

THE STATE OF TEXAS	§	IN THE DISTRICT COURT OF
	§	
<i>ex rel.</i>	§	
VEN-A-CARE OF THE	§	
FLORIDA KEYS, INC.	§	
	§	
<i>Plaintiffs,</i>	§	
	§	TRAVIS COUNTY, TEXAS
v.	§	
	§	
WARRICK PHARMACEUTICALS	§	
CORPORATION, SCHERING-PLOUGH	§	
	§	
CORPORATION, SCHERING	§	
CORPORATION	§	
ROXANE LABORATORIES, INC.	§	
	§	
<i>Defendants.</i>	§	53 <sup>rd</sup> JUDICIAL DISTRICT

**SEVENTH AMENDED PETITION**

TO THE HONORABLE JUDGE OF SAID COURT:

The State of Texas, by and through the Attorney General of Texas, Greg Abbott, brings this cause of action. These claims are asserted pursuant to the Texas Medicaid Fraud Prevention Act, V.T.C.A. Human Resources Code Chapter 36 (“the Act” or “TMFPA”) and common law. Pursuant to §36.107(a) of the Act, the State of Texas has primary responsibility for prosecuting this action. Private Person Plaintiff/Relator Ven-A-Care of the Florida Keys, Inc. (“VAC” or “Ven-A-Care”) originally provided information to the State of Texas which is the basis for this suit and is included as a named party plaintiff in this case.

***STATEMENT TO THE COURT ONLY***

The Dey/Merck Defendants prominent in Plaintiffs’ Sixth Amended Petition are not specifically named in this pleading because a compromise settlement with these parties is imminent. However, by the omission of naming of these parties in this pleading, Plaintiffs DO NOT intend to non-suit them. Separate agreed orders will be submitted at a later time to accomplish that purpose.

Until that time, in order to preserve claims against the Dey/Merck Defendants, Plaintiffs incorporate by reference the allegations against Dey/Merck as contained in Plaintiffs' Sixth Amended Petition.

## **I. DEFENDANTS**

The Defendants complained of and sued in this action are:

1.1 Warrick Pharmaceuticals Corporation ("Warrick") allegedly is a corporation organized under the laws of Delaware with its principal offices in Reno, Nevada. Discovery in this matter has revealed that Warrick's principal offices and operations are actually in the state of New Jersey. At all times material to this civil action, Warrick has transacted business in the State of Texas by, including but not limited to, selling and distributing to purchasers in the State of Texas pharmaceutical products that are the subject of this action, but does not maintain a regular place of business in this state or a designated agent for service of process

1.2 Schering-Plough Corporation ("Schering-Plough") is a corporation organized under the laws of New Jersey with its principal offices in Madison, New Jersey. At all times material to this civil action, Schering-Plough and its subsidiaries have transacted business in the State of Texas by, including but not limited to, selling and distributing to purchasers in the State of Texas pharmaceutical products that are the subject of this action and out of which this action arises.<sup>1</sup>

1.3 Schering Corporation ("Schering") is a corporation organized under the laws of New Jersey with its principal offices located at 1 Giralda Farms, P.O. Box 1000, Madison, New Jersey 07940

1.4 Defendant Warrick has indicated in other pleadings to this Court that Schering-Plough is a stock holding company and that Schering is the direct parent corporation of Warrick. Schering

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<sup>1</sup> Schering Laboratories is described as "the U.S. pharmaceutical arm of Schering-Plough Corporation," and appears to be the operating unit of Schering-Plough through which Schering-Plough conducts much of its pharmaceutical business. It is unclear at this point whether Schering Laboratories exists as a separate corporate entity. Schering Laboratories is not registered with the Secretary of State for the State of Texas.

and Schering-Plough are the actual manufacturers, marketers, sellers, and/or suppliers of the products involved in this litigation and are Warrick's actual parent(s) or shareholder(s). Therefore, the State includes Schering and Schering-Plough ("Schering/Schering-Plough") in this pleading.

1.5 Roxane Laboratories, Inc. ("Roxane") is a corporation organized under the laws of Delaware with its principal offices in Columbus, Ohio, and is a subsidiary of Boehringer Ingelheim Pharmaceuticals, Inc.. At all times material to this civil action, Roxane has transacted business in the State of Texas by, including but not limited to, selling and distributing to purchasers in the State of Texas pharmaceutical products that are the subject of this action, but does not maintain a regular place of business in this state or a designated agent for service of process.

(All of the above named Defendants have answered and appeared in this cause.)

## ***II. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY***

2.1 The Defendants specified in paragraphs 1.1 to 1.5 are sometimes referred to herein collectively as the "Defendants" or "Defendant Drug Companies." Any and all acts alleged herein to have been committed by any or all of the Defendant Drug Companies were committed by said Defendants' officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s).

2.2 The Defendants identified in paragraphs 1.1 to 1.3 inclusive are all related entities sharing common elements of management, finances, control, supervision, reporting and thus are mutually, jointly and severally liable under legal theories of Respondeat superior and the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity.

### ***III. DISCOVERY CONTROL PLAN***

3.1 Plaintiff, the State of Texas, designates this case as a Level 3 case requiring a discovery control plan tailored to the circumstances of this specific suit.

### ***IV. PRELIMINARY STATEMENT AND NATURE OF THE ACTION***

4.1 This is an action under the common law and the Texas Medicaid Fraud Prevention Act (hereinafter sometimes referred to as “TMFPA”) for restitution, damages, pre-judgment interest, civil penalties of not less than \$1,000.00 or more than \$10,000.00 for each unlawful act, two (2) times the value of the payments, and recovery of costs, attorneys’ fees, and expenses of the Attorney General of the State of Texas and Ven-A-Care against Defendants as well as any and all other monetary amounts as may be allowed at law or in equity under Section 36.052.

