IN THE CIRCUIT COURT OF MASON COUNTY, WEST VIRGINIA

STATE OF WEST VIRGINIA ex rel.
DARRELL V. McGRAW, JR.,
Attorney General ,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

CIVIL ACTION NO. 06-C-31-N
Judge David W. Nibert

2006 FEB 28 PM 3:50

COMPLAINT

This action is brought pursuant to the West Virginia Consumer Credit and Protection Act, West Virginia Code § 46A-1-101 *et seq.*, hereinafter "the Act," and the Medicaid Fraud Act, W. Va. Code § 9-7-1 *et seq.* Plaintiff, the State of West Virginia ex rel. Darrell V. McGraw, Jr., Attorney General, hereinafter "the State," has reason to believe the above-named Defendant, Eli Lilly and Company has violated the Act and the Medicaid Fraud Act. The State brings this action to enjoin and restrain Eli Lilly and Company ("Lilly") from engaging in unfair or deceptive acts or practices in regard to the sale, marketing and distribution of its brand name drug, Zyprexa, among other relief. The State seeks permanent injunctive relief and other equitable relief including, but not limited to, investigative costs, restitution and the creation of a fund for consumers who were harmed and will develop diabetes and other diseases as a result of Lilly's business practices, treble damages, court costs and attorneys' fees.

I. THE PARTIES

1. The Plaintiff, the State of West Virginia, by and through Darrell V. McGraw, Jr., the duly elected and current Attorney General, brings this action in its sovereign capacity on behalf of its natural citizens and public agencies of the State, including the Department of Health and Human Resources and its Bureau for Medical Services ("Medicaid"), under W. Va. Code §9-7-1, *et seq.*, the Public Employees Insurance Agency ("PEIA") and the Bureau of Employment Programs ("WCD"). The Attorney General is authorized to bring this action pursuant to W. Va. Code §§ 9-7-6, 46A-7-108, and -111.

2. Eli Lilly and Company is a corporation organized under the laws of the state of Indiana with its headquarters in Indianapolis, Indiana.

3. At all times herein mentioned, Lilly acted by itself, or by and through agents and employees, in doing the acts alleged herein, and at all times, said agents and employees were acting within the purpose and scope of said agency and employment, and all said acts were ratified and approved by Lilly.

II. JURISDICTION AND VENUE

4. This Court has jurisdiction to hear this matter pursuant to Article VIII, Section 6 of the West Virginia Constitution and W. Va. Code § 51-2-2.

5. Venue is proper in this Court pursuant to W. Va. Code §§ 46A-7-114 and 56-1-1.

III. FACTS COMMON TO ALL CAUSES OF ACTION

6. Lilly is authorized to transact business in the State of West Virginia.

7. Lilly does, and for many years has done, business in West Virginia through

the sale and marketing of products carrying the Eli Lilly brand.

8. At all times herein mentioned, Lilly designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical product hereinafter referred to as Zyprexa (also known as olanzapine).

Zyprexa General Facts

9. Zyprexa is the brand name for olanzapine, a prescription drug manufactured by Lilly, which is prescribed and sold in all states, including West Virginia.

10. Lilly first started selling Zyprexa in West Virginia in 1996.

11. Zyprexa is among a group of drugs known as "atypical antipsychotic drugs" prescribed for the treatment of schizophrenia and bipolar mania. Zyprexa, although only approved by the federal Food and Drug Administration ("FDA") to treat schizophrenia and bipolar mania, has been prescribed for "off-label" uses such as depression. An off-label use means the drug is being used for the treatment of a disease or condition that has not been specifically approved by the FDA.

12. Zyprexa also has been prescribed for other off-label uses for the treatment of conditions such as dementia, anxiety, ADD, ADHD, sleep disorders and anger management. Zyprexa also has been prescribed off-label for children and adolescents with severe behavioral problems, such as those seen in autism and attention deficit disorder.

14. Zyprexa is approved for use as therapy alone or in combination with mood stabilizing drugs, such as lithium or valproate.

15. Zyprexa is the most expensive, largest selling atypical antipsychotic in the world and the most widely prescribed antipsychotic of any kind in the United States. Its 2004 United States sales were $2.4 billion. United States sales for 2005 were $2 billion.

16. West Virginia's Department of Health and Human Services has paid at least $70 million for Zyprexa in its Medicaid program since 1996.

17. Lilly was at all times mentioned in this complaint engaged in trade and commerce, relating to the marketing, distribution and sale of Zyprexa, which directly and indirectly affected people in West Virginia.

Lilly's Misrepresentations and Omissions Relating to Zyprexa

18. Even before the launch of Zyprexa in 1996, and continuing after its launch, Lilly became increasingly aware of various evidence, including but not limited to its own clinical studies, and subsequent epidemiological studies, showing that treatment with atypical antipsychotic drugs, especially Zyprexa, increases the risk of developing diabetes mellitus.

19. At least as early as 1998, the medical literature conclusively revealed data which linked Zyprexa with causing diabetes. An indicative report was published on October 15, 1998 in the Society of Biological Psychiatry, Volume 44, Number 8, pages 778-83, titled "Novel Antipsychotics and New Onset Diabetes." Other numerous reports and studies are prevalent throughout the medical literature from 1998 through the present which detail a causal link between the ingestion of Zyprexa and the development of hyperglycemia, diabetes and ketoacidosis, as well as many other undisclosed risks. On July 1, 2002, Duke University Medical Center issued a Press Release about a finding that linked Zyprexa to early onset diabetes. The researchers identified 289 cases of diabetes in patients who had been prescribed Zyprexa. These findings were published on July 2, 2002

in the medical journal Pharmacotherapy, Vol. 22, No. 7, pages 841-52. The known danger that Lilly's Zyprexa was causing hyperglycemia and diabetes was never disclosed to the State by Lilly.

20. On, or shortly after, September 15, 2003, Lilly changed the Warnings section of the Package Insert (hereinafter "PI") for Zyprexa, which contains full prescribing information for the drug, to include the risk of developing diabetes from taking it. The revised PI states:

> "Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including ZYPREXA®. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologic studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available."
>
> "Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics would undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug."

21. Lilly sent a Dear Health Care Provider Letter (hereinafter "DHCP Letter 1") to hundreds of thousands of healthcare providers, including healthcare providers in West

Virginia, dated March 1, 2004, indicating the above change to the Zyprexa PI, but only in the context of a "class" labeling change, and offering no other explanation for the change.

