

# EXHIBIT 1

to

Relator's Motion for Leave  
to Amend the  
First Amended Complaint

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

_____ )	
PLAINTIFFS UNDER SEAL )	Civil Action No. 07-10304
)	Judge Woodlock
)	
v. )	
)	<b><u>FILED UNDER SEAL</u></b>
)	
DEFENDANT UNDER SEAL )	<b><u>JURY TRIAL DEMANDED</u></b>
_____ )	

**SECOND AMENDED COMPLAINT**  
**FOR FALSE CLAIMS ACT VIOLATIONS**  
**31 U.S.C. § 3729, ET SEQ.**

W. Scott Simmer  
Thomas J. Poulin  
Blank Rome LLP  
Watergate  
600 New Hampshire Ave., NW  
Washington, DC 20037  
(202) 772-5800  
Facsimile: (202) 572-8412

Anthony A. Froio  
Alan E. McKenna  
Robins, Kaplan, Miller & Ciresi LLP  
800 Boylston Street  
Suite 2500  
Boston, MA 02199-7080  
(617) 267-2300  
Facsimile: (617) 267-8288

*Counsel for Plaintiffs/Relators*

**SECOND AMENDED COMPLAINT**  
**FOR FALSE CLAIMS ACT VIOLATIONS**  
**31 U.S.C. § 3729, ET SEQ.**

**FILED UNDER SEAL**

I.	JURISDICTION AND VENUE .....	9
II.	PARTIES .....	9
	<b>A. PLAINTIFFS/RELATORS .....</b>	9
	<b>B. DEFENDANT PFIZER .....</b>	11
III.	SUMMARY OF PFIZER’S ILLEGAL CONDUCT.....	12
	<b>A. THE PLAN AND PURPOSE OF THE FRAUDULENT MARKETING SCHEME.....</b>	12
	<b>B. THE MANNER AND MEANS OF EXECUTING THE SCHEME.....</b>	12
IV.	MARKETING OF DRUGS FOR UNAPPROVED OFF-LABEL INDICATIONS.....	13
	<b>A. THE MARKETING OF PRESCRIPTION DRUGS TO MEDICAL DECISION</b> <b>MAKERS.....</b>	13
	1. Sales Representatives’ Marketing of Drugs. ....	14
	2. The Use of “Key Opinion Leaders” to Promote Drugs. ....	16
	3. The Manipulation of Clinical Studies to Promote Off-Label Use of Drugs. ....	17
	<b>B. OFF-LABEL MARKETING: THE RISKS AND REWARDS FOR DRUG</b> <b>MANUFACTURERS.....</b>	19
	<b>C. NEURONTIN®: THE POSTER CHILD FOR OFF-LABEL PROMOTION. ....</b>	22
V.	PROMOTING LYRICA® FOR OFF-LABEL USES.....	24
	<b>A. THE DEVELOPMENT OF LYRICA® AS THE FOLLOW-ON PRODUCT TO</b> <b>NEURONTIN®. ....</b>	25
	<b>B. THE LAUNCH OF LYRICA®: FRAUDULENT MARKETING SCHEME TO</b> <b>GROW OFF-LABEL USE OF LYRICA®.....</b>	27
	1. Unsubstantiated Lyrica® Superiority Claims to Gabapentin (Neurontin®). ....	28
	(a) Pre-Launch Marketing Claims of Lyrica® Superiority. ....	29
	(b) Lyrica® Launch: Superiority Claims Over Gabapentin. ....	30
	(c) Post-Launch Superiority Claims and the Use of Side-By- Side Promotional Materials With Unsupported Comparative Claims.....	33

