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MYLAN PHARMACEUTICALS, INC.;	)
PAR PHARMACEUTICAL, INC.;	)
RANBAXY PHARMACEUTICALS, INC.;	)
SANDOZ, INC.;	)
TEVA PHARMACEUTICALS USA, INC.;	)
and	)
WATSON PHARMACEUTICALS, INC.;	)
	)
Defendants.	)
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Plaintiff, the State of Utah (hereinafter "Plaintiff" or "the State"), by and through its Attorney General Mark L. Shurtleff, hereby complains of the above-named Defendants and alleges, on information and belief, the following:

**INTRODUCTION**

1. The Defendants have engaged in false, misleading, wanton, unfair, and deceptive acts and practices in the pricing and marketing of their prescription drug products. The Defendants' fraudulent pricing and marketing of their prescription drugs have caused the State's Medicaid program ("Utah Medicaid") to pay grossly excessive prices for the Defendants' prescription drugs. Utah Medicaid is administered by the Division of Health Care Financing within the single state agency, the Utah Department of Health.

2. Fair and honest drug pricing is a matter of great importance to the State and its citizens. Expenditures by Utah Medicaid for prescription drug reimbursement have increased dramatically in the past several years as a result, in part, of Defendants' fraudulent pricing scheme. Each year Utah Medicaid spends tens of millions of dollars on prescription drugs. In fiscal year 2005 alone, Utah Medicaid spent \$207.6 million on prescription drugs. Significant increases in prescription drug costs in recent years have contributed to a health care funding

crisis within the State that requires action to ensure fair dealing between the Defendants and the State.

3. The State is accountable to its citizens and taxpayers for how it spends limited State resources, and it is obligated to pursue any party whose unlawful conduct has led to the excessive expenditure of State funds. Consequently, the State, by and through its Attorney General, brings this action to recover amounts overpaid for prescription drugs by Utah Medicaid, including pharmacy-dispensed drugs and co-payments for drugs covered by Medicare Part B, which are primarily physician-administered drugs, as a result of the fraudulent and wanton conduct of Defendants.

4. This lawsuit seeks legal redress for the fraudulent and wanton marketing and pricing conduct of Defendants, who have profited from their wrongful acts and practices at the expense of the State.

#### **JURISDICTION AND VENUE**

5. Jurisdiction over the subject matter of this cause of action is based upon the Utah False Claims Act, Title 26, Chapter 20 of the Utah Health Code, which provides remedies to redress Defendants' actions under Utah Code Annotated § 26-20-1 et seq.

6. Personal jurisdiction over these Defendants is proper under the Utah Long Arm Statute as codified in §§ 78-27-22 and 78-27-24 of the Utah Code Annotated.

7. Venue is proper in the Third Judicial District and Salt Lake County pursuant to Utah Code Annotated § 78-13-7 in that the false or fraudulent Utah Medicaid claims caused to be filed by Defendants' unlawful acts were filed in Salt Lake County with the State of Utah, its departments, agencies, instrumentalities and contractors.

## PARTIES

8. Plaintiff is the State of Utah. The Utah Attorney General is authorized to initiate and maintain this action pursuant to Utah Code Annotated § 67-5-1(18).

9. The Defendants listed in paragraphs 10 through 26 are engaged in the business of manufacturing, distributing, marketing and/or selling prescription drugs that are reimbursed by Utah Medicaid. A comprehensive analysis is currently in process to identify each Defendant's prescription drugs reimbursed by Utah Medicaid for which a claim is made in this litigation; however, a few recent representative examples are listed in the attached Exhibit A.

### Defendant Actavis

10. Defendant Actavis US, Inc. ("Actavis") is a Delaware corporation with its principal place of business located at 14 Commerce Drive, Suite 301, Cranford, NJ 07016.

### Defendant Barr

11. Defendant Barr Laboratories, Inc. ("Barr"), a subsidiary of Barr Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 2 Quaker Road, P.O. Box 2900, Pomona, NY 10970-0519.

