

DC-14-08476

Smith Gay

CAUSE NO. \_\_\_\_\_

**THE STATE OF TEXAS,  
Plaintiff,**

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**IN THE DISTRICT COURT OF**

**VS.**

**DALLAS COUNTY, TEXAS,**

**WYETH PHARMACEUTICALS INC.  
Defendant.**

**\_\_\_\_ JUDICIAL DISTRICT**

**PLAINTIFF'S ORIGINAL PETITION**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, THE STATE OF TEXAS, acting by and through Attorney General GREG ABBOTT ("State"), filing Plaintiff's Original Petition complaining of and against WYETH PHARMACEUTICALS INC. ("Defendant") and would respectfully show the court the following:

**AUTHORITY**

1. This action is brought by Attorney General Greg Abbott, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by § 17.47 of the Texas Deceptive Trade Practices – Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, et seq. ("DTPA"), upon the grounds that Defendant has engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§ 17.46(a) and (b) of the DTPA.

**PARTY DEFENDANT**

2. Defendant WYETH PHARMACEUTICALS INC. is a wholly owned subsidiary of Pfizer Inc, a Delaware corporation with its principal place of business at

235 East 42nd Street, New York, NY 10017. At all relevant times, Wyeth did business in Texas selling and promoting the prescription drug Rapamune®.

### **VENUE**

3. Venue for this action properly lies in Dallas County on the basis of § 17.47(b) of the DTPA because Defendant's acts and practices that violate these statutes occurred throughout Texas, including Dallas County, Texas.

### **PUBLIC INTEREST**

4. Because Plaintiff STATE OF TEXAS has reason to believe that Defendant has engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendant has caused and will cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

### **ACTS OF AGENTS**

5. Whenever in this petition it is alleged Defendant did any act or thing, it is meant that Defendant performed or participated in such act or thing or that such act was performed by agents or employees of Defendant and in each instance, the agents or employees of Defendant were then authorized to and did in fact act on behalf of Defendant or otherwise acted under the guidance and direction of Defendant.

### **TRADE AND COMMERCE**

6. Defendant has, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by § 17.45(6) of the

DTPA.

### **NOTICE BEFORE SUIT**

7. Plaintiff informed Defendant herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

### **DEFENDANT'S CONDUCT**

8. With certain limited exceptions not relevant here, a drug may not be distributed in interstate commerce without FDA approval.

9. To gain FDA approval, data from adequate and well-controlled clinical trials must demonstrate that the drug is safe and effective for a particular use.

10. As part of the approval process, the FDA must approve the drug's labeling which is required to set forth detailed information about the drug, including the approved medical conditions of use, dosages, and patient populations(s).

11. Once the FDA has found a drug to be safe and effective for a particular use and approved it for that use, doctors are free to exercise their medical judgment to prescribe the drug for other, unapproved (or "off-label") uses. However, manufacturers are proscribed by federal law from promoting the drug for off-label uses.

12. Rapamune (sirolimus) is an immunosuppressant drug that was approved by the FDA in 1999 as an "adjunct" drug in combination with cyclosporine and steroids to prevent rejection of the transplanted kidney. It is not approved for use by any other type of organ transplant patient. Nor is it approved for combination with other drugs.

13. Rapamune is only approved as "de-novo" treatment – meaning for use immediately after a transplant. It is not approved for "conversion" - meaning switching to another immunosuppressant sometime after the transplant.

14. In 2002, FDA required a “black box warning” to be added to Rapamune’s labeling. This warning informed prescribers and patients that Rapamune use by liver transplant patients is associated with serious risks, including graft loss and death.

15. In 2003, FDA required another “black box warning” be added to Rapamune’s labeling. This time, to caution that Rapamune use by lung transplant patients is associated with serious risks, including death.

16. In 2007, another warning was added regarding a serious side effect called proteinuria (protein in urine).

17. In June, 2009, yet another warning was added based on the results of a Wyeth study that suggested that liver transplant patients prescribed Rapamune experience “significantly higher” organ rejection than patients treated with alternative immunosuppressant drugs.

**ALLEGATIONS RELATING TO DEFENDANT’S MARKETING AND  
PROMOTION OF RAPAMUNE**

18. Despite Rapamune’s limited approval for use in kidney (renal) transplant only, and despite black box warnings relating to use in lung and liver transplants, Wyeth promoted Rapamune off-label for non-renal transplants patients such as liver, heart, pancreas, islet (pancreas cells) and lung transplant patients.

19. Wyeth also promoted Rapamune off-label using a “conversion” protocol (switching a patient to Rapamune after de novo use of a different transplant rejection drug).

20. Wyeth also promoted Rapamune off-label for use after kidney transplant in combination with drugs other than indicated in the product’s FDA approved labeling.

