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1 FRANKIE SUE DEL PAPA
Attorney General
2 State Bar No. 0192
DAVID WASICK
3 Special Assistant Attorney General
State Bar No. 4786
4 L. TIMOTHY TERRY
Chief Deputy Attorney General
5 Nevada Bar No. 2341
100 N. Carson Street
6 Carson City, Nevada 89701-4717
7 Telephone: (775) 684-1113
8 Attorneys for Plaintiff State of Nevada

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

13 STATE OF NEVADA,)
14) Plaintiff,) CASE NO. _____
15 v.) DEPT. NO. _____
16 AMERICAN HOME PRODUCTS)
CORPORATION; AMGEN INC.;)
17 ASTRAZENECA; AVENTIS PHARMA;)
18 CHIRON; PHARMACIA CORPORATION;)
HOECHST MARION ROUSSEL, INC.;)
19 IMMUNEX CORPORATION; ELI LILLY)
AND COMPANY; SCHERING-PLOUGH)
20 CORP.; and DOES 1 through 100; DOES 101-)
125; DOES 126-150 and DOES 151-200,)
21)
22 Defendants.)

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

2 1. The STATE OF NEVADA, through Attorney General Frankie Sue Del Papa, brings this
3 action for monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement
4 of profits and punitive damages on behalf of the State of Nevada, and restitution on behalf of persons in
5 Nevada including thousands of Patients¹ who have paid inflated charges for medications based in whole
6 or in part on defendants' use of the Average Wholesale Price ("AWP") Scheme, as described below.

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

13 3. Prescription drugs are an increasingly important part of life for most Nevada citizens.
14 The development of new drugs can benefit consumers through better overall health, avoidance of more
15 expensive surgical procedures, and, in some cases, longer life. Because for many people prescription
16 drugs are necessary to live or function normally, consumers often have no choice but to pay whatever
17 price is necessary to obtain their medications. In economic terms, this means that demand for some
18 prescription drugs is highly inelastic: the quantity demanded does not drop significantly even if prices
19 rise. Drug manufacturers, therefore, spend enormous sums to develop and market new drugs,
20 recognizing that they likely will be able to charge prices that will ultimately generate substantial profits
21 for their investors. Of course, if the profit incentive was completely removed from drug manufacturers,
22 much of the research and development that now takes place would vanish. Thus, the optimal market
23 would both reward innovative drug manufacturers and keep prices as affordable as possible. Balancing
24 these worthwhile goals can be difficult and, unfortunately, abuses take place that have unfairly gouged
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¹ 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 consumers and injured the State and its Medicaid program as described below. The Attorney General
2 seeks to enjoin and remedy these abuses.

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

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

9 5. Physicians and pharmacies purchase the prescription drugs for which they are
10 reimbursed directly from the pharmaceutical manufacturer or indirectly through wholesalers.

11 6. The AWP is generally not independently determined by *First Data Bank* or other third-
12 party reporting agencies. Rather, as part of the AWP Scheme described in this Complaint,
13 pharmaceutical companies purportedly "self-police" and "self-report" the AWP to third-party
14 publications (such as *First Data Bank*), which then publish the purported AWP, as provided to them by
15 the pharmaceutical manufacturers.

16 7. Pursuant to federal regulation and industry and State practice, reimbursement for
17 prescription drugs is based upon the reported AWP.

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

23 9. Specifically, defendants' AWP Scheme involves the reporting by each defendant of
24 inflated Average Wholesale Prices. The fraudulent reporting of Average Wholesale Prices has the
25 effect of materially misrepresenting the actual prices paid to defendants by physicians and pharmacies
26 for prescription drugs.

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1 10. Plaintiff alleges upon information and belief that, in many instances, the purported AWP
2 reported by the defendant pharmaceutical manufacturers bears little or no relationship to the prices
3 actually paid by physicians or pharmacies.

4 11. In addition, while federal Medicaid law requires the defendants to provide quarterly
5 rebates to the State of Nevada if it charges the State more than the lowest or “best price” offered to any
6 commercial customer, the defendants routinely failed to do so as a direct result of the AWP Scheme.

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

13 **B. THE DAMAGES CAUSED BY DEFENDANTS’ ILLEGAL CONDUCT.**

14 13. The intended and foreseeable consequences of the defendants’ scheme are several and
15 far reaching, including, but not limited to, increased drug costs to the State of Nevada and its agencies,
16 and increased drug costs to Patients who are Nevada residents.

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

18 14. One of the foreseeable and intended consequences of defendants’ conduct has been to
19 unjustly enrich the defendants at the expense of Nevada’s health care system, the state health care
20 authority, and ultimately, all Nevada residents and taxpayers.

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

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

25 17. Finally, numerous state agencies purchase medications at illegally inflated prices based
26 on the AWP Scheme.