22. At all times before the DHCP Letter was mailed, including but not limited to the time between the date when the Zyprexa label was supposed to be changed and the date when DHCP Letter was mailed:

a. Lilly's sales representatives made personal contacts with physicians and other health care professionals in West Virginia, by visiting their offices in this state and by other means, and they orally made willfully misleading and deceptive statements regarding the safety and efficacy of Zyprexa.

b. Lilly's sales representatives persistently and willfully disparaged competitors' products by falsely and misleadingly misrepresenting to physicians and other health care professionals in West Virginia that Zyprexa had been shown to have an efficacy, safety and overall risk-benefit profile superior to other drugs in its class.

c. Lilly distributed Zyprexa promotional brochures, containing essentially the same willfully deceptive and misleading information above, to physicians and other health care professional in West Virginia.

d. Lilly ran advertisements for Zyprexa in medical professional journals and in other magazines with medical professionals as their target audience, which were mailed by their publishers to physicians and other health care professionals in West Virginia; and these advertisements deceptively perpetuated the understatement of risk and overstatement of benefit above.

e. Lilly otherwise willfully, deceptively, and misleadingly misrepresented Zyprexa's risk-benefit profile to heath care professionals in West Virginia.

f. Lilly specifically promoted Zyprexa to physicians, including but not

limited to primary care physicians in West Virginia, for non-approved indications such as symptoms of anxiety, irritability, disruptive sleep, and mood swings.

g. Lilly specifically promoted Zyprexa to physicians, including but not limited to primary care physicians in West Virginia, for use in children, including treatment for attention deficit hyperactivity disorder, though Zyprexa was never approved for such use.

h. Lilly specifically promoted Zyprexa to physicians, including but not limited to primary care physicians in West Virginia, for use in the elderly, including treatment for dementia, though Zyprexa was never approved for such use.

23. At all times prior to the date of the DHCP Letter, Lilly knew, or should have known, that Zyprexa was extremely and unreasonably unsafe for use by the general public. The dangers of Zyprexa, included, by way of example, the increased likelihood of developing hyperglycemia, pancreatitis, diabetes, ketoacidosis, hyperosmolar coma and other injuries. Lilly knowingly, willfully and maliciously failed to take appropriate action to either cure the nature of these defects or to warn users of the product or physicians of such dangerous characteristics.

COUNT I
West Virginia Consumer Credit and Protection Act
(W. Va. Code § 46A-1-101, *et seq.*)

24. The State hereby incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows.

25. Lilly engaged in a course of repeated and willful conduct, through the acts and omissions described above.

26. Lilly's willful and repeated acts and omissions relating to Zyprexa, as described above, constitute unfair methods of competition, and they constitute unfair or deceptive acts or practices in the conduct of commerce, both of which violate W. Va. Code, § 46A-6-104.

a. Lilly represented to health care professionals in West Virginia that Zyprexa has benefits it does not have in violation of W. Va. Code, § 46A-6-102(7)(E).

b. Lilly disparaged competitors' drugs by making false and misleading misrepresentations of fact to health care professionals in West Virginia as to the risk-benefit profile of Zyprexa relative to other atypical antipsychotics, in violation of W. Va. Code, § 46A-6-102(7)(H).

c. Lilly engaged in conduct that created a likelihood of confusion or misunderstanding as to the risk-benefit profile of Zyprexa in the minds of health care professionals in West Virginia in violation of W. Va. Code, § 46A-6-102(7)(L).

d. Lilly made misrepresentations of material facts with the intention of having health care professionals in West Virginia rely on them in connection with the sale and promotion of Zyprexa in violation of W. Va. Code § 46A-6-102-(7)(M).

e. Lilly's Zyprexa promotional activities included publishing and distributing statements to health care professionals in West Virginia, which were misleading and deceptive, and which omitted material information necessary to make the statements not be misleading and deceptive in violation of W. Va. Code, § 46A-6-102(7)(N).

f. Lilly specifically promoted Zyprexa for non-approved and non-indicated uses, including but limited to treatment of sleep disorders, depression, behavior disorders in children, and dementia in the elderly, in violation of W. Va.

Code § 46A-6-102(7)(B) & (E).

27. Each exposure of a West Virginia health care professional to misleading and deceptive information regarding Zyprexa communicated in any manner by a sales representative constitutes a separate violation of W. Va. Code § 46A-6-104.

28. Each exposure of a West Virginia health care professional, as shown by Audit Bureau of Circulation figures, to a misleading Zyprexa print advertisement in the relevant time period constitutes a separate violation of W. Va. Code, § 46A-6-104.

29. Each exposure of a West Virginia health care professional or other person to a misleading Zyprexa brochure constitutes a separate violation of W. Va. Code, § 46A-6-104.

30. Each other exposure of a West Virginia health care professional to other misleading Zyprexa information, provided directly or indirectly by Lilly, e.g., by means of CD-ROM's, dinners sponsored by Lilly, PowerPoint presentations, promotional items, continuing medical education events sponsored by Lilly, and meetings sponsored by Lilly, constitutes a separate violation of W. Va. Code, § 46A-6-104.

31. Each exposure of a West Virginia resident to Zyprexa resulting from the aforementioned conduct of Lilly constitutes a separate violation of W. Va. Code § 46A-6-104.

COUNT II
Violation of W. Va. Code §9-7-1, *et seq.*
(Fraud and Abuse in the Medicaid Program)

32. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows.

33. Lilly willfully made false representations of the safety of Zyprexa and the side

effects caused by Zyprexa which misled providers in the State of West Virginia, resulting in the sales of Zyprexa which benefitted Lilly at the expense of the State Medicaid program.

34. Lilly engaged in a fraudulent scheme which allowed providers to obtain payments from Medicaid based upon sales of Zyprexa that would not have occurred if Lilly had disclosed to medical providers, the State and the public the risks of developing diabetes and other diseases from the use of Zyprexa.

35. Lilly knows the State relies on Lilly and other drug manufacturers to design, market and sell prescription drugs that are effective and safe for use by the State's Medicaid program recipients.

36. Lilly caused Zyprexa to be marketed as safe and effective with the intent that the State, medical providers and the general public rely on its representations so that the medical providers would not prescribe, and the State pay for, other effective, safe prescription drugs for treatment of schizophrenia and bi-polar disorder.

37. Some of the alternative drugs that could have been prescribed by medical providers, and paid for by the State cost less than Zyprexa, thereby causing the State to pay far more for Lilly's Zyprexa than it would have for competitors' drugs.

38. Lilly benefitted from its misrepresentations and fraudulent conduct by gaining sales of Zyprexa at the expense of other, safe, effective drugs. The money paid by the State would not have been paid to Lilly except for its fraudulent conduct.

39. Lilly further benefitted from its misrepresentations and fraudulent conduct by gaining sales of Zyprexa for medical conditions not specifically approved by the FDA.

40. The State is entitled to three times the amount of the overpayments, reasonable attorney fees and all other fees and costs of litigation.

COUNT III
Fraudulent Misrepresentation

41. The State realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:

42. Lilly materially misrepresented the safety and uses of Zyprexa to West Virginia, medical providers and the citizens of West Virginia.

43. Lilly knew that these material representations were false when made and Lilly intended that the representations would be relied upon by the State of West Virginia and its agencies. The State reasonably relied upon the material misrepresentations when determining to pay for Zyprexa.

44. Lilly had sole access to material facts regarding the true facts regarding off-label uses and the safety of Zyprexa, yet affirmatively concealed material facts from the State and its agencies, medical providers and the public.

45. Lilly's acts constitute fraudulent misrepresentations. As a direct and proximate cause of Lilly's fraudulent misrepresentations, the State and its agencies have been damaged and have spent money for these drugs that they otherwise would not have incurred had Lilly not misrepresented the safety and uses of Zyprexa.

