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 8  
 9 **IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA**  
 10 **IN AND FOR WASHOE COUNTY**  
 11

12 STATE OF NEVADA, )  
 )  
 13 Plaintiff, )  
 )  
 14 v. )  
 )  
 15 ABBOTT LABORATORIES, INC.; BAXTER )  
 PHARMACEUTICAL PRODUCTS, INC.; )  
 16 BAYER CORPORATION; BRISTOL-MYERS )  
 SQUIBB COMPANY; DEY, INC.; )  
 17 GLAXOSMITHKLINE CORPORATION; )  
 GLAXO WELLCOME, INC.; PHARMACIA )  
 18 CORPORATION; PHARMACIA & UPJOHN )  
 COMPANY; SMITH KLINE BEECHAM )  
 19 CORPORATION; TAP HOLDINGS, INC.; )  
 WARRICK PHARMACEUTICALS )  
 20 CORPORATION; and DOES 1 through 100, )  
 )  
 21 Defendants. )

CASE NO. \_\_\_\_\_  
 DEPT. NO. \_\_\_\_\_

22 **COMPLAINT FOR INJUNCTIVE RELIEF, DAMAGES, RESTITUTION**  
 23 **DISGORGEMENT, FORFEITURE, CIVIL PENALTIES AND OTHER**  
**RELIEF EXEMPT FROM ARBITRATION THIS COMPLAINT:**  
 24 **1. SEEKS INJUNCTIVE RELIEF; 2. PROBABLE JURY VALUE EXCEEDS \$40,000; AND**  
**3. PRESENTS SIGNIFICANT PUBLIC POLICY ISSUES.**

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1 I.

2 **INTRODUCTION**

3 1. The STATE OF NEVADA, through Attorney General Frankie Sue Del Papa, brings this  
4 action for monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement  
5 of profits and punitive damages on behalf of the State of Nevada, and restitution on behalf of persons in  
6 Nevada including thousands of Patients<sup>1</sup> who have paid inflated charges for medications based  
7 in whole or in part on defendants' use of the Average Wholesale Price ("AWP") Scheme, as described  
8 below.

9 2. Each of the defendants is or has been engaged in the business of manufacturing,  
10 marketing and selling prescription pharmaceuticals throughout the United States. The principal payors  
11 for such prescription pharmaceuticals are federal and/or state governments (under, respectively, the  
12 Medicare and Medicaid Programs), private insurers and self-insured employers (Third-Party Payors),  
13 and private individuals (Patients), including elderly patients who make payments for drugs under the  
14 Medicare program.

15 **A. THE DEFENDANTS' UNLAWFUL SCHEME**

16 3. The standard practice in the pharmaceutical industry is that the federal Medicare  
17 Program, state Medicaid agencies, Third-Party Payors and Patients reimburse physicians and  
18 pharmacies for hundreds of prescription drugs based upon the Average Wholesale Price ("AWP"), as  
19 published and reported by third-party publications such as *First Data Bank*, *Red Book*, *Blue Book*, or  
20 *Medispan*.

21 4. Physicians and pharmacies purchase the prescription drugs for which they are  
22 reimbursed directly from the pharmaceutical manufacturer or indirectly through wholesalers.

23 5. The AWP is generally not independently determined by the *First Data Bank* or other  
24 third-party reporting agencies. Rather, as part of the AWP Scheme described in this Complaint,  
25 pharmaceutical companies purportedly "self-police" and "self-report" the AWP to third-party  
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27 <sup>1</sup> As used herein, Patients refers to two groups of persons as follows: (1) Persons who were prescribed drugs  
28 manufactured by any defendants which were subject to defendants' Average Wholesale Price scheme as alleged herein and  
who paid for such drugs out-of-pocket, and (2) Persons who were prescribed such drugs and incurred an obligation for co-  
payment (or actually made co-payments) under either a government or private insurance program where the amount of co-  
payment was based on the total reimbursement by the government or private insurer.

1 publications (such as *First Data Bank*), which then publish the purported AWP, as provided to them by  
2 the pharmaceutical manufacturers.

3 6. Pursuant to federal regulation and industry and State practice, reimbursement for  
4 prescription drugs is based upon the reported AWP.

5 7. In fact, as an extensive and ongoing Congressional investigation has recently revealed,  
6 numerous pharmaceutical manufacturers (including each of the defendants named herein as well as  
7 others not yet named herein) have engaged in a scheme involving the fraudulent reporting of fictitious  
8 AWP for certain prescription pharmaceuticals including but not limited to prescription pharmaceuticals  
9 covered by Medicare and Medicaid.

10 8. Specifically, defendants' AWP Scheme involves the reporting by each defendant of  
11 inflated Average Wholesale Prices. The fraudulent reporting of Average Wholesale Prices has the  
12 effect of materially misrepresenting the actual prices paid to defendants by physicians and pharmacies  
13 for prescription drugs.

14 9. Plaintiff alleges upon information and belief that, in many instances, the purported AWP  
15 reported by the defendant pharmaceutical manufacturers bears little or no relationship to the prices  
16 actually paid by physicians or pharmacies.

17 10. In addition, while federal Medicaid law requires the defendants to provide quarterly  
18 rebates to the State of Nevada if it charges the State more than the lowest or "best price" offered to any  
19 commercial customer, the defendants routinely failed to do so as a direct result of the AWP Scheme.

20 11. As a result of the fraudulent and illegal manipulation of AWP for certain drugs by the  
21 defendant pharmaceutical manufacturers, they and the other manufacturers have reaped tens of millions  
22 of dollars in illegal profits at the expense of American governmental payors and consumers, including  
23 the State of Nevada, and Patients who are residents of the State of Nevada. In particular, the elderly  
24 who are on Medicare bear the burden of this scheme as they make payments or co-payments based on  
25 the fictitious AWP charges.

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1 **B. THE DAMAGES CAUSED BY DEFENDANTS' ILLEGAL CONDUCT.**

2 12. The intended and foreseeable consequences of the defendants' scheme are several and  
3 far reaching, including but not limited to increased drug costs to the State of Nevada and its agencies,  
4 and increased drug costs to Patients who are Nevada residents.

5 **1. DAMAGES TO THE STATE OF NEVADA.**

6 13. One of the foreseeable and intended consequences of defendants' conduct has been to  
7 unjustly enrich the defendants at the expense of Nevada's health care system, the state health care  
8 authority, and ultimately, all Nevada residents and taxpayers.

9 14. In particular, the AWP Scheme has cost the State of Nevada millions of dollars in excess  
10 Medicaid payments made for medications as a direct result of the illegal AWP Scheme.

11 15. In addition, the AWP Scheme has cost the State of Nevada millions of dollars in excess  
12 drug costs for the public employees for whom it provides health care.

13 16. Finally, numerous state agencies purchase medications at illegally inflated prices based  
14 on the AWP Scheme.

15 17. The State seeks to recover these costs as actual damages and/or restitution in this case.

16 **2. DAMAGES TO PATIENTS.**

17 18. As further intended and foreseeable effects of the defendants' AWP Scheme, many  
18 private persons residing in Nevada also suffered losses.

19 19. The general public, who must make co-payments for drugs based upon these inflated  
20 AWP prices, suffered immense damages. A major group of consumers adversely impacted by this  
21 practice are the elderly who make co-payments as part of Medicare.

22 20. Through its *parens patriae* and statutory powers, the State of Nevada also seeks  
23 restitution of these losses in this case.

24 **C. THE OBJECTIVES OF THIS ACTION.**

25 21. In this action, the Attorney General seeks to secure for the people of the State of Nevada  
26 a fair and open market, free from unfair or deceptive acts or practices, and to enable Patients in this  
27 State to better shoulder the financial burden of necessary medications.

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1 sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. This Court has  
2 personal jurisdiction over Bayer and venue is properly laid in this County.

3 27. Defendant Bristol-Myers Squibb Company (“Bristol”) is a highly diversified health care  
4 company whose principal business is the development, manufacture and sale of health care products  
5 and services, including pharmaceuticals. Bristol conducts extensive business in the State of Nevada,  
6 including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. This  
7 Court has personal jurisdiction over Bristol and venue is properly laid in this County.

8 28. Defendant Dey, Inc. (“Dey”) is a highly diversified health care company whose principal  
9 business is the development, manufacture and sale of health care products and services, including  
10 pharmaceuticals. Dey conducts extensive business in the State of Nevada, including the sale of the  
11 pharmaceuticals that are the subject of the AWP Scheme alleged herein. This Court has personal  
12 jurisdiction over Dey and venue is properly laid in this County.

13 29. Defendant GlaxoSmithKline Corporation (“GSK”) is a highly diversified health care  
14 company whose principal business is the development, manufacture and sale of health care products  
15 and services, including pharmaceuticals. GSK conducts extensive business in the State of Nevada,  
16 including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. This  
17 Court has personal jurisdiction over GSK and venue is properly laid in this County.

18 30. Defendant Glaxo Wellcome, Inc. (“Glaxo”) is a highly diversified health care company  
19 whose principal business is the development, manufacture and sale of health care products and services,  
20 including pharmaceuticals. Glaxo conducts extensive business in the State of Nevada, including the  
21 sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. This Court has  
22 personal jurisdiction over Glaxo and venue is properly laid in this County.

