principal place of business in Somerset, NJ. Medpointe was previously known as Carter-Wallace, Inc. up to 2001.

N. Mylan, Inc., ("MYLAN"), f/k/a Mylan Laboratories, Inc., is a Pennsylvania corporation, with its principal place of business in Canonsburg, PA. Mylan sold its product Granulex under two different labeler numbers at issue herein. The first, 62794, is Bertek Pharmaceuticals and the second, 00514 Dow Hickham Pharmaceuticals, Inc., both of which have become Mylan Bertek Pharmaceuticals, Inc., a subsidiary and/or division of Mylan, Inc. For brevity all Granulex sales are identified in the complaint by reference to Mylan.

O. Pamlab, L.L.C., ("PAN AMERICAN"), f/k/a Pan American Laboratories, Inc., is a Louisiana Limited Liability Company with its principal place of business in Covington, LA.

P. Qualitest Pharmaceuticals, Inc. ("QUALITEST"), a subsidiary of Apax Partners, is an Alabama Corporation with its principal place of business in Huntsville, AL.

Q. Rugby Laboratories, Inc. ("RUGBY"), is a New York Corporation with its principal place of business in Corona, CA.

R. Sciele Pharma, Inc. ("SCIELE"), f/k/a First Horizon Pharmaceutical Corporation, is a Delaware Corporation with its principal place of business in Atlanta, GA. Shareholders approved the name change at the company's Annual Meeting in June 2006.

S. Shire US, Inc. ("SHIRE"), a subsidiary of Shire Pharmaceuticals Group (of the United Kingdom), is a New Jersey Corporation with its principal place of business in Florence, KY.

T. Teva Pharmaceuticals USA, Inc. ("TEVA"), f/k/a Copley Pharmaceutical, Inc., is a Delaware Corporation with its principal place of business in North Wales, PA.

U. The Harvard Drug Group, LLC, d/b/a Major Pharmaceuticals ("MAJOR"), is a Michigan Limited Liability Corporation with its principal place of business in Livonia, MI.

V. United Research Laboratories, Inc. ("UNITED"), a/k/a United Research Laboratories/Mutual Pharmaceutical Company (URL/Mutual), is a Pennsylvania Corporation with its principal place of business in Philadelphia, PA.

W. Warner Chilcott, Corporation ("WARNER"), f/k/a Warner Chilcott, Inc., is a Delaware Corporation with its principal place of business in Rockaway, NJ.

X. Watson Laboratories, Inc. - Florida ("WATSON"), f/k/a Andrx Laboratories, Inc., is a Florida Corporation with its principal place of business in Davie, FL. In September 2008, after it was purchased by Watson Pharmaceuticals, Inc., Andrx Pharmaceuticals Inc.'s name was changed to Watson Laboratories, Inc. - Florida.

19. At all times relevant hereto, Defendants acted through their agents and employees and the acts of Defendants' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this Complaint were conducted on a regular, repeated and continuous basis, as a regular course of doing business over a substantial period of years. Whenever reference is made in this Tenth Amended Complaint to any representation, act or transaction of any of the Defendants, such allegation shall be deemed to mean that the principals, officers, directors, employees, agents or representatives, while actively engaged in the course and scope of their employment, engaged in or authorized such representations, acts or transactions on behalf of each of said Defendant, deliberately ignored the truth or falsity of the information provided to Medicaid, or acted with reckless disregard of the truth or falsity of such information.

IV. Applicable Law And Medicaid Rebate Program Requirements

A. The False Claims Act

20. The FCA provides that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim, is liable for a civil penalty ranging from $5,000 up to $10,000 for each such claim as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus three times the amount of the damages sustained by the Government. 31 U.S.C.

§§ 3729(a)(1). A "claim" means any request or demand for money or property provided by the Government under one of its programs, such as Medicaid. 31 U.S.C. §§ 3729(b)(2). Claims made to the states are actionable if the Government will reimburse the state for any portion of the claim. 31 U.S.C. § 3729(b)(2)(A).

21. The Act allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. Based on these provisions, *qui tam* Relator seeks through this action to recover all available damages, civil penalties, and other relief for the violations alleged herein.

B. The Food, Drug And Cosmetic Act

22. Under the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.,* every "New Drug" must be approved by the FDA for safety and effectiveness before it can be marketed. 21 U.S.C. § 355(a). The FDA has determined all of the drugs identified in this Complaint to be "New Drugs", and therefore these drugs cannot be legally sold without FDA approval.

23. The sale of unapproved drugs is illegal, with rare exceptions for drugs that meet compelling medical need. *See* FDA's Final (2006) *Marketed Unapproved Drugs- Compliance Policy Guide* (hereinafter "*Final Compliance Guide*"), a copy of which is attached as **Exhibit A**.

24. The use of unapproved, illegally marketed drugs poses a serious health risk to patients, particularly Medicaid recipients, many of whom are elderly or disabled, and who have extensive healthcare needs. The FDA has acknowledged this threat: "[r]ight now, many unapproved drugs represent a public health threat because consumers wrongly assume that these widely marketed and available drugs are approved and have been found to be safe and effective by the FDA." June 8, 2006 FDA Press Release, *FDA Acts To Improve Drug Safety And Quality*.

The FDA estimates that there are several thousand illegally marketed drugs in use today and is constantly striving to identify these drugs and get them off the market. *See Final Compliance Guide*, Exhibit A at 2.

C. Medicaid And Its Outpatient Prescription Drug Coverage

25. Medicaid is a joint federal-state program that provides healthcare benefits for low income Americans.

26. The Government reimburses state Medicaid agencies for portions of certain expenses, including the purchase of prescription drugs. This federal reimbursement is known as the Federal Medical Assistance Percentage ("FMAP") or Federal Financial Participation ("FFP"). 42 U.S.C. § 1396d(b).

27. To make their products eligible for Medicaid reimbursement, manufacturers first must enter into a Drug Rebate Agreement with the U.S. Department of Health and Human Services ("HHS"), under which they agree to rebate a portion of the drug's purchase price to the states as consideration for participation in the Medicaid program. Once a manufacturer enters into a Rebate Agreement, all of that manufacturer's "Covered Outpatient Drugs" become eligible for coverage under state Medicaid programs that provide prescription drug benefits, as all do. The Rebate Agreement requires manufacturers to submit quarterly reports to CMS reaffirming and updating the products that the manufacturer expressly represents as eligible for Medicaid reimbursement.

28. The manufacturers typically sell their products to wholesalers and other distributors of drug products, who in turn sell to pharmacies and other providers. When a provider dispenses to a Medicaid recipient an ostensibly eligible "Covered Outpatient Drug", so indicated by the product being on the Medicaid Drug Product Rebate Initiative ("MDRI") List,

the provider makes a claim and is reimbursed by the state Medicaid program. The state Medicaid program then seeks FFP for the ostensibly eligible product, and, again relying on the MDRI List, the government pays the state its FFP share. It is by this process that the manufacturers illegally profit from their participation in the Medicaid rebate program.

29. Drug manufacturers have a compelling incentive to participate in the Medicaid Drug Rebate Program, as it guarantees them access to the huge Medicaid market. In 2007 alone, Medicaid and other government healthcare programs spent more than $70 billion on prescription drugs, representing more than 30% of all U.S. prescription drug spending.

D. The Definition of Covered Outpatient Drug

30. Medicaid provides prescription drug reimbursement only for statutorily defined "Covered Outpatient Drugs." Covered Outpatient Drugs, generally speaking, are only those drugs which may be dispensed by prescription and which are approved for safety and effectiveness as a prescription drug by the FDA. 42 U.S.C. § 1396r-8(k)(2)(A).

31. Substances for which an FDA-issued National Drug Code number is not required – dietary supplements, for example – are not Covered Outpatient Drugs. 42 U.S.C. § 1396r-8(k)(3).

32. In 1962, Congress amended the Federal Food, Drug and Cosmetic Act to provide greater regulation of drugs sold in the United States. Under those amendments, all new drugs must be shown by adequate studies to be both "safe and effective" before they can be marketed. Drugs approved as merely "safe" prior to 1962 (i.e. those approved between 1938 and 1962) had to be reviewed as to their effectiveness under the Drug Efficacy Study Implementation ("DESI") program. A DESI review of over 3,400 drugs that entered the market between 1938 and 1962 was undertaken in the 1960s and 1970s. If the DESI review indicated a lack of substantial

evidence of a drug's effectiveness for all of its labeled indications, the FDA published a Notice of Opportunity for a hearing concerning its proposal to withdraw approval of the drug for marketing. A manufacturer of that drug, or drugs "identical, related or similar" ("IRS") to that drug, could request a hearing and attempt to provide evidence of the drug's effectiveness. Drugs for which a Notice of Opportunity for hearing has been published are referred to as "less-than-effective" ("LTE" or "DESI-LTE") drugs unless they receive FDA approval. The IRS counterpart of a DESI-LTE drug is also considered less than effective. "DESI drugs" deemed "Less Than Effective for *all* indications" are not Covered Outpatient Drugs under the Medicaid program.

33. Even if the FDA's final DESI determination classifies the drug product as effective for all or just some of its labeled indications, the drug and its IRS counterparts may only be marketed—and thus qualify as a Covered Outpatient Drug— if the manufacturer obtains FDA approval of a New Drug Application establishing the drug's safety and effectiveness for those indications. All drugs in the DESI program, LTE or not, are New Drugs for which FDA approval is required.

34. The drugs and other products named in this Complaint also fail to meet the definition of a Covered Outpatient Drug because they generally could not be prescribed for a "medically accepted indication." 42 U.S.C. §1396r-8(k)(3) excludes any drug from the definition of a "Covered Outpatient Drug" which is "used for a medical indication, which is not a medically accepted indication." 42 U.S.C. §1396r-8(6) defines "medically accepted indication" as "any use for a Covered Outpatient Drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." Since the

drugs identified in this Complaint are not FDA-approved, neither they nor their ingredients are supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

35. At all times, Congress and CMS have intended that only Covered Outpatient Drugs be included in the Medicaid Drug Rebate Program and have not intended for non-FDA approved drugs to be covered by Medicaid.

E. The Manufacturers' Responsibility To Accurately Report Their Covered Outpatient Drugs To CMS

36. Each defendant entered into its respective Medicaid Drug Rebate Agreement with the Government on or about the dates listed below:

Defendant	Labeler Code	Effective Date
ABBOTT	(00074)	January 1, 1991
ACTAVIS	(00472)	January 1, 1991
BLANSETT	(51674)	January 1, 1991
DURAMED	(51285)	January 1, 1991
BERTEK	(62794)	January 1, 1997
	(00514)	July 1, 2004
BIOVAIL	(64455)	April 1, 1999
CYPRESS	(60258)	October 1, 1993
ROBINS	(00095)	October 1, 1991
FERNDALE	(00496)	January 1, 1991
GOLDLINE	(00182)	January 1, 1991
HEALTHPOINT	(00064)	July 1, 1995
HAWTHORN	(63717)	July 1, 1999
HI-TECH	(50383)	January 1, 1991
MAJOR	(00904)	January 1, 1991
MEDPOINTE	(00037)	January 1, 1991
MYLAN	(62794)	January 1, 1997
f/k/a Bertek		
MYLAN	(00514)	July 1, 2004
f/k/a Dow Hickam		
PAN AMERICAN	(00525)	January 1, 1991
QUALITEST	(00603)	January 1, 1991
RUGBY	(00536)	January 1, 1991
SCIELE	(59630)	January 1, 1991
SHIRE	(54092)	April 1, 1993
TEVA	(38245)	January 1, 1991

UNITED	(00677)	January 1, 1991
WARNER	(00047)	January 1, 1991
WATSON	(62022)	January 1, 1996

37. In signing a Rebate Agreement and becoming a participating Medicaid provider, Defendants agreed to abide by all laws, regulations and procedures applicable to Medicaid, including those governing reimbursement. A copy of the form Medicaid Drug Rebate Agreement, to which all Defendants are subject, is attached as **Exhibit B**.

38. The Rebate Agreement requires manufacturers to provide CMS with a list of all their Covered Outpatient Drugs, identified by NDC number, as well as other information, in accordance with CMS's specifications. Exhibit B, at II(a). This list must be updated quarterly in Form CMS 367 (the "Quarterly Report").

39. In the Quarterly Report, manufacturers must submit the following information relevant to this lawsuit with respect to each Covered Outpatient Drug: NDC; product name; FDA approval date; the date the drug entered the market; whether it is available by prescription or over-the-counter (OTC); and its Drug Efficacy Study Implementation (DESI) rating.

40. To assist manufacturers in submitting accurate information describing their drugs, CMS periodically issues Medicaid Drug Rebate Program Releases to manufacturers which contain additional information and instructions regarding the submission of drug data, including instructions for products which are not Medicaid eligible.

41. The Rebate Agreement explicitly states that only Covered Outpatient Drugs as defined in the statute are eligible. None of the products identified in this Complaint meet the definition of Covered Outpatient Drug, yet Defendants falsely represented them as such.

42. Initially, and each quarter thereafter, Manufacturers thus expressly represent to CMS that each "drug" they designate as a Covered Outpatient Drug meets the statutory definition of such, and is therefore eligible for the Rebate Program.

V. How Defendants' False Submissions Corrupted The Covered Outpatient Drug Database And Caused The Submission Of False Claims

43. CMS compiles and maintains a database containing all the "Covered Outpatient Drugs" – the drugs that are eligible for Medicaid reimbursement from the federal Government. This database is the previously mentioned Medicaid Drug Product Rebate Initiative ("MDRI") List.