## **VIOLATIONS OF DTPA**

21. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of the prescription drug Rapamune®, has engaged in a course of trade or commerce which constitutes false, misleading, or deceptive acts or practices, and is declared unlawful by § 17.46 (a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, and specifically § 17.46 (b)(5) of the DTPA, by making representations about Rapamune® when Defendant knew the representations were not true.

22. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drug Rapamune®, has engaged in a course of trade or commerce which constitutes false, misleading, or deceptive acts or practices, and is declared unlawful by § 17.46 (a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, and specifically § 17.46 (b)(5) of the DTPA, by representing that Rapamune® has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

## **CONTINUING VIOLATIONS**

23. Defendant has violated and could continue to violate the laws as hereinabove alleged. Defendant, unless restrained by this Honorable Court, could continue to violate the laws of the State of Texas. Defendant has violated and could continue to violate the Deceptive Trade Practices-Consumer Protection Act.

## **PRAYER**

24. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendant be cited accorded to law to appear and answer herein and that upon final

hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendant and its agents, servants, employees, representatives, subsidiaries, divisions, successors, and assigns from engaging in false, misleading, or deceptive acts or practices.

25. The STATE OF TEXAS further prays, that upon final hearing, this Court order Defendant to pay civil penalties of not more than \$20,000.00 per violation, as provided in § 17.47(c)(1) of the DTPA.

26. The STATE OF TEXAS further prays that the Office of the Attorney General be awarded their investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including the Tex. Gov't Code Ann. § 402.006(c).

27. The STATE OF TEXAS further prays that upon final hearing that this Court grants all other relief to which the State may be justly entitled.

Respectfully submitted,

**Plaintiff State of Texas**

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# CIVIL CASE INFORMATION SHEET

CAUSE NUMBER (FOR CLERK USE ONLY): \_\_\_\_\_ COURT (FOR CLERK USE ONLY): \_\_\_\_\_

## STYLED IN RE: WYETH PHARMACEUTICALS INC.

(e.g., John Smith v. All American Insurance Co; In re Mary Ann Jones; In the Matter of the Estate of George Jackson)

A civil case information sheet must be completed and submitted when an original petition or application is filed to initiate a new civil, family law, probate, or mental health case or when a post-judgment petition for modification or motion for enforcement is filed in a family law case. The information should be the best available at the time of filing.