23 31. Defendant Pharmacia Corporation (“Pharmacia”) is a highly diversified health care  
24 company whose principal business is the development, manufacture and sale of health care products  
25 and services, including pharmaceuticals. Pharmacia conducts extensive business in the State of  
26 Nevada, including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged  
27 herein. This Court has personal jurisdiction over Pharmacia and venue is properly laid in this County.

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1           32. Defendant Pharmacia & Upjohn Company (“Pharmacia Upjohn”) is a highly diversified  
2 health care company whose principal business is the development, manufacture and sale of health care  
3 products and services, including pharmaceuticals. Pharmacia Upjohn conducts extensive business in  
4 the State of Nevada, including the sale of the pharmaceuticals that are the subject of the AWP Scheme  
5 alleged herein. This Court has personal jurisdiction over Pharmacia Upjohn and venue is properly laid  
6 in this County.

7           33. Defendant SmithKline Beecham Corporation (“SmithKline”) is a highly diversified  
8 health care company whose principal business is the development, manufacture and sale of health care  
9 products and services, including pharmaceuticals. SmithKline conducts extensive business in the State  
10 of Nevada, including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged  
11 herein. This Court has personal jurisdiction over SmithKline and venue is properly laid in this County.

12           34. Defendant TAP Holdings, Inc. (“TAP”), originally established as TAP Pharmaceuticals,  
13 Inc., is a joint venture of Abbott Laboratories located in Abbott Park, Illinois, and Takeda Chemical  
14 Industries, Ltd. of Osaka, Japan. TAP headquarters is located at 2355 Waukegan Road, Deerfield,  
15 Illinois.

16           35. Defendant Warrick Pharmaceuticals Corporation (“Warrick”) is a corporation organized  
17 under the laws of Delaware with its principal place of business in Reno, Nevada. At all times material  
18 to this action, Warrick has transacted business in the State of Nevada including but not limited to,  
19 selling and distributing to purchasers in the State of Nevada pharmaceutical products that are the  
20 subject of this action. This Court has personal jurisdiction over Warrick and venue is proper in this  
21 County.

22           36. The true names and capacities, whether individual, corporate, associate, or otherwise, of  
23 defendants named herein as Does 1 – 100 are unknown to plaintiff, who therefore sues such defendants  
24 by such fictitious names. Each of the defendants designated herein as a Doe Defendant is legally  
25 responsible in some manner for the unlawful acts referred to herein. Plaintiff will seek leave of Court  
26 to amend this Complaint to reflect the true names and capacities of the defendants designated herein as  
27 Does when such identities become known. Collectively, these companies are referred to as the  
28 “pharmaceutical defendants” or defendants.



1 (b) Methodology. Payment for a drug or biological described in  
2 paragraph (a) of this section is based on the lower of the actual charge on  
the Medicare benefits *or 95 percent of the national average wholesale  
price of the drug or biological.*

3 (c) Multiple-source drugs. For multiple-source drugs and biologicals, for  
4 purposes of this regulation, the average wholesale price is defined as the  
5 lesser of the median average wholesale price for all sources of the generic  
forms of the drug or biological or the lowest average wholesale price of  
the brand name forms of the drug or biological. (Emphasis added.)

6 43. Medicare and many Medicaid programs and other Third-Party Payors base  
7 reimbursement to physicians and other providers of drugs on AWP. AWP is published for each drug  
8 identified by a National Drug Code (“NDC”).<sup>2</sup> Manufacturers periodically report AWP for NDCs to  
9 publishers of drug pricing data, such as Medical Economics Company, Inc., which publishes the *Red  
10 Book*, or First Data Bank, which compiles the National Drug Data File. Publishers of AWP and other  
11 drug prices state that they list the prices reported to them by the manufacturers. There is no required  
12 frequency for manufacturers to report AWP, but publishers claim that they attempt to update AWP at  
13 least annually. Medicare carriers, the contractors responsible for paying Part B claims, use published  
14 AWP to determine the Medicare-allowed amount, or payment level, which is 95 percent of AWP for  
15 each HCPCS-coded drug.<sup>3</sup>

16 44. Physicians are able to obtain drugs at prices significantly below current Medicare  
17 reimbursements. The widely available prices that are available from wholesalers and group purchasing  
18 organizations (“GPOs”) for physician-administered drugs are considerably less than AWP used to  
19 establish the Medicare payment. For most of the high-expenditure or high-volume physician-  
20 administered drugs, widely available discounts from AWP ranged from 13 percent to 34 percent.  
21 Physicians who have been identified as low-volume billers for oncology drugs can also purchase drugs  
22 for considerably less than Medicare’s payment. In addition to receiving reimbursement for drugs,  
23 physicians are paid separately for services associated with drug administration under the Medicare  
24 physician fee schedule.

25 \_\_\_\_\_  
26 <sup>2</sup> NDCs are the universal product identifiers for drugs for human use; the Food and Drug Administration assigns the first  
27 part of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug. Each NDC is specific to a  
chemical entity, dosage form, manufacturer, strength, and package size. For example, a drug made by one manufacturer, in  
one form and strength, but in three package sizes, would have three NDCs.

28 <sup>3</sup> HCPCS is the Health Care Financing Administration Common Procedure Coding System, as maintained and  
distributed by the Department of Health and Human Services.

1           45.     Prior to January 1, 1998, the Medicare Part B “allowed amount” was interpreted as being  
2 the lower of the “estimated acquisition cost” *or* 95% of the “national average wholesale price,” *i.e.*, the  
3 AWP for the drug. The estimated acquisition cost for a drug could be determined by the Medicare  
4 Program “based on surveys of the actual invoice prices paid for the drug,” taking into consideration the  
5 estimated acquisition cost, including “factors such as inventory, waste and spoilage.” However,  
6 historically the AWP published in the *First Data Bank* and similar publications has been used to  
7 determine Medicare reimbursement.

8           46.     In determining the AWP, HCFA uses the AWP published in industry publications such  
9 as *First Data Bank*, *Blue Book*, or *Medispan* as the basis for reimbursement. Specifically, in PM AB-  
10 99-63 (as of January 1, 1998), HCFA stated that it will pay drug and biologicals based on the lower of  
11 the actual billed charge or 95 percent of the AWP reflected in pharmaceutical industry publication  
12 sources such as *Red Book*, *Blue Book*, or *Medispan*.

13           47.     In fact, and by common understanding, usage and practice in the industry, Medicare,  
14 Medicaid and other providers have continued to determine the allowable payment for a prescription  
15 drug based upon the AWP reported by the applicable pharmaceutical manufacturer. This is due, in  
16 large measure, to practical problems with ascertaining “actual” or “estimated acquisition cost” charges,  
17 given necessary adjustments for the enumerated factors such as spoilage, waste, and inventory.

18           48.     Medicare Part B reimburses medical providers for 80% of the allowable amount. The  
19 remaining 20% is paid by the Medicare beneficiary and is called the “co-payment” amount. In  
20 addition, beneficiaries under Medicare Part B are required to pay an annual deductible amount before  
21 Part B benefits are payable.

22           49.     Throughout the 1990s, the *Red Book* and other publications such as *Blue Book* and  
23 *Medispan* published AWPs for pharmaceuticals. The *Red Book* and other publications simply publish  
24 the prices that are supplied to them by the pharmaceutical manufacturers, including defendants,  
25 generally without independent verification. Defendants knew that they could directly control and  
26 fraudulently inflate the AWP for pharmaceuticals at any time by simply forwarding a higher, fictitious  
27 AWP to the *Red Book* or other publication.

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1           50.     The actual price that providers pay for Medicare Part B drugs is not disclosed to the  
2 State and certainly not to patients. Physicians and suppliers may belong to “GPOs” that pool the  
3 purchase of multiple entities to negotiate prices with wholesalers or manufacturers. GPOs may  
4 negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In  
5 addition, providers can purchase Part B-covered drugs from general or specialty pharmaceutical  
6 wholesalers or they can have direct purchase agreements with manufacturers.

7           51.     Certain practices involving these various entities has resulted in prices paid at the time of  
8 sale that do not reflect the final net cost to the purchaser. Manufacturers or wholesalers offer  
9 purchasers rebates based on the volume of products purchased not in a single sale but over a period of  
10 time. Manufacturers also establish “chargeback” arrangements for end purchasers, which result in the  
11 AWP overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a  
12 price with the manufacturer that is lower than the price the wholesaler charges for the product. The  
13 wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer  
14 then pays the wholesaler the difference between the wholesale price and the negotiated price.

15           52.     Most manufacturers sell drug products to physicians at a discount from AWP.  
16 Sometimes these discounts are substantial. As noted herein, under Medicare rules physicians are  
17 permitted to bill for such drugs at 95 percent of AWP, regardless of the drug’s cost to the physician.  
18 This practice of taking advantage of the difference between the physician’s purchase price and the  
19 amount that a physician is permitted to bill Medicare is referred to internally by defendants as  
20 “marketing the spread.”