44. More than 500 drug manufacturers submit lists of their Covered Outpatient Drugs and other required information to CMS, updating this information each quarter. All but those manufacturers with very small product lines make these submissions electronically.

45. In compiling and maintaining the MDRI List, CMS relies upon and incorporates in the List the products each manufacturer identifies as "Covered Outpatient Drugs" in the manufacturer's original Drug Rebate Agreement and Quarterly Report updates. Hence, the MDRI List is a list of all the drugs that manufacturers have submitted to CMS and represented to be Covered Outpatient Drugs.

46. CMS sends the MDRI List to the states each quarter in electronic form.

47. CMS directs the states to use the MDRI List to verify coverage of the drugs for which they claim FFP reimbursement and to calculate the rebates that the manufacturers owe.

48. State Medicaid programs accordingly determine whether a given product is a "Covered Outpatient Drug" and therefore eligible for FFP under the Medicaid Drug Rebate program solely by reference to the MDRI List.

49. Despite their statutory obligation to truthfully report Covered Outpatient Drugs to CMS, when the Defendants submitted their Rebate Agreements on the dates identified above in paragraph 38 and in Quarterly Reports submitted each quarter thereafter, they listed false FDA approval dates and false DESI status for their Illegal Drugs; and false FDA approval dates and rogue NDC numbers for their Non-Drugs. This false information made their ineligible products appear to be Covered Outpatient Drugs.

50. CMS relied on Defendants' misrepresentations when it compiled the MDRI List and unwittingly included the ineligible products on the MDRI List it sent to the states, along with the false information reported by the Defendants. The states, in turn, relied on the MDRI List in unwittingly paying claims for these ineligible products and in submitting reimbursement claims to CMS for those same products. CMS similarly relied on the MDRI List when it paid the states' claims.

A. False Claims Submitted For Unapproved Drugs, Under The Guise Of Their Being Covered Outpatient Drug Products

51. From 1996 to date, the Defendants knowingly made, used, or caused to be made or used false records or statements, submitted to CMS, which were material to a false or fraudulent claim; knowingly caused false claims to be submitted for payment or approval; and, as a direct result of Defendants falsely representing in their Drug Rebate Agreements and Quarterly Reports that the products identified below were Covered Outpatient Drugs, caused the states and CMS to pay false claims for these ineligible products. Had the Defendants truthfully reported these products, CMS would not have placed them on the MDRI List, and Medicaid payments for these products would not have been made.

52. The following paragraphs describe three categories of Illegal Drugs billed to and paid for by Medicaid as a result of the conduct described herein: (1) Unapproved "New Drugs";

(2) DESI LTE's; and (3) Levothyroxine products. These categories are not mutually exclusive. In fact, often an Illegal Drug will fit into more than one category, and will be excluded from Medicaid eligibility for more than one reason. Although described separately, all have in common that they are not Covered Outpatient Drugs, despite being passed off as such by the Defendants. This deception is the fundamental basis of liability for all of the Defendants' products, no matter what category they occupy.

53. All monetary figures set out below represent approximate sales under the Medicaid program for only the years indicated, and therefore do not reflect the total amount of damages sustained by the United States, or all of the Illegal Drugs for which Medicaid paid reimbursement.

1. Unapproved New Drugs

54. The following drugs are New Drugs within the meaning of the Food, Drug & Cosmetic Act, are not FDA approved, and therefore do not meet the definition of a Covered Outpatient Drug.

a. Carbinoxamine

55. On June 9, 2006, the FDA gave notice that it was taking enforcement action to stop the manufacture and sale of unapproved carbinoxamine products because of serious safety concerns. 71 Fed. Reg. 33462. The FDA explained that drug products containing carbinoxamine, which is an antihistamine, were determined through the DESI Review process in 1973 to be New Drugs that require approved applications. *Id. See* DESI 6303 (38 Fed. Reg. 7265, March 19, 1973), and DESI 6514, 47 Fed. Reg. 11973, March 19, 1982, reiterating this status).

56. Since 1985, there have been only two FDA approved carbinoxamine products, both approved in 2003. However, as the FDA noted, numerous unapproved drugs containing carbinoxamine have been and are being marketed without FDA approval. 71 Fed. Reg. at 33463.

57. For example, in the CMS June 25, 2008 and October 16, 2008 Memos to the State Medicaid Drug Program Drug Rebate Technical Contacts, attached hereto as composite **Exhibit C,** CMS identified multiple identical carbinoxamine products as not meeting the definition of Covered Outpatient Drugs.

58. The sale of unapproved carbinoxamine is particularly disturbing because some carbinoxamine products were marketed for use by young children and infants. The FDA stated that it was "aware of 21 deaths since 1983 in children under 2 years of age associated with carbinoxamine-containing products" and that "the agency is especially concerned about those unapproved CM [carbinoxamine] products that are being promoted for and may be associated with serious and life-threatening adverse outcomes in this vulnerable age group." *Id.*

59. The following drug products contain carbinoxamine and are not approved by the FDA. As a result, they do not meet the definition of Covered Outpatient Drug.

60. The NDC numbers, partial, representative amounts paid by Medicaid and false FDA approval dates are as follows:

(a)

Defendant **Cypress**		**Product** **Cydec Drops and Cydec Syrup – CBM/BF*/DM***
NDC	**False FDA Approval Date**	**Amount Paid (96-02)**
60258 0439	09/30/1990	$1,642,255.00
60258 0438	09/30/1990	$321,713.00
	TOTAL:	**$1,963,968.00**

(b)

Defendant Cypress	**Formulation**		**Product Andehist DM – CBM/DM/PSE**
NDC		**False FDA Approval Date**	**Amount Paid (96-02)**
60258 0435	(Andehist NR Liquid) (CBM1mg; PSE 15mg)	6/30/90	$2,471,783.00
60258 0437	(Andehist Liquid) (CBM 2mg/mL; PSE 15mg/mL)	9/30/90	$574,347.00
60258 0443	(Andehist DM Liquid) (CBM 2mg/mL; DM 4mg/mL; PSE 15mg/mL)	9/30/90	$1,722,084.00
60258 0445	(Andehist DM NR Oral Drops) (CBM 1mg/mL; DM 4mg/mL; PSE 15mg/mL)	6/30/90	$5,964,227.00
		TOTAL:	**$10,732,441.00**

(c)

Defendant Cypress		**Product Carboxine PSE– CBM/PSE**
NDC	**False FDA Approval Date**	**Amount Paid (03-06)**
60258 0439	06/30/1990	$1,125,698.00
	TOTAL:	**$1,125,698.00**

(d)

Defendant Biovail	**Formulation**		**Product Rondec DM Drops Oral – Carbinox/PSE/DM – Rondec Oral Drops – CBM, PSE**
NDC		**False FDA Approval Date**	**Amount Paid (Thru 03)**
64455 0050	(Rondec DM)	09/01/70	$5,239,404.00
64455 0051	(Rondec DM)	09/01/70	$5,360,254.00
64455 0024	(Rondec DM)	09/01/70	$137,244.00
64455 0071	(Rondec DM)	09/01/70	$4,162,411.00
64455 0070	(Rondec DM)	09/01/70	$4,508,418.00
64455 0080	(Rondec Oral Drops)	07/01/68	$1,474,594.00
		TOTAL:	**$20,882,325.00**

(e)

Defendant Goldline		**Product Cardec DM – Carbinoxamine and/or Bromphen, PSE, DM**
NDC	**False FDA Approval Date**	**Amount Paid (96-02)**
00182 6171	09/18/80	$502,270.00
	TOTAL:	**$502,270.00**

(f)

Defendant Actavis	**Formulation**		**Product Cardec DM and Cardec DM Syrup – Carbinox/PSE/DM**
NDC		**False FDA Approval Date**	**Amount Paid (96-04)**
00472 0733	(Cardec DM Drops)	1/15/86	$9,358,618.00
00472 0731	(Cardec DM Syrup)	1/02/86	$12,177,736.00
		TOTAL:	**$21,536,354.00**

(g)

Defendant Actavis		**Product Cardec-S Syrup Carbinoxamine/PSE**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
00472 0727	10/21/86	$3,116,811.00
	TOTAL:	**$3,116,811.00**

(h)

Defendant Qualitest		**Product Cardec Liquid – carbinoxamine mal/pse and Cardec DM – carbinoxamine mal/dextromethorphan hydrobromide**
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
00603 1062	10/01/01	$1,712,352.00
00603 1064	10/01/01	$5,331,292.00
	TOTAL:	**$7,043,644.00**

(i)

Defendant Hi-Tech		**Product Carbofed DM – carbinoxamine maleate/dextromethorphan bydrobromide liquid**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
50383 0576	12/20/01	$3,116,811.00
	TOTAL:	**$3,116,811.00**

(j)

Defendant Hi-Tech	**Formulation**		**Product Carbofed DM – CBM/DM/PSE**
NDC		**False FDA Approval Date**	**Amount Paid (96-02)**
50383 0571	(Carbofed DM Syrup)	9/01/01	$576,010.00
50383 0572	(Carbofed DM Oral Drops)	9/01/01	$483,928.00
50383 0575	(Carbofed DM Syrup)	12/20/01	$3,670,561.00
50383 0750	(Carbofed DM Oral Drops Sugar Free)	10/01/90	$1,249,169.00
50383 0751	(Carbofed DM Syrup Sugar Free)	10/01/90	$1,202,125.00
		TOTAL:	**$7,181,793.00**

(k)

Defendant Rugby		**Product Carbodec DM – Carbinox/PSE/DM**
NDC	**False FDA Approval Date**	**Amount Paid (96-02)**
00536 0439	None	$547,191.00
00536 0440	None	$189,801.00
00536 0454	None	$377,382.00
00536 0456	None	$365,202.00
00536 0452	None	$130,441.00
	TOTAL:	**$1,610,017.00**

(l)

Defendant Major			**Product Rondamine DM Drops Liquid and Syrup – Carbinoxamine, PSE, DM**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-02)**
00904 0702	09/30/90	47 Fed. Reg. 22606	$220,377.00
00904 0703	09/30/90		$168,361.00
		TOTAL:	**$388,738.00**

(m)

Defendant Sciele		**Product Tanafed DM – CPM/DEX/PSE Suspension**
NDC	**False FDA Approval Date**	**Amount Paid (96-02)**
59630 0125	08/01/93	$3,023,640.00
	TOTAL:	**$3,023,640.00**

(n)

Defendant Watson		**Product Histex PD Liquid – Carbinoxamine Maleate**
NDC	**False FDA Approval Date**	**Amount Paid (1997-2007)**
62022 0257	11/27/01	$8,758,151.00
62022 0254	11/27/01	$3,540,314.00
	TOTAL:	**$12,298,495.00**

(o)

Defendant Watson		**Product Histex HC Liquid – Carbinoxamine Maleate/ Hydrocodone/PSE**
NDC	**False FDA Approval Date**	**Amount Paid (1997-2007)**
62022 0901	01/01/97	$1,783,917.00
	TOTAL:	**$1,783,917.00**

(p)

Defendant Cypress	Formulation		Product Cordron 12 – CBM/DM/PSE
NDC		**False FDA Approval Date**	**Amount Paid (2003-2006)**
60258 0419	(Cordron 12 DM) (cbm tan;dm tan; pse tan)	6/30/90	$334,274.00
60258 0421	(Cordron D NR) (cbm; pse)	9/30/90	$615,739.00
60258 0422	(Cordron DM NR) (cbm tan;dm tan; pse tan)	9/30/90	$409,079.00
		TOTAL:	**$1,359,092.00**

b. Extended Release Products

61. Since 1959, the FDA has deemed all drugs in timed-release/extended release dosage forms to be New Drugs which are therefore required to obtain FDA approval. 24 Fed. Reg. 3756 (May 9, 1959). According to the FDA, "review of individual applications is needed to ensure that the finished product releases its active ingredients at a rate that is both safe, without "dumping" of the dose, and effective, sustaining the intended effect over the entire period during which the therapeutic benefit is claimed …. The agency's determination that all products in timed-release form are New Drugs requiring approved applications has been codified since 1959 in 21 CFR 310.502(a)(14)." 72 Fed. Reg. 29517.

62. Timed-release drugs that have been sold without FDA approval have been targeted for enforcement by the FDA.

63. Many of the products described in this section are timed-release drug products containing guaifenesin, which is used to treat colds and coughs. These products were subject to a May 29, 2007 notification by the FDA of its intention to take enforcement action against

unapproved drug products in timed-release dosage forms containing guaifenesin. 72 Fed. Reg. 29517.

64. CMS has reiterated that timed-release products are not Covered Outpatient Drugs unless they have received FDA approval, citing 21 CFR 310.502(a)(14). *See, e.g.*, letters from CMS Rebate Program dated April 8, 2008, April 10, 2008 and August 14, 2008 attached as composite **Exhibit D**.

65. The following extended release drug products do not meet the definition of a Covered Outpatient Drug for multiple reasons, including that they are timed-release drugs, yet they were paid for by Medicaid as a result of the Defendants' false representations.