	(d) Pfizer Withdraws Misleading Lyrica® Marketing Materials on November 27, 2006.....	37
2.	Unsupported Superiority Claims to Keppra®. ....	39
3.	Marketing Lyrica® For All Neuropathic Pain and Nociceptive Pain Indications. ....	42
4.	Marketing Lyrica as Monotherapy for Treatment of Epilepsy. ....	43
5.	Using Secondary Endpoints to Off-Label Promote Lyrica®.....	44
6.	Failure to Engage in Fair and Balanced Promotion of Lyrica®’s Side Effects.....	46
7.	Falsified Call Notes to Support Unsolicited Medical Inquiry Requests for Lyrica® Off-Label Information.....	47
8.	Quota System to Induce Marketing to Doctors and Facilities Who Do Not Treat Patients With Conditions Requiring the On-Label Use of Lyrica®.....	49
9.	Using “Insell” to Hospitals to Avoid Detection of Off-Label Promotion. ....	50
10.	The Lyrica® “Upgrade” Scheme to Defraud the Medi-Cal Program.....	52
11.	Using Pfizer-Sponsored Presentations by “Key Opinion Leaders” to Promote Off-Label Use of Lyrica®. ....	53
12.	Use of Regional Medical Research Specialists to Promote Lyrica® Off-Label.....	54
	(a) RMRS Bart Brown, R.Ph.....	55
	(b) RMRS Bernard Effertz, Ph.D. ....	56
	(c) Carl Wilbanks’ April 28, 2008 E-mail Admits RMRS Abuses.....	58
VI.	<b>MANIPULATION OF FIBROMYALGIA INDICATION TO GROW OFF-LABEL USE OF LYRICA®.</b> .....	58
	<b>A. USE OF “FREEDOM” TRIAL RESULTS TO MARKET LYRICA® FOR FIBROMYALGIA BEFORE FDA APPROVAL.</b> .....	59
	<b>B. OFF-LABEL MARKETING OF LYRICA® FOR CHRONIC WIDESPREAD PAIN.</b> .....	62
VII.	<b>PAYMENT OF SPEAKER FEES TO INDUCE PHYSICIANS TO PRESCRIBE LYRICA® AND TO INCLUDE LYRICA® ON GOVERNMENT FORMULARIES.</b> .....	63

A.	<b>PFIZER SPEAKER FEES TO DR. UDAYA KABADI TO INFLUENCE PRESCRIBING OF LYRICA® AT THE VA HOSPITAL AND THE ADDITION OF LYRICA® TO THE UNIVERSITY HOSPITALS' FORMULARY.</b>	64
B.	<b>RECRUITING PHYSICIANS AS SPEAKERS TO INDUCE THEIR PRESCRIBING OF LYRICA®.</b>	65
VIII.	<b>PFIZER'S FRAUDULENT MARKETING SCHEME VIOLATED FEDERAL PROGRAM LIMITATIONS.</b>	66
IX.	<b>PFIZER'S PROMOTION OF LYRICA® CAUSED SUBMISSION OF OFF-LABEL CLAIMS TO GOVERNMENT PROGRAMS.</b>	69
X.	<b>PFIZER'S FALSE REPORTING IN CONNECTION WITH THE NEURONTIN® CORPORATE INTEGRITY AGREEMENT.</b>	71
XI.	<b>PFIZER'S RETALIATION AGAINST EMPLOYEES WHO RAISE CONCERNS ABOUT COMPLIANCE VIOLATIONS.</b>	72
A.	<b>SENIOR VP IAN READ AUGUST 16, 2007 E-MAIL ADMITS COMPLIANCE VIOLATIONS, INCLUDING "USE OF UNAPPROVED MATERIALS" AND OFF-LABEL PROMOTION.</b>	73
B.	<b>RETALIATION AGAINST RELATORS FOR BLOWING THE WHISTLE.</b>	74
1.	Relator David Farber	74
2.	Relator Casey Schildhauer	76
	COUNT I VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, <i>ET SEQ.</i>	76
	COUNT II VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, <i>ET SEQ.</i>	77
	COUNT III VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3730(H)	78
	COUNT IV ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT, ARK. CODE ANN. § 20-77-901, <i>ET SEQ.</i>	78
	COUNT V VIOLATION OF THE STATE OF CALIFORNIA FALSE CLAIMS ACT, CAL GOV'T CODE § 12650, <i>ET SEQ.</i>	80
	COUNT VI VIOLATION OF THE STATE OF DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL. CODE ANN. TIT. 6, § 1201, <i>ET SEQ.</i>	81
	COUNT VII VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT, D.C. CODE ANN § 2-308.13, <i>ET SEQ.</i>	83
	COUNT VIII VIOLATION OF THE STATE OF FLORIDA FALSE CLAIMS ACT, FLA. STAT. 68-081, <i>ET SEQ.</i>	84
	COUNT IX VIOLATION OF STATE OF GEORGIA FALSE MEDICAID CLAIMS ACT, GA. CODE ANN. § 49-4-168 (2007), <i>ET SEQ.</i>	85
	COUNT X VIOLATION OF THE STATE OF HAWAII FALSE CLAIMS ACT FALSE CLAIMS TO THE STATE, HAWS REV. STAT. § 661-21, <i>ET SEQ.</i>	87