21           53.     There is a wide disparity between a drug’s estimated acquisition cost and Medicare’s  
22 payment for that drug. Physician-billed drugs account for the bulk of Medicare spending on Part B  
23 drugs. Of those billed by physicians, drugs used to treat cancer accounted for most of Medicare’s  
24 expenditures.

25           54.     In a September 21, 2000, report, the United States Government Accounting Office  
26 (“GAO”) found that:

27                   Widely available discounts for 17 of the physician-billed drugs we  
28                   examined averaged between 13 percent and 34 percent less than AWP.

For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger – 65 percent and 86 percent less than AWP.

55. Two drugs, albuterol and ipratropium bromide for respiratory conditions, account for most of the pharmacy-supplied drugs paid for by Medicare. In 2001, they were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP.

56. Two of the four high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent. Wholesale price information on the other two was not available, but retail prices from online pharmacies were as much as 13 percent and 8 percent below AWP.

57. According to the GAO report, the discounts on physician-billed drugs, based on wholesaler and the GPOs' catalogue prices, are notably lower than Medicare's payment, which reflects a discount of five (5) percent below AWP. The discounts indicate that, on a national level, Medicare's payments for these drugs were *at least \$532 million higher* than providers' acquisition costs in just the year 2000. Further, the discounts reported may only be the starting point for additional discounts provided to certain purchasers, as chargebacks, rebates, and other discounts may drive down the final sale price.

58. The following table illustrates some of the discounts provided to physicians<sup>4</sup>:

**Table 1: Widely Available Discounts From AWP for Medicare-Covered Drugs Billed Primarily by Physicians, 2001**

<b>Drug name</b>	<b>Specialty most frequently billed for drug</b>	<b>Average AWP<sup>a</sup></b>	<b>Average widely available discount from AWP (percentage)<sup>b</sup></b>
Leuprolide acetate (for depot suspension)	urology	\$618.93	17.6
Rituximab	oncology <sup>c</sup>	\$478.47	19.2
Goserelin acetate implant	urology	\$469.99	21.9
Docetaxel	oncology	\$313.51	22.0
Filgrastim (G-CSF) 480 mcg	oncology	\$300.40	18.0 <sup>d</sup>
Pamidronate disodium	oncology	\$279.86	16.8
Hylan G-F 20	orthopedic surgery	\$225.13	17.7 <sup>d</sup>
Filgrastim (G-CSF) 300 mcg	oncology	\$193.62	18.4 <sup>d</sup>
Paclitaxel	oncology	\$180.57	19.0
Irinotecan	oncology	\$141.32	22.9

<sup>4</sup> Source: September 2001 GAO Report-01-1118.

1	Carboplatin	oncology	\$120.48	20.3
	Gemcitabine HCl	oncology	\$112.34	21.3
2	Dolasetron mesylate, injection	oncology	\$45.02	65.0 <sup>d</sup>
	Granisetron HCl, injection	oncology	\$19.52	29.3
3	Leucovorin calcium	oncology	\$18.44	85.6
	Epoetin alpha for non-ESRD use	oncology	\$12.91	15.2
4	Ondansetron HCl, injection	oncology	\$6.41	12.8
	Botulinum toxin type A	neurology	\$4.86	N/a <sup>e</sup>
5	Imiglucerase	oncology	\$3.95	N/a <sup>e</sup>
	Dexamethasone sodium phosphate	oncology	\$1.44	14.2
6	Heparin sodium	oncology	\$0.43	34.4

7 <sup>a</sup>“Average AWP” is the average of AWP of each NDC for that product adjusted to the HCPCS-defined dosage.

8 <sup>b</sup>“Average widely available discount from AWP” for each drug was calculated by  
9 (1) determining the average widely available price(s) for each NDC for that drug,  
10 (2) determining the percentage difference between the average widely available price(s) and the  
11 AWP for each NDC for the drug, and (3) averaging the percentage differences for all NDCs for  
12 that drug.

13 <sup>c</sup>“Oncology” specialty includes hematology/oncology and medical oncology.

14 59. The “spread” is so significant that in some instances a patient’s 20% co-payment is more  
15 than the cost of the drug to the doctor or provider, as evidenced in the table below<sup>5</sup>:

16	<b>Drug</b>	<b>HCPCS Code</b>	<b>1999 Florida Medicare Allowable</b>	<b>20% Co-Payment</b>	<b>1999 Wholesale Cost</b>
17	Leucovorin 50mg	J0640	\$19.50	\$3.90	\$1.48
18	Gentamycin 80mg	J1580	\$4.74	\$0.95	\$0.56
19	Sodium Chloride 0.9% 500ml	J7040	\$10.30	\$2.06	\$1.46
20	5% Dextrose/Sodium Chloride 0.9% 500ml	J7042	\$10.75	\$2.15	\$2.00
21	Sodium Chloride 0.9% 250ml	J7050	\$10.90	\$2.18	\$1.33
22	5% Dextrose in Water 500ml	J7060	\$9.73	\$1.95	\$1.50
23	Lacted Ringers 1000ml	J7120	\$12.67	\$2.53	\$2.25
24	Doxorubicin 10mg	J9000	\$46.42	\$9.28	\$6.10
25	Cyclophosphamide Lyophilized	J9096	\$48.85	\$9.77	\$9.95
26	Etoposide 10mg	J9181	\$12.93	\$2.59	\$0.75
27	Etoposide 100mg	J9182	\$129.34	\$25.87	\$7.50
28	Vincristine 1mg	J9370	\$30.16	\$6.03	\$3.50
	Vincristine 2mg	J9375	\$33.33	\$6.67	\$5.95

<sup>5</sup> Source: Stark Investigative Materials.

1           60.     Examples of the manipulation of AWP are contained in the investigative materials  
2 compiled by Congressman Pete Stark (D-Calif.):

3           (a)     In the 2000 edition of the *Red Book*, defendant Bristol reported an AWP of  
4 \$1,296.64 for one 20mg/ml, 50ml vial of Vepesid (Etoposide) for injection, while selling the exact  
5 same drug to a GPO for \$70. This represents a spread between Bristol’s falsely inflated AWP and the  
6 real price of \$1,226.64.

7           (b)     As the following excerpts from Bristol’s own documents reveal, Bristol’s earlier  
8 participation in the false price manipulation scheme with respect to Etoposide (Vepesid) interfered with  
9 physicians’ medical decisions to use Etopophos: “The Etopophos product profile is significantly  
10 superior to that of etoposide injection....” “Currently, physician practice can take advantage of the  
11 growing disparity between VePesid’s [name brand for Etoposide] list price (and, subsequently, the  
12 Average Wholesale Price [AWP] and the actual acquisition cost when obtaining reimbursement for  
13 etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician’s  
14 financial incentive for selecting the brand is largely diminished.”

15           (c)     Thus, defendant Bristol acknowledges that financial inducements influence the  
16 professional judgment of physicians and other healthcare providers. Bristol’s strategy of increasing the  
17 sales of its drugs by enriching, with taxpayer dollars, the physicians and others who administer drugs is  
18 reprehensible and a blatant abuse of the privileges that Bristol enjoys as a major pharmaceutical  
19 manufacturer in the United States.

20           (d)     Bristol employed a number of other financial inducements to stimulate the sales  
21 of its drugs at the expense of the Medicare and Medicaid Programs that were concealed from the U.S.  
22 Government and the State of Nevada. Such inducements included volume discounts, rebates, off-  
23 invoice pricing and free goods designed to lower the net cost to the purchaser while concealing the  
24 actual cost of the drug from reimbursement officials. For example, Bristol provided free Etopophos to  
25 Drs. Lessner and Troner in exchange for these Miami, Florida oncologists’ agreement to purchase other  
26 Bristol cancer drugs. This arrangement had the effect of lowering the net cost of the cancer drugs to the  
27 oncologists and creating an even greater spread than would already result from the invoiced prices. The  
28 value of the free goods is often significant. Similarly, other documents show that Bristol provided free

1 Cytogards in order to create a lower than invoice cost to physicians that purchased other cancer drugs  
2 through the Oncology Therapeutic Network.

3 (e) The above-referenced free goods examples created financial incentives to the  
4 physicians that were over and above the spread created by the difference between Bristol's reported  
5 prices and regular prices provided to the market.

6 (f) Bristol's price manipulation scheme was directed at both the Medicare and  
7 Medicaid Programs. Bristol commonly reported prices directly to Medicare carriers as well as state  
8 Medicaid Programs.

9 (g) Defendant Glaxo was no different, as evidenced in a letter from SmithKline. In  
10 an apparent effort to increase reimbursement to physicians and clinics, effective January 10, 1995,  
11 defendant Glaxo increased the AWP for Zofran by 8.5% while simultaneously fully discounting this  
12 increase to physicians. The net effect of these adjustments was to increase the amount of  
13 reimbursements available to physicians from Medicare and other Third-Party Payors whose  
14 reimbursement is based on the AWP. Because the net price paid to Glaxo for the non-hospital sales of  
15 the Zofran multi-dose vial is actually lower, it does not appear that the increase in the AWP was  
16 designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment  
17 appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive  
18 increased reimbursement from Medicare and other Third-Party Payors.