RELIEF REQUESTED

WHEREFORE, Plaintiff, the State of West Virginia, prays for a judgment against Lilly as follows:

A. Adjudge and decree that Lilly engaged in conduct in violation of W. Va. Code § 9-7-1, *et seq.*

B. Adjudge and decree that Lilly engaged in conduct in violation of the West Virginia Consumer Credit and Protection Act, W. Va. Code

§ 46A-1-101, *et seq.*;

C. Grant judgment in favor of the State and against Lilly for its fraudulent conduct and award damages to the State.

D. Order Lilly to pay to the State three times the amount of such benefits, payments or allowances paid under West Virginia's Medicaid program as allowed by W. Va. Code § 9-7-6, caused by Lilly's' wrongful conduct.

E. Grant the State all equitable relief, including injunctive relief, disgorgement, restitution and reimbursement, and require Lilly to create a fund for the payment of costs of future medical care that will be paid by the State and the public for injuries caused by Lilly's conduct;

F. Award maximum civil penalties as provided by law;

G. Grant the State the costs of prosecuting this action, together with interest, including prejudgment interest, and reasonable attorneys' fees in connection with the prosecution of this case; and

H. Grant such further relief as this Court may deem just and proper under the circumstances.

JURY DEMAND

The State demands trial by jury on all claims for which there is a right to a jury trial.

Respectfully submitted,

STATE OF WEST VIRGINIA ex rel.
DARRELL V. McGRAW, JR.,
ATTORNEY GENERAL,

By Counsel,

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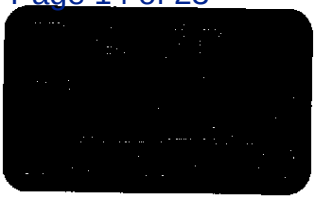

LEXSEE 2005 U.S. DIST. LEXIS 34453

COUNTY OF SANTA CLARA, on behalf of itself and all others similarly situated, Plaintiff, v. ASTRA USA, INC., ASTRAZENECA PHARMACEUTICALS LP, AVENTIS PHARMACEUTICALS, INC., BAYER CORP., BRISTOL-MYERS SQUIBB CO., BURROUGHS WELLCOME CO., GLAXO WELLCOME, INC., PFIZER, INC., SCHERING-PLOUGH CORP., TAP PHARMACEUTICAL PRODUCTS, INC., WYETH-AYERST LABORATORIES, INC., ZENECA, INC., ZLB BEHRING LLC, and DOES 1 through 100, inclusive, Defendants.

No. C 05-03740 WHA

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

401 F. Supp. 2d 1022; 2005 U.S. Dist. LEXIS 34453

December 2, 2005, Decided
December 2, 2005, Filed

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff county asserted state claims for unfair-competition, for making false-claims, for an accounting of alleged overcharges, and for unjust enrichment. Defendant pharmaceutical manufacturers removed the action to federal court. The county moved for joinder of additional defendants and, based on such joinder, for remand to state court for lack of subject-matter jurisdiction, or, alternatively, for dismissal due to lack of jurisdiction.

OVERVIEW: All the claims asserted by the county explicitly involved allegations that it was victimized by drug prices in excess of those allowed under a federal statute, 42 U.S.C.S. § 256b, and under a contract between the federal government and the manufacturers. The court held that contrary to the county's assertions determination of at least one of the stated federal issues was necessary. The alleged misconduct undergirding the county's claims distilled to the manufacturers purporting to sell drugs in accordance with the federal-government's price prescriptions yet actually charging more. This conduct injured the county because it was obligated for those overcharges under state law, *Cal. Welf. & Inst. Code § 17000* (which holds counties responsible for indigent medical care). For the case to be resolved on its merits, at least one of the federal issues embedded in the complaint had to be addressed. The court also held that as for the county's motion for necessary joinder of three medical distributors under *Fed. R. Civ. P. 19(a)*, joinder of the distributors was not required to accord complete relief among the county and the manufacturers.

OUTCOME: The motions for remand and, in the alternative, for dismissal were denied. The motion for joinder was denied as unnecessary.

LexisNexis(R) Headnotes

Evidence > Criminal Evidence > Judicial Notice
[HN1] Under *Fed. R. Evid. 201*, a court must take judicial notice of adjudicative facts if a party requests it to, if it supplies the necessary information to decide the request and if the facts are not subject to reasonable dispute because they are capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Federal Question Jurisdiction
Civil Procedure > Removal > Basis for Removal
[HN2] 28 U.S.C.S. § 1331 confers jurisdiction upon a federal court when an issue of federal law undergirds a claim otherwise based in state law. Such a claim, however, may only be removed to federal court if it meets certain conditions: (1) it must raise a stated federal legal issue, (2) determination of the federal issue must be necessary to resolution of the claim, (3) the federal issue must be actually disputed, (4) the federal issue must be substantial, and (5) the federal court must be able to en-

tertain the claim without disturbing any congressionally approved balance of federal and state judicial responsibilities. If only one of several state claims satisfies the requirements for removal on federal-question grounds, then any other purely state claims in the same complaint may also be determined by the federal court under its supplemental jurisdiction. 28 U.S.C.S. 1441(c).

Civil Procedure > Remedies > Equitable Accounting
[HN3] An essential element of a claim for accounting is that there is a balance due from the defendant that can only be ascertained by an accounting.

Antitrust & Trade Law > Trade Practices & Unfair Competition
[HN4] An unfair-competition claim, pursuant to *Cal. Bus. & Prof. Code § 17200*, is made out if the alleged conduct was either unfair, fraudulent, or unlawful.

Contracts Law > Remedies > Equitable Relief
[HN5] Unjust enrichment requires that the defendant improperly obtained a benefit. Recovery consists of restitution of the ill-gotten gains to the party who rightfully should have them.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Federal Question Jurisdiction
[HN6] There are two ways to judge the substantiality of a federal issue. First, if it has legal substance and some prospect of success, it survives. Courts have fashioned an alternative way to evaluate substantiality: the importance of the federal issue. Under this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme.

Civil Procedure > Joinder of Claims & Parties
Civil Procedure > Joinder of Claims & Parties > Joinder of Necessary Parties
[HN7] The heart of *Fed. R. Civ. P. 19(a)* is a disjunctive analysis. If either of two prongs is satisfied, joinder is mandatory. First, if complete relief cannot be had between the parties, joinder is required. Second, the court must join the non-party if it has a legally protected interest in the subject of the action and disposition in its absence would either (1) impede or destroy its ability to protect that interest or (2) leave the parties subject to a substantial risk of multiple or inconsistent obligations.

Civil Procedure > Remedies > Equitable Accounting
[HN8] An accounting is an equitable remedy by which a party opens its books so that the other side may calculate amounts owed.

Civil Procedure > Preclusion & Effect of Judgments > Collateral Estoppel
[HN9] The collateral estoppel doctrine stands for the principle that when a final judgment has determined an ultimate issue of fact, it is conclusive in any subsequent lawsuit based on different claims but involving a party to the prior litigation. Even some entities that were not party to the original litigation may be bound by it. This generally applies, however, only when they effectively were represented in the first litigation and had interests closely aligned with the actual party.