4.2 The Defendants knowingly and intentionally made false representations of prices and costs for certain of their inhalation drugs directly or indirectly to the Texas Medicaid Program. The Defendants knew that the Texas Medicaid Program intended to base its payments of claims for the specified drugs on estimations of acquisition costs incurred by physicians, pharmacies, and other providers submitting claims for payment. The Texas Medicaid Program relied on the false and misleading prices and costs reported by the Defendants and thus was defrauded into paying reimbursement in excessive amounts.

4.3 The Defendants, both directly and through sales visits and presentations, telemarketing, and other forms of contact, as well as indirectly through various pharmacy inventory software distributed by wholesalers and other pharmacy inventory software, as part of an unlawful combination, marketed their specified products to pharmacies, in part through financial inducements, including but not limited to: false price markups, the difference between actual cost and

reimbursement (the “Spread”), discounts, rebates, chargebacks, free goods, and other financial incentives. As specified more fully hereinafter, such conduct constitutes common law fraud as well as fraud under the TMFPA, Chapter 36, Tex. Hum. Res. Code. The Defendants were in a position to mislead the Texas Medicaid Program, in part, because other drug manufacturers typically reported truthful prices for brand drugs marketed under patent protection that are not the subject of this action. The Defendants thus wrongfully exploited and defrauded the Texas Medicaid Program by inducing it to pay the claims of pharmacies, at grossly inflated amounts that far exceeded a reimbursement based upon a reasonable estimate of acquisition costs of those Defendants’ pharmaceuticals to pharmacies, wholesalers and distributors.

(Amendment Responsive to Special Exception)

Plaintiffs seek redress and recovery under the TMFPA as well as under principles of Common Law Fraud as an alternative claim under T.R.C.P. Rule 48. The Defendants Warrick, Schering-Plough and Schering, acting sometimes in combination and other times individually did the following:

- (a) Made material representations to the TVDP as to prices and costs of drugs which information was used to calculate reimbursement for those drugs.
- (b) Reported drug prices and costs which were false and misleading.
- (c) Knowingly reported such false, misleading and material information to TVDP and other price and cost reporting services as well as creating “dummy prices” and invoices which were misleading and concealing of true information.
- (d) Committed these acts and omissions with the intent and knowledge that TVDP would use and rely on directly reported information and would be further misled if price and cost information reported to national pricing services was accessed as verification of

directly reported information, when the TVDP made its decisions concerning reimbursement amounts to be paid for the drugs at issue.

- (e) That the false information supplied by Defendants was relied upon and was used to authorize Medicaid drug reimbursement payments greatly in excess of what should have been paid had Defendants provided non-fraudulent drug price/cost information as required by common law fraud principles and by state and federal Medicaid law and regulations.
- (f) The foregoing acts and omissions caused monetary loss and damage to the Medicaid program in Texas in amounts set forth in the “Damages” paragraphs of this pleading.

4.4 (Amended in response to Special Exceptions.) Defendants also combined and otherwise acted in concert, amongst themselves, their wholesalers, their distributors, their customers, or their competitors, and as part of an illegal combination to defraud the Medicaid program in Texas of millions of dollars in payments by supplying falsely inflated price information on certain drugs. By definition under relevant Texas Statute Law, Tex. Penal Code Ann. § 71.01 a combination means three or more persons (companies) who collaborate to bring about an unlawful result although:

- (1) participants may not know each other’s identity;
- (2) membership in the combination may change from time to time; and
- (3) participants may stand in a wholesaler-retailer or other arm’s length relationship.

It is not essential to the existence of such an illicit combination that the members thereof consciously agree and intentionally conspire in joint enterprise. Pleading in the alternative as allowed under T.R.C.P. 48 it is alleged that the named Defendants in this case acted intentionally in combination with each other (Warrick, Schering-Plough and Schering) and even though outside of a direct or indirect agreement and conspiracy, with other persons and companies in the generic pharmaceutical

industry to create, maintain and promote a system of reporting and marketing which would reward these Defendants as well as others for going along in combination to perpetuate the schemes described in detail herein. Not all of these “other persons and companies” are known and not all can be known at this time.

The other companies who are known to have acted in combination with Warrick and/or Schering-Plough and or Schering are:

- (a) Wholesalers: McKesson, Bergen-Brunswig, Cardinal, AmeriSource, Fox Meyer, and Bindley Western
- (b) Regional Wholesalers: Walsh and Morris & Dickson
- (c) Institutional Purchasers: RDI (Respiratory Distributors, Inc.), Apria, Caremark and Gerimed (AKA I.V. Med)
- (d) Generic Wholesalers: J.J. Balan, ANDA and Harvard
- (e) Price Publishing Services: First Data Bank, Medi-Span and Red Book

The other companies who are known to have acted in combination with Roxane are:

- (a) Cardinal, McKesson, Bergen-Brunswig, and AmeriSource
- (b) Morris & Dickson
- (c) Apria, RDI (Respiratory distributors, Inc.), and Gerimed (AKA I.V.Med)
- (d) First Data Bank, Medi-Span and Red Book

Some or many of these identified companies may not have been aware that their conduct in being a part of such combination was allowing or facilitating violations of the TMFPA. Whether or not the other members of such combination acted with intent to violate any law is irrelevant to the claims asserted herein against the named Defendants. For example some wholesalers did agree or acquiesce to use invoices and billing records which did not overtly disclose and reflect multiple

conditions and terms which caused the actual price/cost of drugs to be much less than what was reflected on invoices and billing records. These other members of such combination may or may not have engaged in the conduct actionable under the TMFPA and without question they, whoever they are, have not been sued in this case. The liability of the named Defendants herein is neither dependent upon nor contingent upon liability of other members of the combination. The Defendants' creation, maintenance and promotion of the combination of persons and companies nurtured the scheme of creating the large "spread" on the reimbursement of the subject Medicaid drugs. The relevance and importance of the existence of the combination is to show that the named Defendants were knowing and willing participants in the creation and promotion of this combination which caused Texas Vendor Drug Program to be defrauded.