66. The NDC numbers, partial, representative amounts paid by Medicaid and false FDA approval dates are as follows:

(a)

Defendant Ferndale		**Product Kronofed-A Capsules Chlorpheniramine Maleate 8mg and Pseudoephedrine Hydrochloride 120mg**
NDC	**False FDA Approval Date**	**Amount Paid (96-04)**
0496 0382	9/30/90	$94,569.00
0496 0434	9/30/90	$164,157.00
	TOTAL:	**$258,726.00**

(b)

Defendant Sciele		**Product Defen LA - guaifenesin and pseudoephedrine Hcl**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
59630 0110	2/1/93	$285,971.00
	TOTAL:	**$285,971.00**

(c)

Defendant Sciele		**Product Mescolor Tablets Chlorpheniramine Maleate 8mg; Pseudoephedrine 120mg; Methscopolamine Nitrate 2.5mg**
NDC	**False FDA Approval Date**	**Amount Paid (96-04)**
59630 0150	12/01/94	$739,844.00
	TOTAL:	**$739,844.00**

(d)

Defendant Sciele		**Product Tannafed DP Extended Release – Dexchlorpheniramine Tannate, Pseudoephedrine Tannate**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
59630 0465	8/01/02	$3,287,839.00
	TOTAL:	**$3,287,839.00**

(e)

Defendant Sciele		**Product Tanafed DMX – Suspension, extended release dexchlorpheniramine tannate, dextromethorphan tannate**
NDC	**False FDA Approval Date**	**Amount Paid (96-02)**
59630 0470	9/01/02	$6,263,283.00
	TOTAL:	**$6,263,283.00**

(f)

Defendant Sciele		**Product Protuss DM Ext. Rel. -Guaifenesin 600mg; Pseudoephedrine Hydrochloride 60 mg; Dextromethorphan Hydrobromide 30mg**
NDC	**False FDA Approval Date**	**Amount Paid (96-04)**
59630 0160	2/28/97	$1,302,581.00
	TOTAL:	**$1,302,581.00**

(g)

Defendant Qualitest		Product De-Congestine chlorpheniramine maleate and pseudoephedrine HCI
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
0603 3143	10/1/91	$637,740.00
	TOTAL:	**$637,740.00**

(h)

Defendant Goldline		Product Q-Bid LA 250
NDC	**False FDA Approval Date**	**Amount Paid (2003)**
00182 1042	1/1/00	$1,532,208.00
	TOTAL:	**$1,532,208.00**

(i)

Defendant Goldline		Product Guaifenesin ER Tablets – extended release single-ingredient guaifenesin
NDC	**False FDA Approval Date**	**Amount Paid (96-04)**
00182 1188	01/01/00	$786,074.00
	TOTAL:	**$786,074.00**

(j)

Defendant United Research		Product Guaifenesin, Pseudoephedrine
NDC	**False FDA Approval Date**	**Amount Paid (2003)**
00677 1487	None	$76,277.00
	TOTAL:	**$76,277.00**

(k)

Defendant United Research	Formulation		Product Guaifenesin LA, SR, Tablets – Single ingredient Guaifenesin extended release
NDC		**False FDA Approval Date**	**Amount Paid**
00677 1475	LA	01/01/93	$3,009,655.00
00677 1643	SR	06/30/90	$730,075.00
00677 1661	Tablet	06/30/90	$182,754.00
		TOTAL:	**$3,922,484.00**

(l)

Defendant Major		**Product Guaifenesin LA Caplets – Guaifenesin single ingredient extended release**
NDC	**False FDA Approval Date**	**Amount Paid (96-04)**
0904 7759	04/30/93	$597,972.00
	TOTAL:	**$597,972.00**

(m)

Defendant Duramed		**Product Generic Pseudoephedrine HCL, Guaifenesin Extended Release**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
51285 0401	9/30/90	$1,623,014.00
	TOTAL:	**$1,623,014.00**

(n)

Defendant Duramed		**Product Generic Phenylpropanolamine, Guaifenesin LA Tablets**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
51285 0295	9/30/90	$523,973.00
	TOTAL:	**$523,973.00**

(o)

Defendant Duramed		**Product R-Tanna Suspension – Chlorpheniramine tannate, phenylephrine tannate**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
51285 0722	1/01/01	$977,728.00
	TOTAL:	**$977,728.00**

(p)

Defendant Duramed		Product Guaifenesin Tablets Sustained Release – single ingredient guaifenesin
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
51285 0417	12/29/94	$5,501,659.00
	TOTAL:	**$5,501,659.00**

(q)

Defendant Duramed		Product Guaifenesin DM Tablets Sustained Release – single ingredient guaifenesin
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
51285 0420	11/14/95	$971,603.00
	TOTAL:	**$971,603.00**

(r)

Defendant Pan American	Formulation		Product Panmist LA & Jr. – Guaifenesin & Pseudoephedrine
NDC		**False FDA Approval Date**	**Amount Paid (96-03)**
00525 0742	LA	01/01/84	$581,920.00
00525 0775	LA	01/01/84	$642,912.00
00525 0776	LA	None	$19,742.00
00525 0762	Jr.	01/01/84	$1,075,172.00
		TOTAL:	**$2,319,746.00**

(s)

Defendant Pan American		Product Panmist DM – PSE HC1, Guaif/Dextromethorphan
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00525 0754	06/07/96	$1,027,179.00
	TOTAL:	**$1,027,179.00**

(t)

Defendant Robins		**Product Lodrane LD and Liquid – PSE & Brompheniramine**
NDC	**False FDA Approval Date**	**Amount Paid (02-06)**
00095 6004	09/01/94	$2,353,948.00
00095 6006	02/08/93	$683,042.00
00095 0645	07/01/02	$2,210,674.00
00095 1200	11/01/04	$2,015,565.00
00095 1290	12/15/06	4,674,030.00
	TOTAL:	**$11,937,259.00**

(u)

Defendant Robins		**Product Lodrane 12 Hour – brompheniramine maleate extended release**
NDC	**False FDA Approval Date**	**Amount Paid (2003 - 3rd qtr 2008)**
00095 0006	7/01/01	$858,983.00
	TOTAL:	**$858,983.00**

(v)

Defendant United Research		**Product Guaifenesin/Pseudoephedrine Extended Release Tablets**
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
00677 1476	1/01/93	$1,330,592.00
00677 1785	9/30/90	$245,622.00
00677 1790	7/30/90	$256,310.00
	TOTAL:	**$1,832,524.00**

(w)

Defendant Hi-Tech		**Product Ry-T-12 – phenylephrine tannate/pyrilamiine tannate**
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
50383 0864	10/01/90	$827,174.00
	TOTAL:	**$827,174.00**

(x)

Defendant Hi-Tech		**Product Tannate DM Suspension– dm tannate/dexchlorpheniramine tannate/pse tannate**
NDC	**False FDA Approval Date**	**Amount Paid (03-06)**
50383 0866	None	$3,362,071.00
	TOTAL:	**$3,362,071.00**

(y)

Defendant Cypress		**Product CPM 8/PE 20/ MSC 1.25 Extended Release Tablets**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0250	9/30/90	$287,710.00
	TOTAL:	**$287,710.00**

(z)

Defendant Cypress		**Product GFN 1200/DM Extended Release Tablet – dm/gg/phenyleph hcl**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
60258 0252	6/30/90	$234,741.00
	TOTAL:	**$234,741.00**

(aa)

Defendant Cypress		**Product GFN 1200/DM and GFN 1000/DM Extended Release Tablets – dm/gg/**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
60258 0263	6/30/90	$614,424.00
60258 0267	6/30/90	$524,852.00
	TOTAL:	**$1,139,276.00**

(bb)

Defendant Cypress		**Product GFN 600/PSE Extended Release Tablet – dm/gg/pse**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
60258 0264	6/30/90	$189,310.00
	TOTAL:	**$189,310.00**

(cc)

Defendant Cypress		**Product GFN/PSE 12 Extended Release Tablet – gg/pse**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
60258 0266	6/30/90	$146,671.00
60258 0275	9/30/90	$238,178.00
	TOTAL:	**$384,849.00**

(dd)

Defendant Cypress		**Product GFN 600/PE 2 Extended Release Tablet – gg/phenylephrine hcl**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
60258 0269	6/30/90	$607,563.00
	TOTAL:	**$607,563.00**

(ee)

Defendant Cypress		**Product PCM LA Tablets – cpm/methscopolamine nit./pse hcl**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0280	9/30/90	$274,857.00
	TOTAL:	**$274,857.00**

(ff)

Defendant Cypress		Product GFN 800/DM Extended Release Tablets – dm/gg
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
60258 0292	9/30/90	$158,087.00
	TOTAL:	**$158,087.00**

(gg)

Defendant Cypress			Product Chlordex A 12 Extended Release Tablet – cpm/phenylephrine hcl
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
60258 0283	9/30/90	On 8-4-09 CMS DESI LTE List	$709,954.00
60258 0313	9/30/90		$791,639.00
		TOTAL:	**$1,501,593.00**

(hh)

Defendant Cypress		Product Bellahist D LA - Atropine/Cpm/Hyoscyamine/Pe Scopolamine
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
60258 0283	9/30/90	$709,954.00
	TOTAL:	**$709,954.00**

(ii)

Qualitest		Product Bromuphed Extended Release Capsules– bromopheniramine maleate/pseudoephedrine hcl
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
00603 2505	7/01/90	$76,052.00
00603 2506	7/01/90	$140,919.00
	TOTAL:	**$216,971.00**

(jj)

Defendant Qualitest		Product Guaifen-PS – guaifenesin/pseudoephedrine hcl
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
00603 3767	10//01/02	$1,210,152.00
	TOTAL:	**$1,210,152.00**

(kk)

Defendant Qualitest			Product Hyoscyamine Sulfate Extended Release Capsules and Extended Release Tablets
NDC		**False FDA Approval Date**	**Amount Paid (03-07)**
00603 4004	Capsules	7/01/90	$137,114.00
00603 4005	Tablets	1/01/95	128,933.00
		TOTAL:	**$266,047.00**

c. Hydrocodone Products

67. Hydrocodone is an opioid derived from codeine.

68. Hydrocodone is a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and combination products with hydrocodone and non-narcotic active ingredients, which are labeled either for use as analgesics or for use as antitussives, are Schedule III narcotics. Hydrocodone is one of the most potent drugs available to relieve pain and treat cough symptoms.

69. The FDA determined in 1982 that hydrocodone bitartrate is a New Drug and that FDA approval was required for marketing. 47 Fed. Reg. 23809 (June 1, 1982). This status is reiterated in the DESI history recounted at 72 Fed. Reg. 55780 (October 1, 2007). In CMS's August 27, 2008 and October 16, 2008 Memos to the State Medicaid Drug Program Drug Rebate Technical Contacts, other identical hydrocodone products were named as failing to meet the definition of a Covered Outpatient Drug.

70. In October 2007, FDA gave notice that it would take enforcement action against unapproved hydrocodone products and those who manufacture them or cause them to be manufactured or shipped in interstate commerce. 72 Fed. Reg. 55780. The FDA stated it "is taking action at this time against these products because: (1) hydrocodone is a drug with significant safety risks and (2) there are FDA-approved drug products containing hydrocodone; thus the continued marketing of unapproved versions is a direct challenge to the drug approval process." A copy of 72 Fed. Reg. 55780 is attached as **Exhibit E.**

71. In the Notice, the FDA stated: "Under its DESI review, FDA determined that hydrocodone bitartrate is a New Drug. Firms must, therefore, have an approved application before marketing any drug product that contains hydrocodone bitartrate, or any other salt or ester of hydrocodone (collectively, "hydrocodone")." The DESI review determination that hydrocodone is a New Drug was the one made in 1982. 47 Fed. Reg. 23809.

72. The following drug products have never been FDA-approved. As a result, they do not meet the definition of a Covered Outpatient Drug. *See, e.g.* CMS's August 27, 2008 and October 16, 2008 Memos to the State Medicaid Drug Program Drug Rebate Technical contacts, attached hereto as composite **Exhibit F.**

73. The NDC numbers, partial, representative amounts paid by Medicaid and false FDA approval dates are as follows:

(a)

Defendant Qualitest			**Product Codituss DH (AF) Syrup – HCD/Phenyleph/PYRIL**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03 & 06)**
00603 1111	10/11/97	DESI 6514; 47 Fed. Reg. 22609	$248,978.00
		TOTAL:	**$248,978.00**

(b)

Defendant Qualitest			**Product HC Tussive Syrup – Hydrocodone/Chlorphen/Phenyl**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (2006)**
00603 1284	07/01/90	DESI 6514; 47 Fed. Reg. 22609	$779,983.00
		TOTAL:	**$779,983.00**

(c)

Defendant Qualitest		**Product HC Tussive D Syrup – Hydrocodone/PSE**
NDC	**False FDA Approval Date**	**Amount Paid (2006)**
00603 1285	10/11/97	$6,412.00
	TOTAL:	**$6,412.00**

(d)

Defendant Qualitest		**Product Vi-Q-Tuss – Hydrocodone/PSE**
NDC	**False FDA Approval Date**	**Amount Paid (2006)**
00603 1853	07/01/90	$261,646.00
	TOTAL:	**$261,646.00**

(e)

Defendant Qualitest	**Formulation**		**Product Quendal HD and Plus– CPM/HDC/PHENYLEPH**
NDC		**False FDA Approval Date**	**Amount Paid**
00603 1621	HD Liquid	7/01/90	$1,696,246.00
00603 1622	HD Plus Liquid	7/01/90	$356,478.00
		TOTAL:	**$2,052,724.00**

(f)

Defendant Qualitest			**Product Quintex Liquid**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00603 1635	07/01/02	48 Fed. Reg. 5685447	$454,219.00
		TOTAL:	**$454,219.00**

(g)

Defendant Duramed		**Product Duradal HD Liquid – Chlorpheniramine, hydrocodone, phenylephrine**
NDC	**False FDA Approval Date**	**Amount Paid (02-06)**
51285 0726	11/01/96	$501,510.00
	TOTAL:	**$501,510.00**