COUNT XI VIOLATION OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT, IND. CODE § 5-11-5.5, <i>ET SEQ.</i> .....	88
COUNT XII VIOLATION OF THE STATE OF ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT, 740 ILL. COMP. STAT. ANN. 175/1, <i>ET SEQ.</i> .....	90
COUNT XIII VIOLATION OF THE STATE OF LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, LA. REV. STAT. § 46:437.1, <i>ET SEQ.</i> .....	91
COUNT XIV VIOLATION OF THE STATE OF MASSACHUSETTS FALSE CLAIMS ACT, MASS LAWS ANN. CH. 12, § 5A, <i>ET SEQ.</i> .....	93
COUNT XV VIOLATION OF THE STATE OF MICHIGAN MEDICAID FALSE CLAIMS ACT, MICH. COMP. LAWS SERV. § 400.601, <i>ET SEQ.</i> .....	94
COUNT XVI VIOLATION OF STATE OF MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. § 17-8-401, <i>ET SEQ.</i> .....	96
COUNT XVII VIOLATION OF STATE OF NEW HAMPSHIRE MEDICAID FALSE CLAIMS ACT, N.H. REV. STAT. ANN. § 167:61-B, <i>ET. SEQ.</i> .....	97
COUNT XVIII VIOLATION OF STATE OF NEW JERSEY FALSE CLAIMS ACT, N.J. STAT. ANN. § 2A:32C-3 (2007), <i>ET SEQ.</i> .....	98
COUNT XIX VIOLATION OF STATE OF NEW MEXICO MEDICAID FALSE CLAIMS ACT, N.M STAT. ANN. § 27-14-1, <i>ET SEQ.</i> .....	100
COUNT XX VIOLATION OF THE STATE OF NEW YORK FALSE CLAIMS ACT, N.Y. CLS. ST. FIN. § 187 <i>ET SEQ.</i> .....	102
COUNT XXI VIOLATION OF THE STATE OF NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT, NEV. REV. STAT. ANN. § 357.010, <i>ET SEQ.</i> .....	103
COUNT XXII VIOLATION OF STATE OF OKLAHOMA MEDICAID FALSE CLAIMS ACT, OKLA. STAT. TIT. 63, § 5053 (2007), <i>ET SEQ.</i> .....	104
COUNT XXIII VIOLATION OF STATE OF RHODE ISLAND FALSE CLAIMS ACT, R.I. GEN. LAWS § 9-1.1-1 (2007), <i>ET SEQ.</i> .....	106
COUNT XXV VIOLATION OF THE STATE OF TENNESSEE MEDICAID FALSE CLAIMS ACT, TENN. CODE ANN. § 71-5-181 <i>ET SEQ.</i> .....	107
COUNT XXVI VIOLATION OF THE STATE OF TEXAS HUMAN RESOURCES CODE, TEX. HUM. RES. CODE § 36.001 <i>ET SEQ.</i> .....	109
COUNT XXVII VIOLATION OF THE COMMONWEALTH OF VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA CODE ANN. § 8.01-216.1, <i>ET SEQ.</i> .....	110
COUNT XXVIII VIOLATION OF THE STATE OF WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE, WIS. STAT. § 20.931 (2007), <i>ET SEQ.</i> ; .....	112



**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA )  
ex rel. DAVID FARBER and )  
CASEY SCHILDHAUER, and on behalf of )  
the STATES of ARKANSAS, CALIFORNIA, )  
DELAWARE, DISTRICT OF COLUMBIA, )  
FLORIDA, GEORGIA, HAWAII, ILLINOIS, )  
INDIANA, LOUISIANA, MASSACHUSETTS, )  
MICHIGAN, MONTANA, NEW HAMPSHIRE, )  
NEW JERSEY, NEW MEXICO, NEW YORK, )  
NEVADA, OKLAHOMA, RHODE ISLAND )  
TENNESSEE, TEXAS, VIRGINIA, and )  
WISCONSIN, )  
Plaintiffs, )  
v. )  
PFIZER, INC., )  
Defendant. )