### Defendant Endo

12. Defendant Endo Pharmaceuticals, Inc. ("Endo"), formerly Endo Laboratories, L.L.C., and a subsidiary of Endo Pharmaceuticals Holdings, Inc., is a Delaware corporation with its principal place of business located at 100 Painters Drive, Chadds Ford, PA 19317.

### Defendant ETHEX

13. Defendant ETHEX Corporation ("ETHEX"), a wholly-owned subsidiary of K-V Pharmaceutical Company, is a Missouri corporation with its principal place of business at 10888 Metro Court, St. Louis, MO 63043-2413.

The Mylan Defendants

14. Defendant Mylan Laboratories, Inc. ("Mylan") is a Pennsylvania corporation with its principal place of business located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

15. Defendant Dey, Inc. ("Dey"), a wholly-owned subsidiary of Mylan, is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Dr., Napa, CA 94558.

16. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharm"), a wholly-owned subsidiary of Mylan, is a West Virginia corporation with its principal place of business located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

17. Defendant UDL Laboratories, Inc. ("UDL"), a wholly-owned subsidiary of Mylan, is an Illinois corporation with its principal place of business located at 1718 Northrock Court, Rockford, IL 61103.

18. Mylan, Dey, Mylan Pharm, and UDL are collectively referred to as the "Mylan Defendants."

Defendant Par

19. Defendant Par Pharmaceutical, Inc. ("Par") is a New Jersey corporation with its principal place of business located at One Ram Ridge Road, Spring Valley, NY 10977.

Defendant Ranbaxy

20. Defendant Ranbaxy, Inc. ("Ranbaxy") is a New Jersey corporation with its principal place of business located at 600 College Road East, Suite 2100, Princeton, NJ 08540.

Defendant Sandoz

21. Defendant Sandoz, Inc. ("Sandoz"), formerly known as Geneva Pharmaceuticals,

Inc., and a member of the Novartis group of companies, is a Delaware corporation with its principal place of business located at 506 Carnegie Center, Suite 400, Princeton, NJ 08540-6243.

#### Defendant Teva

22. Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), a wholly-owned American subsidiary of Teva Pharmaceutical Industries, Ltd., and formerly Lemmon Pharmaceutical Company, is a Delaware corporation with its principal place of business located at 1090 Horsham Road, P O Box 1090, North Wales, PA 19454-1090.

#### The Watson Defendants

23. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Nevada corporation with its principal place of business located at 311 Bonnie Circle, Corona, CA 92880.

24. Defendant Watson Laboratories, Inc. ("Watson Labs"), a wholly-owned subsidiary of Watson, is a Nevada corporation with its principal place of business located at 311 Bonnie Circle, Corona, CA 92880.

25. Defendant Watson Pharma, Inc. ("Watson Pharma"), a wholly-owned subsidiary of Watson since 2000, is a Delaware corporation with its principal place of business located at 311 Bonnie Circle, Corona, CA 92880.

26. Watson, Watson Labs, and Watson Pharma are collectively referred to as the "Watson Defendants."

#### NATURE OF THE CASE

27. This is a civil action for damages and civil penalties pursuant to the Utah False Claims Act, Utah Code Annotated § 26-20-1 et seq., and Utah common law. No federal claims are asserted.

## FACTUAL BACKGROUND

### The Utah Medicaid Program

28. Utah Medicaid is a state-administered program with federal matching funds that pays for medical care, including prescription drug benefits, for Utah's low-income and disabled citizens. Utah Medicaid currently covers about 300,000 individuals. Prescription drug benefits represent about 14% of Utah Medicaid's annual cost of approximately \$1.5 billion. The prescription drug benefit cost has increased dramatically in recent years from \$47.5 million in 1996 to \$207.6 million in 2005, an increase of 437% in nine years or a compounded rate of 17.8% per year.

29. Utah Medicaid reimburses medical providers, including pharmacies and physicians, pursuant to statutory and administrative guidelines and formulae for drugs prescribed for, and dispensed or administered to, Utah Medicaid recipients. Utah Medicaid also pays the 20% co-payment for Medicare Part B prescription drugs, primarily physician-administered, for Utah beneficiaries who are qualified to receive Medicaid benefits, often referred to as "dual-eligible" individuals.