19 (h) Defendant Pharmacia also engaged in use of inflated AWP; for example, it wrote  
20 to an oncology clinic boasting of the savings offered off AWP:

21 Some of the drugs on the multi-source list offer you savings of over 75%  
22 below list price of the drug. For a drug like Adriamycin, the reduced  
23 pricing offers [the clinic] a reimbursement of over \$8,000,000 profit  
when reimbursed at AWP.

24 (i) Defendant Bayer acknowledged the AWP Scheme in an internal e-mail message,  
25 stating that "many" health care providers are "paid on a discount from AW[P]."

26 (j) In a document entitled "Confidential Baxter Internal Use Only," defendant  
27 Baxter admitted to the impact of the AWP Scheme:

28 //

1 Increasing AWP's was a large part of our negotiations with the large  
2 homecare companies.

3 Homecare companies that reimburse based on AWP make a significantly  
4 larger margin . . . .

5 (k) TAP offered free samples to doctors to effectuate the AWP Scheme. According  
6 to an indictment issued by the U.S. Attorney in Boston, Dr. SF was a urologist with a principal place of  
7 business in the San Francisco area in California. Dr. SF from time to time in the 1990s diagnosed and  
8 treated patients suffering from prostate cancer, many of whom were insured by the Medicare Program.  
9 As a part of the treatment of some of those patients, and beginning as early as 1993, Dr. SF prescribed  
10 Lupron. Dr. SF informed the sales representatives calling upon Dr. SF, who so informed TAP  
11 employees, that he would switch his business and prescribe Zoladex to his patients suffering from  
12 prostate cancer if TAP and its employees did not provide him financial incentives that were being  
13 provided to him by another company. In order to prevent Dr. SF from switching his patients to  
14 Zoladex, and as an inducement to him to continue to purchase Lupron and to prescribe that drug to his  
15 patients, many of whom were insured by the Medicare Program, TAP authorized its sales  
16 representatives calling upon Dr. SF to give to him free samples of Lupron. At times, TAP approved  
17 giving Dr. SF ten free samples in exchange for each order by him of more than 100 one-month  
18 injections of Lupron, and at times, TAP's corporate headquarters authorized those free samples for  
19 Dr. SF. Beginning in or about July 1994 and continuing through in or about December 1997, TAP sales  
20 representatives gave to Dr. SF more than 85 one-month doses of Lupron for free, on or about the dates  
21 indicated in the following chart:

Date	Quantity
7/1/94	10
1/27/95	10
7/22/95	10
11/20/95	10
8/9/96	10
4/16/97	15

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These 85 samples, more or less, were given by sales representatives as an inducement to get and keep his business. That doctor thereafter prescribed and administered these free dosages to patients insured by the Medicare Program and other insurance companies and submitted claims to those insurers and the patients for the prescription of these free dosages to turn those samples into a cash kickback and rebate. These free samples were not used by TAP in calculating AWP.

**(I) OTHER EXAMPLES INCLUDE THE FOLLOWING:**

Adriamycin, an antibiotic used in cancer treatment and manufactured by Pharmacia, had an AWP of \$241.36 as of April 2000. The real wholesale price was \$33.43. In 1997, when the reported AWP for this drug was \$946.94, it was being offered to physicians for as low as \$152.00.

Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of \$54.56. The actual best price was \$6.75.

Toposar, also manufactured by Pharmacia, is used to treat testicular and lung cancer. Its AWP as of April 2000 was \$28.38; DOJ found that retailers were buying it for \$1.70.

Vancomycin, an antibiotic used to treat intestinal infections and manufactured by Abbott, had an AWP of \$68.77 as of April 2000. DOJ adjusted it to \$8.14.

61. Upon information and belief, each of the defendant pharmaceutical companies has also utilized a large array of other inducements to stimulate sales of their drugs. These inducements, including “educational grants,” volume discounts, and rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug item might really only cost the purchaser one-half that amount. If we assume a subsequent shipment of an additional ten units at no charge, or a “grant,” “rebate” or “credit memo” in the amount of \$50, the transaction would truly cost just \$5.00 per unit net. Through all these “off-invoice” means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWPs and inflated reimbursement from Medicaid and Medicare. Some examples of this are set forth below:

1 BAYER: "I have been told that our present Kogennate price, \$.66, is the  
2 highest price that Quantum is paying for recombinant factor VIII. In  
3 order to sell the additional 12mm/u we will need a lower price. I suggest  
4 a price of \$.60 to \$.62 to secure this volume. From Quantum's stand  
5 point, a price off invoice, is the most desirable. We could calculate our  
6 offer in the form of a marketing grant, a special educational grant,  
7 payment for specific data gathering regarding Hemophilia treatment, or  
8 anything else that will produce the same dollar benefit to Quantum Health  
9 Resources."

6 BAXTER: "The attached notice from Quantum Headquarters was sent  
7 on April 10<sup>th</sup> to all their centers regarding the reduction on Recombinate  
8 pricing. Please note that they want to continue to be invoiced at the 4.81  
9 price. They have requested that we send them free product every quarter  
10 calculated by looking at the number of units purchased in that quarter and  
11 the \$.13 reduction in price.....free product given to achieve overall price  
12 reduction"<sup>6</sup>

10 62. In 2000, state and federal investigators challenged the reported AWP of various drugs.  
11 Thereafter Abbott lowered its reported AWP on various drugs, thereby admitting that prior reported  
12 AWPs were artificially inflated.

13 63. Among those directly harmed by the defendants' manipulation of the AWP in the  
14 Medicare context are Nevada residents who, as Patients, have been compelled to pay excessive  
15 co-payments for medications based upon the falsely inflated AWPs.

16 **IV.**

17 **THE AWP SCHEME ALSO INFLICTS DAMAGES ON THE STATE OF NEVADA**

18 64. The damages inflicted by the AWP Scheme are not confined to Medicare payors.

19 65. In addition, numerous State agencies have overpaid for medications based upon the  
20 fraudulently reported AWPs.

21 66. Likewise, most Medicaid payors including the State of Nevada historically have also  
22 typically based reimbursement on the AWP.

23 67. On August 10, 2001, the U.S. Department of Health and Human Services, Office of the  
24 Inspector General ("OIG"), reported the results of a survey of 216 pharmacies in eight states and  
25 obtained 16,024 invoices for brand name drug products. The OIG report concluded that nationally,  
26 pharmacy cost was 21.84 percent below AWP, a 19.3 percent increase from 1994. This report further  
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<sup>6</sup> Source: Attachments to U.S. House Committee on Ways and Means correspondence dated September 28, 2000.

1 concluded that although many states paid a discount of 10 percent off AWP, this was not sufficient to  
2 “ensure that a reasonable price is paid for drugs.”

3 68. Recently, defendant Bayer agreed to settle claims asserted by the U.S. Government  
4 arising from this practice. According to the Department of Justice’s litigation release:

5 The government’s investigation of the allegations revealed that Bayer  
6 beginning in the early 1990s falsely inflated the reported drug prices –  
7 referred to by the industry as the Average Wholesale Price (AWP), the  
8 Direct Price and the Wholesale Acquisition Cost – used by state and  
9 federal governments to set reimbursement rates for the federally and state  
10 funded Medicaid Program. By setting an extremely high AWP and,  
11 subsequently, selling the product to doctors at a dramatic discount, Bayer  
12 enabled physicians to receive excess reimbursement from private and  
13 government insurers. The Bayer AWP, at issue in the investigation,  
14 involved several of Bayer’s biologic products such as Kogenate, Koate-  
15 HP, and Gamimmune, which are widely used in treating hemophilia and  
16 immune deficiency diseases.

17 The investigation further revealed that Bayer was engaging in a practice  
18 referred to as “marketing the spread” that also has the effect of  
19 discouraging market competition from companies that do not inflate  
20 AWP as a way of attracting doctors to their products. The department’s  
21 probe also showed that some physicians and home health companies  
22 ignore the products of companies that refuse to create these profit  
23 windfalls for customers.

24 The parties also are settling allegations that Bayer knowingly underpaid  
25 the Medicaid Program for rebates owed by it to the states. The Medicaid  
26 Rebate program was initiated in 1991 to require drug companies to pay  
27 quarterly rebates to states in a way that accounts for discounts that drug  
28 companies give to customers. Under the program, Bayer was required to  
report the best price offered to any commercial, for-profit customer to the  
government and calculate a quarterly rebate based, in part, upon the best  
price. The investigation revealed that certain of Bayer’s customers  
received discounts unaccounted for by the multi-national pharmaceutical  
company in its quarterly best price calculations thereby allowing Bayer to  
underpay the rebates it owed.

69. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products  
compensated under a state’s Medicaid Program, the manufacturer had to enter into a rebate agreement  
with the Secretary of Health and Human Services. Pursuant to the rebate agreement, the manufacturer  
promised to report to the Medicaid Program its best price. The statute defines the best price as “the  
lowest price available from the manufacturer during the rebate period to any wholesaler, retailer,  
provider, health maintenance organization, nonprofit entity or governmental entity.” The section also

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1 provides that “best price” includes “cash discounts, free goods that are contingent on any purchase  
2 requirement, volume discounts and rebates” and does not include “prices that are merely nominal in  
3 amount.”