Civil Action No. 07-10304  
Judge Woodlock

**FILED UNDER SEAL  
JURY TRIAL DEMANDED**

**SECOND AMENDED COMPLAINT**  
**FOR FALSE CLAIMS ACT VIOLATIONS**  
**31 U.S.C. § 3729, et seq.**

This is an action brought on behalf of the United States of America and the *Qui Tam* States, by David Farber and Casey Schildhauer (“Relators”), by and through their attorneys, Blank Rome LLP and Robins, Kaplan, Miller & Ciresi L.L.P., against Defendant Pfizer, Inc. (“Pfizer”), pursuant to the *qui tam* and retaliation provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*; the Arkansas Medicaid Fraud False Claims Act, ARK. CODE ANN. § 20-77-901 (2007), *et seq.*; the California False Claims Act, CAL. GOV’T CODE § 12650 (Deering 2000), *et seq.*; the Delaware False Claims and Reporting Act, DEL. CODE

ANN. Tit. 6, § 1201 (2000), *et seq.*; the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.13 (2000), *et seq.*; the Florida False Claims Act, FLA STAT. 68-081 (2000), *et seq.*; the Georgia False Medicaid Claims Act, GA. CODE ANN. § 49-4-168 (2007), *et seq.*; the Hawaii False Claims Act, HAW. REV. STAT. § 661-22, (2006) *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. § 175/1 (2000), *et seq.*; the Indiana False Claims and Whistleblower Protection Act, INDIANA CODE 5-11-5.5, (2007) *et seq.*; the Louisiana Medical Assistance Programs Integrity, LA. REV. STAT. ANN. § 46.439.1 (2006), *et seq.*; the Massachusetts False Claims Act, MASS. ANN. LAWS ch. 12, § 5(A), (2007) *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.601, (2007) *et seq.* (2007); the Montana False Claims Act, MONT. CODE ANN. § 17-8-401 (2005), *et seq.*; the New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-b (2005), *et seq.*; the New Jersey False Claims Act, N.J. STAT. ANN. § 265 (2007), *et seq.*; the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1 (2007), *et seq.*; the New York False Claims Act, N.Y. CLS ST. FIN. § 190.6. (2007), *et seq.*; the Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. § 357.010 (1999), *et seq.*; the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*; the Rhode Island False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*; the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-181(c) (2006), *et seq.*; the TEX. HUM. RES. CODE § 36.001 (2006), *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 (2006), *et seq.*, and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931 (2007), *et seq.*; (“State *qui tam* statutes” or “*Qui Tam* States”).

## **I. JURISDICTION AND VENUE**

1. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. This Court has personal jurisdiction over the Defendant because, among other things, the Defendant transacts business in this District, and Defendant engaged in wrongdoing in this District. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State *Qui Tam* Statutes for the recovery of government program funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence as the claims brought on behalf of the United States under 31 U.S.C. § 3730.

2. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendant transacts business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

3. The causes of action alleged herein are timely brought because, among other reasons, of efforts by the Defendant to conceal from the United States and the *Qui Tam* States its wrongdoing in connection with the allegations made herein.

## **II. PARTIES**

### **A. PLAINTIFFS/RELATORS**

4. Plaintiff/Relator David Farber (“Relator Farber”) is a resident of Iowa City, Iowa, and is a former employee of Pfizer. In 1999, Farber joined Parke-Davis as a Territory Manager in Lafayette, Indiana and later moved back to work in Des Moines, Iowa. After the Parke-Davis and Pfizer merger in 2000, Relator Farber took a position with Pfizer as a Professional Healthcare Representative (“PHR”), a general sales representative responsible for promoting or

detailing certain drugs to healthcare professionals. In 2003, Relator Farber was promoted to a specialty position as a PRO (pain, rheumatology, and orthopedics) representative. He became a Specialty Representative, responsible for detailing drugs such as Bextra® and Celebrex® to medical specialists (e.g., neurologists, anesthesiologists, rheumatologists, and orthopedic surgeons). During his almost eight (8) year tenure with Pfizer, Relator Farber was the recipient of numerous sales awards. Relator Farber has provided the government with information and documents prior to the filing of this complaint in accordance with 31 U.S.C. § 3730(b)(2). Relator Farber is an original source of this information, and this Second Amended Complaint is not based upon publicly disclosed information. Prior to filing this Second Amended Complaint, Relator Farber had brought the wrongdoing described herein to the attention of Pfizer. As a result of Relator Farber's whistle-blowing activities, Pfizer retaliated against Relator Farber in violation of 31 U.S.C. § 3730(h).