30. Reimbursement amounts for pharmacy-dispensed prescription drugs under Utah Medicaid are based on pricing information supplied by Defendants to industry reporting services. This information includes the following price indices: (i) Average Wholesale Price ("AWP"), which is commonly understood to be the average price charged by wholesalers to retailers, such as hospitals, doctors and pharmacies, for prescription drugs, (ii) Wholesale Acquisition Cost ("WAC"), which is commonly understood to be the average price paid by wholesalers to the manufacturers for prescription drugs, and (iii) on occasion (but prior to 2003), Direct Price, which is commonly understood to be the price charged by drug manufacturers to non-wholesaler

customers for prescription drugs. At all times relevant to this action, Defendants were aware of Utah Medicaid's drug reimbursement guidelines, formulae and procedures for prescription drugs.

**The Defendants' Reporting of Inflated Pricing Information**

31. Defendants knowingly, willfully, wantonly, and/or intentionally provided, or caused to be provided, false and inflated AWP, WAC, and/or Direct Price information for their respective drugs to various nationally known drug industry reporting services, including First DataBank (a/k/a Blue Book), Medical Economics, Inc. (a/k/a Red Book), and Medispan. These reporting services provide the pricing information to various third party payers, such as Utah Medicaid, who have contracted to receive the pricing data as a basis to determine reimbursement amounts to the providers who dispense or administer the drugs to Utah Medicaid patients. Given the tens of thousands of separate National Drug Codes ("NDCs") and the hundreds of thousands of prescription drug claims electronically filed each month with Utah Medicaid, the State has no other feasible alternative to relying on these drug industry reporting services. The State quite literally relies on the honesty and fair dealing of the pharmaceutical manufacturers in reporting their pricing information to these drug industry reporting services. Pharmaceutical manufacturers are keenly aware of this reliance and some, including the Defendants, have chosen to exploit it to their benefit and to the detriment of taxpayer-funded Medicaid.

32. Utah Medicaid purchased and utilized the Defendants' published AWP, WAC, and/or Direct Price information from First DataBank (Blue Book), and Medical Economics, Inc. (Red Book). The information from Blue Book was and is used by Utah Medicaid with respect to reimbursement for pharmacy-dispensed drugs. As a general matter, the information from Red Book was and is used with respect to reimbursement for Medicare Part B drug co-payments. At all relevant times to this action, Utah Medicaid relied upon the AWP, WAC, and/or Direct Price

provided by Defendants to the industry reporting services in determining the amount Utah Medicaid reimburses providers.

33. Defendants knew that the false and deceptive inflation of AWP, WAC, and/or Direct Price for their drugs would cause Utah Medicaid to pay excessive amounts for these drugs. Defendants' inflated AWPs, WACs, and/or Direct Prices greatly exceeded the actual prices at which they sold their drugs to retailers (physicians, hospitals, and pharmacies) and wholesalers. Defendants' reported AWPs, WACs, and/or Direct Prices were false and misleading and bore no relation to any price, much less a wholesale or actual sales price. A few representative examples are listed in attached Exhibit A.

34. Defendants knowingly, willfully, wantonly, and/or intentionally concealed the true AWP, WAC, and/or Direct Price information for their respective drugs from Utah Medicaid. Each Defendant knows its own AWP, WAC, and Direct Price that it reports to the industry reporting services for use by the state Medicaid agencies and other third party payers, including Utah Medicaid. Each Defendant also knows whether the prices it reports to the reporting services accurately and truthfully represent the actual prices as reflected by market experience and conditions. Unless governmental or industry surveys, lawsuits, or criminal or regulatory investigations publicly reveal the true AWP, WAC, or Direct Price for a particular drug at issue, Utah Medicaid, like other state Medicaid agencies, is not privy to the actual market prices which can then be compared to the reported prices. Defendants have concealed true market pricing information from the State for the purpose of avoiding detection of the fraudulent scheme described herein.

35. Defendants used undisclosed discounts, rebates, charge-backs and other inducements which had the effect of lowering the actual wholesale or sales prices charged to

their customers as compared to the reported prices. In addition, Defendants employed secret agreements to conceal the lowest prices charged for their pharmaceutical products. As a result of these concealed inducements and agreements, Defendants have prevented third parties, including Utah Medicaid, from determining the true prices it charges its customers.