4 70. Each defendant entered into a Rebate Agreement with the U.S. Secretary of Health and  
5 Human Services. In that agreement, each agreed to comply with Section 1396r-8, and hence:

6 (a) Agreed to report its best price, inclusive of cash discounts, free goods contingent  
7 upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates  
8 where necessary;

9 (b) Agreed that it would determine its best price based upon its average  
10 manufacturer’s price, calculated as “net Sales divided by numbers of units sold, excluding free goods  
11 (*i.e.*, drugs or any other items given away, but not contingent on any purchase requirements)” and that it  
12 would include in that calculation cash discounts and all other price reductions “which reduce the actual  
13 price paid”; and

14 (c) Agreed that the best price would not take into account nominal prices, defined as  
15 prices that are less than 10 percent of the average manufacturer’s price in that quarter, so long as the  
16 sale of product at a nominal price was not contingent on any other sale.

17 71. After execution of this agreement, each defendant reported its average manufacturer’s  
18 price in each quarter to the Medicaid Program.

19 72. In keeping with their artificial inflation of the AWP, each defendant did not report the  
20 actual “best price” but, instead, excluded from best price discounts and other inducements offered to  
21 physicians to increase use of a drug being reimbursed by governmental entities at AWP.

22 **V.**

23 **MOTIVATION FOR DEFENDANTS’ AWP PRICING SCHEME**

24 73. The purpose and intent of defendants’ fraudulent AWP Scheme is to manipulate and  
25 thereby increase the amount of reimbursement received by physicians or other health care providers  
26 who prescribe drugs manufactured and sold by defendants.

27 74. Specifically, defendants’ AWP Scheme contemplates that (a) defendants will  
28 intentionally report falsely and fraudulently inflated AWP prices for these drugs to industry

1 publications; and (b) defendants will actually charge health care providers amounts for these drugs that  
2 are substantially less than the AWP that defendants have fraudulently reported.

3 75. The health care provider then receives reimbursement from Medicare, Medicaid, or a  
4 Third-Party Payor based upon the fraudulently inflated AWP. This circumstance results in a substantial  
5 financial incentive to the provider, representing the difference between the inflated AWP-based  
6 reimbursement to the provider and the significantly lower direct price charged by defendants to the  
7 health care provider.

8 76. Defendant pharmaceutical manufacturers refer to the amount received by the health care  
9 provider resulting from the difference between the fraudulently inflated AWP reimbursement and the  
10 price actually paid by the provider as the “spread.”

11 77. Each of the defendants has sought to manipulate the market for drugs covered by Part B  
12 by inducing health care providers to prescribe these drugs, rather than competing drugs, because of the  
13 higher “spread” resulting from the falsely and fraudulently inflated AWP.

14 78. By participating in the AWP Scheme, defendants seek to influence doctors to prescribe  
15 the drug with the greatest “spread” between the AWP and the actual direct price paid by the provider to  
16 the manufacturer. In fact, defendants have greatly increased their market share and resulting profits by  
17 manipulating the AWP to create falsely inflated “spreads” and resulting financial incentives to  
18 providers to prescribe specific drugs subject to the AWP Scheme.

19 79. The manipulation of AWP at the expense of Medicare, Medicaid and their respective  
20 patients is further revealed when the defendants sell drugs that are not reimbursed by Medicare or  
21 Medicaid. In these circumstances, the drug companies often report accurate AWP and actually  
22 compete with other drug companies on the basis of having a lower AWP than the other company. The  
23 company with the lower AWP will urge physicians to consider the cost to the patient when selecting  
24 drugs and promote its lower AWP as a selling tool. Thus, where Medicare and Medicaid are not  
25 involved, defendants often ensure that their AWP are accurate so as to compete for market share based  
26 on price.

27 80. Defendants were aware that physicians would purchase and utilize products that have the  
28 widest spread between the providers’ true costs and the reimbursement paid by third parties. All

1 defendants made representations of their AWP for various drugs, which representations were not  
2 accurate. In doing so, defendants hoped that providers would view the inflated AWP as a reason for  
3 selecting their drug. Defendants also knew that this selection would be at the expense of patients who  
4 were making a co-payment and at the expense of governmental payors.

5 81. For example, a GAO report focusing on sales of a drug in Florida found that Medicaid  
6 usage of Vancomycin nearly doubled when Abbott raised the AWP. When Bayer retained its spread on  
7 Whin Rho while other manufacturers did not, its use “skyrocketed.”

8 82. The AWP Scheme has a profound and dangerous additional effect by influencing some  
9 medical practitioners’ judgments. This is acknowledged, for example, by defendant Bristol who  
10 developed a second-generation etoposide, namely, Etopophos:

11 Bristol: “The Etopophos produce profile is significantly superior to that of  
12 etoposide for injection...”

13 “Currently, physician practices can take advantage of the growing  
14 disparity between VePesid’s lists price (and, subsequently, the Average  
15 Wholesale Price [AWP]) and the actual acquisition cost when obtaining  
16 reimbursement for etoposide purchase. If the acquisition price of  
17 Etopophos is close to the list price, the physicians’ financial incentive for  
18 selecting the brand is largely diminished.”<sup>7</sup>

19 83. This influence is further demonstrated by SmithKline Beecham and TAP:

20 SMITHKLINE: “In the clinic setting however, since Medicare  
21 reimbursement is based on AWP, product selection is largely based upon  
22 the spread between acquisition cost and AWP ..... Therefore, the spread  
23 between the AWP and clinic cost represents a profit to the clinic of  
24 \$50.27 for the medication alone.... From this analysis, there seems to be  
25 no other reason, other than profitability, to explain uptake differentials  
26 between the hospital and clinic settings, therefore explaining why  
27 physicians are willing to use more expensive drug regiments.”

28 TAP: “As we have also discussed, Northwest Iowa Urology is very  
upset about the allowable not going up. I personally met with the doctors  
to discuss the issue 4/17. The physicians have started using Zoladex but  
would stop if the allowable issue was taken care of. NWI Urology has  
180 patients on Lupron.”<sup>8</sup>

84. Thus, although they are competitors, each of the defendants agreed to a scheme whereby  
each would publish in the *Red Book*, *Blue Book* and *Medispan* its artificially inflated “AWP.” Each

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<sup>7</sup> Source: Correspondence from Committee on Ways and Means dated September 28, 2000, to Alan Holmes.

<sup>8</sup> Source: *Id.*

1 defendant knew that the AWP's were fictitious, but each one followed course and published its own  
2 fictitious AWP pursuant to its express or tacit agreement to do so.

3 **VI.**

4 **THE CONGRESSIONAL INVESTIGATION**

5 85. The United States Congress has been investigating defendants' wrongful activities. In a  
6 letter sent to each of the defendants dated October 31, 2000, Congressman Stark stated in pertinent part:

7 You should by now be aware of Congressional investigations revealing  
8 that Abbott has for many years reported and published inflated and  
9 misleading data and has engaged in other deceptive business practices.  
10 This letter is a call for your company to immediately cease overcharging  
11 taxpayers and jeopardizing public health . . . The price manipulation  
12 scheme is executed through Abbott's inflated representations of average  
13 wholesale price (AWP) and direct price ("DP") which are utilized by the  
14 Medicare and Medicaid Programs in establishing drug reimbursements to  
15 providers. The difference between the inflated representations of AWP  
16 and DP versus the true price providers are paying, is regularly referred to  
17 in your industry as "the spread." The evidence amassed by Congress  
18 clearly shows that Abbott has intentionally reported inflated prices and  
19 has engaged in other improper business practices in order to cause its  
20 customers to receive windfall profits from Medicare and Medicaid when  
21 submitting claims for certain drugs. The evidence further reveals that  
22 Abbott manipulated prices for the express purpose of expanding sales and  
23 increasing market share of certain drugs. This was achieved by arranging  
24 financial benefits or inducements that influenced the decisions of health  
25 care providers submitting Medicare and Medicaid claims . . . Based on  
26 the evidence collected, Abbott should make arrangements to compensate  
27 taxpayers for the financial injury caused to federally funded programs.  
28 Any refusal to accept responsibility will most certainly be indicative of  
the need for Congress to control drug prices. If we cannot rely upon drug  
companies to make honest and truthful representations about their prices,  
then Congress will be left with no alternative but to take decisive action  
to protect the public.

21 86. In a letter dated September 28, 2000, sent from the House of Representatives Committee  
22 on Ways and Means, Subcommittee on Health to the President of the trade organization known as the  
23 Pharmaceutical Research and Manufacturers of America, Congressman Stark stated:

24 This corruptive scheme is perverting financial integrity of the Medicare  
25 program and harming beneficiaries who are required to pay 20% of  
Medicare's current limited drug benefit.

26 87. In his letter, Congressman Stark made the following five "shocking conclusions":

27 First – Certain drug manufacturers have abused their position of privilege  
28 in the United States by reporting falsely inflated drug prices in order to  
create a de facto improper kickback for their customers.

1 Second – Certain drug manufacturers have routinely acted with impunity  
2 in arranging improper financial inducements for their physicians and  
other healthcare provider customers.