COUNSEL: [**1] For The County of Santa Clara, On Behalf of Itself and All Others Similarly Situated, Plaintiff: Jacqueline E. Mottek, Lerach Coughlin Stoia Geller Rudman & Robbins LLP, San Francisco, CA; Aelish M. Baig, Lerach Coughlin Stoia Geller Rudman & Robbins LLP, San Francisco, CA; Ann Miller Ravel, Office of the County Counsel, San Jose, CA; Cheryl A. Stevens, County of Santa Clara, San Jose, CA; Jennie Lee Anderson, Lerach Coughlin Stoia Geller Rudman & Robbins LLP, San Francisco, CA; Patrick J. Coughlin, Lerach Coughlin Stoia Geller Rudman & Robbins LLP, San Francisco, CA.

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For Burroughs Wellcome Co, Glaxo Wellcome Inc., Defendants: Paul Jeffrey Riehle, Esq., Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, CA.

For Pfizer Inc., Defendant: Molly Moriarty Lane, Morgan Lewis & Bockius LLP, San Francisco, CA; Paul Jeffrey Riehle, Esq., Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, CA; Brian W. Shaffer, Jennifer B. Jordan, Morgan, Lewis & Bockius LLP, Philadelphia, PA.

For Schering-Plough Corporation, Defendant: Paul Jeffrey Riehle, Esq., Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, CA; Brien T. O'Connor, Justin J. Wolosz, Ropes [**3] & Gray LLP, Boston, MA; Colin T. Kemp, Kirke M. Hasson, Pillsbury Winthrop Shaw Pittman LLP, San Francisco, CA.

For Tap Pharmaceutical Products Inc, Defendant: Paul Jeffrey Riehle, Esq., Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, CA; Peter Nels Larson, Jones Day, San Francisco, CA.

For Wyeth-Ayerst Laboratories, Inc, Defendant: Fletcher C. Alford, Gordon & Rees LLP, San Francisco, CA; Paul Jeffrey Riehle, Esq., Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, CA; Kelly Jeanne Davidson, Stephen Craig Holden, Ober, Kaler, Grimes & Shriver, Baltimore, MD.

For Zeneca Inc, Defendant: Paul Jeffrey Riehle, Esq., Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, CA; Sharon Douglass Mayo, Arnold & Porter LLP, Los Angeles, CA; Jeffrey Lawrence Handwerker, Robert S. Litt, Arnold & Porter LLP, Washington, DC.

For ZLB Behring, LLC, Defendant: Alicia J. Donahue, Shook Hardy & Bacon LLP, San Francisco, CA; Paul Jeffrey Riehle, Esq., Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, CA; Sara J. Romano, Shook, Hardy & Bacon, L.L.P., San Francisco, CA.

For Smithkline Beecham Corp., Defendant: [**4] Valerie M. Wagner, Dechert, LLP, Palo Alto, CA.

JUDGES: WILLIAM ALSUP, UNITED STATES DISTRICT JUDGE.

OPINIONBY: WILLIAM ALSUP

OPINION:

[*1023] **ORDER (1) DENYING MOTION FOR REMAND OR DISMISSAL, (2) GRANTING REQUESTS FOR JUDICIAL NOTICE AND (3) DENYING MOTION FOR *RULE 19(a)* JOINDER**

INTRODUCTION

Asserting four state-law claims, plaintiff County of Santa Clara moves for joinder of additional defendants and, based on such joinder, for remand to state court for lack of subject-matter jurisdiction. As an alternative to remand, it moves for dismissal due to lack of jurisdiction. Santa Clara and the defendants, all pharmaceutical manufacturers, separately have requested judicial notice of certain facts. The requests for judicial notice are unopposed and are **GRANTED.** The motion for remand or dismissal is **DENIED;** this Court has federal-question subject-matter jurisdiction. [*1024] The *Rule 19(a)* motion for joinder is **DENIED.**

STATEMENT

Defendants make pharmaceuticals, including common medicines such as Turns, Excederin and the antibiotic, Zithromax (Compl. PP 19-21). n1 They provide these medications to distributors who sell them to public hospitals and health-care clinics (Br. 2). As [**5] required by state law, Santa Clara County pays the cost of drugs given to many indigent and other patients at such medical facilities, including the Santa Clara Valley Medical Center. *See Cal. Welf. & Inst. Code § 17000.* In 2004, the county spent more than $ 30 million on prescription and over-the-counter medications given to outpatients at such facilities (Compl. PP 1, 3, 7).

n1 For purposes of this order, all factual allegations in the complaint are deemed true. Defendants have not in any way responded to those allegations; a formal answer is not yet required.

The federal government sets maximum prices at which such medications can be sold to public health-care institutions for use in outpatient treatment (Compl. PP 26-27). *42 U.S.C. 256b.* Santa Clara sued defendants in Alameda County Superior Court, claiming they had bled the county's finances with overcharges for these medicines. Santa Clara asserted four claims on behalf of itself and similarly afflicted [**6] California counties: violations of the state's unfair-competition law and false-

claims act, for an accounting that would reflect the amount of overcharges and for unjust enrichment (Compl. PP 68-87). Defendants removed the action here claiming diversity and federal-question jurisdiction (Notice of Removal of Action 1). Santa Clara made a timely motion for remand.

ANALYSIS

1. JUDICIAL NOTICE.

Santa Clara requested judicial notice of a publication in the Federal Register describing federal price limitations on prescription medications (Pl.'s Req. 1). Defendants requested judicial notice of six different matters: a description of the price-control regime on a Department of Health and Human Services web site; a report by the same department; the Pharmaceutical Pricing Agreement (the standard drug-pricing contract between the government and drug makers participating in the price-control program); complaints filed in two federal lawsuits; and a list of California cities by the League of California Cities (Defs.' Req. 1-3).

[HN1] Under *Federal Rule of Evidence 201*, a court must take judicial notice of adjudicative facts if a party requests it to, [**7] if it supplies the necessary information to decide the request and if the facts are "not subject to reasonable dispute" because they are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."

The time has passed for parties to object to the requests. They have not done so. Both sides have met their *Rule 201* requirements. This order takes notice of the requested matters.

2. FEDERAL-QUESTION JURISDICTION.

District courts have jurisdiction over civil cases arising under the Constitution, laws and treaties of the United States. *28 U.S.C. 1331*. When such a case is filed in state court, defendants may remove it to federal court. *28 U.S.C. 1441(b)*. Federal courts must construe the removal statute strictly. *Shamrock Oil & Gas Corp. v. Sheets, 313 U.S. 100, 108-09, 61 S. Ct. 868, 85 L. Ed. 1214 (1941)*.

[*1025] Federal-question jurisdiction arises most obviously for rights of action conferred by a federal statute or constitutional provision. [HN2] *Section 1331* also confers jurisdiction when an issue of federal law undergirds a claim otherwise based in state law. Such a claim, however, may only be removed [**8] to federal court if it meets certain conditions: (1) it must raise a stated federal legal issue, (2) determination of the federal issue must be necessary to resolution of the claim, (3) the federal issue must be actually disputed, (4) the federal issue must be substantial, and (5) the federal court must be able to entertain the claim "without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., U.S. , 125 S.Ct. 2363, 2366-68, 162 L. Ed. 2d 257 (2005)*. If only one of several state claims satisfies the requirements for removal on federal-question grounds, then any other purely state claims in the same complaint may also be determined by the federal court under its supplemental jurisdiction. *28 U.S.C. 1441(c)*. This order now analyzes whether the *Grable and Sons* requirements are met here.