#### **Defendants' Marketing of the "Spread"**

36. Defendants refer to the difference between the reported AWP and WAC, on the one hand, and the actual price of a drug, on the other, as the "spread" or, alternatively, "return to practice" or "return on investment." Defendants knowingly and intentionally created a "spread" on their drugs and used the "spread" to increase their sales and market share of their drugs, thereby increasing their profits. Defendants induced physicians and pharmacies to purchase their drugs, rather than a competitor's drugs, by persuading them that the larger "spread" on Defendants' drugs would allow the providers to receive more money, and thereby make more of a profit, through higher reimbursement at the expense of Utah Medicaid.

37. Defendants manipulated and controlled the size of the "spread" on their respective drugs by both increasing their reported AWPs, WACS, and/or Direct Prices and decreasing their actual prices to wholesalers and providers over time.

38. In addition to manipulating the reported AWP, WAC, and/or Direct Price, Defendants used free goods, educational grants and other incentives to induce providers to purchase their drugs, all of which lowered the actual prices of the Defendants' drugs, resulting in increased profits for providers, as well as increased market share and profits for the Defendants, at the expense of Utah Medicaid.

39. The unfair, fraudulent, wanton, and deceptive practices engaged in by the Defendants in creating and reporting, or causing to be reported, false and inflated AWP, WAC,

and/or Direct Price information for their drugs, or otherwise concealing actual pricing information, and marketing the "spread" on their drugs as an inducement to providers to utilize Defendants' drugs, has resulted in the State paying tens of millions of dollars in excess Medicaid payments, while at the same time enriching Defendants with excessive, unjust and illegal profits primarily from the resulting increased sales of their drugs.

40. Generic or multi-source drug manufacturers, such as Defendants, are aware of the AWP's reported by their competitors and of the actual sales prices of their generic competitors' products. Generic drug manufacturers manipulate their own AWP's in order to gain or maintain a competitive advantage in the market for their generic products. The natural and expected result is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP exceeding actual costs by over 50,000% or 500 times.

41. Some of the conduct described herein goes back over 10 years prior to the filing of the original complaint in this action. As explained above, however, the nature and extent of the fraudulent scheme were not known to the State because information concerning the true prices which should have been reported to the reporting services was concealed and not publicly available. It has only been through recent regulatory investigations, criminal actions, and civil actions that the impact of the fraudulent scheme on the State has been indicated or revealed. Even today, the true market prices for virtually all of the drugs in question for the entire time period at issue are not known by the State.

42. Additionally, it would be impractical, if not impossible, to list in this Complaint, for the entire time period that the inflated pricing scheme has been in effect, the true market price as compared to the reported price for each NDC in question. It is not unusual for a drug manufacturer to report fluctuating prices for a particular drug on multiple occasions within a

particular year, month, week, or even day. To display pricing reports for all of the Defendants and all of the NDCs in question over a ten-year-plus period would be a massive undertaking. Limitations of time and space do not permit that information, even if it were available, to be set forth in this pleading; however, some recent representative examples from July, 2006 and July, 2007 are listed in the attached Exhibit A.

43. For purposes of specificity of pleading, particularly with respect to the fraud allegations, suffice it to say that Defendants are and have been on notice of the claims asserted herein as a result of the many investigations and actions undertaken around the country on this same subject. Indeed, each Defendant should know without further allegation from the State exactly how its reported prices compare to its true prices and whether or not it has engaged in an inflated pricing scheme regarding prescription drugs.

**FIRST CLAIM FOR RELIEF**  
**(Restitution, Costs and Civil Penalties under the Utah False Claims Act)**

44. Plaintiff incorporates paragraphs 1 through 43 as if fully set forth herein and further alleges as follows:

45. Defendants violated the Utah False Claims Act as codified in the Utah Health Code at Title 26, Chapter 20 of the Utah Code Annotated. Defendants issued false and inflated AWP, WAC, and/or Direct Price information for publication by the industry reporting services, in violation of Utah Code Annotated §§ 26-20-3 and 26-20-7. Because of Defendants' fraudulent conduct and misrepresentations, Utah Medicaid relied on false information in setting prescription drug reimbursement rates. Defendants "knowingly" acted in deliberate ignorance or reckless disregard of the truth, and in so doing, caused the State to pay false claims due to the grossly excessive reimbursements for Defendants' prescription drugs.