3 Third – Certain drug manufacturers engage in the fraudulent price  
4 manipulation for the express purpose of causing federally funded health  
5 care programs to expend scarce tax dollars in order to arrange de facto  
kickbacks for the drug manufacturers’ customers at a cost of billions of  
dollars.

6 Fourth – Certain drug manufacturers arrange kickbacks to improperly  
7 influence physicians’ medical decisions and judgments notwithstanding  
the severely destructive effect upon the physician/patient relationship and  
8 the exercise of independent medical judgment.

9 Fifth – Certain drug manufacturers engage in illegal price manipulation in  
10 order to increase utilization of their drugs beyond that which is necessary  
and appropriate based on the exercise of independent medical judgment  
not affected by improper financial incentives.

11 **VII.**

12 **DIRECT DAMAGE SUSTAINED BY THE STATE OF NEVADA,**  
13 **PATIENTS AND THIRD-PARTY PAYORS**

14 88. Patients are directly damaged by defendants’ AWP Scheme because patients frequently  
15 are required to make a co-payment for a pharmaceutical, or because patients occasionally make  
16 payment in full. The amount of the co-payment is often a direct function of the overall reimbursement  
17 paid on behalf of the patient by Medicare or Third-Party Payors.

18 89. For example, as alleged herein, Medicare recipients must pay 20% of the total amount  
19 that is reimbursed by Medicare to the pharmaceutical manufacturer. Thus, if Medicare reimburses \$100  
20 for a covered drug based upon the reported AWP, the Medicare beneficiary is responsible for 20% (or  
21 \$20) in this situation.

22 90. Many Medicare beneficiaries obtain supplemental insurance known as “Medigap” or  
23 “Medicare Plus” to cover the costs of pharmaceuticals as well as other costs not paid by Medicare.  
24 Such supplemental insurers are also Third-Party Payors who are damaged by the AWP Scheme.

25 91. The AWP Scheme also affected the State of Nevada because, in each instance of a drug  
26 payment made under Medicaid, the State paid an inflated amount.

27 /////

28 /////



1 (a) Defendants have failed to disclose material facts in  
2 connection with the sale of goods in that they have not disclosed that the  
3 AWP does not reflect the true average wholesale price of the drug  
4 products they sell, but are instead inflated in order to drive up the prices  
5 paid by Patients within the State of Nevada;

6 (b) Defendants have made false or misleading statements of  
7 facts concerning the price of goods in that they have lied about the true  
8 AWP paid for their medications in order to drive up the prices paid by  
9 Patients within the State of Nevada;

10 (c) Defendants have knowingly made false representations in  
11 a transaction by representing that the AWP is an accurate reflection of the  
12 average wholesale price paid for their drugs; and

13 (d) Defendants have violated state and federal statutes and  
14 regulations relating to the sale or lease of goods including, without  
15 limitation, the Nevada RICO statute (NRS 207.470 *et seq.*), the federal  
16 regulations governing the determination of Medicare payments for drugs  
17 (42 C.F.R. § 405.517), the federal mail and wire fraud statutes, 18 U.S.C.  
18 §§ 1341 and 1343 and the Racketeer Influenced and Corrupt  
19 Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) & (d).

20 100. Defendants acted willfully and knowingly in committing the actions set forth above.

21 101. The wrongful conduct alleged in this Complaint occurs and continues to occur in the  
22 ordinary course of defendants' business or occupation and has caused great harm to the State of Nevada  
23 and its residents, who were foreseeable and direct victims of defendants' wrongful conduct.

24 102. Defendants' violations of the Deceptive Trade Practices Act were committed with the  
25 intent to mislead and defraud.

26 103. Defendants' wrongful, deceptive and illegal conduct has resulted in excessive and illegal  
27 profits to defendants and excessive payments made by Patients who are Nevada residents.

28 WHEREFORE, the State of Nevada prays as follows:

A. That the Court adjudge and decree that defendants have engaged in the conduct alleged  
herein.

B. That the Court adjudge that the conduct is unlawful and in violation of  
NRS 598.0915(13), 598.0915(15) and 598.0923(3).

C. That the Court enjoin and restrain defendants and their officers, agents, servants, and  
employees, and those in active concert or participation with them, from continuing to engage in such  
conduct or other conduct having similar purpose or effect.

/////

1 D. That the Court enjoin defendants and order that any and all future disseminations of  
2 AWP and “best price” accurately reflect the average wholesale prices paid by physicians and  
3 pharmacies.

4 E. That, pursuant to NRS 598.0993, the Court make such orders or judgments as may be  
5 necessary to restore to Patients who reside in the State of Nevada all moneys which defendants acquired  
6 from them by means of any of the deceptive trade practices complained of herein.

7 F. That the State of Nevada recover from defendants the costs of this action, including  
8 reasonable attorneys’ fees.

9 G. That the Court Order such other and further relief as it may deem just, necessary and  
10 appropriate.

11 **COUNT II**

12 **DECEPTIVE TRADE PRACTICES DIRECTED AT ELDERLY NEVADA RESIDENTS**  
13 **(Violations Of NRS 598.0973)**

14 **CLAIM FOR CIVIL PENALTIES AND INJUNCTIVE RELIEF**

15 104. The State of Nevada repeats and realleges the preceding paragraphs of this Complaint as  
16 if fully set forth herein.

17 105. This Claim is brought for civil penalties and injunctive relief to prevent the harm caused  
18 to elderly Patients in Nevada by the AWP Scheme.

19 106. Defendants’ conduct as alleged in this Complaint constitutes deceptive acts or practices  
20 in violation of NRS 598.0915(13), 598.0915(15), 598.0923(2), and 598.0923(3) in that:

21 (a) Defendants have failed to disclose material facts in  
22 connection with the sale of goods in that they have not disclosed that the  
23 AWP does not reflect the true average wholesale price of the drug  
products they sell, but are instead inflated in order to drive up the prices  
paid by Patients within the State of Nevada;

24 (b) Defendants have made false or misleading statements of  
25 facts concerning the price of goods in that they have lied about the true  
26 AWP paid for their medications in order to drive up the prices paid by  
elderly Patients within the State of Nevada;

27 (c) Defendants have knowingly made false representations in  
28 a transaction by representing that the AWP is an accurate reflection of the  
average wholesale price paid for their drugs; and

1 (d) Defendants have violated state and federal statutes and  
2 regulations relating to the sale or lease of goods including, without  
3 limitation, the Nevada RICO statute (NRS 207.470 *et seq.*), the federal  
4 regulations governing the determination of Medicare payments for drugs  
(42 C.F.R. § 405.517), the federal mail and wire fraud statutes, 18 U.S.C.  
§§ 1341 and 1343 and the Racketeer Influenced and Corrupt  
Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) & (d).

5 107. Defendants' conduct was in disregard of the rights of elderly persons, many of whom are  
6 forced to make expensive co-payments based on defendants' falsified AWP. The defendants knew or  
7 should have known that their AWP Scheme would adversely affect elderly persons, and such persons  
8 are more vulnerable to defendants' scheme given their age and/or conditions and their need for  
9 defendants' drugs. Further, defendants' conduct caused elderly persons to suffer substantial economic  
10 damage.

11 108. The wrongful conduct alleged in this Complaint occurs and continues to occur in the  
12 ordinary course of defendants' business or occupation and has caused great harm to the State of Nevada  
13 and its residents.

14 109. Defendants' violations of the Deceptive Trade Practices Act were committed with the  
15 intent to mislead and defraud.

16 110. Defendants' wrongful, deceptive and illegal conduct has resulted in excessive and illegal  
17 profits to defendants and excessive payments made by elderly Patients in Nevada.

18 WHEREFORE, the State of Nevada prays as follows:

19 A. That the Court adjudge and decree that defendants have engaged in the conduct alleged  
20 herein.

21 B. That the Court adjudge that the conduct is unlawful and in violation of  
22 NRS 598.0915(13), 598.0915(15), 598.0923(2), 598.0923(3) and 598.0973.

23 C. That the Court enjoin and restrain defendants and their officers, agents, servants, and  
24 employees, and those in active concert or participation with them, from continuing or engaging in such  
25 conduct or other conduct having similar purpose or effect.

26 D. That the Court enjoin defendants and order that any and all future disseminations of  
27 AWP accurately reflect the average wholesale prices paid by physicians and pharmacies.

28 //

1 E. That, pursuant to NRS 598.0973(1), the Court assess civil penalties of \$10,000 from  
2 each defendant for each violation directed toward an elderly person as complained of herein.

3 F. That the State of Nevada recover from defendants the costs of this action, including  
4 reasonable attorneys' fees.

5 G. That the Court order such other and further relief as it may deem just, necessary and  
6 appropriate.

7 **COUNT III**

8 **DECEPTIVE TRADE PRACTICES**  
9 **(Violations Of NRS 598.0903 *Et Seq.*)**

10 **CLAIM FOR CIVIL PENALTIES, INJUNCTIVE RELIEF, AND**  
11 **RESTITUTION FOR THE STATE OF NEVADA**

12 111. The State of Nevada repeats and realleges the preceding paragraphs of this Complaint as  
13 if fully set forth herein.