(h)

Defendant Pan American	**Formulation**			**Product Pancof XP – Guaifenesin & Hydrocodone**
NDC		**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
00525 9611	Coditrate	10/08/87	47 Fed. Reg. 11973	$802,966.00
00525 9758		10/08/96		$1,104,178.00
00525 0711		None		$125,319.00
			TOTAL:	**$2,032,463.00**

(i)

Defendant Watson		**Product Histex HC Liquid – Carbinoxamine Maleate/Hydrocodone/PSE**
NDC	**False FDA Approval Date**	**Amount Paid (1997-2007)**
62022 0901	01/01/97	$1,783,917.00
	TOTAL:	**$1,783,917.00**

(j)

Defendant Cypress		**Product Hydro-PC II – chlorpheniramine maleate/hydrocodone bitartrate/phenyleph hcl**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0701	6/30/90	$1,973,852.00
	TOTAL:	**$1,973,852.00**

(k)

Defendant Cypress		**Product Cytuss HC – chlorpheniramine maleate/hydrocodone bitartrate/phenyleph hcl**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0704	9/30/90	$258,244.00
	TOTAL:	**$258,244.00**

(l)

Defendant Qualitest		**Product Vi-Q-Tuss – guaifenesin/hydrocodone bitartrate**
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
00603 1853	7/01/90	$1,726,664.00
	TOTAL:	**$1,726,664.00**

(m)

Defendant Qualitest		**Product Q-V Tussin – chlorpheniramine maleate/hydrocodone bitartrate/pse hcl**
NDC	**False FDA Approval Date**	**Amount Paid (03-07)**
00603 1609	1/01/92	$162,871.00
	TOTAL:	**$162,871.00**

(n)

Defendant Cypress		Product Hydron PSC – chlorpheniramine maleate/hydrocodone bitartrate/pse
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0708	9/30/90	$196,219.00
	TOTAL:	**$196,219.00**

(o)

Defendant Cypress		Product Hydron CP CIII – chlorpheniramine maleate/hydrocodone bitartrate/phenyleph
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0714	9/30/90	$665,969.00
	TOTAL:	**$665,969.00**

(p)

Defendant Cypress		Product Hydro DP CIII – diphenhydramine hcl/hydrocodone bitartrate/phenyleph hcl
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0709	9/30/90	$1,735,237.00
	TOTAL:	**$1,735,237.00**

(q)

Defendant Cypress		Product Hydro GP – guaifenesin/hydrocodone bitartrate/phenylephrin hydrochloride/
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0782	9/30/90	$92,151.00
	TOTAL:	**$92,151.00**

(r)

Defendant Cypress		Product Hyphed – chlorpheniramine mal./hydrocodoone bit./pse hcl
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0790	9/30/90	$162,742.00
	TOTAL:	**$162,742.00**

(s)

Defendant Cypress		**Product De-Chlor HC – chlorpheniramine maleate/hydrocodone bitartrate/phenyleph hcl**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0710	9/30/90	$1,288,768.00
		$1,288,768.00

(t)

Defendant Cypress		**Product De-Chlor MR – hydrocodone bitartrate/phenylephrin hydrochloride/pyril mal**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0775	9/30/90	$354,600.00
	TOTAL:	**$354,600.00**

(u)

Defendant Cypress		**Product Su-Tuss HD – gg/hydrocodone bit./phenyleph hcl**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0715	9/30/90	$261,039.00
	TOTAL:	**$261,039.00**

(v)

Defendant Cypress		**Product APAP/Hydrocodone – acetaminophen/hydrocodone bitartrate**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0720	9/30/90	$1,370,434.00
	TOTAL:	**$1,370,434.00**

(w)

Defendant Cypress		**Product Codal DH – hydrocodone bitartrate/phenylephrin hydrochloride/pyril**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
60258 0770	9/30/90	$731,465.00
	TOTAL:	**$731,465.00**

(x)

Defendant Actavis		Product Hydromet Syrup – homatropine methylbromide/hydrocodone bitartrate
NDC	**False FDA Approval Date**	**Amount Paid (2003-2007)**
00472 1030	7/05/08	$816,380.00
	TOTAL:	**$816,380.00**

(y)

Defendant Watson		Product Histex SR Extended Release – Brompheniramine Maleate/Pseudoephedrine hcl
NDC	**False FDA Approval Date**	**Amount Paid (97-02)**
62022 0088	None	$634,217.00
62022 0089	None	$583,769.00
	TOTAL:	**$1,217,986.00**

(z)

Defendant Hawthorn	Formulation		Product Dytan CS Suspension and Extended Release Tablet – Carbetapentane tannate/phenylephrine tannate/diphenhydramine tannate
NDC		**False FDA Approval Date**	**Amount Paid (2003 - 3rd qtr 2008)**
63717 0580	Suspension	9/30/90	$3,430,376.00
63717 0581	TER	6/30/90	$1,965,638.00
		TOTAL:	**$5,396,014.00**

d. Other Unapproved New Drugs That Do Not Meet The Definition Of A Covered Outpatient Drug

74. Some unapproved drugs were first marketed, or were changed in formulation, dosage strength, labeling or otherwise, after October 10, 1962, the date on which the 1962 FDCA amendments became effective. These products are deemed New Drugs, which must be approved for safety and effectiveness in order to be legally sold.

75. FDA has unequivocally stated that "unapproved drugs which were first marketed (or changed) after 1962 … are on the market illegally. Some also may have already been the subject of a formal Agency finding that they are new drugs. *See, e.g.,* See 21 CFR 310,502 (discussing, among other things, controlled/timed release dosage forms)." *Final Compliance Guide,* at 10.

76. The following products were either first sold after October 10, 1962, or changed the product label, strength, formulation or dosage after that date and as such are unapproved New Drugs, yet they were paid for by Medicaid as a result of the Defendants' false representations that they were Covered Outpatient Drugs.

77. The NDC numbers, partial, representative amounts paid by Medicaid and false FDA approval dates are as follows:

(a)

Defendant Healthpoint	**Post 62 New Technology*	**Product Panafil 40 – chlorophyllin copper complex/papain/urea**
NDC	**False FDA Approval Date**	**Amount Paid (2003-2006)**
00064 3410 Panafil 40	12/31/99	$32,179,257.00
00064 3510 Panafil SE	12/21/03	4,024,126.00
	TOTAL:	**$36,203,383.00**

(b)

Healthpoint	**Post 62 New Technology*	**Product Accuzyme – papain/urea SPR, TP (debriding)**
NDC	**False FDA Approval Date**	**Amount Paid (03-06)**
00064 1001	6/21/04	$580,883.00
	TOTAL:	**$580,883.00**

2. DESI Less Than Effective Drugs

78. DESI drugs are limited to those that came on the market between 1938 and 1962 with an approved NDA, as well as all drugs identical, related or similar ("IRS") to them. 21 C.F.R. § 310.6(b)(1). DESI drugs are those drugs described in Section 107(c)(3) of the Drug Amendments of 1962.

79. If the DESI review described in ¶32 and ¶33 resulted in an FDA conclusion that there was a lack of substantial evidence of a drug's effectiveness for *all* of its labeled indications, and the manufacturer was unable to subsequently obtain FDA approval of a New Drug Application establishing the drug's safety and effectiveness for those indications, the drug is ineligible for Medicaid, unless "the secretary [of HHS] has determined there is a compelling justification for its medical need…" 42 U.S.C. § 1396r-8(k)(2)(A)(iii). None of the Defendants' products below are the subject of such an HHS determination.

80. Manufacturers must provide CMS with the proper code to identify their DESI-LTE drugs in their Quarterly Reports. The applicable DESI codes are as follows:

2 = Safe and effective or non-DESI drug;
3 = Drug under review (no Notice of Opportunity for Hearing [NOOH] issued);
4 = LTE/IRS drug for some indications;
5 = LTE/IRS drug for all indications;
6 = LTE/IRS drug withdrawn from market.

Code 5 is required to be inserted for all DESI-LTE's for all indications, Code 6 for those withdrawn from sale.

81. If a manufacturer enters Code 5 or 6 for a drug, CMS disqualifies that drug from the MDRI List and the product is categorically ineligible for Medicaid. Federal law enacted well before the Medicaid Rebate Program was established in 1990 expressly precludes payment for such DESI-LTE drugs (42 U.S.C. § 1396b (i)(5); 42 U.S.C. § 1395y(c); 42 C.F.R. §441.25) and

the definition of Covered Outpatient Drug in the Medicaid Rebate Program legislation, 42 U.S.C. § 1396r-8(k)(2)(A)(iii), expressly excludes such drugs.

82. Manufacturers are responsible for truthfully reporting their products' FDA, LTE, or IRS classifications to CMS, subject to civil penalties of up to $100,000 per item of false information knowingly provided to CMS. *See CMS Medicaid Drug Rebate Program Release No. 12 To Drug Manufacturers*.

83. The Defendants identified below submitted false records or statements to CMS, caused the submission of false claims and also caused false claims to be paid or approved for the DESI-LTE products identified below. Had the DESI-LTE drugs been reported by these Defendants truthfully as category 5 DESI drugs, they would not have been placed on the MDRI List, and their ineligibility for Medicaid reimbursement would have been disclosed by their Code 5 designation.

84. The Defendants' submissions included a false representation that the drug met the definition of a Covered Outpatient Drug, a false DESI status of "2" ("safe and effective") or "3" ("drug under review (no NOOH issued)") for products which are DESI 5 ("DESI-LTE"), and in many instances a false FDA approval date.

a. Nitroglycerin Transdermal

85. The FDA declared nitroglycerin in a transdermal delivery system form a "New Drug" on July 15, 1993 in a Federal Register Notice. *See* 58 Fed. Reg. 38129. The Notice required manufacturers of conditionally approved nitroglycerin transdermal products to submit additional information regarding their drugs' composition, bioavailability and other matters, in order to continue marketing the drugs. The 1993 Notice, expressly applied to IRS drugs.

86. On March 25, 1999, the FDA issued a NOOH (hereinafter "March 1999 NOOH"), proposing to withdraw approval of the nitroglycerin transdermal drug products listed in the NOOH, on the grounds that they lacked substantial evidence of effectiveness for all indications, because the sponsors of the products had not submitted any bioavailability/bioequivalence or other required data. 64 Fed. Reg. 14451. This Notice expressly applied to all IRS drugs as well. *Id.* The Notice also applied to all other manufacturers or distributors of nitroglycerin transdermal products which were not the subject of an approved application.

87. The following ignored the March 1999 NOOH and continued to market their products without FDA approval, and despite FDA's finding that their drugs were ineffective.

88. The unapproved nitroglycerin transdermal products paid for by Medicaid along with their NDCs, and partial representative amounts paid are as follows. None of these products were approved by the FDA after the 1993 Notice.

(a)

Defendant Major		**Product NitroTransderm**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00904 0653	09/30/90	$698,345.00
00904 0652	09/30/90	$728,768.00
	TOTAL:	**$1,427,113.00**

(b)

Defendant Warner		**Product NitroTransderm**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00047 0835	09/01/90	$4,836,471.00
00047 0837	09/01/90	$4,238,043.00
00047 0839 (Transderm Nitro .6 mg)	09/01/90	$715,068.00
	TOTAL:	**$9,789,582.00**

(c)

Defendant Qualitest		Product NitroTransderm
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00603 4725	07/01/90	$782,762.00
00603 4726	07/01/90	$733,167.00
00603 4727	None	$84,932.00
	TOTAL:	**$1,600,861.00**

(d)

Defendant Goldline		Product NitroTransderm
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00182 1240	06/09/86	$761,700.00
00182 1267	08/01/87	$724,930.00
	TOTAL:	**$1,486,630.00**

(e)

Defendant Shire		Product NitroTransderm
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
54092 0343	None	$1,399,317.00
54092 0342	None	$368,404.00
54092 0344	None	$316,492.00
	TOTAL:	**$2,084,213.00**

b. Oral Nitroglycerin (Controlled Release)

89. On September 7, 1984, the FDA issued a Notice (hereinafter "the 1984 Notice") declaring that any "drug product that contains oral nitroglycerin (controlled-release) is a 'New Drug', and setting conditions for the marketing of such products. 49 Fed. Reg. 35428. The 1984 Notice required that manufacturers with previously approved applications submit supplements containing additional information about their products, including bioavailability, in order to obtain approval on the basis of safety *and* effectiveness. The manufacturers were given one year

to do so, a deadline which was later extended to June, 1989. The Notice informed manufacturers that marketing these products without providing the required information would subject them to FDA enforcement.

90. On April 20, 1999, the FDA issued a second Notice ("April 1999 Notice"), declaring that certain sponsors of oral nitroglycerin products had not complied with the 1984 Notice, because "they either have not submitted any bioavailability/bioequivalence data or have not submitted additional data on incomplete or inadequate studies." 64 Fed. Reg. 19373. The FDA therefore proposed to withdraw approval of their applications and declared that the products lacked evidence of effectiveness. *Id.*

91. The April 1999 Notice expressly applied to all IRS drugs - other nitroglycerin controlled release capsules that were also not the subject of an approved application.

92. The following Defendants ignored the 1984 and 1999 Notices and continued to market their products without FDA approval and despite FDA's finding that there was a lack of evidence that their products were effective. The Defendants nevertheless expressly represented to CMS that their drugs were Covered Outpatient Drugs.