46. Pursuant to Utah Code Annotated § 26-20-9.5, Defendant is liable for the following damages:

- a. full and complete restitution to the State for all damages that the State sustained;
- b. the costs of enforcement, including but not limited to the cost of investigators and attorneys;
- c. a civil penalty equal to three times the restitution amount; and
- d. a civil penalty of \$5,000 to \$10,000 for each false claim filed.

47. These costs and penalties are in addition to and not a substitute for other damages caused by Defendants' actions.

**SECOND CLAIM FOR RELIEF**  
**(Common Law Fraudulent Misrepresentation)**

48. Plaintiff incorporates paragraphs 1 through 47 as if fully set forth herein and further alleges as follows:

49. Defendants committed fraud against the State and its single state agency administering Utah Medicaid, the Utah Department of Health. Defendants reported or caused to be reported AWP, WAC, and/or Direct Price for their respective products on a periodic and continuing basis for publication and dissemination to state Medicaid programs and other third party payers, including Utah Medicaid. Defendants knew that the AWP, WAC, and/or Direct Price information that they provided and caused to be reported was false and material to the determination of Utah Medicaid reimbursement rates.

50. Defendants misrepresented the pricing information with the intent of inducing Utah Medicaid to rely on the false information in setting prescription drug reimbursement rates.

51. Utah Medicaid reasonably relied on the false pricing data in setting prescription drug reimbursement rates and making payments based on said rates. Defendants'

misrepresentations are continuing, as they regularly and periodically continue to issue false and inflated AWP, WAC, and/or Direct Price information for publication by the industry reporting services.

52. As a result of Defendants' fraudulent conduct, the State has been damaged by paying grossly excessive amounts for Defendants' prescription drugs.

53. By engaging in the acts and practices described above, the Defendants have engaged and continue to engage in repeated fraudulent acts and practices in violation of Utah common law.

54. Defendants' conduct was and is knowing, intentional, gross, oppressive, malicious, wanton, and/or committed with the intention to cause injury. These actions subject Defendants to an award of punitive damages sufficient to punish the Defendants and make an example of them.

#### **JURY DEMAND**

The State respectfully requests a trial by jury pursuant to Rule 38, Utah R. Civ. Proc.

#### **PRAAYER FOR RELIEF**

Wherefore, Plaintiff, the State of Utah, prays for relief as follows:

1. for the costs of enforcement pursuant to § 26-20-9.5(2)(b), Utah Code Ann.;
2. for an award of full and complete restitution to the State in such amount as is proved at trial;
3. for punitive damages for the wanton and reckless conduct as outlined herein and as an example for the benefit of all other drug manufacturers who wrongly misrepresent the prices of their products to the detriment of Utah Medicaid;
4. for civil penalties pursuant to § 26-20-9.5(2)(c), Utah Code Ann., equal to:

- a. three times the restitution amount; and
  - b. \$5,000 to \$10,000 for each false claim filed with Utah Medicaid;
5. for an award of costs and prejudgment interest; and
  6. for such other and further relief as may be justified and which Plaintiff may be entitled to by law including, but not limited to, all court costs, witness fees and deposition fees.

Respectfully SUBMITTED and DATED this 21<sup>st</sup> day of September, 2007.