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

2 **2. DAMAGES TO PATIENTS.**

3 19. As further intended and foreseeable effects of the defendants’ AWP Scheme, many
4 private persons residing in Nevada also suffered losses.

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

8 21. Through its *parens patriae* and statutory powers, the State of Nevada also seeks
9 restitution of these losses in this case.

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

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

14 23. In addition, the Attorney General brings this action to return to the State and its resident
15 Patients the increased medication costs caused by defendants’ wrongful conduct and to disgorge
16 defendants’ excessive profits from the artificially inflated AWP Scheme accomplished through
17 violations of state law.

18 **II. PARTIES**

19 **A. PLAINTIFF.**

20 24. This action is brought for and on behalf of the State of Nevada and damaged persons and
21 entities within the State of Nevada, by Frankie Sue Del Papa, Attorney General of the State of Nevada,
22 pursuant to, *inter alia*, the provisions of the Nevada Deceptive Trade Practice Act, NRS 598.0903 *et*
23 *seq.*, Nevada’s Civil RICO statute, NRS 207.470 *et seq.*, Nevada’s Medicaid Fraud Statutes,
24 NRS 422.580 and the common law and statutory authority of the Attorney General to represent the
25 State of Nevada and its residents.

26 **B. DEFENDANTS.**

27 28 25. Defendant American Home Products Corporation (“AHP”) is the parent company of

1 Wyeth Worldwide. It is organized and exists under the laws of the state of New Jersey. American
2 Home Products is one of the largest pharmaceutical and health care product companies in the world. Its
3 annual sales in 2000 exceeded \$13.3 billion. Through its subsidiaries, AHP manufactures and
4 distributes prescription drugs, including Ativan® (convulsive disorder medication), for clinical
5 distribution by Medicare providers nationwide, and sells Premarin® in the state.

6 26. Defendant Amgen Inc. is a corporation organized and existing under the laws of the state
7 of California. Amgen is in the business of manufacturing and distributing prescription pharmaceuticals,
8 including Epogen/Procrit® (for treatment of anemia), Neupogen® (bone marrow transplant infection
9 prevention), and Aransep (anemia in kidney patients) for clinical distribution by Medicare providers
10 nationwide. In 2000, Amgen's revenues exceeded \$3.6 billion.

11 27. Defendant AstraZeneca US is a corporation organized and existing under the laws of the
12 state of Delaware. AstraZeneca is in the business of manufacturing and distributing prescription
13 pharmaceuticals, including Zoladex® and Casdex (for prostate cancer), for clinical distribution by
14 Medicare providers nationwide.

15 28. Defendant Aventis Pharma ("Aventis") is a corporation organized and existing under the
16 laws of the state of New Jersey and operating in more than 120 countries in the world. Aventis is in the
17 business of manufacturing and distributing prescription pharmaceuticals, including Pentacarinat®
18 (pneumonia treatment), for clinical distribution by Medicare providers nationwide. In 1999, Aventis's
19 *pro forma* sales for its pharmaceuticals were \$3.3 billion.

20 29. Defendant Chiron is a corporation organized and existing under the laws of the state of
21 California. Chiron is in the business of manufacturing pharmaceuticals, including Depocyt®
22 (anticancer drug), among other prescription drugs, for distribution to Medicare clinical outsourcers.
23 Revenues for 2000 were \$972 million.

24 30. Defendant Hoechst Marion Roussel, Inc. ("HMR") is a wholly-owned subsidiary of
25 Aventis S.A. (former Hoechst AG). HMR is a corporation organized and existing under the laws of the
26 state of Delaware, and has its headquarters located at 10236 Marion Park Drive, Kansas City, Missouri.

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1 HMR develops and manufactures prescription drugs, including Lasix® (high blood pressure
2 treatment), for clinical distribution by Medicare providers nationwide.

3 31. Defendant Immunex Corporation is a corporation organized and existing under the laws
4 of the state of Washington. Its principal place of business is located at 51 University Street, Seattle,
5 Washington. Immunex manufactures immune system disorder and cancer treatment prescription drugs,
6 including Novantrone®, for clinical distribution by Medicare providers nationwide. Immunex's total
7 revenues for 1999 were \$542 million.

8 32. Defendant Eli Lilly and Company ("Lilly") is a corporation organized and existing under
9 the laws of Indiana. Lilly is in the business of manufacturing prescription drugs, such as Nebcin® (for
10 bacterial eye infection treatment), Vancocin® (bacterial infection treatment), and Oncovin® (for the
11 treatment of some cancerous conditions), for clinical distribution by Medicare providers nationwide.

12 33. Defendant Schering-Plough Corp. is a corporation organized and existing under the laws
13 of the state of New Jersey. Its headquarters are located at 2000 Galloping Hill Rd., Kenilworth, New
14 Jersey. Schering-Plough manufactures prescription drugs, including Garamycin® (eye infection
15 treatment), IntronA® (cancer) and Temodar® (cancer), for distribution by Medicare providers
16 nationwide.