93. These unapproved oral nitroglycerin products, along with their NDC numbers, partial, representative amounts paid by Medicaid, and false FDA approval dates, are as follows:

(a)

Defendant **Goldline**		**Product** **Time Capsules**
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
0182 0702	09/08/80	$684,802.00
0182 0703	06/13/88	$782,678.00
0182 1670	08/23/88	$115,944.00
	TOTAL:	**$1,583,424.00**

(b)

Defendant Major		Product Oral Nitroglycerin
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
0904 0643	09/30/90	$302,453.00
0904 0644	09/30/90	$397,597.00
0904 0647	09/30/90	$74,161.00
	TOTAL:	**$774,211.00**

(c)

Defendant United		Product Oral Nitroglycerin
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00677 0485	09/30/90	$263,639.00
00677 0486	09/30/90	$252,322.00
00677 0967	09/30/90	$40,753.00
	TOTAL:	**$556,714.00**

(d)

Defendant Rugby		Product Oral Nitroglycerin
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00536 4083	08/01/79	$380,481.00
00536 4090	None	$96,694.00
00536 4820	None	$6,475.00
	TOTAL:	**$483,650.00**

(e)

Defendant Qualitest		Product Oral Nitroglycerin
NDC	**False FDA Approval Date**	**Amount Paid (96-03)**
00603 4782 21	07/01/90	$377,758.00
00603 4783 21	07/01/90	$513,063.00
00603 4784 20	07/01/90	$401,814.00
	TOTAL:	**$1,292,635.00**

c. Other DESI LTE Drugs

94. Each product below is unapproved and is identical, related or similar to other DESI-LTE Code 5 products and is therefore considered DESI-LTE as well, under 21 CFR 310.6.

95. Some of the products below were made up of brompheniramine/ pseuedoephedrine in extended release form. In 47 Fed. Reg. 23809 (June 1, 1982), the FDA declared this formulation to be a New Drug, specifically naming Disophrol Tablets containing dexbrompheniramine maleate and pseudoephedrine sulfate. Further, to the extent these are IRS to other Brompheniramine extended release products, then FDA determined these Brompheiniramine extended release products to be DESI LTE in 47 Fed. Reg. 4346 (January 28, 1982). *See also* 49 Fed. Reg. 153 (January 3, 1984).

96. The NDC numbers, partial, representative amounts paid by Medicaid, false FDA approval date and the applicable DESI Notice and/or Federal Register citations demonstrating DESI-LTE 5 status (less than effective for *all* indications), are as follows:

(a)

Defendant Healthpoint			**Product Xenaderm – Trypsin/Castor Oil & Peruvian Balsam Ointment**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
00064 3900	12/21/01	#10110 (2/12/72)	$11,160,698.00
		TOTAL:	**$11,160,698.00**

(b)

Defendant Mylan			**Product Granulex – Trypsin/Castor Oil & Peruvian Balsam Topical Spray**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
62794 0002 (Bertek)	9/30/90	#10110 (2/12/72)	$6,221,853.00
00514 0001 (Dow Hickam)	9/30/90		$10,396,756.00
		TOTAL:	**$16,618,609.00**

(c)

Defendant Rugby		**Product Granumed**
NDC	**DESI Notice(s)**	**Amount Paid (96-03)**
00536 1371	#10110 (2/12/72)	$422,684.00
	TOTAL:	**$422,684.00**

(d)

Defendant Qualitest			**Product Granulderm – Trypsin/Castor Oil & Peruvian Balsam Ointment**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
00603 1270	7/01/90	#10110 (2/12/72)	$2,015,262.00
		TOTAL:	**$2,015,262.00**

(e)

Defendant Qualitest			**Product Proctosert Hydrocortisone Acetate Suppository**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00603 8136	09/01/02	#11114, 39 Fed. Reg. 841 (1/3/74)	$2,758,086.00
		TOTAL:	**$2,758,086.00**

(f)

Defendant Qualitest			**Product Zolene HC Otic Solution – Pramoxine-HC-Chloroxylenol Otic**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00603 7495	01/01/03	53 Fed. Reg. 25013	$516,354.00
		TOTAL:	**$516,354.00**

(g)

Defendant Qualitest			Product Zolene HC Aqueous Otic Drops – Pramoxine-HC-Chloroxylenol
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00603 7496	01/01/01	53 Fed. Reg. 25013	$504,562.00
		TOTAL:	**$504,562.00**

(h)

Defendant Ferndale			Product Pramosone – pramoxine – HC cream 1-2.5%
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00496 0716	09/30/90	53 Fed. Reg. 25013	$497,574.00
00496 0717	09/30/90		$1,436,737.00
00496 0729	09/30/90		$461,320.00
00496 0763	09/30/90		$75,618.00
00496 0777	09/30/90		$200,295.00
		TOTAL:	**$2,671,544.00**

(i)

Defendant Ferndale			Product Analpram HC Cream & Lotion – Hydrocortisone Acetate with Pramoxine
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00496 0800	09/30/90	53 Fed. Reg. 25013	$2,950,224.00
00496 0778	09/30/90		$2,064,673.00
00496 0829	09/30/90		$88,955.00
		TOTAL:	**$5,103,852.00**

(j)

Defendant United			Product Uni-Hist DM – PSE, Bromphen, DM, GG
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00677 1878	09/30/90	47 Fed. Reg. 11973	$515,433.00
00677 1879	09/30/90		$2,899,246.00
		TOTAL:	**$3,414,679.00**

(k)

Defendant Sciele			**Product Protuss Liquid - Hydrocodone/PotGuaiac/PSE**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid**
59630 0100	1/01/93	47 Fed. Reg. 11973	$903,833.00
		TOTAL:	**$903,833.00**

(l)

Defendant Sciele			**Product Zoto HC Ear Drops – pramoxine, HC, Chloroxylenol, Otic**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid**
59630 0135	3/06/94	53 Fed. Reg. 25013	$848,991.00
		TOTAL:	**$848,991.00**

(m)

Defendant Actavis			**Product Hemorrhoidal HC Suppositories 25mg – hydrocortisone acetate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
00472 0511	9/30/90	53 Fed. Reg. 25013	$154,012.00
		TOTAL:	**$154,012.00**

(n)

Defendant Actavis			**Product Palgic D Ext. Rel. – Carbinoxamine/PSE**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-04)**
00472 0727	01/01/85	47 Fed. Reg. 21301 48 Fed. Reg.34514	$4,162,020.00
		TOTAL:	**$4,162,020.00**

(o)

Defendant **Pan American**			**Product** **Palgic – CBM, PSE: SR – Palgic DS– CBM, PSE**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-04)**
00525 6121	05/25/95	47 Fed. Reg. 21301	$6,625,798.00
00525 6123	05/25/95	48 Fed. Reg. 34514	$653,278.00
00525 6131	10/11/85		$9,208,188.00
00525 6367	None		$4,580,375.00
00525 6425	08/08/95		$5,957,598.00
		TOTAL:	**$27,025,237.00**

(p)

Defendant **Pan American**			**Product** **Pannaz -- phenylephrine HC1, chlorpheniramine maleate, methscopolamine nitrate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (Thru 03)**
00525 0780	None	48 Fed. Reg. 56854	$857,607.00
00525 0788	1/1/84		$562,447.00
		TOTAL:	**$1,420,054.00**

(q)

Cypress			**Bromhist PDX – Phenyleph, Bromphen, DM, Guaifen**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (04)**
60258 0429	None	47 Fed. Reg. 11973 On 8/4/09 CMS DESI LTE List	$303,372.00
		TOTAL:	**$303,372.00**

(r)

Cypress			**Bromhist DM – PSE, Bromphen, DM, GG**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-06)**
60258 0446	06/30/90	47 Fed. Reg. 11973	$578,243.00
		TOTAL:	**$578,243.00**

(s)

Defendant Medpointe			**Product Rynatan Pediatric Suspension – chlorpheniramine tannate, phenylephrine tannate, pyrilamine tannate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
00037 0713	None		$990,225.00
00037 0714	9/30/90	48 Fed. Reg. 5864	$2,567,218.00
00037 0715	9/30/90		$3,467,588.00
		TOTAL:	**$7,025.301.00**

(t)

Defendant Medpointe			**Product Rynatuss and Rynatuss Pediatric – cpm tan/carbetapentane tan/eph tan/phenyleph tan**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
00037 0717	9/30/90	37 Fed. Reg. 25249 [DESI 11562]	$1,265,629.00
00037 0718	9/30/90		$607,797.00
		TOTAL:	**$1,873,426.00**

(u)

Defendant Major			**Product Rondamine TR Tablets Extended Release – Carbinoxamine, PSE**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
0904 3250	9/30/90	47 Fed. Reg. 2130; 48 Fed. Reg. 34514	$52,315.00
		TOTAL:	**$52,315.00**

(v)

Defendant Hi-Tech			**Product Tannate – chlorpheniramine, carbetapentane**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
50383 0861	10/01/90	38 Fed. Reg. 4006 72 Fed. Reg. 29517	$1,240,604.00
		TOTAL:	**$1,240,604.00**

(w)

Defendant Teva			**Product Granulderm – Trypsin, Castor Oil, Peruvian balsam**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
38245 0607	None	#10110 (2/12/72)	$68,403.00
		TOTAL:	**$68,403.00**

(x)

Defendant Teva	**Formulation**			**Product R-Tannate Tablets – Chlorpheniramine tannate, Phenylephrine tannate, pyrilamine tannate**
NDC		**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
38245 0113	(R-Tannate Tablets)	9/30/90	48 Fed. Reg. 5864	$1,474,070.00
38245 0109	(R-Tannate Pediatric Suspension)	9/30/90		$6,140,082.00
			TOTAL:	**$7,614,152.00**

(y)

Defendant Duramed			**Product Triotann Pediatric Suspension – Chlorpheniramine tannate, phenylephrine tannate, pyrilamine tannate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (96-03)**
51285 0717	10/01/93	48 Fed. Reg. 5864	$4,362,154.00
		TOTAL:	**$4,362,154.00**

(z)

Defendant Blansett	Formulation			Product Cortane-B Lotion & Solution – Chloroxylenol/ hydrocortisone/ pramoxine HCl
NDC		**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (97-3rd Qtr 08)**
51674 0116	(Cortane-B Solution)	03/01/93		$4,212,509.00
51674 0117	(Cortane-B Lotion)	03/01/93	DESI Notice 8656 53 Fed. Reg. 25013	$4,015,954.00
51674 0118	(Cortane-B Solution)	06/01/98		$893,062.00
			TOTAL:	**$9,121,525.00**

(aa)

Defendant Blansett			Product Poly DH Liquid – hydrocodone; potassium guaiacolsulfonate
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
51674 0212	11/01/00	47 Fed. Reg. 11973 DESI 5914 and 6514	$1,127,268.00
51674 0012	09/01/93		$548,783.00
		TOTAL:	**$1,676,051.00**

(bb)

Defendant Robins			Product Lodrane LD and Liquid – PSE & Brompheniramine
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (02-06)**
00095 6004	09/01/94	47 Fed. Reg. 4346	$2,353,948.00
00095 6006	02/08/93		$683,042.00
00095 0645	07/01/02		$2,210,674.00
00095 1200	11/01/04		$2,015,565.00
00095 1290	12/15/06		4,674,030.00
		TOTAL:	**$11,937,259.00**

(cc)

Defendant Medpointe			**Product Tussi 12 & Tussi 12 S – carbetapentane tannate/chlorpheniramine tannate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
00037 0681	9/30/90	37 Fed. Reg. 25249 [DESI 11562]	$551,221.00
00037 0682	9/30/90		$858,115.00
		TOTAL:	**$1,409,336.00**

(dd)

Defendant Medpointe			**Product Tussi 12 D & Tussi 12 D S – carbetapentane tannate/phenylephrine tannate/pyrilamine tannate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
00037 0691	9/30/90	37 Fed. Reg. 25249 [DESI 11562]	$3,224,875.00
00037 0692	9/30/90		$7,272,213.00
		TOTAL:	**$10,497,088.00**

(ee)

Defendant Actavis			**Product Auroto – antipyrine/benzocaine**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
00472 0016	9/30/90	51 Fed. Reg. 28656 47 Fed. Reg. 35874 [DESI 12813]	$793,788.00
		TOTAL:	**$793,788.00**

(ff)

Defendant Hi-Tech			Product Quad-Tuss Tannate Pediatric Suspension– carbetapentane tannate/chlorpheniramine tannate/eph tannate
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-06)**
50383 0809	9/30/90	37 Fed. Reg. 25249 [DESI 11562]	$2,818,288.00
		TOTAL:	**$2,818,288.00**

(gg)

Defendant Hi-Tech			Product Tannate 12's Suspension – carbetapentane tannate/chlorpheniramine tannate/
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-06)**
50383 0863	10/01/90	37 Fed. Reg. 25249 [DESI 11562]	$1,502,324.00
		TOTAL:	**$1,502,324.00**

(hh)

Defendant Cypress			Product Chlordex GP – cpm/dm/gg/phenylephrine hcl
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
60258 0246	9/30/90	On 8-4-09 CMS DESI LTE List	$115,217.00
		TOTAL:	**$115,217.00**

(ii)

Defendant Cypress			Product Chlordex A 12 Extended Release Tablet – cpm/phenylephrine hcl
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
60258 0283	9/30/90	On 8-4-09 CMS DESI LTE List	$709,954.00
60258 0313	9/30/90		$791,639.00
		TOTAL:	**$1,501,593.00**

(jj)

Defendant Cypress			**Product Tannic 12 S – carbetapentane tannate/chlorpheniramine tannate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
60258 0302	9/30/90	37 Fed. Reg. 25249 [DESI 11562]	$939,802.00
		TOTAL:	**$939,802.00**