The instant case raises two stated federal legal issues: one contractual and one statutory. All the claims asserted by Santa Clara explicitly involve allegations that it was victimized by drug prices in excess of those allowed under a federal statute, *42 U.S.C. 256b*, [**9] and under the Pharmaceutical Pricing Agreement, a contract between the federal government and the manufacturers (*see* Compl. PP 2, 7, 34; Defs.' Req. for Judicial Notice, Exh. B). n2 The contract, by its own terms, must be "construed in accordance with Federal common law" (Pharmaceutical Pricing Agreement at § VII(g), Defs.' Req. for Judicial Notice, Exh. B). Both violations of the federal statute and breaches of the federal contract raise obviously federal issues. *See Boyle v. United Techs. Corp., 487 U.S. 500, 504, 108 S. Ct. 2510, 101 L. Ed. 2d 442 (1988)* ("[O]bligations to and rights of the United States under its contracts are governed exclusively by federal law."); *Illinois v. City of Milwaukee, Wis., 406 U.S. 91, 100, 92 S. Ct. 1385, 31 L. Ed. 2d 712 (1972)* ("*[Section] 1331* jurisdiction will support claims founded upon federal common law as well as those of a statutory origin.").

n2 Santa Clara states that its claim for violation of the California False Claims Act does not mention any violations of federal law (Reply 4, n.5). This is misleading. The claim incorporates all 80 of the preceding paragraphs of the complaint "as through set forth in full herein" (Comp. P 81). Those 80 paragraphs provide a rash of allegations that defendants trampled federal laws.

[**10]

Contrary to Santa Clara's assertions at the hearing, determination of at least one of the stated federal issues is necessary. The alleged misconduct undergirding Santa Clara's claims distills to this: defendants purported to sell drugs in accordance with the federal-government's price prescriptions yet actually charged more. This conduct injured Santa Clara because it was obligated for those overcharges under state law. *See Cal. Welf. & Inst. Code § 17000* (counties responsible for indigent medical

care). For this case to be resolved on its merits, at least one of the federal issues embedded in the complaint must be addressed. There is simply no other way.

The necessity of determining the federal issues was hotly disputed by the parties in the briefs and at the hearing. This order therefore carefully examines each claim, demonstrating why it requires determination of at least one federal issue. Again, even if only one of the claims falls under [*1026] federal-question jurisdiction, all may be heard here. *See 28 U.S.C. 1441(c).*

First, Santa Clara claims that it is entitled to an accounting. It wants this remedy so it may determine [**11] whether it paid more than allowed under the federal price-control statute and the Pharmaceutical Pricing Agreement (Compl. P 74). [HN3] An essential element of a claim for accounting is that there is a balance due from the defendant that can only be ascertained by an accounting. *St. James Church of Christ Holiness v. Super. Ct. in and for L.A. County, 135 Cal. App. 2d 352, 359, 287 P.2d 387 (Cal. Ct. App. 1955).* The only way in which Santa Clara claims that a balance is due is by asserting that defendants charged in excess of the amount required by federal statute and contract. The only methods to determine the proper price are to construe or interpret the relevant federal statutes and contract. The accounting claim therefore requires determination of a federal issue.

Second, Santa Clara claims that defendants engaged in "an unfair, unlawful, and deceptive scheme to collect inflated charges that exceed the . . . ceiling price . . . and unlawfully and fraudulently charged . . . substantially more than the . . . ceiling price." Plaintiff claims this violated the state unfair-competition law (Compl. P 77). *See Cal. Bus. & Prof. Code § 17200.* [HN4] An unfair-competition [**12] claim is made out if the alleged conduct was either unfair, fraudulent or unlawful. An allegation that defendants violated *Section 17200* by *unlawful* conduct obviously requires determination of whether they violated the federal price-control statute or contract. An allegation that they acted fraudulently or unfairly also requires determination of a federal issue because it boils down to claims that defendants said they were providing the federally mandated discounts but did not (*see* Compl. PP 76-79).

Santa Clara asserts that its allegations of unfair and fraudulent conduct provide theories of liability independent of any federal-law issue (Br. 13-14; Reply 4). It claims that defendants acted unfairly and fraudulently when they allegedly "misrepresented and failed to disclose . . . the true facts regarding their prices" (Reply 4). Liability under the unfair and fraudulent prongs of *Section 17200* does not always require violation of a separate law. *Cel-Tech Communications, Inc. v. L.A. Cellular Tel. Co., 20 Cal. 4th 163, 180, 83 Cal. Rptr. 2d 548, 973 P.2d 527 (1999).* If, for example, Santa Clara had alleged that defendants were *not* required to provide the discounts yet falsely claimed to be [**13] providing them nevertheless, its claim of unfair or fraudulent acts would not have turned on a federal issue. Santa Clara, however, did not assert any such thing. The only reasons it has given for believing that defendants behaved unfairly or fraudulently were that they failed to give *required* discounts. The *Section 17200* claim therefore requires determination of whether defendants violated any federal statutory or federal contractual obligation to provide the discounts and, if they did, by how much they overcharged.

Third, Santa Clara asserted a violation of the state *False Claims Act. See Cal. Gov't Code § 12651.* The county alleges that defendants did one or more of the following: (1) falsely billed in excess of the amount owed for medications, (2) made false records to support such claims, (3) falsely sought to avoid obligations to pay money back to Santa Clara or (4) benefitted from inadvertent false billings for drug payments, discovered their falsity and yet failed to rectify the errors (Compl. P 82). In theory, perhaps, such a claim could be made out independent of any federal issue. For instance, Santa Clara could have alleged that defendants [**14] were *not* required to provide the discounts yet nevertheless [*1027] falsely claimed to have done so. The county, however, has not made any such accusation. In fact, it repeatedly stated that discounts were required. The only basis on which it claims the billings were false are that the manufacturers were required by federal law and contract to provide lower prices. If there was a false billing that did not turn on the federal price limits, Santa Clara may seek leave to amend its claim. Until it does so, there is no way around the federal issues.

Fourth, Santa Clara alleges unjust enrichment. [HN5] Unjust enrichment requires that the defendant improperly obtained a benefit. Recovery consists of restitution of the ill-gotten gains to the party who rightfully should have them. *See Kossian v. Am. Nat'l Ins. Co., 254 Cal. App. 2d 647, 649-51, 62 Cal. Rptr. 225 (Cal. Ct. App. 1967); see also* 1 B.E. Witkin, *Summary of Cal. Law* § 1013 (10th ed. 2005). In alleging unjust enrichment, Santa Clara claims defendants "agreed to supply drugs . . . at prices no greater than the . . . ceiling price . . . [yet] failed and refused to comply with that agreement[] and[,] as a result[,] defendants [**15] have retained monies to which they are not entitled" (Compl. P 85). Whether they failed to comply with the agreement requires a determination of (1) the price limits and (2) whether defendants had any federal statutory or contractual obligation to comply with them. There is simply no way to ignore federal law.