MARK L. SHURTLEFF  
Attorney General of Utah

RAYMOND A. HINTZE  
Chief Deputy Attorney General

ROBERT STEED  
Assistant Attorney General  
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**ATTORNEYS FOR THE STATE OF UTAH**

**EXHIBIT A**

*As of July, 2007*

<u>Mfgr.</u>	<u>NDC</u>	<u>Drug</u>	<u>List Price</u>	<u>Actual Price</u>	<u>AWP/AMP</u>
			<u>AWP</u>	<u>AMP *</u>	
Teva	00093720422	FLUCONAZOLE	\$ 14.010	\$ 0.110	12736.4%
	00093715498	SIMVASTATIN	\$ 4.920	\$ 0.040	12300.0%
	00172541211	FLUCONAZOLE	\$ 13.930	\$ 0.310	4493.5%
Sandoz	00781507701	LORATADINE	\$ 0.830	\$ 0.010	8300.0%
	00781211317	CLINDAMYCIN HCL	\$ 4.030	\$ 0.060	6716.7%
Watson	00591325001	NITROFURANTOIN MONOHYD MACRO	\$ 2.040	\$ 0.070	2914.3%
	00591316801	HYDROCODONE BIT-IBUPROFEN	\$ 1.150	\$ 0.040	2875.0%
Mylan	00378315101	FINASTERIDE	\$ 3.130	\$ 0.010	31300.0%
	00378963943	BUTORPHANOL TARTRATE	\$ 30.100	\$ 0.660	4560.6%
Actavis	00228272309	SERTRALINE HCL	\$ 2.850	\$ 0.070	4071.4%
	00472173803	MICONAZOLE 3	\$ 14.930	\$ 0.070	21328.6%
Barr	00555097302	AMPHETAMINE SALT COMBO	\$ 1.370	\$ 0.050	2740.0%
	00555024171	MIRTAZAPINE	\$ 2.600	\$ 0.190	1368.4%
	50111091601	TORSEMIDE	\$ 0.700	\$ 0.050	1400.0%
Par	49884008703	DEXAMETHASONE	\$ 1.920	\$ 0.040	4800.0%
	49884009201	DOXYCYCLINE MONOHYDRATE	\$ 4.990	\$ 0.210	2376.2%
Endo	60951065570	MORPHINE SULFATE	\$ 3.310	\$ 0.190	1742.1%
	60951079670	ENDOCET	\$ 1.450	\$ 0.250	580.0%
ETHEX	58177033304	PROPAFENONE HCL	\$ 2.970	\$ 0.020	14850.0%
	58177022204	ISOSORBIDE MONONITRATE	\$ 1.290	\$ 0.030	4300.0%
Ranbaxy	63304080512	FLUCONAZOLE	\$ 13.930	\$ 0.080	17412.5%
	63304091001	AMPHETAMINE SALT COMBO	\$ 1.370	\$ 0.020	6850.0%

*As of July, 2006*

<u>Mfgr.</u>	<u>NDC</u>	<u>Drug</u>	<u>List Price</u>	<u>Actual Price</u>	<u>AWP/AMP</u>
			<u>AWP</u>	<u>AMP *</u>	
Teva	00172541211	Fluconazole	\$ 13.932500	\$ 0.077308	18022.1%
Sandoz	00781192106	Fluconazole	\$ 14.010000	\$ 0.073307	19111.4%
Watson	00591236668	Cefazolin Sodium	\$ 41.660000	\$ 0.138902	29992.4%
Mylan	00378033001	Amitriptyline W/Perphenazine	\$ 0.262000	\$ 0.002522	10388.6%
	00378963943	Butorphanol Tartrate	\$ 30.100000	\$ 0.750716	4009.5%
Actavis	00228271711	Diclofenac Sodium	\$ 2.815000	\$ 0.238299	1181.3%
	00472173803	Miconazole 3	\$ 14.933330	\$ 0.091406	16337.4%
Barr	00555096802	Fluvoxamine Maleate	\$ 2.573500	\$ 0.140362	1833.5%
	50111096776	Carboplatin for injection	\$ 765.510000	\$ 1.548829	49425.1%
Par	49884094099	Fluconazole	\$ 14.010000	\$ 0.665540	2105.1%
Endo	60951065270	Morphine Sulfate	\$ 0.891700	\$ 0.078640	1133.9%
ETHEX	58177022211	Isosorbide Mononitrate	\$ 1.328500	\$ 0.029523	4499.9%
Ranbaxy	63304069316	Clindamycin Hcl	\$ 4.028120	\$ 0.020424	19722.5%

*Based on data obtained from the Utah Department of Health (\* AMP = Average Manufacturer Price)*