5. Plaintiff/Relator Casey Schildhauer ("Relator Schildhauer") is a resident of Los Angeles, California, and is a former employee of Pfizer. Relator Schildhauer joined Pfizer on October 8, 2004 as a PHR promoting (or "detailing") Pfizer drugs to prescribers and pharmacies. Relator Schildhauer detailed a number of Pfizer drugs, including Bextra®, Celebrex®, Zyvox®, Zoloft®, and Lyrica®, based out of the Iowa City, Iowa regional sales area. He was relocated by Pfizer to Los Angeles in September, 2006, where he continued to detail Pfizer drugs, including Lyrica®. Relator Schildhauer has provided the government with information and documents prior to the filing of this Second Amended Complaint in accordance with 31 U.S.C. § 3730(b)(2). Relator Schildhauer is an original source of this information, and this Second Amended Complaint is not based upon publicly disclosed information. Prior to filing this Second

Amended Complaint, Relator Schildhauer brought the wrongdoing described herein to the attention of Pfizer. As a result of his whistle-blowing activities, Pfizer retaliated against Relator Schildhauer in violation of 31 U.S.C. § 3730(h), and then terminated him on March 27, 2007.

**B. DEFENDANT PFIZER**

6. Defendant Pfizer is incorporated under the laws of Delaware, with its principal place of business in New York, New York. Pfizer is engaged in the development, manufacture, distribution, and sale of pharmaceutical and health care products throughout the United States. Throughout the relevant period, Pfizer manufactured and sold substantial quantities of its drugs products, including Lyrica®, in Massachusetts and in the United States, during which time Pfizer was operating under a Corporate Integrity Agreement entered into with the United States Department of Health and Human Services Office of Inspector General. Pfizer employs as many as 12,000 sales representatives located across the United States whose function it is to promote, market or otherwise sell Pfizer drugs, including Lyrica®.

7. Pfizer manufactures, markets and sells brand-name prescription drug products, including Lyrica®, paid or reimbursed by various governmental programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits (“FEHB”) program under a prime contract with the Blue Cross Blue Association (“BCBSA”), the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395, *et seq.*, Medicare Part C, also known as Medicare+Choice, patients covered by Medicare Part D, the Indian Health Service, Medicaid, the Mail Handler’s Health Benefit Plan (“MHHBP”), the U.S. Secret Service Employees Health Association (“SSEH”) Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services

("CHAMPUS," now known as "TRICARE") and the Veteran's Health Administration ("VHA") (collectively, "government programs").

### **III. SUMMARY OF PFIZER'S ILLEGAL CONDUCT**

#### **A. THE PLAN AND PURPOSE OF THE FRAUDULENT MARKETING SCHEME.**

8. It was the plan and purpose of Pfizer's scheme to illegally market Lyrica® beginning at least as early as August 2005 and continuing to the present in order to fraudulently obtain government program reimbursement by causing false and fraudulent claims to be submitted for payment.

#### **B. THE MANNER AND MEANS OF EXECUTING THE SCHEME.**

9. As part of the scheme, Pfizer illegally promoted the off-label sale and use of Lyrica® in order to obtain reimbursement for non-medically accepted indications and other off-label treatments in order to maximize profits by making false and fraudulent statements to the public, healthcare providers and the Food and Drug Administration ("FDA").

10. Pfizer's unlawful promotion of Lyrica® involved the unlawful making of false records or statements for the purpose of getting false records or statements to bring about the government programs' payment of false or fraudulent claims.

11. Pfizer's conduct had a material effect on the government programs' payment for Lyrica®. Had the government programs known that reimbursements were being made for Lyrica® caused by Pfizer's unlawful promotion, the government programs would not have made such reimbursements.

12. It was further part of the scheme that Pfizer attempted to conceal and cover up the off-label marketing of Lyrica® by making false statements to the FDA and directing employees to conceal evidence.

13. The unlawful promotion of Lyrica® involved the unlawful making of false records or statements for the purpose of getting false records or statements to bring about the government programs' payment of false or fraudulent claims.

14. Had the government programs known that reimbursements were being made for Lyrica® caused by Pfizer's unlawful promotion, the government programs would not have made such reimbursements.

15. The scheme is referred to herein as the "Fraudulent Marketing Scheme."

#### **IV. MARKETING OF DRUGS FOR UNAPPROVED OFF-LABEL INDICATIONS**

##### **A. THE MARKETING OF PRESCRIPTION DRUGS TO MEDICAL DECISION MAKERS.**

16. The standard upon which doctors are expected to rely when making treatment decisions for their patients is "evidence-based medicine." The Center for Evidence-Based Medicine (CEBM) provides the following definition: "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." See Sackett, et al., "Evidence Based Medicine: What It Is and What It Isn't: It's About Integrating Individual Clinical Expertise and the Best External Evidence," *British Medical Journal*, 312:71-72 (1996).