14 112. This Claim is brought for restitution of the losses suffered by State of Nevada as a result  
15 of the AWP Scheme and the failure to accurately report the "best price," to recover civil penalties for  
16 defendants' massive violations of Nevada law, and to impose injunctive relief ending the unlawful  
17 AWP Scheme.

18 113. Defendants' conduct as alleged in this Complaint constitutes deceptive acts or practices  
19 in violation of NRS 598.0915(13), 598.0915(15), 598.0923(2), and 598.0923(3) in that:

20 (a) Defendants have failed to disclose material facts in  
21 connection with the sale of goods in that they have not disclosed that the  
22 AWP does not reflect the true average wholesale price of the drug  
23 products they sell, and that the "best prices" they report are not the actual  
24 "best prices" offered to other commercial entities, but are instead inflated  
25 in order to drive up the prices paid for medications by the State of  
26 Nevada;

27 (b) Defendants have made false or misleading statements of  
28 facts concerning the price of goods in that they have lied about the true  
29 AWP and "best prices" paid for their medications in order to drive up the  
30 prices paid by the State of Nevada;

31 (c) Defendants have knowingly made false representations in  
32 a transaction by representing that the AWP is an accurate reflection of the  
33 average wholesale price paid for their drugs, and that their reported "best  
34 prices" are in fact the "best prices" offered to a commercial entity for  
35 their drugs; and

1 (d) Defendants have violated state and federal statutes and  
2 regulations relating to the sale or lease of goods including, without  
3 limitation, the “best price” requirement of the Medicaid statute (Nevada  
4 RICO statute (NRS 207.470 *et seq.*), the federal regulations governing the  
5 determination of Medicare payments for drugs (42 C.F.R. § 405.517), the  
6 federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 and 1343 and the  
7 Racketeer Influenced and Corrupt Organizations Act (RICO), particularly  
8 18 U.S.C. § 1962(c) & (d).

9 114. Defendants acted willfully and knowingly in committing the actions set forth above.

10 115. The wrongful conduct alleged in this Complaint occurs and continues to occur in the  
11 ordinary course of defendants’ business or occupation and has caused great harm to the State of Nevada  
12 and its residents.

13 116. Defendants’ violations of the Deceptive Trade Practices Act were committed with the  
14 intent to mislead and defraud.

15 117. Defendants’ wrongful, deceptive and illegal conduct has resulted in excessive and illegal  
16 profits to defendants and excessive payments by the State of Nevada and its residents.

17 WHEREFORE, the State of Nevada prays as follows:

18 A. That the Court adjudge and decree that defendants have engaged in the conduct alleged  
19 herein.

20 B. That the Court adjudge that the conduct is unlawful and in violation of  
21 NRS 598.0915(13), 598.0915(15) and 598.0923(3).

22 C. That the Court enjoin and restrain defendants and their officers, agents, servants, and  
23 employees, and those in active concert or participation with them, from continuing to engage in such  
24 conduct or other conduct having similar purpose or effect.

25 D. That the Court enjoin defendants and order that any and all future disseminations of  
26 AWP and “best price” accurately reflect the average wholesale prices paid by physicians and  
27 pharmacies, and the “best price” offered to any commercial entity, respectively.

28 E. That, pursuant to NRS 598.0999, the Court assess civil penalties of \$2,500 from each  
defendant for each willful violation of NRS 598.0903 to 598.0997 complained of herein.

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1 F. That, pursuant to NRS 598.0993, the Court make such additional orders or judgments as  
2 may be necessary to restore to the State all moneys which defendants acquired from it by means of any  
3 of the deceptive trade practices complained of herein.

4 G. That, pursuant to NRS 598.0993, the Court order defendants to pay restitution which  
5 restores the State to the financial position that it would be in, absent the defendants' conduct.

6 H. That the State of Nevada recover from defendants the costs of this action, including  
7 reasonable attorneys' fees.

8 I. That the Court order such other and further relief as it may deem just, necessary and  
9 appropriate.

10 **COUNT IV**

11 **RACKETEERING**  
12 **(Violations of NRS 207.470 *Et Seq.*)**

13 **CLAIM FOR TREBLE DAMAGES TO STATE OF**  
14 **NEVADA AND CIVIL FORFEITURE**

15 118. The State of Nevada incorporates by reference all preceding paragraphs as if fully set  
16 forth herein.

17 119. This Claim is brought for treble damages to the State of Nevada and civil forfeiture of  
18 the profits wrongfully obtained by defendants as a result of their racketeering activities as detailed  
19 herein.

20 120. At all relevant times, defendants each conducted the affairs of an association-in-fact  
21 enterprise within the meaning of NRS 207.380.

22 121. Subsequent to July 1, 1983, and within five-year periods, each defendant engaged in far  
23 more than two crimes related to racketeering that have the same or similar pattern, intents, results,  
24 accomplices, victims or methods of commission, and are otherwise related by distinguishing  
25 characteristics and are not isolated instances.

26 122. The "enterprise" is an association-in-fact consisting of the various and independent  
27 medical providers (physicians) who prescribed the Covered Drugs and engaged in fraudulent billing  
28 practices on the one hand, and defendants, including their directors, employees, and agents on the other

1 hand (“the AWP Enterprise”). The AWP Enterprise is an ongoing and continuing business organization  
2 consisting of both corporations and individuals that are and have been associated for the common  
3 purposes of selling, purchasing, prescribing, and administering the Covered Drugs to Patients in the  
4 State of Nevada and across the country, and deriving profits from these activities.

5 123. The AWP Enterprise affects commerce by engaging in the sale and/or purchase of the  
6 Covered Drugs, the transmission of sales and marketing literature, and the transmission and/or receipt  
7 of invoices and payments related to the use of the Covered Drugs within the State of Nevada. In  
8 addition, the AWP Enterprise prescribes and/or administers the Covered Drugs to thousands of  
9 individuals located within the State of Nevada.

10 124. Defendants’ illegal conduct and practice was carried out by an array of employees,  
11 working across state boundaries including Nevada, who necessarily relied upon frequent transfer of  
12 false information, products and funds.

13 125. Defendants have exerted control over the AWP Enterprise, and have directly or  
14 indirectly conducted or participated in the conduct of the affairs of that enterprise, in the following  
15 ways:

16 (i) Defendant pharmaceutical companies have directly controlled the price at which  
17 medical providers purchase the Covered Drugs;

18 (ii) Defendants have directly controlled the AWP’s that are reported in the *Red Book*  
19 and similar industry publications;

20 (iii) Defendants have directly controlled the price at which medical providers  
21 (physicians) are reimbursed by the Medicare and Medicaid Programs;

22 (iv) Defendants have directly controlled the creation and distribution of marketing,  
23 sales, and other materials used to inform medical providers (physicians) nationwide of the profit  
24 potential of the Covered Drugs;

25 (v) Defendants have directly controlled the marketing and sales scheme to artificially  
26 and unlawfully inflate the Medicare and Medicaid reimbursement rates (and co-payment rate) to induce  
27 medical providers (physicians) to prescribe the Covered Drugs to their patients;

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1 (vi) Defendants have directly controlled the use and distribution of free samples of  
2 the Covered Drugs to medical providers (physicians);

3 (vii) Defendants have directly or indirectly controlled the ability of medical providers  
4 (physicians) to unlawfully seek reimbursement from the Medicare Program for free samples;

5 (viii) Defendants have relied upon their employees and agents to promote the  
6 fraudulent marketing schemes alleged herein; and

7 (ix) Defendants have controlled and participated in the affairs of the AWP Enterprise  
8 by using a fraudulent scheme to manufacture, market and sell the Covered Drugs through the use of  
9 unlawful inducements to medical providers (physicians).

10 126. Defendants have conducted and participated in the affairs of the AWP Enterprise  
11 through a pattern of racketeering activity that includes acts indictable under NRS 205.380. In  
12 particular, by (i) reporting artificially high AWP, and (ii) not selling medications to Medicaid  
13 providers at the “best price” as required, and (iii) representing that their sales price was related to the  
14 AWP, defendants obtained money from the State of Nevada, and Patients and Third-Party Payors  
15 residing therein, under false pretenses.

16 127. In conducting the AWP Scheme as detailed above and throughout this Complaint, each  
17 defendant: (1) had the intent to defraud the State of Nevada, and Patients and Third-Party Payors  
18 residing therein, and (2) made numerous false representations concerning AWP and the “best price”  
19 paid for their medications.

20 128. The State of Nevada, and Patients and Third-Party Payors residing therein, were  
21 defrauded out of money by the AWP Scheme in that (1) they relied on defendants’ representations  
22 concerning AWP and the “best price” paid for their medication, and (2) they paid excessive prices for  
23 the medications as a result.

24 129. Defendants’ pattern of racketeering involved hundreds, if not thousands, of separate  
25 instances of obtaining money under false pretenses pursuant to NRS 205.380, and insurance fraud in  
26 violation of NRS 686A.291 and 686A.2815. Each of these instances constitutes a “crime related to

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1 racketeering” within the meaning of NRS 207.360.26. Collectively, these violations constitute  
2 “racketeering activity” within the meaning of NRS 207.390 in which the defendants intended to defraud  
3 Plaintiff and other intended victims of the scheme.