The stated federal issues are disputed in the instant case. Defendants claim to dispute plaintiff's interpretations of "average manufacturer price" and "best price," terms used to determine the proper drug prices (Opp. 5, *see* Pharmaceutical Pricing Agreement 1(a)-(b) (defining both terms), Defs.' Req. for Judicial Notice, Exh. B). *See also 42 U.S.C. 1396r-8(k)(1)* (definition of average manufacturer price); *42 U.S.C. 1396r-8(c)(1)(C)(i)-(ii)* (definition of best price). Defendants also claim that they disagree with Santa Clara over the proper interpretation of the statute dictating how to calculate maximum prices, *42 U.S.C. 1396r-8.*

The pricing issues in the instant case are substantial questions of federal law. [HN6] There are two ways to judge the substantiality of a federal issue. First, if it [**16] has legal substance and some prospect of success, it survives. *Hagans v. Lavine, 415 U.S. 528, 536-38, 94 S. Ct. 1372, 39 L. Ed. 2d 577 (1974)* (holding that constitutional claims are insubstantial "only if its unsoundness so clearly results from the previous decisions of this court as to foreclose the subject and leave no room for the inference that the questions sought to be raised can be the subject of controversy"). The *Hagans* rule also applies to purely statutory cases. *See Mackey v. Pioneer Nat'l Bank, 867 F.2d 520, 523 (9th Cir. 1989)* (addressing the 1986 Comprehensive Omnibus Budget Reconciliation Act).

Courts have fashioned an alternative way to evaluate substantiality: the importance of the federal issue. Under this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme. *Grable & Sons, 125 S.Ct. at 2368* (holding that construction of IRS notice requirements were substantial because they would have a direct impact on tax collection); *Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1329 (Fed. Cir. 1998)* [**17] (holding that the validity and enforceability of patents, under exclusive federal jurisdiction, are substantial enough to warrant federal-question jurisdiction over a state-law tort claim); *Broder v. Cablevision Sys. Corp., 418 F.3d 187, 195 (2d Cir. 2005)* (holding that interpretation [*1028] of complex federal cable-television-rate statutes was substantial).

This order next examines the merit of the arguments in the instant case that are based on federal law. Then, it determines the likely impact of resolving the federal issues.

There is no decision directly deciding whether defendants' statutory-construction and contractual-interpretation arguments are substantial. This order finds, however, that defendants raise sufficiently plausible issues to withstand remand. In fact, a substantial amount of judicial ink already has been spilled over the meaning of a term that may be significant in the instant case. *See Pharm. Research & Mfrs. of Am. v. Thompson, 346 U.S. App. D.C. 158, 251 F.3d 219, 224-26 (D.C. Cir. 2001)* (addressing meaning of "payment" in Medicaid statute). The Medicaid statute considered by the District of Columbia Circuit and the Medicaid statute now before this court [**18] apparently use "payment" in the same way. The definition of this term could be significant in the instant case because the only drugs that are covered by the discount program are those "purchased by the [health-care provider] for which *payment* is made by the State under the State plan for medical assistance under [the Medicaid statute]." *42 U.S.C. 256b(a)(3)* (emphasis added). If a drug is not one "for which payment is made by the State" then it presumably is not subject to the price-control statute. Whether or not a drug used in Santa Clara's public health-care facilities is subject to the price controls could determine both liability and damages. Construction of the statute is therefore a substantial issue. Another heavily litigated federal case makes clear that there are significant disputes over how to determine the maximum price. *See, generally, In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005).*

Interpreting the federal statute and contract at issue here may significantly affect federal interests. Determination of the federal issues in this case could heal or injure the complex regulatory scheme [**19] of distributing outpatient medications to the poor and other disadvantaged people. Although the instant case currently is confined to the claims of just one county, it is a putative statewide class action and the federal issues have the potential to affect many people: approximately 12,000 healthcare providers participated in the price-control program in 2003, spending $ 3.4 billion for outpatient drugs (Dep't of Health and Human Services, Office of Inspector Gen., Deficiencies in the Oversight of the 340B Drug Pricing Program at I (Oct. 2005), Defs.' Req. for Judicial Notice, Exh. C).

Santa Clara claims the issues are insubstantial. It argues that, if it wins the instant lawsuit, Medicaid reimbursements would not change. This argument is not lethal to defendants' removal. The important federal interest in price controls involves much more than the administration and amount of Medicaid reimbursements. They involve the broader issue of who should pay for indigent medical care in a nation hobbled by the lowest rate of health insurance coverage in the Western world. Santa Clara urged this Court to adapt a ruling by the District Court of Minnesota, claiming the decision bolstered its [**20] argument that the issues are insubstantial (Reply 7). *See Minnesota v. Pharmacia Corp., 2005 U.S.*

*Dist. LEXIS 27638, No. 05-1394, 2005 WL 2739297 at *4 (D. Minn. Oct. 24, 2005)*). Santa Clara mistakenly cites the case for the proposition that the Medicare issues in that case were insubstantial (Reply 7). In fact, the district court in the portion of *Pharmacia* quoted by Santa Clara was addressing the proper "balance of federal and state judicial responsibilities." *See Pharmacia, 2005 U.S. Dist. LEXIS 27638, 2005 WL 2739297 at *4.*

[*1029] The substantiality of the federal issues in this case is driven home by conflict within the federal government itself over how to calculate the ceiling price. These calculations evidently involve more than mechanical and undisputable interpretations of federal law (*see* Deficiencies in the Oversight of the 340B Drug Pricing Program at ii ("[O]versight of the program is . . . hindered by the lack of detailed, written procedures for calculating 340B ceiling prices. Consequently, the 340B ceiling prices calculated by [the Centers for Medicare & Medicaid Services] . . . yielded incorrect ceiling prices."), Defs.' Req. for Judicial Notice, Exh. C).

The final sub-issue relevant [**21] to federal-question jurisdiction is whether hearing this lawsuit would disturb "any congressionally approved balance of federal and state judicial responsibilities." *See Grable & Sons at 2368.* This Court might pause before finding federal-question jurisdiction here if unfair-competition cases previously had been heard only in state court. Such *Section 17200* cases, however, are already endemic in federal court, as Santa Clara effectively concedes (Reply 10 ("U[nfair-competition law] claims are often predicated on federal law.")). *See, e.g., Lockyer v. Dynegy, Inc., 375 F.3d 831, 841 (9th Cir. 2004)* (unfair-competition claim predicated on federal issues subject to exclusive federal jurisdiction; holding unaffected by subsequent amendment at *387 F.3d 966, 968 (9th Cir 2004)*); *Nat'l Credit Reporting Ass'n v. Experian Info. Solutions, Inc., No. C 04-01661 WHA, 2004 U.S. Dist. LEXIS 17303 at *10 (N.D. Cal. July 21, 2004)* (denying remand of *Section 17200* claim).