(kk)

Defendant Cypress			**Product Bellahist D LA Atropine/Cpm/Hyoscyamine/Pe/ Scopolamine**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (03-07)**
60258 0283	9/30/90		$709,954.00
		TOTAL:	**$709,954.00**

(ll)

Defendant Cypress	** 47 Fed. Reg. 11973(DESI). See also letter dated 3-12-04 from FDA to Carolina Pharmaceuticals ("These products are new drugs because they contain potassium guaicolsulfonate"*		**Product Hy-KXP – hydrocodone bitartrate/potassium guaicolsulfonate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (2003-2007)**
60258 0735	9/30/90	41 Fed. Reg. 38359 (DESI 6514); also see 47 Fed. Reg. 11973 (DESI 5914)	$177,951.00
		TOTAL:	**$177,951.00**

(mm)

Defendant Hawthorn			**Product Dytan CS Suspension and Extended Release Tablet – Carbetapentane tannate/phenylephrine tannate/diphenhydramine tannate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (2003 - 3rd qtr 2008)**
63717 0580 Suspension	9/30/90	37 Fed. Reg. 25249 [DESI 11562]	$3,430,376.00
63717 0581 TER	6/30/90		$1,965,638.00
		TOTAL:	**$5,396,014.00**

(nn)

Defendant Hawthorn			**Product Dytan CD Suspension – Carbetapentane/Diphenhydramine/Phenylephrine**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (2003 - 3rd qtr 2008)**
63717 0585	None	37 Fed. Reg. 25249 [DESI 11562]	$660,337.00
		TOTAL:	**$660,337.00**

(oo)

Defendant Hawthorn			**Product Dytan AT Suspension– Carbetapentane tannate/Diphenhydramine tannate**
NDC	**False FDA Approval Date**	**DESI Notice(s)**	**Amount Paid (2003 - 3rd qtr 2008)**
63717 0590	None	37 Fed. Reg. 25249 [DESI 11562]	$239,276.00
		TOTAL:	**$239,276.00**

3. Unapproved Levothyroxine – A Serious Threat To Public Health

97. For more than forty years, Levothyroxine sodium tablets (hereinafter "LS") have been prescribed by physicians for the treatment of thyroid diseases, including hypothyroidism.

98. The prescription drug LS was lawfully on the market until 1997, when it was the subject of a final determination by the Secretary of HHS, through the FDA, that it was a "new drug" within the meaning of 21 U.S.C. §321(p).

99. On August 14, 1997, FDA announced that, despite a long history of use, orally-administered LS products were "new drugs" and that manufacturers who wished to continue marketing them would have to submit New Drug Applications for FDA approval. 62 Fed. Reg. 43535 (hereinafter "August 1997 Notice").

100. The August 1997 Notice also stated that "no currently marketed orally-administered LS product has been shown to demonstrate consistent potency and stability and, thus, no currently marketed orally-administered LS product is generally recognized as safe and effective." *Id*. at 43538. The FDA stated that no alternative drug to LS is relied on by the medical community as an adequate substitute.

101. The August 1997 Notice stated that there was "new information showing significant stability and potency problems with orally administered LS products" and that the "lack of stability and consistent potency has the potential to cause serious health consequences to the public." *Id*.

102. The August 1997 Notice stated that after August 14, 2000 (later amended to 2001 as explained below) any orally-administered drug product containing LS marketed without an FDA-approved new drug application would be subject to adverse regulatory action.

Nevertheless, the Defendants identified below have continued to market, distribute, and/or sell unapproved levothyroxine since that time.

103. Unapproved levothyroxine is not a Covered Outpatient Drug.

104. Since the introduction of orally administered LS products, almost every manufacturer of the drug has regularly reported recalls that were the result of potency and stability problems.

105. On August 21, 2000, the FDA approved Jerome Stevens Pharmaceuticals, Inc.'s (hereinafter "Jerome") NDA for Unithroid™, the first LS drug approved by the FDA under the new requirements. *See*, FDA *Unithroid Approval Talk Paper*, available at http://www.scienceblog.com/community/older/archives/M/1/fda0638.htm. In the *Talk Paper*, the FDA announced: "With the approval of the NDA for Unithroid™, patients and physicians now have available to them an oral levothyroxine sodium drug product that has been determined to be safe and effective by the FDA and that also meets FDA standards for manufacturing processes, purity, potency and stability." *Id*. The FDA further stated:

> Although oral levothyroxine drugs products have been marketed in the Unites States since the 1950's, the approval of Unithroid represents the first time that a single ingredient oral levothyroxine product has been approved by the FDA. The unapproved thyroid hormone replacement products that have been on the market have been associated with stability and potency problems. These problems have resulted in product recalls and have the potential to cause serious health consequences to the public.

Id.

106. On July 12, 2001, the FDA issued its *Guidance on Levothyroxine Sodium Products Compliance* (hereinafter "*LS Guidance*"). The *LS Guidance* and a simultaneous press

release made it clear that (1) "Manufacturers of unapproved oral levothyroxine sodium drug products who *"[did] not have an NDA pending"* with the FDA by August 14, 2001, should cease distribution of their products by that date or they will be subject to regulatory action," and that (2) manufacturers of unapproved oral levothyroxine sodium drug products *with NDAs pending as of August 14, 2001,* were to reduce the distribution of these products according to an incremental reduction of average monthly distribution, with complete ceasing of distribution by August 14, 2003 (emphases added).

107. The Defendants identified below submitted false records or statements to CMS, caused the submission of false claims and also caused false claims to be paid or approved for the levothyroxine products identified below. The Defendants' submissions included a false representation that their levothyroxine drugs met the definition of a Covered Outpatient Drug, and in many instances contained a false FDA approval date.

108. The NDC numbers, partial, representative amounts paid by Medicaid and false FDA approval dates are as follows:

109. QUALITEST submitted false information to CMS for its *generic levothyroxine* product, thereby ostensibly qualifying that drug for reimbursement from the Medicaid programs. The NDC numbers and false FDA approval dates submitted by Qualitest are as follows:

Defendant Qualitest	**Product Generic Levothyroxine**
NDC	**False FDA Approval Date**
00603 4192	10/01/91
00603 4193	10/01/91
00603 4194	10/01/91
00603 4195	07/01/90
00603 4196	07/01/90
00603 4197	10/01/91

00603 4198	10/01/91
00603 4199	10/01/00
00603 4200	01/01/97
00603 4201	10/01/00
00603 4202	10/01/00
00603 4203	10/01/00

The yearly breakdown for the QUALITEST Levothyroxine Medicaid damages beginning with third quarter 2001, is as follows:

Defendant Qualitest	**Product Generic Levothyroxine**
Year	**Amount Paid**
2001 (3rd & 4th Quarter Only)	$1,132,210.00
2002	$573,677.00
2003	$33,470.00
2004	$4,521.00
2005	$13,694.00
TOTAL:	**$1,757,572.00**

110. UNITED RESEARCH submitted false information to CMS for its *generic levothyroxine* product, thereby ostensibly qualifying that drug for reimbursement from the Medicaid programs.

The NDC numbers, and the false FDA approval dated submitted to CMS by United Research are as follows:

Defendant United Research	**Product Generic Levothyroxine**
NDC	**False FDA Approval Date**
00677 0078	09/30/90
00677 0079	09/30/90
00677 0769	None
00677 0992	09/30/90

00677 1637	06/30/90
00677 1648	06/01/98
00677 1649	None
00677 1650	None
00677 1690	03/01/98
00677 1691	07/01/98
00677 1692	09/01/98
00677 1693	09/30/90
00677 1694	09/30/90
00677 1695	09/30/90
00677 1696	09/30/90
00677 1697	09/30/90

111. The yearly breakdown for the UNITED RESEARCH Levothyroxine Medicaid damages beginning with third quarter 2001 is as follows:

Defendant **United Research**	**Product** **Generic Levothyroxine**
Year	**Amount Paid**
2001 (3rd & 4th Quarter Only)	$264,217.00
2002	$78,786.00
2003	$5,011.00
2004	$322.00
2005	$688.00
TOTAL:	**$349,024.00**

B. How Defendants' False Submissions Caused False Claims For Vitamins, Minerals And Other Dietary Supplements

112. By statute, only drugs – as opposed to vitamins and other dietary supplements – are eligible for federal reimbursement under the Medicaid program. Yet hundreds of millions of dollars of federal Medicaid funds have been used to pay for ineligible vitamins, minerals and other dietary supplements as a result of false claims caused by Defendants' actions.

113. A Covered Outpatient Drug must: (1) be a drug, (2) for which an NDC is required, (3) used for a medically accepted indication. 42 U.S.C. §§ 1396r-8(k)(2)-(3). Dietary supplements do not meet any of these three criteria, although all three are required.

114. First, dietary supplements are not drugs. The FDCA defines both drugs and dietary supplements. A "dietary supplement" is a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

21 U.S.C. § 321(ff).

115. A drug is defined as an "article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" or intended to affect the structure or function of the body. 21 U.S.C. § 321(g)(1).

116. Because dietary supplements are not drugs, they are not subject to approval by the FDA. 21 U.S.C. § 355(a). Only products subject to FDA approval can be Covered Outpatient Drugs. 42 U.S.C. § 1396r-8(k)(2)(a). None of the dietary supplements included in this complaint were or could be approved by the FDA as drugs.

117. Second, only drugs are required to have an NDC, and each drug's NDC must be registered with the FDA. 21 U.S.C. § 360. The definition of Covered Outpatient Drug expressly excludes any products for which an NDC is not required. 42 U.S.C. § 1396r-8(k)(3). Thus, vitamins and other dietary supplements cannot be Covered Outpatient Drugs because an NDC is not required for them. In fact, manufacturers are prohibited from assigning NDCs to non-drugs,

such as dietary supplements. *See e.g.* FDA Warning Letter, # 2001-NOL-41, to PharmaScience Laboratories, LLC., attached as **Exhibit G**. Valid NDCs must be registered with the FDA. None of the NDCs assigned by manufacturers to the dietary supplements included in this complaint are registered with the FDA.

118. Third, only drugs used for "medically accepted indications" can be Covered Outpatient Drugs. 42 U.S.C. § 1396r-8(k)(3). A "medically accepted indication" is a use for a *drug* which is either approved by the FDA or supported by a citation in the specified drug compendia. 42 U.S.C. § 1396r-8(k)(6). Dietary supplements, as above, are neither approved by the FDA nor do they appear in the drug compendia. Dietary supplements are not used for "medically accepted indications."

119. For these reasons, CMS has repeatedly emphasized in its periodic releases to manufacturers and state Medicaid programs that dietary supplements are not Covered Outpatient Drugs, and should not have NDCs.

120. For example, manufacturers were reminded in 1997 that "[i]f any of your non-drug products (vitamins or other products) have been improperly assigned an NDC and included in your submission of covered outpatient drugs to the HCFA, please notify HCFA staff so that those items can be deleted from the HCFA and state data systems." Medicaid Drug Rebate Program Release to Drug Manufacturers, No. 30 (September 15, 1997).

121. CMS has attempted over the years to find and remove Non-Drugs from the innumerable items on the MDRI List. These efforts have been largely ignored by the Defendants, who continue to submit their ineligible products as Covered Outpatient Drugs, causing the federal Medicaid program to pay for them.

122. When it deletes or excludes non-drug products from the MDRI List, CMS consistently cites the following explanation:

> The abovementioned products were *not approved as prescription drugs* by the Food and Drug Administration (FDA) under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act and therefore, *do not meet the definition of Covered Outpatient Drugs* as defined in Section 1927(k)(2) of the Social Security Act. (emphasis added)

See, e.g. CMS Medicaid Drug Rebate Program For State Medicaid Directors, Release No. 145, March 7, 2007, at 6.

C. Defendants' False Statements Caused Medicaid Payments To Be Made For Their Non-Drug Products

123. Despite the fact that their non-drug products meet none of the Covered Outpatient Drug criteria, the Defendants knowingly represented in their Drug Rebate Agreements and Quarterly Reports that their dietary supplements were in fact Covered Outpatient Drugs.

124. From 1996 to date, the Defendants knowingly made, used or caused to be made or used false records or statements, submitted to CMS, which were material to a false or fraudulent claim; knowingly caused false claims to be submitted for payment or approval; and, as a direct result of Defendants falsely representing in their Drug Rebate Agreements and Quarterly Reports that the non-drug products identified below were Covered Outpatient Drugs, caused the states and CMS to pay false claims for these ineligible products.

125. CMS relied on Defendants' misrepresentations and included the Non-Drugs on the MDRI List which it sent to the states, which in turn relied on this list in paying for these products and submitting FFP claims for reimbursement to the federal government.

126. When they submitted their Rebate Agreements and Quarterly Reports, the Defendants knowingly used false FDA approval dates, and/or false NDC numbers to make their

ineligible products appear eligible. The Defendants knew that CMS would rely on these false statements.

127. By including Non Drugs in Rebate Agreements and in Quarterly Reports, the Defendants have caused Medicaid to pay hundreds of millions of dollars of false claims. The amounts listed below for each product are approximations.

1. Non-Drugs Medicaid Paid For As A Result Of Defendants' Fraud

128. The following is a list of the Non-Drugs identified in this Complaint, the False FDA Approval Dates, rogue NDC numbers, and the approximate amount of Medicaid reimbursements paid for these Non-Drugs for the years listed.