4.5 (Amended in Response to Special Exception) As is usually true of illegal combinations, the named Defendants in this case did not enter into a formalized written and dated combination agreement. However, the actions they took speak even more eloquently of their intent to defraud the Texas Medicaid Program operated by the Texas Vendor Drug Program (TVDP) and the taxpayers in the State of Texas and nationwide who fund the various Medicaid pharmaceutical benefit programs. Such activities began before 1994 and continue in some forms to the present date. The officers, managers, sales force and other employees of the named Defendants Warrick, Schering-Plough and Schering herein entered into an agreement or combination among themselves as follows:

- (a) By reporting false drug prices to the TVDP.
- (b) By failing and purposefully refusing to timely update and report declining drug prices.
- (c) By purposefully omitting and refusing to provide truthful drug prices which were specifically requested by category.

(d) By reporting false drug prices to TVDP and to recognized industry price reporting services with the intent (and result) of creating an illegal “spread” which caused the payment of inflated and excessive reimbursement amounts for each company’s relevant drugs named in this pleading.

(e) By directly and indirectly causing their own sales and marketing force employees, as well as independent contractor telemarketers, to “market the spread” by advertising and urging pharmaceutical vendors to purchase and dispense their particular brand of drugs based upon the illegally inflated and excessive reimbursement amounts made possible by the combined actions of the Defendants and others in the industry. Some or all of these acts and omissions also constitute common law fraud as well as violations of TMFPA.

4.6. (Amended in Response to Special Exception) The Defendants created, promoted and fostered a complex scheme using undisclosed chargebacks, rebates, discounts, instant rebates, price protection, stock adjustments and contract prices which had no true and bona fide business purpose other than to enable the use of arbitrary pricing on invoices and other ostensible purchase records and documents which concealed the true sales prices and acquisition costs. In fact, these false invoices only revealed “Dummy Prices” and other incorrect and misleading financial information which would hinder or prevent the discovery of true price/cost information by persons and organizations which might need to investigate, survey or audit invoices in search of true price/cost information. By causing their various customers to accept and acquiesce in these extraordinary invoicing practices, these Defendants created and maintained various combinations with other companies as identified in paragraph 4.4 who participated in the combination(s) but who may have been completely unaware and unconcerned about the reasons for ~~or~~ and results of these extraordinary invoicing methods and procedures.

4.7 (Amended in Response to Special Exception) With regard to the Defendants Warrick, Schering-Plough and Schering and their efforts to deal with activities of Dey, Inc. and its affiliates (all parties who were originally Defendants in this case but who have now settled), it is alleged that the Defendants, acting through their authorized officers and employees, engaged in a game of one-upsmanship in that when one would report fraudulent prices to authorities so as to create a more attractive profit spread on Medicaid reimbursement prices, the other would compound its fraudulent actions by reporting an increasingly inflated price in order to “out-fraud” the other. These activities have been documented in documents and deposition testimony pertaining to both Dey and Warrick.

4.8 Defendants Warrick, Schering and Roxane made conscientious efforts in their business operations avoid reporting truthful price/cost information. Furthermore, their legal obligations to truthfully and candidly report such information to Medicaid authorities in Texas and elsewhere and to price reporting services was intentionally subverted or ignored. Thus, the Defendants were able to further the combinations by limiting disclosure or deleting the publication or reporting of such information. Also, certain of Roxane’s employees whose job it was to report price/cost information and to comply with all legal requirements, including those of the State of Texas, were intentionally instructed: (a) to provide incorrect or incomplete price/cost information or (b) to fail to supply all requested and required price/cost information and updates about changes in such data.

## **V. JURISDICTION & VENUE**

5.1 Jurisdiction over the subject matter is founded in part upon the TMFPA, which prohibits, and provides exclusive remedies to redress, the conduct of the Defendants and which

provides for this action to be brought by the State of Texas and by Private Person Plaintiff, Ven-A-Care.

5.2 Venue is proper in Travis County pursuant to Texas Human Resources Code §36.052(d) in that many of the unlawful acts committed by the Defendants were committed in Travis County including the making of false statements and misrepresentations of material fact to the State of Texas, its departments, agencies, instrumentalities, contractors and to the Texas Medicaid Program.

5.3 A copy of pleadings and written disclosure of substantially all material evidence and information Ven-A-Care possesses were served on the State pursuant to §36.102 of the Act before the Original Petition was filed.

5.4 The Private Person Plaintiff is the original source of the information and has direct and independent knowledge of the information on which these allegations are based within the meaning of §36.113(b) of the Act and has voluntarily provided the information to the State of Texas before filing pleadings which are based upon the information provided by the Private Person Plaintiff

to the State of Texas.

5.5 Additionally, venue is proper against these Defendants in Travis County as all or a substantial portion of the events giving rise to the instant claims occurred in Travis County. TEX. CIV. PRAC. & REM. CODE §§ 15.001, 15.002 (Vernon 2001).