17 **C. CO-CONSPIRATORS AND DOE DEFENDANTS**

18 34. Various other individuals, partnerships, sole proprietors, business entities, companies,
19 and corporations, presently unknown to the State and not named as defendants in this Complaint,
20 participated as co-conspirators in the violations alleged in this Complaint and performed acts and made
21 statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided,
22 abetted, or participated with defendants in the commission of the wrongful acts alleged herein or
23 otherwise caused the damages suffered by the State and its residents.

24 35. DOES 1-100 are corporations, companies, partnerships, or other business entities that
25 participated in the illegal course of conduct that is the subject of this action as alleged herein.

26 36. DOES 101-125 are residents of the state of Nevada and are officers, employees, or
27 agents of the defendants and/or entities owned or controlled by the defendants. DOES 101-125
28 participated in the illegal course of conduct that is the subject of this action as alleged herein.

1 37. DOES 126-150 are residents of states other than the state of Nevada and are officers,
2 employees, or agents of the defendants and/or entities owned or controlled by the defendants. DOES
3 126-150 participated in the illegal course of conduct that is the subject of this action as alleged herein.

4 38. DOES 151-200 are residents of countries other than the United States and are officers,
5 employees, or agents of the defendants and/or entities owned or controlled by the defendants. DOES
6 151-200 participated in the illegal course of conduct that is the subject of this action as alleged herein.

7 39. Except as described herein, plaintiffs are, as yet, ignorant of the true names, capacities,
8 nature and extent of the participation in the course of conduct alleged herein of the persons sued as
9 DOES 1-200 inclusive and, therefore, sues these defendants by such fictitious names. The state will
10 amend this Complaint to allege the true names and capacities of the Doe defendants when ascertained.

11 40. In addition, defendants unknown at this time may include independent physicians and
12 other medical providers who prescribed Covered Drugs and engaged in fraudulent billing practices, as
13 well as various other persons, partnerships, sole proprietors, firms, corporations and individuals that
14 may have participated as co-conspirators with defendants in the offenses alleged in this Complaint and
15 may have performed acts and made statements in furtherance of the alleged illegal conduct.

16 41. Each of the defendants designated herein as a Doe Defendant is legally responsible in
17 some manner for the unlawful acts referred to herein. Plaintiff will seek leave of Court to amend this
18 Complaint to reflect the true names and capacities of the defendants designated herein as Does when
19 such identities become known. Collectively, these companies are referred to as the “pharmaceutical
20 defendants” or defendants.

21 42. Each of the defendants named above participated in the Medicaid Rebate Program.

22 43. At all times relevant hereto, each of the defendants transacted business in the state of
23 Nevada, including but not limited to, selling and distributing products in the State.

24 **III. THE MEDICARE INSURANCE PROGRAM**

25 44. America’s prescription drug prices, already the highest in the world, have risen nearly
26 three times faster than inflation in the last ten years. This rapid increase has forced some people to
27 make difficult choices between drugs that keep them healthy or other life necessities like food and rent.

1 Although a variety of factors have contributed to the price increases, in some instances the
2 competitive market for prescription drugs has been abused.

3 45. Many state Medicaid administrators have been placed in the unenviable position of
4 having to ration needed health care services to the poor due to a lack of funds. For example, major
5 newspapers such as the Washington Post reported that the Clinton Administration abandoned its effort
6 to extend Medicaid coverage for AIDS therapies due to the high cost of drugs needed to treat HIV
7 patients (December 5, 1997).

8 46. While this case is not solely about Medicare, the Medicare program and its method of
9 using AWP as a basis for reimbursement is an important factual predicate to the scheme alleged herein.

10 47. In 1965, Congress enacted Title XVIII of the Social Security Act (known as “Medicare”
11 or the “Medicare Program”) to pay for the cost of certain medical services and care.

12 48. The Department of Health and Human Services (“HHS”) is an agency of the United
13 States Government that is responsible for the funding, administration and supervision of the Medicare
14 Program. At all relevant times, the Health Care Financing Administration (“HCFA”) was a division of
15 HHS, now known as the Center for Medicare and Medicaid Services (“CMS”), and was directly
16 responsible for the administration of the Medicare Program.

17 49. As a general matter, the Medicare Program does not cover the cost of prescription
18 pharmaceuticals which a Medicare beneficiary obtains pursuant to a prescription and thereafter self
19 administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover
20 some drugs, namely, those that cannot be self-administered and are furnished incident to a physician’s
21 services, including injectables that are administered by a medical provider.

22 50. Medicare calculates the “allowable amount” (*i.e.*, the amount that Medicare will pay)
23 based upon the payment methodology set forth in 42 C.F.R. § 405.517, which regulation was published
24 in the Federal Register on November 25, 1991, and became effective on or about January 1, 1992.