17. Physicians' primary sources of the evidence upon which their evidence-based decisions are based are the results of gold standard double-blind, randomized, controlled clinical

trials (“RCTs”) and systematic reviews of RCTs published in peer-reviewed journals. The medical “literature” thus defines the scientific evidence that provides the foundation for “evidence-based medicine.” Yet, much of this research and the reports summarizing it are increasingly controlled or funded by pharmaceutical manufacturers.

18. Pharmaceutical companies have both in-house and third-party marketing firms to assist them in the branding and product placement of prescription drugs. Marketing, of which sales or drug representatives are only one aspect, generally includes the oversight of all printed material concerning a prescription drug, the look and feel of all advertisements, the pictures and colors used, the product message and the way that the risks and benefits of the product are described.

1. **Sales Representatives’ Marketing of Drugs.**

19. Sales representatives act as a primary source of information for physicians. Especially with internists and primary care physicians, drug representatives are often the first to present a clinical trial. The number of drug representatives making sales calls in doctors’ offices tripled between the early 1990s and 2001, and now there are about 90,000 drug representatives making calls on practicing physicians or one full time representative for every four-and-a-half office-based doctors. Scott Hensley, “As Drug-Sales Teams Multiply, Doctors Start to Tune Them Out,” *Wall Street Journal*, June 13, 2003. Between 80-90% of office-based doctors talk to drug representatives. See Moynihan, “Who Pays for the Pizza? Redefining the Relationships Between Doctors and Drug Companies,” *British Medical Journal*, 326:1189-92 (2003). Somewhat paradoxically, the busier a doctor is the more likely he or she is to talk to drug representatives. See Ferguson, et al., “Encounters with Pharmaceutical Representatives among

Practicing Internists,” *American Journal of Medicine*, 107:149-152 (1999). According to a 2002 survey conducted by the Kaiser Family Foundation, 74% of doctors consider the information provided by drug representatives very or somewhat useful, and 81% of doctors consider the information provided very or somewhat accurate. See *National Survey of Physicians, Part II: Doctors and Prescription Drugs*, The Kaiser Family Foundation, March 2002.

20. Drug representatives provide what can seem to busy doctors to be a useful service. Along with their trinkets, doughnuts, and free lunches, they arrive with reprints of articles from medical journals and the drug company’s own educational materials summarizing the latest medical research. Most doctors firmly believe that their opinions about drugs and scientific evidence are not compromised by these interactions. The research shows otherwise. A study of doctor-drug representative interactions shows that these interactions have a mostly negative effect on the quality of medical care. The more a doctor sees a sales representative, the less likely the doctor is to identify false claims about the drug, and the greater the tendency to prescribe more drugs overall. Doctors who interact with drug companies are about fifteen (15) times more likely to request that drugs manufactured by specific companies be stocked in hospital pharmacies. John Abramson, M.D., Overdosed America, 125-126 (2004).

21. Drug makers buy prescribing information from pharmacies, so know exactly what the doctors prescribe, and can precisely measure the effect of their office calls and enticements. As a result, drug companies know more about doctor’s prescribing habits than the doctors know themselves.

22. Despite all the education they receive from drug companies, surprisingly doctors have little awareness of the cost of drugs. Nine (9) out of ten (10) doctors underestimate the cost

of brand-name drugs, and an equal proportion think that generic drugs cost more than they actually do. Most important, in terms of the cost of health care, the drugs for which doctors are most likely to underestimate the cost are those that are most widely prescribed.

23. Skilled sales representatives can solicit questions about off-label use from doctors. Either by “cueing” the doctor to ask an off-label question or falsifying records to make it appear that the doctor asked the off-label question, the representative can fill out a postcard or call the company to send a packet of off-label information from the medical affairs office. The packet may contain company-approved reprints and a “standardized letter,” created by the drug information department of the company, discussing any research on the off-label use.

## 2. **The Use of “Key Opinion Leaders” to Promote Drugs.**

24. Doctors reasonably believe the knowledge that informs their clinical decisions and standards of care are derived from the scientific evidence published in medical journals, presented in review articles, and endorsed by “Key Opinion Leaders” and trusted organizations.