4 130. Defendants’ fraudulent and unlawful scheme consisted first of deliberately overstating  
5 the AWP’s for the Covered Drugs, creating a “spread” based on the inflated figure to induce medical  
6 providers to prescribe the Covered Drugs to their patients, thereby causing the Medicare Program to  
7 pay an artificially-inflated rate of reimbursement for the Covered Drugs. Defendants’ fraudulent and  
8 unlawful marketing scheme also consisted of providing free samples of the Covered Drugs to medical  
9 providers, instructing these professionals to bill the Medicare Program for these free samples, and  
10 providing other unlawful financial incentives, including kickbacks, to induce use of the Covered Drugs.  
11 Through the AWP Scheme, the defendants also deliberately misstated the “best price” paid by  
12 commercial entities in order to illegally deprive the State of its Medicaid rebates, as well as to  
13 overcharge other State agencies.

14 131. Finally, in order to obtain higher payments from residents in Nevada, the defendants  
15 fraudulently misrepresented that the AWP’s accurately reflected the average wholesale prices paid by  
16 hospitals and physicians for their drugs, thereby committing insurance fraud within the meaning of  
17 NRS 686A.2815(2)-(4), (6) and (8).

18 132. These schemes were calculated and intentionally crafted so as to ensure that the  
19 Medicare and Medicaid Programs would be over-billed for the Covered Drugs, as well as Patients  
20 residing in Nevada. In designing and implementing these fraudulent schemes, defendants were at all  
21 times cognizant of the fact that: (1) the entire Medicare Program and all patients for whom the Covered  
22 Drugs are prescribed; and (2) the State of Nevada in its Medicaid payments for prescription drugs, as  
23 well as payments made by other state agencies all rely upon the honesty of defendants in setting the  
24 AWP as reported in the *Red Book* and similar publications.

25 133. By intentionally and artificially inflating the AWP and by providing medical providers  
26 with unlawful financial inducements to use the Covered Drugs, and by subsequently failing to disclose  
27 such practices to the Patients and others from whom reimbursement was sought, defendants engaged in  
28 a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

1           134. These racketeering activities amounted to a common course of conduct, with similar  
2 pattern and purpose, intended to deceive plaintiff and other victims of the scheme. Each separate  
3 instance of racketeering activity perpetrated by the defendants was related, had similar intended  
4 purposes, involved similar participants and methods of execution, and had the same results affecting the  
5 same victims, including the State of Nevada, and Patients residing therein. Defendants have engaged in  
6 this racketeering activity for the purpose of conducting the ongoing business affairs of the AWP  
7 Enterprise.

8           135. Defendants' violations and pattern of racketeering activity have directly and proximately  
9 caused the State of Nevada and Patients and Third-Party Payors residing therein to be injured in their  
10 property insofar as they have paid millions of dollars in inflated reimbursements or other payments for  
11 the Covered Drugs, and the State has been deprived of its proper Medicaid rebates.

12           136. The State of Nevada and Patients residing therein have relied to their detriment on  
13 billing statements that were based on information reported directly or indirectly by defendants. As a  
14 result of defendants' fraudulent acts, the billing statements so distributed have resulted in inflated  
15 payments for the State and its resident Patients.

16           WHEREFORE, the State of Nevada prays as follows:

17           A. That the Court adjudge and decree that defendants have engaged in the conduct alleged  
18 herein.

19           B. That the Court adjudge that the conduct is unlawful and in violation of NRS 207.400,  
20 and NRS 207.360.26.

21           C. That the Court enjoin and restrain defendants and their officers, agents, servants, and  
22 employees, and those in active concert or participation with them, from continuing to engage in such  
23 conduct or other conduct having similar purpose or effect.

24           D. That the Court enjoin defendants and order that any and all future disseminations of  
25 AWP accurately reflect the average wholesale prices and best prices paid by physicians and  
26 pharmacies.

27           E. That, pursuant to NRS 207.460, the Court order that defendants forfeit all property,  
28 including money, derived from or gained through defendants' conduct in violation of NRS 207.400.

1 F. That, pursuant to NRS 207.470, the Court find that defendants are jointly and severally  
2 liable to the State of Nevada for three times the damages it has sustained as a result of the defendants'  
3 violations of NRS 207.400.1.

4 G. That, pursuant to NRS 207.480, the Court order defendants to pay restitution that  
5 restores the State to the financial position that it would be in, absent the defendants' conduct.

6 H. That, pursuant to NRS 207.480, the State of Nevada recover from defendants the costs of  
7 this action, including reasonable attorneys' fees.

8 I. That the Court order such other and further relief as the Court deems just, necessary and  
9 appropriate.

10 **COUNT V**

11 **BREACH OF CONTRACT**

12 **CLAIM BROUGHT TO RECOUP STATE'S DAMAGES**

13 137. The State of Nevada incorporates by reference all preceding paragraphs as if fully set  
14 forth herein.

15 138. As required by 42 U.S.C. § 1396r-8, each defendant entered into a Rebate Agreement  
16 with the Secretary of Health and Human Services ("DHHS"). In that agreement, each agreed to comply  
17 with Section 1396r-8, and hence:

18 (a) Agreed to report its best price, inclusive of cash discounts, free goods contingent  
19 upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates  
20 where necessary; and

21 (b) Agreed that it would determine its best price based upon its average  
22 manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods  
23 (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it  
24 would include in that calculation cash discounts and all other price reductions "which reduce the actual  
25 price paid;" and

26 (c) Agreed that the best price would not take into account nominal prices, defined as  
27 prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the  
28 sale of product at a nominal price was not contingent on any other sale.

1 139. The State of Nevada was an intended third-party beneficiary of these contracts between  
2 the defendants and the DHHS.

3 140. After execution of this agreement, each defendant reported its average manufacturer's  
4 price in each quarter to the Medicaid Program.

5 141. In keeping with their artificial inflation of the AWP's, each defendant did not report the  
6 actual "best price," but instead excluded discounts and other inducements offered to physicians to  
7 increase use of a drug being sold at AWP.

8 142. Defendants have therefore breached their contracts with the DHHS, and caused massive  
9 damage to the State of Nevada.

10 WHEREFORE the State of Nevada prays as follows:

11 A. That the Court adjudge and decree that defendants have engaged in the conduct alleged  
12 herein.

13 B. That the Court order defendants to pay damages to the State of Nevada in an amount to  
14 be determined after trial.

15 C. That the Court order such other and further relief as the Court deems just, necessary and  
16 appropriate.

17 **COUNT VI**

18 **MEDICAID FRAUD**  
19 **(Violations Of NRS 422.540 *Et Seq.*)**

20 **CLAIM FOR CIVIL PENALTIES**

21 143. The State of Nevada incorporates by reference all preceding paragraphs as if fully set  
22 forth herein.

23 144. This Claim is brought for civil penalties pursuant to NRS 422.580.

24 145. Each of the defendant pharmaceutical companies is a manufacturer of drugs included in  
25 the Nevada Medicaid drug formulary.

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1           146. Pursuant to 42 U.S.C. § 1396r-8, each of the defendant pharmaceutical companies  
2 entered into a rebate agreement with the Medicaid Program under which the Medicaid Program would  
3 receive rebates determined in part by “best price,” which is defined as “the lowest price available from  
4 the manufacturer.”

5           147. In particular, as part of the rebate agreement, each defendant agreed that:

6                   (a) It would determine its best price, taking into account discounts, free goods  
7 contingent upon any purchase requirements, volume discounts and rebates, in any quarter and would  
8 make quarterly rebates where necessary to bring the price down to the actual lowest price offered to any  
9 commercial entity;

10                   (b) It would also determine its best price based upon its average manufacturer’s  
11 price, calculated as “net Sales divided by numbers of units sold, excluding free goods (*i.e.*, drugs or any  
12 other items given away, but not contingent on any purchase requirements)” and that it would include in  
13 that calculation cash discounts and all other price reductions “which reduce the actual price paid;” and

14                   (c) It would not take into account nominal prices, defined as prices that are less than  
15 10 percent of the average manufacturer’s price in that quarter, so long as the sale of a product at a  
16 nominal price was not contingent on any other sale.

17           148. After execution of its agreement, each defendant reported its “best price” in each quarter  
18 to the Medicaid Program.

19           149. In keeping with their artificial price inflation scheme, each defendant did not report the  
20 actual “best price” or “average manufacturer’s price,” but instead (i) reported higher prices and (ii)  
21 excluded discounts and other inducements offered to physicians that resulted in lower prices than the  
22 prices reported to the Medicaid Program.

23           150. Each of the defendants thereby violated NRS 422.540(1)(a) in that, acting with the intent  
24 to defraud, each defendant made or caused claims to be made to the effect that the Medicaid Program  
25 was receiving rebates based upon accurately reported “best price” information, knowing the claims to  
26 be rendered false, in whole or in part, by falsely reporting the prices paid by commercial entities for its  
27 products and not accounting for the discounts and other inducements offered to commercial entities.

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