25 Section 405.517 provides:

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1 Payment for drugs and biologicals that are not paid on a cost or
prospective payment basis.

2 (a) Applicability. Payment for a drug or biological that is not paid on a
3 cost or prospective payment basis is determined by the standard
4 methodology described in paragraph (b) of this section. Examples of
5 when this procedure applies include a drug or biological furnished
6 incident to a physician's service, a drug or biological furnished by an
independent dialysis facility that is not included in the ESRD composite
rate set forth in § 413.170(c) of this chapter, and a drug or biological
furnished as part of the durable medical equipment benefit.

7 (b) Methodology. Payment for a drug or biological described in
8 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
9 price of the drug or biological.**

10 (c) Multiple-source drugs. For multiple-source drugs and biologicals, for
11 purposes of this regulation, the average wholesale price is defined as the
12 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.)

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

23 52. Physicians are able to obtain drugs at prices significantly below current Medicare
24 reimbursements. The widely available prices that are available from wholesalers and group purchasing

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26 ² NDCs are the universal product identifiers for drugs for human use; the Food and Drug Administration assigns the first
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.

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

1 organizations (“GPOs”) for physician-administered drugs are considerably less than AWP used to
2 establish the Medicare payment. For most of the high-expenditure or high-volume physician-
3 administered drugs, widely available discounts from AWP ranged from 13 percent to 34 percent.
4 Physicians who have been identified as low-volume billers for oncology drugs can also purchase drugs
5 for considerably less than Medicare’s payment. In addition to receiving reimbursement for drugs,
6 physicians are paid separately for services associated with drug administration under the Medicare
7 physician fee schedule.

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

15 54. In determining the AWP, HCFA uses the AWP published in industry publications such
16 as *First Data Bank*, *Blue Book*, or *Medispan* as the basis for reimbursement. Specifically, in PM AB-
17 99-63 (as of January 1, 1998), HCFA stated that it will pay drug and biologicals based on the lower of
18 the actual billed charge or 95 percent of the AWP reflected in pharmaceutical industry publication
19 sources such as *Red Book*, *Blue Book*, or *Medispan*.

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

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

1 57. Throughout the 1990s, the *Red Book* and other publications such as *Blue Book* and
2 *Medispan* published AWP for pharmaceuticals. The *Red Book* and other publications simply publish
3 the prices that are supplied to them by the pharmaceutical manufacturers, including defendants,
4 generally without independent verification. Defendants knew that they could directly control and
5 fraudulently inflate the AWP for pharmaceuticals at any time by simply forwarding a higher, fictitious
6 AWP to the *Red Book* or other publications.

7 58. The actual price that providers pay for Medicare Part B drugs is not disclosed to the
8 State and certainly not to patients. Physicians and suppliers may belong to “GPOs” that pool the
9 purchases of multiple entities to negotiate prices with wholesalers or manufacturers. GPOs may
10 negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In
11 addition, providers can purchase Part B-covered drugs from general or specialty pharmaceutical
12 wholesalers or they can have direct purchase agreements with manufacturers.

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

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

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

5 62. In a September 21, 2000, report, the United States Government Accounting Office
6 (“GAO”) found that:

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

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

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

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

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

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66. The following table illustrates some of the discounts provided to physicians⁴:

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

Drug name	Specialty most frequently billed for drug	Average AWP^a	Average widely available discount from AWP (percentage)^b
Leuprolide acetate (for depot suspension)	urology	\$618.93	17.6
Rituximab	oncology ^c	\$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 ^d
Pamidronate disodium	oncology	\$279.86	16.8
Hylan G-F 20	orthopedic surgery	\$225.13	17.7 ^d
Filgrastim (G-CSF) 300 mcg	oncology	\$193.62	18.4 ^d
Paclitaxel	oncology	\$180.57	19.0
Irinotecan	oncology	\$141.32	22.9
Carboplatin	oncology	\$120.48	20.3
Gemcitabine HCl	oncology	\$112.34	21.3
Dolasetron mesylate, injection	oncology	\$45.02	65.0 ^d
Granisetron HCl, injection	oncology	\$19.52	29.3
Leucovorin calcium	oncology	\$18.44	85.6
Epoetin alpha for non-ESRD use	oncology	\$12.91	15.2
Ondansetron HCl, injection	oncology	\$6.41	12.8
Botulinum toxin type A	neurology	\$4.86	N/a ^e
Imiglucerase	oncology	\$3.95	N/a ^e
Dexamethasone sodium phosphate	oncology	\$1.44	14.2
Heparin sodium	oncology	\$0.43	34.4

^a“Average AWP” is the average of AWP of each NDC for that product adjusted to the HCPCS-defined dosage.

^b“Average widely available discount from AWP” for each drug was calculated by (1) determining the average widely available price(s) for each NDC for that drug, (2) determining the percentage difference between the average widely available price(s) and the AWP for each NDC for the drug, and (3) averaging the percentage differences for all NDCs for that drug.