25. In the world of medicine, “Key Opinion Leader” is used to describe the senior doctors who help drug companies sell drugs. These influential doctors are engaged by industry to advise on marketing and help boost sales of new medicines. Across all specialties, in hospitals and universities everywhere, many leading specialists are being paid generous fees to peddle influence on behalf of the world’s biggest drug companies.

26. These “Key Opinion Leaders” (also called “KOLs”) help “word-of-mouth” or “buzz” marketing. They support labeled marketing efforts as well, and are crucial for the promotion of off-label uses. Industry-paid KOLs are never company employees. Rendering

purportedly independent opinions, via articles and lectures, KOLs are used by drug manufacturers to elude laws against off-label promotion.

27. Physician-speakers are trained in presenting talks to other physicians, sometimes called “dinner talks” or “lunch-and-learns.” Some speakers are genuinely unaware of the marketing messages they are responsible for disseminating. For example, messages that a certain disease is under-diagnosed, under-treated, or more serious than commonly believed can bolster a company’s marketing goals even if drugs are never mentioned.

28. Although company-provided materials usually do not recommend off-label use, speakers may modify the slides, or simply address off-label uses verbally. Companies are supposed to stop using speakers who consistently promote off-label uses, but that may not happen, particularly for speakers who help generate sales.

### 3. **The Manipulation of Clinical Studies to Promote Off-Label Use of Drugs.**

29. Clinical studies provide key references for the industry-produced reviews and commentaries, signed by KOLs, used for promoting off-label sales. Case studies about off-label uses may be solicited; physicians may be paid for combing patient medical records for cases that help industry goals. A physician—or a medical writer—will write up the case or case series, which may be submitted for publication or presented as a meeting abstract. Industry-sponsored reprints may be included in continuing medical education (CME) activities sponsored by medical education companies (MECs), often distributed by direct mail.

30. Abstracts or posters may be “published” in conference proceedings, medical journals, “throwaway” journals, or industry-sponsored medical journal supplements. These industry-generated, non-peer-reviewed, covert promotional pieces are now citable items that are

provided to physicians by a company's medical affairs office to support off-label use, and can be referenced in peer-reviewed articles, ads, and other marketing materials. *Id.*

31. Publications and posters provide the foundation for the medical education programs that are key for promoting off-label uses. Committee on Finance United States Senate, "Use Of Educational Grants By Pharmaceutical Manufacturers," <http://www.acme-assn.org/home/prb042507a.pdf> (2007).

32. Pfizer has engaged in the Fraudulent Marketing Scheme to exert control and influence over the sources of information upon which physicians rely in making prescribing decisions as that information related to non-FDA approved, scientifically unsubstantiated indications of Lyrica®. This strategy was designed to exploit the ways that doctors typically assimilate new knowledge, in this case relying heavily on the use of "Key Opinion Leaders," use of financial incentives to physicians, providing off-label Lyrica® information from the Pfizer Medical Information department which had been requested by sales representatives using phony Medical Inquiries, sponsorship of extensive continuing medical education (including journal clubs) designed to encourage off-label prescribing, the use of off-label "Pfizer Math" detailing by drug representatives, and the sales-oriented efforts of medical liaison personnel ("Regional Medical Research Specialists" or "RMRSs") to encourage off-label use of Lyrica®. "Pfizer Math" is what Pfizer employees call the use of completely different clinical studies in order to create a misleading impression that they are actually head-to-head studies.

33. Pfizer's manipulation and suppression of information that was critical and material to the determination of Lyrica®'s efficacy rendered it impossible for those physicians to function as "learned intermediaries" with regard to the off-label uses of Lyrica® at issue.

**B. OFF-LABEL MARKETING: THE RISKS AND REWARDS FOR DRUG MANUFACTURERS.**

34. In the pharmaceutical industry, there are two ways to market an approved drug for a new use: the “indication” route—performing studies necessary for regulatory approval—or the “publication” strategy, which stimulates off-label prescribing by using research “to disseminate the information as widely as possible through the world’s medical literature” Steinman, et al., “The Promotion Of Gabapentin: An Analysis Of Internal Industry Documents,” *Annals of Internal Medicine*, 145: 284–293 (2006).

35. The financial rewards for an off-label publication strategy can be significant, especially in comparison to the indication strategy. In development, drugs may be promising for several uses, and drug companies must choose the conditions on which to focus research. Ease of FDA approval can be the most important factor in this decision. If extensive off-label use is anticipated, a company may seek FDA approval for a narrow indication in order to speed a drug to market. In other words, a drug may be approved for a narrow indication while an extensive off-label campaign is not disclosed to FDA regulators. Once a drug is approved for the narrow indication, labeled and off-label promotion may then occur concurrently.