## **VI. BACKGROUND: HOW PHARMACEUTICAL CLAIMS ARE PAID UNDER THE MEDICAID PROGRAM IN TEXAS**

6.1 The Texas Medicaid Program pays for the use of approved pharmaceuticals provided to Medicaid recipients by eligible providers, including pharmacies. The Vendor Drug Program (TVDP) of the Texas Department of Health (“TDH”)<sup>2</sup> administers this program. Providers can only obtain reimbursement through the Vendor Drug Program for products listed on the Texas Drug Code Index. 25 TEX. ADMIN. CODE § 35.201. To have its particular pharmaceutical products listed on the index, a drug company or manufacturer must file and have approved an application for its products with the Texas Department of Health. 25 TEX. ADMIN. CODE § 35.801. Section 2 of the application requires the manufacturer to report, for each drug submitted, the suggested wholesale price to pharmacies, the price at which the drug is sold to wholesalers and distributors, the direct price to pharmacies, the price to chain warehouses and the price at which the drug is sold to any other special purchasing groups. Additionally, the form contains a separate question in section 4 inquiring as to whether the drug company sells the drug to wholesalers or distributors. The application requires that a manufacturer certify that the information it has provided is correct

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<sup>2</sup> The Vendor Drug Program has recently been transferred to the Texas Health and Human Services Commission.

and that it will provide correct information regarding subsequent changes in pricing of the product within 15 days of such changes occurring. Further, in approving the application, TDH expressly requires that supplemental updated price information be provided timely.

6.2 TDH bases its reimbursement schedule on the prices reported by the manufacturer on the application and subsequent price changes supplied by the manufacturer. Reimbursement to a pharmaceutical provider (i.e., a pharmacy or physician) is based on TDH's best estimate of acquisition cost, referred to as ("EAC"). 1 TEX. ADMIN. CODE § 355.8541 (1).

6.3 When a manufacturer reports false pricing information to TVDP, the calculation of estimated acquisition cost ("EAC") is inflated and thus the reimbursement schedule is also inflated. These circumstances result in drug reimbursement overpayments to drug providers by the State.

## **VII. ACTIONABLE CONDUCT OF DEFENDANTS**

7.1 The Defendants knew that reporting false drug prices and costs would cause the Texas Medicaid Program to be unable to reasonably estimate acquisition costs and it would thus pay excessive reimbursement to the Defendants' Medicaid provider customers. Notwithstanding this knowledge, the Defendants reported false or misleading price, cost, or sales information to the Texas Medicaid program in order to cause it to pay claims for their specified pharmaceuticals in amounts that exceeded the prices at which the Defendants actually sold their products and exceeded a reasonable estimation of acquisition cost. This reporting of false information created a "spread" between the amount reimbursed by Medicaid and a reasonable estimate of the acquisition cost of a drug. The "spread" financially benefitted their Texas Medicaid provider customers and thus induced them to order, prescribe, dispense, or administer the Defendants' specified pharmaceuticals. The specific allegations of Common Law Fraud contained in preceding paragraph 4.3 are incorporated by reference and are specifically asserted against the Defendant Roxane.

7.2 The Defendants were each fully capable of making truthful representations about prices and costs of the specified pharmaceuticals and did so when it was economically beneficial to

them, such as when they reported Average Manufacturers' Prices and Best Prices to the federal government under the Medicaid rebate program mandated by the Omnibus Budget Reconciliation Act of 1990 ("OBRA'90").

7.3 Notwithstanding the Defendants' knowledge that they were required to provide truthful price information vital to Texas Medicaid's ability to estimate the acquisition cost, the Defendants each knowingly or intentionally reported false price information about the specified pharmaceuticals.

7.4 The Defendants acted knowingly or intentionally in making false statements and misrepresentations of material fact when reporting false prices or costs to the Texas Medicaid program in one or more of the following ways:

A. Reporting false prices on initial applications to have specified pharmaceuticals covered by Texas Medicaid;

B. Concealing or otherwise failing to disclose decreases in the prices or costs of the specified pharmaceuticals;

C. Concealing or otherwise failing to disclose transactions that decrease the cost, and thereby the price, of the specified pharmaceuticals such as discounts, rebates, off-invoice pricing, free goods, cash payments, chargebacks, or other financial incentives;

D. Reporting that the price or cost of a specified pharmaceutical was increasing when it in fact was increasing in a lesser proportion, or remained the same, or was decreasing;

E. Reporting that the price or cost of a specified pharmaceutical was the same when in fact it was falling; and

F. Reporting that specified pharmaceuticals were not sold to a specific sector or segment of the market (also known as a "class of trade") when in fact they were, regularly and in significant quantities concealing or failing to disclose such facts.

These acts and omissions were committed by the named Defendants of their own volition and in combination with each other and with other segments of the pharmaceutical industry, knowing that Medicaid officials would rely upon such false information and thus constitute violations of Texas Medicaid Fraud Prevention laws as well as constituting common law fraud.

7.5 Between 1990 and the present, Defendants Schering and/or Schering-Plough also directly marketed and sold “Warrick” products<sup>3</sup> through Schering/Schering-Plough’s “third party home healthcare solution business”, “Production Planning” and/or “Managed Care” divisions, and possibly through other divisions and/or personnel. Schering/Schering-Plough marketed and sold these “Warrick” drugs to customers at prices far below the false prices of the drugs reported by Schering/Schering-Plough and/or Warrick for reimbursement purposes. As a result, customers purchasing these “Warrick” drugs from Schering/Schering-Plough knew they would receive, and did receive, windfall reimbursements as a direct result of the misrepresentations made by Schering/Schering-Plough and/or Warrick to reimbursers, including the Texas Medicaid Program.