^c“Oncology” specialty includes hematology/oncology and medical oncology.

67. The “spread” is so significant that in some instances a patient’s 20% co-payment is more than the cost of the drug to the doctor or provider, as evidenced in the table below⁵:

⁴ Source: September 2001 GAO Report-01-1118.

⁵ Source: Stark Investigative Materials.

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

68. 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 AWP and inflated reimbursement from Medicaid and Medicare.

69. In 2000, state and federal investigators challenged the reported AWP of various drugs. Thereafter, certain companies lowered their reported AWP on various drugs, thereby admitting that prior reported AWP were artificially inflated.

70. Among those directly harmed by the defendants’ manipulation of the AWP in the Medicare context are Nevada residents who, as Patients, have been compelled to pay excessive

1 co-payments for medications based upon the falsely inflated AWP.

2 **IV. THE AWP SCHEME ALSO INFLICTS DAMAGES**
3 **ON THE STATE OF NEVADA**

4 71. The damages inflicted by the AWP Scheme are not confined to Medicare payors.

5 72. In addition, numerous State agencies have overpaid for medications based upon the
6 fraudulently reported AWP.

7 73. Likewise, most Medicaid payors including the State of Nevada historically have also
8 typically based reimbursement on the AWP.

9 74. On August 10, 2001, the U.S. Department of Health and Human Services, Office of the
10 Inspector General (“OIG”), reported the results of a survey of 216 pharmacies in eight states and
11 obtained 16,024 invoices for brand name drug products. The OIG report concluded that nationally,
12 pharmacy cost was 21.84 percent below AWP, a 19.3 percent increase from 1994. This report further
13 concluded that although many states paid a discount of 10 percent off AWP, this was not sufficient to
14 “ensure that a reasonable price is paid for drugs.”

15 75. Recently, one drug company agreed to settle claims asserted by the U.S. Government
16 arising from this practice. According to the Department of Justice’s litigation release:

17 The government’s investigation of the allegations revealed that Bayer
18 beginning in the early 1990s falsely inflated the reported drug prices –
19 referred to by the industry as the Average Wholesale Price (AWP), the
20 Direct Price and the Wholesale Acquisition Cost – used by state and
21 federal governments to set reimbursement rates for the federally and state
22 funded Medicaid Program. By setting an extremely high AWP and,
23 subsequently, selling the product to doctors at a dramatic discount, Bayer
24 enabled physicians to receive excess reimbursement from private and
25 government insurers. The Bayer AWP, at issue in the investigation,
26 involved several of Bayer’s biologic products such as Kogenate, Koate-
27 HP, and Gamimmune, which are widely used in treating hemophilia and
immune deficiency diseases.

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

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

12 76. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products
13 compensated under a state's Medicaid Program, the manufacturer had to enter into a rebate agreement
14 with the Secretary of Health and Human Services. Pursuant to the rebate agreement, the manufacturer
15 promised to report to the Medicaid Program its best price. The statute defines the best price as "the
16 lowest price available from the manufacturer during the rebate period to any wholesaler, retailer,
17 provider, health maintenance organization, nonprofit entity or governmental entity." The section also
18 provides that "best price" includes "cash discounts, free goods that are contingent on any purchase
19 requirement, volume discounts and rebates" and does not include "prices that are merely nominal in
20 amount."

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

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

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

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

1 manipulating the AWP to create falsely inflated “spreads” and resulting financial incentives to
2 providers to prescribe specific drugs subject to the AWP Scheme.

3 86. The manipulation of AWP at the expense of Medicare, Medicaid and their respective
4 patients is further revealed when the defendants sell drugs that are not reimbursed by Medicare or
5 Medicaid. In these circumstances, the drug companies often report accurate AWP and actually
6 compete with other drug companies on the basis of having a lower AWP than the other company. The
7 company with the lower AWP will urge physicians to consider the cost to the patient when selecting
8 drugs and promote its lower AWP as a selling tool. Thus, where Medicare and Medicaid are not
9 involved, defendants often ensure that their AWP are accurate so as to compete for market share based
10 on price.

11 87. Defendants were aware that physicians would purchase and utilize products that have the
12 widest spread between the providers’ true costs and the reimbursement paid by third parties. All
13 defendants made representations of their AWP for various drugs, which representations were not
14 accurate. In doing so, defendants hoped that providers would view the inflated AWP as a reason for
15 selecting their drug. Defendants also knew that this selection would be at the expense of patients who
16 were making a co-payment and at the expense of governmental payors.

17 88. Thus, although they are competitors, each of the defendants agreed to a scheme whereby
18 each would publish in the *Red Book*, *Blue Book* and *Medispan* its artificially inflated “AWP.” Each
19 defendant knew that the AWP were fictitious, but each one followed course and published its own
20 fictitious AWP pursuant to its express or tacit agreement to do so.