<b>1. Contact information for person completing case information sheet:</b>  Name: Joyce W. Iliya Address: 1412 Main Street, Suite 810 City/State/Zip: Dallas, Texas 75202 Signature: Email: <a href="mailto:Joyce.Iliya@texasattorneygeneral.gov">Joyce.Iliya@texasattorneygeneral.gov</a> Telephone: 214-290-8811 Fax: 214-969-7639 State Bar No: 00784319		<b>Names of parties in case:</b>  Plaintiff(s)/Petitioner(s): State of Texas  Defendant(s)/Respondent(s): Wyeth Pharmaceuticals  [Attach additional page as necessary to list all parties]	<b>Person or entity completing sheet is:</b> <input checked="" type="checkbox"/> Attorney for Plaintiff/Petitioner <input type="checkbox"/> Pro Se Plaintiff/Petitioner <input type="checkbox"/> Title IV-D Agency <input type="checkbox"/> Other: _____  Additional Parties in Child Support Case: Custodial Parent: _____ Non-Custodial Parent: _____ Presumed Father: _____	
<b>2. Indicate case type, or identify the most important issue in the case (select only 1):</b>				
<b>Civil</b>		<b>Family Law</b>		
<b>Contract</b> <i>Debt/Contract</i> <input type="checkbox"/> Consumer/DTPA <input type="checkbox"/> Debt/Contract <input type="checkbox"/> Fraud/Misrepresentation <input type="checkbox"/> Other Debt/Contract: _____  <i>Foreclosure</i> <input type="checkbox"/> Home Equity—Expedited <input type="checkbox"/> Other Foreclosure <input type="checkbox"/> Franchise <input type="checkbox"/> Insurance <input type="checkbox"/> Landlord/Tenant <input type="checkbox"/> Non-Competition <input type="checkbox"/> Partnership <input type="checkbox"/> Other Contract: _____	<b>Injury or Damage</b> <input type="checkbox"/> Assault/Battery <input type="checkbox"/> Construction <input type="checkbox"/> Defamation <i>Malpractice</i> <input type="checkbox"/> Accounting <input type="checkbox"/> Legal <input type="checkbox"/> Medical <input type="checkbox"/> Other Professional Liability: _____  <input type="checkbox"/> Motor Vehicle Accident <input type="checkbox"/> Premises <i>Product Liability</i> <input type="checkbox"/> Asbestos/Silica <input type="checkbox"/> Other Product Liability List Product: _____ <input type="checkbox"/> Other Injury or Damage: _____	<b>Real Property</b> <input type="checkbox"/> Eminent Domain/Condemnation <input type="checkbox"/> Partition <input type="checkbox"/> Quiet Title <input type="checkbox"/> Trespass to Try Title <input type="checkbox"/> Other Property: _____  <b>Related to Criminal Matters</b> <input type="checkbox"/> Expunction <input type="checkbox"/> Judgment Nisi <input type="checkbox"/> Non-Disclosure <input type="checkbox"/> Seizure/Forfeiture <input type="checkbox"/> Writ of Habeas Corpus—Pre-indictment <input type="checkbox"/> Other: _____	<b>Marriage Relationship</b> <input type="checkbox"/> Annulment <input type="checkbox"/> Declare Marriage Void <i>Divorce</i> <input type="checkbox"/> With Children <input type="checkbox"/> No Children  <b>Other Family Law</b> <input type="checkbox"/> Enforce Foreign Judgment <input type="checkbox"/> Habeas Corpus <input type="checkbox"/> Name Change <input type="checkbox"/> Protective Order <input type="checkbox"/> Removal of Disabilities of Minority <input type="checkbox"/> Other: _____	<b>Post-judgment Actions (non-Title IV-D)</b> <input type="checkbox"/> Enforcement <input type="checkbox"/> Modification—Custody <input type="checkbox"/> Modification—Other  <b>Title IV-D</b> <input type="checkbox"/> Enforcement/Modification <input type="checkbox"/> Paternity <input type="checkbox"/> Reciprocals (UIFSA) <input type="checkbox"/> Support Order  <b>Parent-Child Relationship</b> <input type="checkbox"/> Adoption/Adoption with Termination <input type="checkbox"/> Child Protection <input type="checkbox"/> Child Support <input type="checkbox"/> Custody or Visitation <input type="checkbox"/> Gestational Parenting <input type="checkbox"/> Grandparent Access <input type="checkbox"/> Parentage/Paternity <input type="checkbox"/> Termination of Parental Rights <input type="checkbox"/> Other Parent-Child: _____
<b>Employment</b> <input type="checkbox"/> Discrimination <input type="checkbox"/> Retaliation <input type="checkbox"/> Termination <input type="checkbox"/> Workers' Compensation <input type="checkbox"/> Other Employment: _____	<b>Other Civil</b> <input type="checkbox"/> Administrative Appeal <input type="checkbox"/> Antitrust/Unfair Competition <input type="checkbox"/> Code Violations <input type="checkbox"/> Foreign Judgment <input type="checkbox"/> Intellectual Property  <input type="checkbox"/> Lawyer Discipline <input type="checkbox"/> Perpetuate Testimony <input type="checkbox"/> Securities/Stock <input type="checkbox"/> Tortious Interference <input checked="" type="checkbox"/> Other: DTPA pursuant to 17.47, Bus. & Commerce code			
<b>Tax</b> <input type="checkbox"/> Tax Appraisal <input type="checkbox"/> Tax Delinquency <input type="checkbox"/> Other Tax	<b>Probate &amp; Mental Health</b> <i>Probate/Wills/Intestate Administration</i> <input type="checkbox"/> Dependent Administration <input type="checkbox"/> Independent Administration <input type="checkbox"/> Other Estate Proceedings  <input type="checkbox"/> Guardianship—Adult <input type="checkbox"/> Guardianship—Minor <input type="checkbox"/> Mental Health <input type="checkbox"/> Other: _____			
<b>3. Indicate procedure or remedy, if applicable (may select more than 1):</b>				
<input type="checkbox"/> Appeal from Municipal or Justice Court <input type="checkbox"/> Arbitration-related <input type="checkbox"/> Attachment <input type="checkbox"/> Bill of Review <input type="checkbox"/> Certiorari <input type="checkbox"/> Class Action	<input type="checkbox"/> Declaratory Judgment <input type="checkbox"/> Garnishment <input type="checkbox"/> Interpleader <input type="checkbox"/> License <input type="checkbox"/> Mandamus <input type="checkbox"/> Post-judgment	<input type="checkbox"/> Prejudgment Remedy <input type="checkbox"/> Protective Order <input type="checkbox"/> Receiver <input type="checkbox"/> Sequestration <input type="checkbox"/> Temporary Restraining Order/Injunction <input type="checkbox"/> Turnover		
<b>4. Indicate damages sought (do not select if it is a family law case):</b>				
<input type="checkbox"/> Less than \$100,000, including damages of any kind, penalties, costs, expenses, pre-judgment interest, and attorney fees <input type="checkbox"/> Less than \$100,000 and non-monetary relief <input type="checkbox"/> Over \$100,000 but not more than \$200,000 <input type="checkbox"/> Over \$200,000 but not more than \$1,000,000 <input checked="" type="checkbox"/> Over \$1,000,000				