7.6 To accomplish this scheme, between 1990 and the present Schering/Schering-Plough sold identical products deriving from the exact same New Drug Application(s), but marketed the drugs differently. Schering/Schering-Plough marketed its drug “Proventil” as a brand with few, if any, discounts and marketed the same Proventil drug under a “Warrick” label and NDC number as a “generic” upon which it offered deep discounts while reporting false price information to Texas. In both instances the two differently labeled product types were made at the same location, and in all chemical and regulatory respects brand products approved by the FDA under a New Drug Application. The only difference between the two types of products was that the “Warrick” products (also referred to as the “brand, generic” in Schering/Schering-Plough/Warrick documents) were marketed and sold at significantly lower prices than the Schering/Schering Plough Proventil

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<sup>3</sup> Some, if not all, of these drugs are at issue in this litigation and are listed in the attached Exhibit A, incorporated herein by reference.

products; thereby providing the purchasers of the “Warrick” drugs with large spreads and large windfall reimbursements as described herein. Schering/Schering Plough used the Warrick label and NDC number to implement a marketing program which induced customers to choose Warrick’s albuterol, which was in fact Schering’s Proventil, over competing products based upon the large windfall reimbursements the customers would receive.

**VIII. THE ACTIONS OF DEFENDANTS CONSTITUTE “UNLAWFUL ACTS” AND VIOLATE THE TEXAS MEDICAID FRAUD PREVENTION ACT**

8.1 At various times on or after September 1, 1995, and continuing through the present date, Defendants knowingly or intentionally reported to the State of Texas’ Medicaid Program false prices for the pharmaceuticals described in the attached Exhibit “A.”

8.2 Defendants have repeatedly and continuously violated the TMFPA. The Act specifies 10 separate acts which are declared to be unlawful. At least four of those unlawful acts were committed by the Defendants in this case on numerous occasions. The Act prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person’s eligibility for a payment under the Medicaid Program. TEX. HUM. RES. CODE § 36.002(1). The Act further prohibits a person from knowingly or intentionally concealing or failing to disclose an event that permits a person to receive a benefit or payment that is not authorized, or that permits a person to receive a benefit or payment that is greater than the benefit or payment that is authorized. TEX. HUM. RES. CODE §36.002(2). Additionally, the Act prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program.

TEX. HUM. RES. CODE §36.002(4). The act also prohibits a person from knowingly or intentionally entering into an agreement combination or conspiracy to defraud the State by obtaining or aiding another to obtain unauthorized Medicaid payments or benefits §36.002(9).

8.3 The Defendants have knowingly or intentionally communicated false price or cost statements or other material misrepresentations or omissions on the Application for Addition of Drugs to the Texas Drug Code Index for certain drugs manufactured by Defendants and subsequent price updates provided by the Defendants in violation of §36.002(4) of the Act. Further, in violation of §36.002(1) of the Act, the Defendants failed to disclose the truthful prices paid by providers and concealed the existence of kickbacks, inducements, discounts, rebates, chargebacks, off invoice pricing, free goods, or grants which reduced the price paid by the Defendants' customers for certain drugs.

8.4 (Amended in Response to Special Exception) Also, in violation of § 36.002(9), the Defendants knowingly or intentionally entered into a combination with wholesalers or Group Purchasing Organizations ("GPO's") or Prescription Benefit Managers or Pharmaceutical/Pharmacy Benefit Managers ("PBM's") or pharmacies (including chain pharmacies) to defraud the State of Texas by obtaining or aiding another person in obtaining unauthorized payments or benefits from the Medicaid program by misrepresenting the prices paid to manufacturers by wholesalers and the prices paid by pharmacies (including chain pharmacies) to manufacturers, as well as by concealing the remunerations paid by manufacturers to GPO's or PBM's. The facts set forth in preceding paragraphs 4.4, 4.5 and 4.6 are incorporated by reference to specify the allegations of a combination under § 36.002(a).

8.5 (Amended in Response to Special Exception) Pleading more specifically, and in addition to the foregoing, the Plaintiff and Relator would allege and show as follows with respect

to other entities and sectors of the pharmaceutical industry who participated directly or indirectly in the combination mentioned previously:

1. The named Defendants entered into a combination and course of dealings with the following as limited by paragraph 4.4:

(a) National Full Line Wholesalers; McKesson, Bergen, Brunswick, Cardinal, AmeriSource, FoxMeyer, Bindley Western.

(b) Regional Full Line Wholesalers (which conducted business and sold the Relevant Drugs of the named Defendants within the State of Texas); Walsh, Behrens, and Morris & Dickson.

(c) Institutional Purchasers; Gerimed, RDI (Respiratory Distributors, Inc), Apria, Accurate Pharmacy, Caremark, Rx Med, MHA (Managed Healthcare Associates).

These other identified companies are not named as Defendants in this suit and no relief or recovery is sought against them herein at this time. These companies were named in response to a demand made by Defendants herein in Special Exceptions. The named Defendants already knew the identity of these other companies because Defendants are the very ones who created the schemes resulting in the combinations which perpetuated the schemes to violate the TMFPA. As part of the combination created by the named Defendants, these wholesalers and institutional purchasers were doing what the Defendants asked them to do or what they obviously were required to do to keep the business of the drug manufacturers. The state of mind and actual knowledge of the wholesalers and institutional purchasers is irrelevant and immaterial to the liability and culpability of the Defendants and the proof relating to their actions only goes to show that they were cogs in the illicit wheel created by the named Defendants. With respect to each wholesaler with which any Defendant joined

in combination, such universe of companies is finite and limited exclusively to those wholesalers with whom each respective Defendant sold its drugs or delivered drugs pursuant to contract. Thus, these wholesalers can be identified with certainty and limitation by each Defendants' own sales history records.

The foregoing wholesaler entities participated in informing and educating their respective pharmacy customers of each and every AWP for the Relevant Drugs. Furthermore, these wholesalers also published information which would reveal the difference between the stated AWP and/or reimbursement on the one hand and, the given pharmacy customer's cost on each of the respective generic products on the other hand. This difference is known as "spread"; "MAC spread", "Gross Profit", "Gross Margin" (among other phrases and terms used within the industry). This information enables virtually all pharmacies within the State of Texas to quickly and easily understand which generic drug will be most profitable to dispense in consideration of the reimbursement level set given the false prices reported.