21 VI. THE CONGRESSIONAL INVESTIGATION

22 89. The United States Congress has been investigating defendants’ wrongful activities. In a
23 letter sent to each of the defendants dated October 31, 2000, Congressman Stark stated in pertinent part:
24

25 You should by now be aware of Congressional investigations revealing
26 that Abbott has for many years reported and published inflated and
27 misleading data and has engaged in other deceptive business practices.
28 This letter is a call for your company to immediately cease overcharging
taxpayers and jeopardizing public health . . . The price manipulation
scheme is executed through Abbott’s inflated representations of average
wholesale price (AWP) and direct price (“DP”) which are utilized by the
Medicare and Medicaid Programs in establishing drug reimbursements to

1 providers. The difference between the inflated representations of AWP
2 and DP versus the true price providers are paying, is regularly referred to
3 in your industry as “the spread.” The evidence amassed by Congress
4 clearly shows that Abbott has intentionally reported inflated prices and
5 has engaged in other improper business practices in order to cause its
6 customers to receive windfall profits from Medicare and Medicaid when
7 submitting claims for certain drugs. The evidence further reveals that
8 Abbott manipulated prices for the express purpose of expanding sales and
9 increasing market share of certain drugs. This was achieved by arranging
10 financial benefits or inducements that influenced the decisions of health
11 care providers submitting Medicare and Medicaid claims . . . Based on
12 the evidence collected, Abbott should make arrangements to compensate
13 taxpayers for the financial injury caused to federally funded programs.
14 Any refusal to accept responsibility will most certainly be indicative of
15 the need for Congress to control drug prices. If we cannot rely upon drug
16 companies to make honest and truthful representations about their prices,
17 then Congress will be left with no alternative but to take decisive action
18 to protect the public.

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

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

25 91. In his letter, Congressman Stark made the following five “shocking conclusions”:

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

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

Third – Certain drug manufacturers engage in the fraudulent price
manipulation for the express purpose of causing federally funded health
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.

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

Fifth – Certain drug manufacturers engage in illegal price manipulation in
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.

1 **VII. DIRECT DAMAGE SUSTAINED BY THE STATE OF NEVADA,**
2 **PATIENTS AND THIRD-PARTY PAYORS**

3 92. Patients are directly damaged by defendants' AWP Scheme because patients frequently
4 are required to make a co-payment for a pharmaceutical, or because patients occasionally make
5 payment in full. The amount of the co-payment is often a direct function of the overall reimbursement
6 paid on behalf of the patient by Medicare or Third-Party Payors.

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

11 94. Many Medicare beneficiaries obtain supplemental insurance known as "Medigap" or
12 "Medicare Plus" to cover the costs of pharmaceuticals as well as other costs not paid by Medicare.
13 Such supplemental insurers are also Third-Party Payors who are damaged by the AWP Scheme.

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

16 96. Moreover, each of the defendants has failed to report accurate best price information as
17 required by federal Medicaid law, and thereby deprived the State of its proper rebates. *See* 42 U.S.C.
18 § 1396r-8.

19 97. Similarly, numerous State agencies have overpaid for medications based upon the
20 fraudulently reported AWPs.

21 98. In addition, Third-Party Payors also typically make reimbursement to health care
22 providers for pharmaceuticals based upon the AWP, where Medicare or Medicaid are inapplicable.

23 99. Although the State knew that, at certain times, the AWP may not have always reflected
24 all of the discounts offered certain providers, the State was not aware of the failure of defendants to
25 accurately report "best prices" for rebate purposes and reasonably believed that defendants were
26 reflecting all discounts in their determination of the "best price."

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

4 106. Defendants' violations of the Deceptive Trade Practices Act were committed with the
5 intent to mislead and defraud.

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

8 WHEREFORE, the State of Nevada prays as follows:

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

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

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

16 D. That the Court enjoin defendants and order that any and all future disseminations of
17 AWP and "best price" accurately reflect the average wholesale prices paid by physicians and
18 pharmacies.

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

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

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

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1 **COUNT II**

2 **DECEPTIVE TRADE PRACTICES DIRECTED AT ELDERLY NEVADA RESIDENTS**
3 **(Violations of NRS 598.0973)**

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

5 108. The State of Nevada repeats and realleges the preceding paragraphs of this Complaint as
6 if fully set forth herein.

7 109. This Claim is brought for civil penalties and injunctive relief to prevent the harm caused
8 to elderly Patients in Nevada by the AWP Scheme.

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

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

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

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

23 (d) Defendants have violated state and federal statutes and
24 regulations relating to the sale or lease of goods including, without
25 limitation, the Nevada RICO statute (NRS 207.470 *et seq.*), the federal
26 regulations governing the determination of Medicare payments for drugs
27 (42 C.F.R. § 405.517), the federal mail and wire fraud statutes, 18 U.S.C.
28 §§ 1341 and 1343 and the Racketeer Influenced and Corrupt
Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) & (d).