(a)

Defendant Abbott	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (1996-2003)**
00074 3741	Dical-D Tablets	4/1/1987	$8,154,793.00
00074 6470	Pedialyte 32oz bottle	None	$14,651,224.00
00074 6471	Pedialyte Fruit Flavored 32oz bottle	None	$14,693,127.00
00074 0240	Pedialyte GrapeFlavored 1L bottle	5/01/1985	$3,108,696.00
00074 0245	Pedialyte Freezer Pops	6/01/1996	$3,259,745.00
00074 5175	Pedialyte Bubble Gum Flavored 1L bottle	7/1/1993	$2,320,686.00
00074 5498	Pedialyte Oral Electrolyte Main Sol.	08/21/1986	$34,215.00
00074 6089	Cefol Film Tablets	09/30/1990	$1,280,505.00
00074 7079	Fero Folic	09/29/1990	$1,277,255.00
NDC		**False FDA Approval Date**	**Amount Paid (2003 & 2006)**
00074 7238	Fero-Grad 500 Controlled Release Iron w/Vit C	9/29/1990	$ 9,899.00

00074 0116	Vidaylin	9/30/1990	$2,685.00
00074 1184	Calcium G	9/30/1990	$2,927.00
00074 1631	Calcium GH	1/28/1990	$1,161.00
00074 2553	Calcium A	9/30/1990	$967.00
00074 8928	Vi-Day F + Iron Multivitamin	9/30/1990	$4,798.00
00074 8929	Vi-Day F ADC + Iron Multivitamin	9/30/1990	$381.00
00074 9157	Vitamin K-1	9/30/1990	$21,553.00
00074 9158	Vitamin K-1	9/30/1990	$259,554.00
00074 7125	Iberet-Folic 500 Controlled Release Iron w/Vit C & B Complex	9/29/90	$237,258.00
		TOTAL:	**$49,321,429.00**

(b)

Defendant Goldline	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (1996-2003)**
00182 4428	Vitamin A	1/8/90	$3,702,696.00
00182 0068	Vitamin C Ascorbic Acid	1/1/87	$1,431,670.00
00182 4440	One Tablet Daily w/Iron	1/17/90	$571,663.00
00182 6054	Goldline Geri-vite liquid	1/1/00	$601,382.00
00182 0047	Vitamin B1 100mg Tabs	9/9/80	$478,921.00
00182 4521	Theragran-M Tablets	None	$8,854.00
00182 4532	Theragran-M Tablets	None	$186.00
00182 6106	Theragran-M Tablets	None	$65,334.00
00182 4158	Certagen Senior Tabs	2/5/94	$264,449.00
00182 4159	Certagen Tabs	None	$10,371.00
00182 4160	Certagen Tabs	None	$71,398.00
00182 4162	Certagen Tabs	2/25/94	$1,383,935.00
00182 4089	Certagen Senior w/Lutein	3/17/00	$2,350.00
00182 6142	Certagen Liquid	1/1/00	$823,668.00
00182 1381	Fer Gen Sol Drops	4/27/81	$706,417.00
00182 0003	Vitamin C Ascorbic Acid	09/09/80	$107,891.00
00182 0082	Vitamin E	9/08/80	$427,570.00
00182 0086	Vitamin B6	9/08/80	$342,036.00
00182 0287	DOS Capsule (Docusate)	1/01/00	$5,174,047.00
00182 0418	Oyst-Cal D	9/08/80	$344,629.00
00182 0507	Folic Acid	3/31/72	$2,220,444.00

00182 0809	Alamag (magnesium/aluminum)	12/07/42	$791,650.00
00182 1407	Z-Gen Vitamin Complex	9/08/80	$345,945.00
00182 1513	Genfiber (psyllium husk)	3/07/01	$1,231,712.00
00182 1514	Genfiber (psyllium husk)	3/07/01	$893,754.00
00182 1576	Oyst-Cal 500	4/28/83	$8,419,686.00
00182 4028	Ferrous Sulfate	9/09/80	$5,347,675.00
00182 4029	Ferrous Sulfate	9/24/80	$793,163.00
NDC		**False FDA Approval Date**	**Amount Paid (2003-2007)**
00182 4031	Ferrous Sulfate		$202,002.00
00182 4048	Glucosamine Sulfate	8/04/99	$149,573.00
00182 4062	B-Plex Vitamin	7/19/89	$466,328.00
00182 4140	Calcarb 600	9/03/84	$410,677.00
00182 4141	Calcarb 600 w/Vitamin D	1/01/87	$1,715,738.00
00182 4151	Calcium Citrate	2/09/94	$120,145.00
00182 4314	Fruity Chews Multivitamins	12/07/95	$157,084.00
00182 4418	One-Tablet (Niacin)	7/12/88	$120,798.00
00182 4439	Oyst-Cal D 500	9/01/87	$9,237,834.00
00182 4491	Stress w/Zinc	3/18/94	$294,355.00
00182 4518	Therapeutic	8/16/90	$1,614,930.00
00182 4519	Therapeutic-M	7/09/90	$2,823,685.00
00182 6107	Theravite	2/05/94	$386,410.00
00182 6205	Pediatric Electrolyte	2/09/94	$1,057,905.00
00182 6206	Pediatric Electrolyte	2/05/94	$1,425,957.00
00182 6207	Pediatric Electrolyte	8/04/94	$462,749.00
		TOTAL:	**$59,848,566.00**

(c)

Defendant Rugby	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (1996-2004)**
00536 4046	Multivitamin tablets	6/7/78	$3,015,519.00
00536 4799	Vitamin E400 Soft Gel Caps	2/18/79	$1,574,056.00
00536 0160	Vitamin C 500mg Syrup	10/19/81	$796,690.00
00536 4408	Vitamin B6 50mg Pyridox	12/10/79	$505,541.00
00536 4680	Vitamin B1 100mg Tabs	3/29/75	$462,845.00
00536 4660	Therems film coated tablets	11/25/80	$460,988.00

00536 4661	Therems-M film coated tablets	11/25/80	$1,351,015.00
00536 4667	Therems-H tablets	7/3/84	$255,482.00
00536 3442	Cerovite Tablets Advanced Formula	7/2/85	$718,626.00
00536 3443	Cerovite Jr. Chewable Tablets 60s	None	$84,542.00
NDC		**False FDA Approval Date**	**Amount Paid (2003-2007)**
00536 2790	Cerovite Liquid 8oz	5/1/93	$1,075,053.00
00536 0410	Daily Vitamins	4/14/97	$390,490.00
00536 3549	Daily Vitamins	None	$12,754.00
00536 3546	Daily-Vite Tablets with Iron	5/9/78	$1,157,820.00
00536 3547	Daily-Vite Tablets 1000s	12/13/77	$2,919,356.00
00536 5890	Ferrous Sulfate 324mg	12/30/79	$5,311,078.00
00536 6889	Calcium Chewable 500mg	2/21/85	$451,307.00
00536 4306	Fiber-lax PolyCarbophil 500mg	1/1/85	$2,603,900.00
00536 6651	Vitamin B	None	$968,357.00
00536 0004	Oralyte Solution Unflavored	8/01/92	$1,198,901.00
00536 0650	Ferrous Sulfate	11/26/79	$535,426.00
00536 0710	Fer-Iron (Ferrous + Iron)	12/10/79	$170,003.00
00536 0935	Oralyte Solution Fruit Flavored	8/01/92	$11,291,436.00
00536 1385	Oralyte	None	$1,370,749.00
00536 1395	Oralyte	None	$238,893.00
00536 2770	Calcionate	8/01/92	$587,691.00
00536 3000	Ear Wax Drops ½ oz.	5/11/78	$342,970.00
00536 3224	Citrus Calcium D	10/01/91	$392,818.00
00536 3292	Vitamin C	1/27/79	$393,896.00
00536 3414	Calcium Carbonate	8/27/79	$2,875,685.00
00536 3416	Calcium Gluconate	12/20/79	$243,270.00
00536 3422	Calcium Lactate	9/05/78	$180,317.00
00536 3424	Calcium 600 D	10/31/84	$436,921.00
00536 3426	Calcium 600	None	$315,064.00
00536 3448	Chewable Vite-Tabs	4/20/79	$109,808.00
00536 3556	Vitamin B12	8/14/79	$123,377.00
00536 4106	Oysco 500	7/03/84	$1,848,165.00
00536 4444	Reguloid Nat. Vegetable (psyllium husk)	10/11/85	$1,423,953.00
00536 4445	Reguloid Nat. Vegetable (psyllium husk)	10/11/85	$1,240,970.00

00536 4742	Cal-Gest (calcium carbonate)	6/01/74	$567,800.00
00536 4787	Vitamin E	7/11/75	$146,698.00
00536 4799	Vitamin E	5/17/79	$719,790.00
00536 4801	Vitamin E	12/03/79	$109,448.00
00536 5090	I Vite Lutein	8/24/90	$150,184.00
00536 5440	Vitamin E	12/01/76	$52,206.00
00536 5904	Senexon (calcium sennosides)	4/01/97	$228,663.00
00536 7817	Oysco 500 D	3/10/93	$1,353,712.00
00536 8450	Poly Vitamin	3/06/79	$239,908.00
00536 8501	Tri-Vitamins	9/01/81	$148,018.00
00536 8530	Poly Vitamin w/Iron	7/03/79	$151,454.00
00536 9920	Alcohol Preps	11/17/78	$281,838.00
		TOTAL:	**$53,717,880.00**

(d)

Defendant Hi-Tech	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (1996-2004)**
50383 0624	Daly Vite	09/30/90	$1,084,719.00
		TOTAL:	**$1,084,719.00**
NDC		**False FDA Approval Date**	**Amount Paid (03-06)**
50383 0120	Geri-Tonic	10/1/90	$13,936.00
50383 0167	Vitamin C Liquid 500	9/30/90	$123,241
50383 0623	Dalyvite w/Iron	9/30/90	$20,879.00
50383 0625	Polyvitamin Drops	9/30/90	$215,040.00
50383 0630	Ferrous Sulfate	9/30/90	$259,436.00
50383 0632	Polyvitamin	9/30/90	$274,707.00
50383 0635	Tri-vitamin	9/30/90	$97,528.00
50383 0778	Ferrous Sulfate	10/1/91	$106,509.00
50383 0785	Equalizer Gas Relief Drops	9/30/90	$45,329.00
50383 0786	Golden Age Liq. Vitamins	10/1/90	$56,596.00
50383 0921	Calcium	10/1/90	$5,511.00
50383 0628	Tri-Vitamin	9/30/90	$48,472.00
50383 0633	Poly Vitamin	8/1/93	$94,000.00
50383 0634	Poly Vitamin	9/30/90	$807,944.00
50383 0636	Tri-Vitamin	9/30/90	$53,231.00
50383 0637	Tri-Vitamin	9/30/90	$762,549.00

50383 0641	Poly Vitamin	9/30/90	$117,617.00
50383 0642	Poly Vitamin	9/30/90	$1,241,727.00
50383 0808	Triple Vitamin	9/30/90	$229,642.00
50383 0683	Thera-Plus	4/01/93	$305,402.00
		TOTAL:	**$4,879,296.00**

(e)

Defendant Major	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (1996-2004)**
00904 0540	Thera-M Tablets	None	$78,266.00
		TOTAL:	**$78,266.00**
NDC		**False FDA Approval Date**	**Amount Paid (03-06)**
00904 2641	Certavite	10/11/90	$11,974.00
00904 2701	Fiber-Eze	9/30/90	$8,465.00
00904 2702	Fiber-Eze	9/30/90	$5,383.00
00904 2705	Twice a Day	9/30/90	$2,081.00
00904 5050	Pedia-Relief	3/24/95	$107,469.00
00904 5118	Pediatric Electrolyte	6/30/90	$367,820.00
00904 5119	Pediatric Electrolyte	10/23/95	$6,849.00
00904 5199	Natural Fiber Therapy	6/30/90	$163,968.00
00904 5200	65 Natural Fiber	6/30/90	$115,295.00
00904 5201	Natural Fiber	6/30/90	$957.00
00904 5202	Natural Fiber	6/30/90	$9,846.00
00904 5217	Twice a Day	6/30/90	$5,924.00
00904 5276	Pediatric	10/11/97	$132,617.00
00904 5395	Ferrex 150	10/11/90	$13,822.00
00904 5396	Ferrex 150	10/11/90	$818.00
00904 5486	Certa Vite	10/1/00	$23,313.00
00904 7611	Fiber-Eze	2/1/93	$1,127.00
00904 7612	Fiber-Eze	2/1/93	$2,582.00
00904 7613	Fiber-Eze	2/1/93	$500.00
00904 7614	Fiber-Eze	2/1/93	$3,513.00
00904 7659	Pediatric Electrolyte	9/30/90	$226,204.00
00904 7660	Pediatric Electrolyte	3/1/93	$420.00
00904 7695	Calcium	6/1/93	$13,452.00
00904 3397	Tricolate 100mg Tablet	9/30/90	$256.00
00904 3430	Amantadine 100MG Red	8/5/86	$59,734.00
00904 3440	Vapocet	4/21/88	$159,360.00
00904 5274	Poly Fi Fl	10/1/97	$8,547.00

00904 7850	Pediatric Electrolyte	1/19/94	$14,105.00
00904 7911	Mag Delay (magnesium)	5/16/94	$610,664.00
		TOTAL:	**$2,155,331.00**

(f)