Based upon documents obtained from the records of Schering/Warrick, it appears that Bindley Western, at one point in time asked to be released from contractual obligations to deal with invoices containing arbitrary, artificially inflated and false price information which served no legitimate business purpose and which caused unnecessary, costly and meaningless bookkeeping and accounting work to be done. Instead, Bindley Western asked to receive invoices in the future which more accurately represented the actual transactions reflected by the respective invoices.

8.6 To the extent that any of the aforementioned full line wholesalers, both regional and national, also offer what is known as "autosubstitution" and or "select", "source" programs which mandate the exclusive dispensing of a particular product within each therapeutic class by those wholesalers' pharmacy customers, these wholesalers choose the generic product which will have a

large “spread” and be most profitable to their customers pursuant to feedback and demand from such customers as a result of the tactics of the Defendants and others as described herein.

These companies were required or invited to participate in the schemes and combinations involving; disseminating reimbursement information, the exclusive use within a therapeutic class of a single generic product (based in part on profitability), dummy pricing, false and fraudulent invoices, hidden discounts, chargebacks, rebates, free goods, price protection plans, or accounting gimmicks to conceal true and accurate price/cost information.

8.7 With respect to Distributors (a/k/a “Generic Wholesalers”) of generic drugs, it is alleged that such Distributors/wholesalers likewise participated in a course of dealings which enabled the combination with named Defendants and which facilitated and enabled the “marketing of the spread” to pharmacies by use of Distributors, agents, employees, or independent contractor telemarketing companies and through telemarketing, sales calls and advertising (both electronically and by print).

Distributors/wholesalers which participated in these activities include Major, J. J. Balan, ANDA, Harvard, Genetco and others known collectively within the Warrick organization as the “Care Group” and “Premier Group”.

These distributors/wholesalers are not named as Defendants in this suit and no relief or recovery is sought at this time against them herein. They were named in response to a demand made by Defendants herein in Special Exceptions. The named Defendants already knew the identity of these other companies because Defendants are the very ones who created the schemes resulting in the combinations which perpetuated the schemes to violate the TMFPA. As part of the combination created by the named Defendants, these distributors were merely doing what the Defendants asked them to do or what they obviously were required to do to keep the business of the drug

manufacturers. The state of mind and actual knowledge of the distributors is irrelevant and immaterial to the liability and culpability of the Defendants and the proof relating to their actions only goes to show that they were cogs in the illicit wheel created by the named Defendants.

8.8 The Defendants Warrick and Schering entered into specific agreements and contracts with one or more telemarketing companies, including TMS (a/k/a Access Worldwide) a company located in the State of Florida, but doing business by making telephonic contacts in the State of Texas and other states. As part of telephone sales pitches, telemarketers would advertise and promote Warrick and Schering products in part by marketing the spread and urging purchases of these products based upon the large and profitable spread between the true net price the pharmacies would pay for the drugs and the high reimbursement amount; those pharmacies would receive; known as the “profit message” and/or ROI; among other phrases.

8.9 The Defendant Schering employed a group known as its Managed Care Sales Force and this group of marketers had as a part of their job responsibilities, the duty to call upon decision makers for Healthcare Management/Maintenance Organization, Pharmaceutical Benefits Manager, Hospitals and other Managed Care Organizations to explain the perspective of generic drug profitability on behalf of Schering and Warrick’s. Thus, employees and agents of Schering combined with Warrick to market the spread on Warrick products and to “bundle” Warrick and Schering products in a manner which was fraudulent and illegal.

8.10 In the TMFPA, The Texas Legislature has specified actions and omissions, conduct and combinations which are illegal and give rise to civil and criminal liability and penalties which can be imposed against drug manufacturers such as the named Defendants who themselves voluntarily chose to place their respective products into the Texas Medicaid Vendor Drug Program and thus submitted to and agreed to be bound by these rules and laws. This is a statute of absolute

strict liability. There are no stated and enumerated defenses and none are allowed. There are no references to common law defenses or allowances for mitigation. With a finding of any violation of the statute, liability is strictly imposed absolutely and the only remaining question is the amount of damages, penalties, fees and expenses to be assessed. This is precisely the same as the very similar Texas Deceptive Trade Practices Act as originally enacted in 1973. In its original form and before subsequent changes and amendments were added by later legislative enactment, there were no defenses to the liability strictly imposed by the DTPA and likewise there are no defenses to the strict liability imposed by the TMFPA.

8.11 (Amended based upon Court instruction to list all drugs, in addition to “damages drugs” which will be used to offer proof at trial)

The Primary drugs which evidence the differing motivations for sometimes, but not always reporting manipulated and misleading prices by Defendants are as follows:

Warrick: Cimetidine, Perphenazine, Albuterol tablets and Albuterol syrup

Schering: Proventil

Roxane: Haloperidol tablets, Mehotrexate tablets, Roxicet tablets, Mexiletine HCL capsules; Dexamethasone tablets, Meperidine, Azathioprine, Cyclophosphamide, Combivent, Lorazepam Intensol, Hydromorphone, Prednisone, Propranolol, Torecan, Azathioprine, Diclofenac Sodium, Hydroxyurea and Lithium Carbonate.

Evidence concerning other drugs is relevant, probative and admissible for at least three different reasons. Defendants were motivated to misrepresent price information when they could profit from such conduct by making one of their drugs more likely to be purchased due to the promise of higher reimbursement. This opportunity routinely and normally arose in the marketing of certain drugs such as those listed in this paragraph. This is the situation where creating the largest

“spread” worked its illegal magic. To the contrary, in the case of drugs where competitive pressures did not drive the misrepresentation of pricing, the tendency was to report prices which were correct and not misleading. An additional result of this situation was that Medicaid programs and officials were lulled into a false sense of security because sometimes many prices reported by a manufacturer would be fair and reasonable.