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

1 112. The wrongful conduct alleged in this Complaint occurs and continues to occur in the
2 ordinary course of defendants' business or occupation and has caused great harm to the State of Nevada
3 and its residents.

4 113. Defendants' violations of the Deceptive Trade Practices Act were committed with the
5 intent to mislead and defraud.

6 114. Defendants' wrongful, deceptive and illegal conduct has resulted in excessive and illegal
7 profits to defendants and excessive payments made by elderly Patients in Nevada.

8 WHEREFORE, the State of Nevada prays as follows:

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

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

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

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

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

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

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

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1 **COUNT III**

2 **DECEPTIVE TRADE PRACTICES**
3 **(Violations of NRS 598.0903 *Et Seq.*)**

4 **CLAIM FOR CIVIL PENALTIES, INJUNCTIVE RELIEF, AND**
5 **RESTITUTION FOR THE STATE OF NEVADA**

6 115. The State of Nevada repeats and realleges the preceding paragraphs of this Complaint as
7 if fully set forth herein.

8 116. This Claim is brought for restitution of the losses suffered by State of Nevada as a result
9 of the AWP Scheme and the failure to accurately report the “best price,” to recover civil penalties for
10 defendants’ massive violations of Nevada law, and to impose injunctive relief ending the unlawful
11 AWP Scheme.

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

14 (a) Defendants have failed to disclose material facts in
15 connection with the sale of goods in that they have not disclosed that the
16 AWP does not reflect the true average wholesale price of the drug
17 products they sell, and that the “best prices” they report are not the actual
18 “best prices” offered to other commercial entities, but are instead inflated
19 in order to drive up the prices paid for medications by the State of
20 Nevada;

21 (b) Defendants have made false or misleading statements of
22 facts concerning the price of goods in that they have lied about the true
23 AWP and “best prices” paid for their medications in order to drive up the
24 prices paid by the State of Nevada;

25 (c) Defendants have knowingly made false representations in
26 a transaction by representing that the AWP is an accurate reflection of the
27 average wholesale price paid for their drugs, and that their reported “best
28 prices” are in fact the “best prices” offered to a commercial entity for
their drugs; and

(d) Defendants have violated state and federal statutes and
regulations relating to the sale or lease of goods including, without
limitation, the “best price” requirement of the Medicaid statute (Nevada
RICO statute (NRS 207.470 *et seq.*), the federal 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).

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

1 119. The wrongful conduct alleged in this Complaint occurs and continues to occur in the
2 ordinary course of defendants' business or occupation and has caused great harm to the State of Nevada
3 and its residents.

4 120. Defendants' violations of the Deceptive Trade Practices Act were committed with the
5 intent to mislead and defraud.

6 121. Defendants' wrongful, deceptive and illegal conduct has resulted in excessive and illegal
7 profits to defendants and excessive payments by the State of Nevada and its residents.

8 WHEREFORE, the State of Nevada prays as follows:

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

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

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

16 D. That the Court enjoin defendants and order that any and all future disseminations of
17 AWP and "best price" accurately reflect the average wholesale prices paid by physicians and
18 pharmacies, and the "best price" offered to any commercial entity, respectively.

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

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

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

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

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

3 **COUNT IV**

4 **RACKETEERING**
5 **(Violations of NRS 207.470 *Et Seq.*)**

6 **CLAIM FOR TREBLE DAMAGES TO STATE OF**
7 **NEVADA AND CIVIL FORFEITURE**

8 122. The State of Nevada incorporates by reference all preceding paragraphs as if fully set
9 forth herein.

10 123. This Claim is brought for treble damages to the State of Nevada and civil forfeiture of
11 the profits wrongfully obtained by defendants as a result of their racketeering activities as detailed
12 herein.

13 124. At all relevant times, defendants each conducted the affairs of an association-in-fact
14 enterprise within the meaning of NRS 207.380.

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

19 126. The “enterprise” is an association-in-fact consisting of the various and independent
20 medical providers (physicians) who prescribed the Covered Drugs and engaged in fraudulent billing
21 practices on the one hand, and defendants, including their directors, employees, and agents on the other
22 hand (“the AWP Enterprise”). The AWP Enterprise is an ongoing and continuing business organization
23 consisting of both corporations and individuals that are and have been associated for the common
24 purposes of selling, purchasing, prescribing, and administering the Covered Drugs to Patients in the
25 State of Nevada and across the country, and deriving profits from these activities.

26 127. The AWP Enterprise affects commerce by engaging in the sale and/or purchase of the
27 Covered Drugs, the transmission of sales and marketing literature, and the transmission and/or receipt
28 of invoices and payments related to the use of the Covered Drugs within the State of Nevada. In

1 addition, the AWP Enterprise prescribes and/or administers the Covered Drugs to thousands of
2 individuals located within the State of Nevada.