Santa Clara nevertheless argues that "shifting" cases to federal court premised on pharmaceutical companies' overcharges would disrupt a the proper federal-state balance (Reply 10). [**22] *See Grable & Sons, 125 S.Ct. at 2368.* There is, however, no congressionally approved balance of judicial responsibilities in this arena. During the approximately 13 years that the price controls have been in place, both state and federal courts have heard cases related to the statutes directly governing them. *See, e.g., Univ. Med. Ctr. of S. Nev. v. Shalala, 335 U.S. App. D.C. 322, 173 F.3d 438 (D.C. Cir. 1999)* (on whether plaintiff had standing to sue over its eligibility for discounts); *Pharmacia Corp., 2005 U.S. Dist. LEXIS 27638, 2005 WL 2739297 at *4* (motion to remand granted in dispute about overcharges); *Wisconsin v. Abbott Labs., 390 F. Supp. 2d 815, 825 (W.D. Wis. 2005)* (same); *Montana v. Abbot Labs., 266 F. Supp. 2d 250, 263 (D. Mass. 2003)* (remanding two overcharge cases and retaining federal jurisdiction over two others); and, *generally, In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61* (heard under federal jurisdiction). n3

n3 Although the decision from the District Court of Massachusetts is captioned with the defendant name Abbot Laboratories, the corporation is actually named Abbott Laboratories (with two t's), after its home base in Abbott, Illinois. The decision of the District Court of Wisconsin is correctly captioned.

[**23]

Santa Clara argued in its briefs that *Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 817, 106 S. Ct. 3229, 92 L. Ed. 2d 650 (1986)*, requires a different result here. At hearing, counsel for Santa Clara also cited three of the decisions named immediately above: *Montana v. Abbot Laboratories, Pharmacia Corp.* (a later decision in the *Montana* case), and *Wisconsin v. Abbott Laboratories.*

In *Merrell Dow*, the Supreme Court held that there was no federal jurisdiction over state tort claims merely because they borrowed a duty of care from a federal statute. The federal statute at issue in *Merrell Dow* conferred no independent right of action and had not preempted [*1030] state law. Counsel here notes that, as in *Merrell Dow*, there is no independent right of action under the drug price-control statute and that it did not preempt state regulation. *Merrell Dow* did not, however, bar federal jurisdiction over state claims in the absence of preemption or a federal cause of action. It merely held that there is no "welcome mat" inviting federal jurisdiction for such cases. *Grable & Sons, 125 S.Ct. at 2370.* What barred federal jurisdiction in *Merrell Dow* was that [**24] it would have attracted a "horde of original filings and removal cases" to federal court. Such a stampede would have bruised federal comity. *Ibid.* The *Montana* decision to remand Minnesota's case to state court was issued before *Grable and Sons* and rested on the once-common interpretation *of Merrell Dow* that it barred federal jurisdiction over state-law claims that used, as a standard, a federal law for which Congress had not provided a right of action. *Montana, 266 F. Supp. 2d at 257.* The *Grable and Sons* Court held that interpretation incorrect. For this reason, the *Montana* court's ruling is not persuasive.

Counsel for Santa Clara also argued that *Pharmacia* and *Wisconsin* persuasively found that federalizing a case such as this one would upset the proper balance of judicial responsibilities. n4 This order disagrees. The

Wisconsin court's first rationale was that the state had as much of an interest in Medicaid drug prices as did the federal government. This analysis confounds two aspects of the *Grable and Sons* analysis: judicial balance and the substantiality of the federal interest. Whether the federal interest is strong is [**25] a question for the substantiality analysis, not the balance analysis. The instant case is also distinct: it involves a federal contract whereas none was at issue in *Wisconsin*. The instant case therefore has a higher quotient of federal interest. The *Wisconsin* court's second rationale was that allowing federal jurisdiction would disrupt the balance of judicial responsibilities to a degree more akin to that feared in *Merrell Dow* than that feared in *Grable and Sons*. Like *Merrell Dow*, the instant case uses a federal standard to measure violation of state-law statutory and common law. But, unlike *Merrell Dow*, the instant cases may involve interpretation of a federal contract under federal common law, the type of task that already falls to federal courts. The *Wisconsin* court also reasoned that, although many drug-pricing cases already were in federal court, this did not reflect the proper balance because those removals took place before *Grable and Sons*. This proves little because, if *Grable and Sons* actually changed the law to deprive those courts of jurisdiction, they could have remanded them to state court *sua sponte*. *See, e.g., Csibi v. Fustos, 670 F.2d 134, 136 & n.3 (9th Cir. 1982)* [**26] ("[L]ack of subject matter jurisdiction can be raised by a court's own motion at any time. . . . [I]t is the duty of the federal courts to assure themselves that their jurisdiction is not being exceeded."); *White v. Gittens, 121 F.3d 803, 806 (1st Cir. 1997)* ("[A] court has an obligation to inquire *sua sponte* into its subject matter jurisdiction, and to proceed no further if such jurisdiction is wanting."). They have not, so far as counsel have identified, done so. This order also disagrees with the *Wisconsin* court's suggestion that moving all state cases involving drug pricing to federal court would work a disruption akin to that feared by the *Merrell Dow* Court. *See Wisconsin, 390 F. Supp. 2d at 823-24*. In *Merrell Dow*, the plaintiffs claimed negligence, breach of warranty, strict liability, fraud and gross negligence. *478 U.S. at 805*. [*1031] For some of these claims, violation of a statute often proves both duty and breach. Allowing such a slim connection to federal law to create *Section 1331* jurisdiction would have moved many garden-variety tort claims from state to federal court. The same can hardly be said in the instant [**27] case. Violation of federal law will rarely be a presumptively conclusive element of claims for accounting, unjust enrichment, false claims or unfair competition. The instant drug-pricing case probably falls somewhere between *Grable and Sons*, on the one hand, and *Merrell Dow*, on the other.

n4 *Pharmacia* quoted *Wisconsin* but added no new analysis. *See 2005 U.S. Dist. LEXIS 27638, 2005 WL 2739297 at *4*. All references to the analysis of *Wisconsin* apply equally to *Pharmacia*.

As a final matter, this Court notes that the federal-question decisions in *Wisconsin* and *Pharmacia* were not essential in granting the motions for remand. In each case, removal had been procedurally defective and provided an independent and adequate reason to remand to state court. *Wisconsin, 390 F. Supp. 2d at 824*; *Pharmacia, 2005 U.S. Dist. LEXIS 27638, 2005 WL 2739297 at *2*.

There is no reason to believe that allowing federal jurisdiction over cases such as the instant one would tip the balance of federal-state judicial [**28] responsibilities. As noted above, such cases already have been heard in both federal and state fora. Furthermore, complaints such as the instant one tend to be class actions, reducing any increase in the number of additional cases such jurisdiction would put into federal courts.

Finally, this order's determination that there is federal jurisdiction comports with the requirement that the removal statute be construed strictly. *Shamrock Oil & Gas, 313 U.S. at 108-09*; *see Duncan v. Stuetzle, 76 F.3d 1480, 1484-91 (9th Cir. 1996)* (analysis identical to this order's consideration of the necessity of the federal issue).

In summary, this order diagnoses the instant action as terminally federal in nature. The district court has federal-question jurisdiction over the complaint.

3. MOTION FOR JOINDER

Santa Clara moves for necessary joinder of three medical distributors under *Federal Rule of Civil Procedure 19(a)*.

It seems obvious that this *Rule 19(a)* argument is a tactic in Santa Clara's larger remand strategy. By deeming the wholesalers part of this case, in a sort of *nunc pro tunc* way, the county hopes [**29] to defeat the diversity basis for removal (*see* Br. 6 ("[T]he propriety of the Court's jurisdiction based upon diversity of citizenship is ordinarily determined at the time the Complaint is filed, ***unless*** the joinder of a party would defeat diversity jurisdiction, in which event the action must be remanded or dismissed."). That strategy would fail, in all events, for the reason that federal-question removal jurisdiction is sufficient without regard to diversity. A separate stand-alone motion for joinder has been made, however. This order therefore must address it.