Therefore evidence that a drug manufacturer routinely reported non-misleading prices for certain drugs and misleading prices for other drugs is admissible:

1. Under T.R.E. 404 (b) as proof of motive, opportunity, intent, plan, knowledge and absence of mistake or accident.
2. Under T.R.E. 406 as proof of routine practice to consistently act illegally where profit resulted yet legally where the profit motive was less compelling and to show that such company was able to comply with the law and did know how to report prices that were not misleading where the motive to act illegally was lessened or missing.
3. Under T.M.R.P.A. § 36.052 (b)(1) through (5) for assessment of a civil penalty.

## **IX. THE COURT SHOULD DISREGARD THE CORPORATE FICTION FOR**

### **WARRICK, SCHERING, AND SCHERING-PLOUGH;**

9.1 The corporate fiction may be disregarded when the corporate form has been used as part of a basically unfair device to achieve an inequitable result, specifically when the corporate fiction is used to perpetrate a fraud, as a mere tool or business conduit of another corporation, as a means of evading existing legal obligations, to achieve or perpetrate a monopoly, to circumvent a

statue, or to protect crime or justify a wrong. *Castleberry v. Branscum*, 721 S.W.2d 270, 271 (Tex. 1986), *superseded on other grounds by* Tex. Bus. Corp. Act Ann. art. 2.21 A (Vernon 2002).

9.2 (Amended in Response to Special Exception) In addition to its own acts for which it is liable, Schering/Schering-Plough Corporation as the parent, owner and primary, if not exclusive, shareholder of Warrick Pharmaceuticals, Inc., is liable for the conduct of any and all agents of Warrick Pharmaceuticals Inc. Schering/Schering-Plough is liable for Warrick's wrongful activities under the equitable doctrines of joint business enterprise, single business enterprise, and alter ego. Each of these theories is advanced in the alternative. The facts set forth in paragraphs 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 7.5, 7.6, 8.2, 8.3, 8.4 and 8.5 are herein incorporated by reference to identify allegations asserted against Defendant Schering Corporation.

9.3 The following allegations support piercing the corporate veil for the "Schering" entities under any or all of these theories. Warrick could not exist without Schering/Schering-Plough. Warrick has only a handful of employees, yet Warrick generates annual sales of over \$150M. Warrick depends upon Schering/Schering-Plough's manufacturing, distribution, accounting and administrative departments for all of these internal functions. Warrick apparently does not even employ persons with those traditional business responsibilities. The only personnel Warrick allegedly employs are those who market and sell Schering/Schering-Plough's generic products. Warrick's business offices are within the offices of Schering/Schering-Plough. Warrick does not conduct its corporate business in Reno, Nevada as its letterhead represents. Instead, Schering/Schering-Plough and Warrick operate from the same office space in New Jersey, use the same computer systems, telephone systems, employees, and centralized departments, and apparently use each other's letterhead interchangeably.

9.4 The companies are so closely aligned that in deposition, even the founder of Warrick did not know whether his “Warrick” consulting contract is with Warrick or Schering/Schering-Plough. These companies are not operated as separate entities, but rather integrate their resources to achieve a common business purpose to sell Schering/Schering-Plough’s generic products. Whether express or implied, Warrick and Schering/Schering-Plough agreed that Warrick would act as Schering/Schering-Plough’s marketing unit for generic products, with the common purpose of selling more of Schering/Schering-Plough’s and Warrick’s products and with Schering/Schering-Plough’s having at least an equal right to direct and control the operation of the enterprise.

9.5 Also, Schering/Schering-Plough’s brand version of Albuterol Sulfate, Proventil, was sold in conjunction with Warrick’s generic Albuterol Sulfate. When Warrick’s customers purchased enough Warrick generic Albuterol Sulfate, Warrick would then give that customer a credit to obtain Proventil. These companies acted as one rather than as two independent drug manufacturers.

9.6 Furthermore, Schering/Schering-Plough may have purposefully under capitalized Warrick in light of the nature and risk of its business in order to avoid financial responsibility and allow Schering/Schering-Plough to break the law without suffering the consequences. Allowing the corporate structure to protect Schering/Schering-Plough from these wrongful acts would lead to injustice. In light of the above allegations, Warrick and Schering/Schering-Plough should be treated as one entity for liability purposes in order to insure Plaintiff can fully and completely recover any judgment rendered in its favor in this matter. Also, Schering/Schering-Plough sells Warrick products to large market segments with full knowledge of the false price representations, and, therefore, benefits from them.

## **X. DAMAGES**

10.1 Pursuant to the terms of the Medicaid Fraud Prevention Act, each Defendant is liable to the State of Texas for the value of any payment . . . provided under the Medicaid program, directly or indirectly, as a result of the unlawful act. Tex. Hum. Res. Code Ann. §36.052 (1). Additionally, each Defendant is liable for interest on the value of the payment, civil penalties ranging from \$1,000 to \$10,000 for each unlawful act, and two times the value of the payment. *Id.* at (2), (3), & (4). Therefore, the Defendants are liable for the following amounts:<sup>4</sup>

1. Schering/Schering-Plough/Warrick Pharmaceuticals Corporation

A. Value of Payments	\$ 32,147,022
B. Statutory Double Damages	\$ 64,294,044
C. Minimum Civil Penalties	<u>\$ 9,125,000</u>
Total (not including interest)	\$105,566,066

2. Roxane Laboratories, Inc.

A. <i>Value of Payments</i>	\$ 3,277,513
B. Statutory Double Damages	\$ 6,555,026
C. Minimum Civil Penalties	<u>\$ 5,475,000</u>

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<sup>4</sup> These calculations are based upon utilizations for periods ending at the end of 2002. These calculations will be updated and increased as additional information becomes available prior to trial consistent with the court's orders. The civil penalty figures are only minimum amounts available under TMFPA and at trial, the State may seek recovery of maximum penalties allowed by law under § 36.052.