3 128. Defendants' illegal conduct and practice was carried out by an array of employees,
4 working across state boundaries including Nevada, who necessarily relied upon frequent transfer of
5 false information, products and funds.

6 129. Defendants have exerted control over the AWP Enterprise, and have directly or
7 indirectly conducted or participated in the conduct of the affairs of that enterprise, in the following
8 ways:

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

11 (ii) Defendants have directly controlled the AWP's that are reported in the *Red Book*
12 and similar industry publications;

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

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

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

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

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

25 (viii) Defendants have relied upon their employees and agents to promote the
26 fraudulent marketing schemes alleged herein; and
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1 (ix) Defendants have controlled and participated in the affairs of the AWP Enterprise
2 by using a fraudulent scheme to manufacture, market and sell the Covered Drugs through the use of
3 unlawful inducements to medical providers (physicians).

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

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

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

18 133. Defendants’ pattern of racketeering involved hundreds, if not thousands, of separate
19 instances of obtaining money under false pretenses pursuant to NRS 205.380, and insurance fraud in
20 violation of NRS 686A.291 and 686A.2815. Each of these instances constitutes a “crime related to
21 racketeering” within the meaning of NRS 207.360.26. Collectively, these violations constitute
22 “racketeering activity” within the meaning of NRS 207.390 in which the defendants intended to defraud
23 Plaintiff and other intended victims of the scheme.

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

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

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

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

22 138. These racketeering activities amounted to a common course of conduct, with similar
23 pattern and purpose, intended to deceive plaintiff and other victims of the scheme. Each separate
24 instance of racketeering activity perpetrated by the defendants was related, had similar intended
25 purposes, involved similar participants and methods of execution, and had the same results affecting the
26 same victims, including the State of Nevada, and Patients residing therein. Defendants have engaged in
27 this racketeering activity for the purpose of conducting the ongoing business affairs of the AWP

28 Enterprise.

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

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

9 WHEREFORE, the State of Nevada prays as follows:

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

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

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

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

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

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

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

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

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

3 **COUNT V**

4 **MEDICAID FRAUD**
5 **(Violations of NRS 422.540 *Et Seq.*)**
6 **CLAIM FOR CIVIL PENALTIES**

7 141. The State of Nevada incorporates by reference all preceding paragraphs as if fully set
8 forth herein.

9 142. This Claim is brought for civil penalties pursuant to NRS 422.580.

10 143. Each of the defendant pharmaceutical companies is a manufacturer of drugs included in
11 the Nevada Medicaid drug formulary.

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

16 145. In particular, as part of the rebate agreement, each defendant agreed that:

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

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

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

1 146. After execution of its agreement, each defendant reported its “best price” in each quarter
2 to the Medicaid Program.

3 147. In keeping with their artificial price inflation scheme, each defendant with respect to, but
4 not limited to the following drugs, did not report the actual “best price” or “average manufacturer’s
5 price,” but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered
6 to physicians that resulted in lower prices than the prices reported to the Medicaid Program. The drugs
7 include: Ativan®, Premarin®, Epogen/Procrit®, Neupogen®, Aransep®, Zoladex®, Casdex®,
8 Pentacarinat®, Depocyt®, Gammagard®, Alkeran®, Hycamtis®, Amikin®, Neosar®, Toposar®,
9 Andrucil®, Camptosar®, Ellence®, Lasix®, Novantrone®, Nebcin®, Vancocin®, Oncovin®,
10 Garamycin®, IntronA®, and Temodar®.

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

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

20 150. Each of the defendants also violated NRS 422.540(1)(b) and (d), in that, acting with the
21 intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific
22 goods, each defendant made or caused to be made false statements promising that it would comply with
23 the mandates of 42 U.S.C. § 1396r-8.

24 151. As a result of the defendants’ violations of NRS 422.540(1)(a), (b) and (d), the Medicaid
25 Program paid substantially higher prices for defendants’ products than it could have, and the Medicaid
26 Program was deprived of its appropriate rebate as a result of defendants’ inaccurate reporting of best
27 price.

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

3 DATED this _____ day of March, 2002.

4 FRANKIE SUE DEL PAPA
5 Attorney General of the State of Nevada

6
7 By: _____

8 FRANKIE SUE DEL PAPA
9 DAVID WASICK
10 L. TIMOTHY TERRY
11 100 N. Carson Street
12 Carson City, NV 89701-4714

13 HAGENS BERMAN LLP
14 Steve W. Berman
15 Andrew M. Volk
16 1301 Fifth Avenue, Suite 2900
17 Seattle, WA 98101

18 THE CAREY LAW FIRM
19 Robert B. Carey
20 2301 E. Pikes Peak
21 Colorado Springs, CO 80909

22 COUNSEL FOR PLAINTIFF
23 STATE OF NEVADA
24
25
26
27