Defendant Qualitest	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (2003 & 2006)**
00603 0095	Calcium	7/1/90	$13,231.00
00603 0096	Calcium	7/1/90	$3,209.00
00603 0097	Calcium	7/1/90	$665.00
00603 0179	Ferrous	1/1/01	$334,752.00
00603 0181	Fibertab	7/1/90	$40,142.00
00603 0325	Vitamin	6/1/99	$49,650.00
00603 0331	Vitamin	6/1/99	$98,617.00
00603 0410	Vitamin	7/1/90	$1,635.00
00603 0762	Ferrous	7/1/90	$204,067.00
00603 0763	Ferrous	7/1/90	$86,398.00
00603 0987	Vegetable Fiber	7/1/90	$41,747.00
00603 0988	Vegetable Fiber	7/1/90	$7,979.00
00603 0989	Vegetable Fiber	7/1/90	$ 17,485.00
00603 0990	Vegetable Fiber	7/1/90	$32,800.00
00603 1256	Gevratonic	7/1/90	$ 21,577.00
00603 1365	L-Tonic	7/1/90	$49,543.00
00603 1449	Multivits	7/1/90	$499,791.00
00603 1450	Multivits	7/1/90	$77,621.00
00603 1452	Multi Vit/	7/1/90	$218,396.00
00603 1453	Multi Vit/	7/1/90	$22,031.00
00603 1785	Trivit/Flu	7/1/90	$384,532.00
00603 1786	Trivit/Flu	7/1/90	$23,145.00
00603 1787	Trivit/Flu	7/1/90	$12,877.00
00603 4170	K-Effervesc	7/1/90	$68,308.00
00603 4710	Multi Vit/	1/1/96	$404,716.00
00603 4711	Multivitamin	7/1/90	$313,644.00
00603 4712	Multivitamin	7/1/90	$188,558.00
00603 6215	Tricosal Choline Magnesium	7/1/90	$16,403.00
00603 6216	Tricosal Choline Magnesium	7/1/90	$59,329.00
00603 6217	Tricosal Choline Magnesium	7/1/90	$11,110.00
00603 6381	Vica Forte Multivit	7/1/90	$171,518.00
00603 6430	Yohimbine	7/1/90	$12,627.00
00603 5969	Therobec	7/01/90	$73,054.00

00603 5970	Therobec Multivitamin	7/01/90	$621,659.00
		TOTAL:	**$4,182,816.00**

(g)

Defendant United Research Labs	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (2003 & 2006)**
00677 0034	Calcium	Not there	$648.00
00677 0069	Ferrous Gluconate	7/1/90	$53,087.00
00677 0070	Ferrous Sulfate	9/30/90	$752,340.00
00677 0071	Ferrous Sulfate	9/30/90	$1,545,720.00
00677 0131	Sodium Bicarbonate	9/30/90	$296,102.00
00677 0163	Uni-Daily w/Iron	7/1/90	$191,489.00
00677 0164	Uni-Daily w/Iron	7/1/90	$25,009.00
00677 0190	Vitamin C	9/30/90	$14,295.00
00677 0210	Vitamin E Reg. Acetate	9/30/90	$53,589.00
00677 0381	Vitamin E Reg. Acetate	6/30/90	$15,114.00
00677 0424	Niacin	9/30/90	$1,671.00
00677 0425	Niacin	9/30/90	$7,163.00
00677 0449	Folic Acid	9/30/90	$228,358.00
00677 0527	Ferrous Sulfate	9/30/90	$86,745.00
00677 0540	Potassium Chloride	9/30/90	$36,927.00
00677 0628	Docusate Sodium w/ Casanthrol	9/30/90	$123,941.00
00677 0765	Vitamin D 50	9/30/90	$84,544.00
00677 0819	Potassium Effervescent	9/30/90	$89,558.00
00677 0990	Multi-Ferrous Folic	9/30/90	$77,349.00
00677 1597	Polysaccharide	11/1/95	$184,756.00
00677 1604	B-Complex	6/30/90	$67,255.00
00677 1652	Glucosamine Chondrotin	6/30/90	$112,329.00
00677 1750	Uni-Thera M Advanced	9/30/90	$41,015.00
00677 0782	Uni-Gine Ergoloid Mesylates	9/30/90	$239,846.00
00677 0827	Fortabs	9/30/90	$72,335.00
00677 1035	Potassium Chloride 20 Meq	9/30/90	$49,866.00
00677 0622	Zinc Sulfate 220mg	9/30/90	$145,594.00

00677 1678	Sodium Fluoride Chew	9/30/90	$152,711.00
00677 1683	Colchicine Tab	9/30/90	$464,023.00
		TOTAL:	**$5,213,379.00**

(h)

Defendant Cypress	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (2003 & 2006)**
60258 0111	Aquavit E	9/30/90	$144,877.00
60258 0121	Calcium	6/30/90	$1,248.00
60258 0160	RenaVite Rx Tablets	11/1/99	$57,612.00
60258 0171	Magnesium	9/30/90	$1,312,016.00
60258 0172	Mag G	9/30/90	$10,461.00
60258 0173	Mag SR	9/30/90	$87,891.00
60258 0174	Mag SR	6/30/90	$19,430.00
60258 0182	Ferrous	9/30/90	$169,240.00
60258 0090	Choline Magnesium	9/30/90	$105,606.00
60258 0158	Neutral	None	$351.00
60258 0159	Stannous Fluoride	9/30/90	$31,537.00
60258 0161	Rena Vite Rx Tablets	9/30/90	$290,695.00
60258 0162	Rena	6/30/90	$1,471,145.00
60258 0180	Hematin Plust Tablets	6/30/90	$1,175,974.00
60258 0181	Hematin F Tablets	6/30/90	$645,404.00
60258 0189	FerroGels	9/30/90	$643,522.00
60258 0001	Cytra-2 Solution	9/30/90	$1,333,097.00
60258 0002	Cytra 3 Syrup	9/30/90	$306,531.00
60258 0003	Cytra K Oral Solution	9/30/90	$242,444.00
60258 0005	Cytra K Crystals	9/30/90	$248,522.00
60258 0006	Phos-NaK	6/30/90	$604,950.00
60258 0185	Poly-Iron	6/30/90	$2,858,210.00
60258 0186	Poly-Iron	6/30/90	$1,651,232.00
60258 0192	Trinate Tablets	6/30/90	$141,113.00
60258 0810	Lapase	6/30/90	$298,519.00
60258 0811	Dygase	6/30/90	$272,515.00
		TOTAL:	**$14,124,142.00**

(i)

Defendant Actavis	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (1996-2003)**
00472 1555	Theravite	01/28/87	$1,085,408.00
NDC		**False FDA Approval Date**	**Amount Paid (2003-2007)**
00472 0924	Diocto Syrup (Docusate)	09/30/90	$237,143.00
00472 0936	Diocto Liquid (Docusate)	09/30/90	$1,333,700.00
00472 1465	Ferrous Sulfate Elixir	09/30/90	$313,535.00
00472 1469	Ferrous Sulfate Drops	01/16/86	$196,688.00
		TOTAL:	**$3,166,474.00**

(j)

Defendant Teva	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (1996-2003)**
38245 0158	Multivitamins	09/30/90	$1,625,112.00
38245 0159	Multivitamins	09/30/90	$701,108.00
		TOTAL:	**$2,326,220.00**

(k)

Defendant Hawthorn	**Product**		
NDC		**False FDA Approval Date**	**Amount Paid (97-3rd Qtr 08)**
63717 0099	Icar-C Tablets	09/30/90	$1,372,874.00
63717 0100	Icar-C Plus Tablets	09/30/90	$4,574,118.00
63717 0102	Icar 15mg Pediatric	06/30/90	$3,112,166.00
63717 0103	Icar 15mg Pediatric	09/30/90	$1,280,915.00
63717 0112	Icar – C Plus Tablets	09/30/90	$1,064,876.00
		TOTAL:	**$11,404,949.00**

VI. Causes of Action

129. Relator realleges and incorporates by reference paragraphs 1 - 128 as though fully set forth herein.

130. Relator brings four claims, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, against Defendants for knowingly presenting or causing the presentment of false claims to the United States and state government Medicaid programs, from at least the 6 years preceding the filing of Relator's initial Complaint through the present.

131. In each instance, by virtue of the false records or false statements made by Defendants in violation of 31 U.S.C. § 3729(a)(1)(B), or the false claims which Defendants presented or caused to be presented in violation of 31 U.S.C. § 3729(a)(1)(A), the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and not more than $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410).

FIRST CAUSE OF ACTION

Making or Using False Records or Statements Material to False or Fraudulent Claims
(31 U.S.C. § 3729(a)(1)(B))

132. Defendants knowingly made and/or used false records or statements – i.e., the false records or statements made by Defendants to CMS misrepresenting their Illegal Drugs and Non-Drugs as Medicaid-eligible Covered Outpatient Drugs – –material to false claims. Defendants intended the false statements or records to be material to the decision of the United States to pay the false claims.

133. In violation of 31 U.S.C. §3729(a)(1)(B), Defendants knowingly and directly submitted to the UNITED STATES, through CMS, in their Medicaid Rebate Agreements, their Quarterly Medicaid Rebate Agreement Updates (Form CMS-367), and other documentation, false information as to the status of their products as Covered Outpatient Drugs, their FDA approval dates, and/or DESI status. Based on the Defendants' inclusion of false information in such documentation, they purported to qualify the Illegal Drugs and/or Non-Drugs as Covered Outpatient Drugs. The UNITED STATES and state governments relied on this information, and the Medicaid Program paid claims for said Illegal Drugs and/or Non-Drugs. In turn, the UNITED STATES was damaged since it paid its FFP to the states in direct reimbursement for those Illegal Drugs and/or Non-Drugs.

SECOND CAUSE OF ACTION

Causing False Records or Statements to be Made Which Are Material to False or Fraudulent Claims
(31 U.S.C. § 3729(a)(1)(B))

134. Defendants knowingly caused to be made or used, false records or statements – i.e., through the use of the false records or statements made by Defendants to CMS misrepresenting their Illegal Drugs and Non-Drugs as Medicaid-eligible Covered Outpatient Drugs –material to false claims. Defendants intended the false statements or records to be material to the decision of the United States to pay the false claims.

135. In violation of 31 U.S.C. §3729(a)(1)(B), Defendants have knowingly and directly caused the UNITED STATES, to pay the states reimbursement for Non-Drugs and Illegal Drugs inasmuch as the states submitted Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) each quarter, and the UNITED STATES, relying on the Defendants' Quarterly Medicaid Rebate Agreement Updates (Form CMS-367), and other documentation, false information as to the status of their products as Covered Outpatient Drugs,

their FDA approval dates, and/or DESI status, paid the state claims. In turn, the UNITED STATES was damaged since it paid its FFP to the states in direct reimbursement for those Illegal Drugs and/or Non-Drugs.

THIRD CAUSE OF ACTION
Causing The Presentation of False Claims For Payment or Approval
(31 U.S.C. § 3729(a)(1)(A))

136. In violation of 31 U.S.C. §3729(a)(1)(A), Defendants knowingly and directly caused the submission of false claims, as they submitted to the UNITED STATES, through CMS, in their Medicaid Rebate Agreements, their Quarterly Medicaid Rebate Agreement Updates (Form CMS-367), and other documentation, false information as to the status of their products as Covered Outpatient Drugs, their FDA approval dates, and/or DESI status.

137. Based on the Defendants' inclusion of the Illegal Drugs and/or Non-Drugs in such documentation as Covered Outpatient Drugs, these products became ostensibly eligible for Medicaid reimbursement and therefore physicians, pharmacies and other providers submitted claims to the Medicaid program for the Illegal Drugs and Non-Drugs. Further and alternatively, the Defendants caused false claims through the promotion and labeling of the Illegal Drugs and/or Non-Drugs were promoted and/or labeled as if they were appropriate for coverage or reimbursement under the Medicaid Program, when they were not.

138. Defendants knowingly caused to be presented false or fraudulent claims for Illegal Drugs and Non-Drugs to the United States.

FOURTH CAUSE OF ACTION
Causing the Presentment of False Claims For Payment or Approval
(31 U.S.C. § 3729(a)(1)(A))

139. In violation of 31 U.S.C. § 3729(a)(1)(A), Defendants have knowingly caused states to submit false claims to the UNITED STATES in various CMS Forms, including Form

CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), by falsely certifying that all drugs paid for were in compliance with federal law. Defendants caused states to submit said false claims by their acts of submitting false information to the UNITED STATES, through CMS, in their Medicaid Rebate Agreements, their Quarterly Medicaid Rebate Agreement Updates (Form CMS-367), and other documentation, as to the status of their products as Covered Outpatient Drugs, their FDA approval dates, and/or DESI status. Based on the Defendants' inclusion of false information in such documentation, they purported to qualify the Illegal Drugs and/or Non-Drugs as Covered Outpatient Drugs.

140. Defendants knowingly caused to be presented false or fraudulent claims for payment or approval of their Illegal Drugs and Non-Drugs to the United States.

WHEREFORE, Relator respectfully requests this Court to enter Judgment against Defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*., provides.

(b) That the maximum civil penalties be imposed for each and every false claim that Defendants presented or caused to be presented under the Federal False Claims Act.

(c) That pre-judgment and post-judgment interest be awarded, along with reasonable attorney's fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant the Federal False Claims Act.

(e) That this Court award such other and further relief as it deems proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Relator Constance Conrad hereby demands a trial by jury in this case on all issues so triable.

DATED this 26th day of July 2011.

Respectfully submitted,

By: */s/ John Roddy*
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CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2011 this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic File (NEF) and electronic copies will be sent by email to those indicated as non-registered participants.

/s/ John Roddy
John Roddy