[HN7] The heart of *Rule 19(a)* is a disjunctive analysis. If either of two prongs is satisfied, joinder is mandatory. First, if complete relief cannot be had between the parties, joinder is required. Second, the court must join the non-party if it has a legally protected interest in the subject of the action and disposition in its absence would either (1) impede or destroy its ability to protect that interest or (2) leave the parties subject to a "substantial risk" of multiple or inconsistent obligations. *FRCP 19(a)*.

Santa Clara seeks to join McKesson Corp., AmerisourceBergen [**30] Corp. and Cardinal Health, Inc. These wholesalers contract with the counties to provide defendants' medications. They allegedly failed to pass on the requisite discounts (Br. 2, 9).

[*1032] Joinder of the distributors is not required to accord complete relief among Santa Clara and defendants. Santa Clara claims that it needs the Court to order the distributors to sell pharmaceuticals at discounted prices (Br. 11-12). This Court's inability to issue such orders absent joinder does not preclude complete relief among the parties already present. It only prevents complete relief as between Santa Clara and the wholesale distributors. This argument therefore collapses.

Santa Clara also claims that complete relief would require a constructive trust to be imposed upon the distributors so that they would not dissipate the overcharges Santa Clara paid to them. Even assuming that a constructive trust is a proper remedy here, imposition of one would not be necessary. Defendants have more than enough assets to satisfy any judgment in this case.

Santa Clara also claimed at the hearing that full relief is impossible without joinder because the distributors' non-party status would hamper its discovery [**31] efforts (*see also* Reply 15). Santa Clara did not back up this claim with any example of the discovery that (1) is so important that without it complete relief cannot be afforded and (2) the distributors would be more likely to give up if they were joined. This argument borders on the frivolous.

Plaintiff argues that its request for an accounting cannot be accomplished without joinder (Br. 8). [HN8] An accounting is an equitable remedy by which a party opens its books so that the other side may calculate amounts owed. In the instant case, the amount owed, if any, to Santa Clara by defendants can be determined in two steps. First, calculate the proper price of the drugs using defendants' sales records and price calculations prescribed by federal statute and contract. Second, determine for which purchases the health-care providers sought reimbursement. All of this information is held either by Santa Clara, its health-care providers or defendants. There is no need to pry into distributors' books outside of normal civil discovery. Santa Clara's accounting-remedy argument therefore does not justify joinder under *Rule 19*.

The county additionally claims that, without joinder, it would have [**32] no way to determine whether defendants met their purported obligation to "ensure that distributors pass along the discounts" (Br. 8). Why not? Santa Clara made no persuasive effort to explain. Again, normal civil discovery seems likely to solve this problem. Furthermore, this alleged problem could not present a difficulty in according relief. It merely would make it more difficult for Santa Clara to prove liability. This argument is therefore rejected.

Santa Clara also argues that joinder is necessary to protect the distributors because of the scope of discovery to which they will be subjected: "[b]ecause the distributors will have the burden of producing all of the relevant evidence[,] they must also have the ability to defend themselves afforded to litigants" (Reply 14). It is silly to suggest that the distributors will have the burden of producing "all of the relevant evidence." Furthermore, Santa Clara can point to no way in which these discovery issues would impact the distributors' interests implicit in this litigation, namely their contracts with Santa Clara and defendants. This argument fails.

Santa Clara additionally claimed at the hearing and in its briefs that, if [**33] the distributors are not joined, disposition of the action will impair their ability to protect the interests they have in contracts with Santa Clara due to the effects of collateral estoppel (Br. 10-11). These arguments were dead on arrival.

[HN9] The collateral estoppel doctrine stands for the principle that when a final judgment has determined an ultimate issue [*1033] of fact, it is conclusive in any subsequent lawsuit based on different claims but involving a party to the prior litigation. *Ashe v. Swenson, 397 U.S. 436, 443, 90 S. Ct. 1189, 25 L. Ed. 2d 469 (1970)*; *Montana v. United States, 440 U.S. 147, 153, 99 S. Ct. 970, 59 L. Ed. 2d 210 (1979)*. Even some entities that were not party to the original litigation may be bound by it. This generally applies, however, only when they effectively were represented in the first litigation and had interests closely aligned with the actual party. *See, e.g., Sea-Land Servs., Inc. v. Gaudet, 414 U.S. 573, 593-94, 94 S. Ct. 806, 39 L. Ed. 2d 9 (1974)* ("[B]eneficiaries are bound by the judgment with respect to the interest which was the subject of the fiduciary relationship.") (internal citation omitted).

Santa Clara has presented no facts to suggest that the instant case could have any [**34] collateral-estoppel effect on the distributors. The distributors do not have a representative and closely aligned relationship with defendants in the context of this litigation. Their interests

actually might be antagonistic to one another, given the possibility that each might blame the other for any alleged overcharges. Furthermore, Santa Clara wants it both ways: in one sentence, it asserts that the distributors would be bound by preclusion and -- in the very next sentence -- it asserts that they must be protected because defendants would not properly represent their interests (Br. 11). Like a fatal drug interaction, the combination of these arguments mortally wounds this motion for joinder. n5

n5 Because there is no possibility that collateral estoppel would prevent the distributors from fully litigating any separate disputes with Santa Clara, its reliance upon *Takeda v. Northwestern National Life Insurance Co., 765 F.2d 815 (9th Cir. 1985)*, and *Aguilar v. Los Angeles County, 751 F.2d 1089 (9th Cir. 1985)* is misplaced. *See Takeda 765 F.2d at 821* (premising joinder of a party on the possibility that it might be collaterally estopped from litigating the same issues in future litigation) and *Aguilar, 751 F.2d at 1092-94* (same).

[**35]

Santa Clara pretends to worry about defendants, asserting that they may be subject to a substantial risk of inconsistent judgments if the distributors must be sued in a separate lawsuit. It does not specify, however, how any judgments would be inconsistent. Presumably, the judgment in any action solely against distributors would be binding only upon the distributors and would not require any remedy necessitating action on the part of the manufacturers.

Plaintiff also argues that, if it is not granted its *Rule 19* motion for joinder, it will be "required" to file a second action against the distributors. Not so. *Rule 19* is not the only procedure to get distributors into the case. *Rule 20* is another way to do so. Santa Clara is free to file a motion under the more permissive standards of *Rule 20*. Santa Clara is always free to bring a normal motion to amend. The accompanying case management order will invite Santa Clara to do so.

Santa Clara has not made a sufficient showing that joinder is necessary to force distributors into this lawsuit. The *Rule 19(a)* motion is therefore denied.

CONCLUSION

This order holds that the instant case is removable because there is federal-question [**36] jurisdiction. It therefore has no need to address diversity-jurisdiction issues raised by both sides. The motions for remand and, in the alternative, for dismissal are **DENIED** for the reasons stated above. Joinder is unnecessary so the *Rule 19(a)* motion also is **DENIED.**

IT IS SO ORDERED.

Dated: December 2, 2005

WILLIAM ALSUP

UNITED STATES DISTRICT JUDGE