Total (not including interest)      \$ 15,307,539

Plaintiff and Relator invoke in the broadest sense all relief possible at law or in equity under § 36.052, whether specified in this pleading or not. By agreement of counsel on June 4, 2003, Defendants withdrew their request to require Plaintiffs to specify a maximum amount being sought as civil penalties. Therefore, Plaintiffs will seek an amount as civil penalties which will be justified and appropriate under the facts relevant to this issue and under the laws as determined by the Court.

(Amended to respond to Special Exception. Specific and maximum monetary damages pled in the alternative under T.R.C.P. 48 and to make specific those damage allegations alleged in general terms in paragraphs 10.1 and 10.2)

10.2      Alternatively, the Defendants are liable to the State for common law fraud in an amount that exceeds the minimum jurisdictional limits of this Court, including, but not limited to actual damages, pre-judgment interest, attorney fees, and punitive damages in an amount not to exceed the amounts set forth as follows:

As monetary damages for the alternative claims based upon common law fraud and as a T.R.C.P. Rule 48 alternative measure of damages under the TMFPA the Plaintiffs seek the following elements of monetary damages:

- A. The difference between the reimbursement amount paid by TVDP for the relevant drugs, on the one hand and the amount that would have been paid but for false price/cost reporting on the other hand.
  
- B. Two times the amount found by the trier of fact in section A, as per TMFPA § 36.052(a)(4). (To the Court Only)
  
- C. Prejudgment interest at 10% per annum. (To the Court Only)
  
- D. A civil penalty to be assessed by the trier of fact using the guidelines at § 36.052 (b) (1)-(5) inclusive.

By agreement of counsel on June 4, 2003, Defendants withdrew their request to require Plaintiffs to specify a maximum amount being sought as civil penalties. Therefore, Plaintiffs will seek an amount as civil penalties which will be justified and appropriate under the facts relevant to this issue and under the laws as determined by the Court.

- E. Reasonable and necessary attorney fees, costs and expenses of litigation of the State and Relator in an amount not to exceed \$15,000,000.00. This amount includes fees to be set and awarded by the Court pursuant to TMFPA § 36.110(c).

10.3 The TMFPA is a statute of absolute strict liability and there are no defenses available for any violation of its provisions and in particular any violation of any part of Section 36.002. Likewise, as a matter of law the defenses of laches and limitations are not available as against the State of Texas, as a Sovereign.

10.4 In order for the trier of fact to be apprised of relevant and probative information upon which to assess a finding of an appropriate civil penalty, the jury will need to receive and hear evidence relating to TMFPA § 36.052 (b) (1)-(4) inclusive. Specifically the trier of fact must receive evidence on the following topics:

- (1) previous and other violations of the law;
- (2) the seriousness of the unlawful act “...including the nature, circumstances, extent, and gravity of the unlawful act;”
- (3) health and safety of the public; and

(4) whether the person acted in bad faith when engaged in the conduct that formed the basis of the unlawful act.

The trier of fact must have a complete and accurate understanding of the total conduct of Defendants in all dealings with TVDP to show that the Relevant Drugs were not an unusual or isolated error of judgment but rather a systematic and calculated plan to defraud the system at every opportunity. Therefore, other drugs placed by the Defendants into the formulary of the TVDP which had relatively small utilization in the State of Texas and which therefore are not the subject of large monetary damages are nonetheless probative evidence of other violations; the seriousness of conduct; the nature, circumstances, extent and gravity as well as evidence of bad faith of the Defendants. The trier of fact should be presented with complete and accurate information of how the Defendants dealt with pricing and price reporting issues relating to government reimbursement programs to understand that the prices the Defendants reported to the TVDP for the Relevant Drugs were not the result of an unusual or isolated error in judgment or mistake, but were the result of a systematic and calculated plan to defraud the system at every opportunity. These are the other drugs

for which damages are not sought in this case, but about which evidence will be offered to show the jury the Defendants' plan or scheme. These are primarily those drugs listed in paragraph 8.11.

## ***XI. JURY DEMAND***

11.1 The State respectfully requests a trial by jury pursuant to Texas Rules of Civil Procedure 216.

## ***XII. PRAYER***

12.1 The State asks that it recover from the Defendants restitution of payments, statutory additional double damages, pre-judgment interest, attorneys fees, costs, and expenses and civil penalties as provided in TEX. HUM. RES. CODE ANN., Chapter 36, or actual damages, pre-judgment interest, attorney fees and punitive damages under common law. Plaintiff and Relator invoke in the broadest sense all relief possible at law or equity under Texas Human Resources Code, Chapter 36 without qualification or limitation. The State asks that citation and notice be issued immediately to the defendants identified herein who have not already answered and appeared in this action and that they be served with process and that upon trial of this case that judgment be entered in favor of the State and against the named defendants in at the amounts set forth. The Relator further asks that it be awarded its costs and expenses; a reasonable attorney fee; and the maximum Relator's share provided for under the TMFPA. The State prays for such other and further relief to which it may show itself entitled either at law or in equity.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing instrument has been served on the following counsel of record via U.S. Mail, certified, return receipt requested, facsimile transmission, or hand delivery on this the \_\_\_\_\_ day of \_\_\_\_\_, 2003:

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