36. In the U.S., although pharmaceutical representatives are not supposed to detail doctors on off-label uses, representatives are rated, and compensated, based on sales. As one industry consultant quoted in *Medical Marketing and Media* stated: “Let’s say the sales goal [for a drug] is larger than if every patient over 60 is already on it. Divide that down to territories, and everybody has to meet it. The message is, sell off-label.” A pharmaceutical industry attorney quoted in the same article stated: “Before engaging in off-label promotion, companies should ascertain the risk profile, safety, efficacy, and potential commercial benefits of the use—without

committing that last bit to print.” Arnold, “Flexible forces,” Medical Marketing Media, 11:40 (2005). As a result, illegal off-label promotion may be cost-effective if potential profits trump potential fines.

37. One way drug makers can get a backdoor approval for a drug’s off-label use without having to go through a costly FDA approval process is to get the off-label use “supported” in one of the approved drug compendia. “Compendia” are compilations of drug information that include both on-label (FDA approved) and off-label uses (uses for which there is some clinical support). Medicare, Medicaid, and many other insurers will cover off-label uses of reimbursable drugs included in major compendia, including the American Hospital Formulary Service–Drug Information (“AHFS” -- prepared by the American Society of Health-System Pharmacists), the US Pharmacopoeia–Drug Information (Micromedex, a division of the Thomson Publishing Company), and Drugdex (also a division of Thomson Publishing). Pharmaceutical companies strive to establish good relationships with compendia staff, and may assign an employee as the designated compendia contact. The pharmacists who write compendia listings are very busy, and are usually delighted to receive organized packets of scientific articles, abstracts, and contact information. Using company-provided articles (which may often contain marketing messages) saves time. All of the company’s assertions for off-label use may be transferred intact to the final compendia write-up about the product.

38. Drugdex by default has become the primary compendia source. Drugdex has been criticized for including indications with scant clinical support. Drugdex publisher Thomson, the private company which now owns two of the three guides, receives substantial revenue from the big drug companies that benefit from Drugdex listings. The company says that does not

influence what Drugdex publishes. Critics say Drugdex's criteria are not strict enough. Drugdex has also been criticized for listing off-label uses based on one-patient observations or on studies that do not use the strict protocols of the FDA. And, it sometimes has disregarded evidence showing that off-label uses are not effective.

39. While off-label use is sometimes necessary, it should be undertaken with care and caution due to the uncontrolled experiment to which a patient is being subjected. Valuable off-label uses should be discussed by unbiased researchers in bona fide medical journals. Promising therapies should be tested in clinical trials. Truly useful off-label benefits of drugs will not remain a secret.

40. Pharmaceutical companies have an obvious incentive not to police off-label promotion by sales representatives when such promotion financially benefits both the representatives and companies. Allowing off-label promotion of drugs for untested, unproven benefits maximizes industry profits at the expense of public health. A risk-benefit ratio cannot be assessed without knowing whether clinically prove benefits exist. Where no benefits exist, no risk is acceptable.

41. Pharmaceutical marketing has distorted the discourse on off-label uses and encouraged the unmonitored, potentially dangerous use of drugs by patients for whom risks and benefits are unknown.

42. In its marketing of Lyrica®, Pfizer engaged in a comprehensive program to exploit physicians' trust in this process of knowledge creation and dissemination. Rather than being the product of unbiased scientific inquiry, the "scientific evidence" supporting off-label use of Lyrica® was the product of the Pfizer's carefully designed and orchestrated campaign..

This campaign established pre-determined marketing-favorable “key messages” as the scientific evidence, and not unbiased scientific inquiry.

43. Because Pfizer is a highly centralized operation with the direction principally coming out of the New York headquarters, at all times material hereto the Fraudulent Marketing Scheme was highly coordinated by Pfizer’s corporate management. Pfizer corporate sales management carefully developed the off-label Lyrica® message, using presentation materials that were initially disseminated to the APM (arthritis, pain and metabolic) sales representatives at the initial launch meeting held in Anaheim, California on September 12-15, 2005, and later at numerous “Plan of Attack” or “POA” meetings held throughout the U.S. At these meetings sales representatives were given exact instructions how to deliver the message that was intended. Before every POA meeting, Pfizer management held planning meetings for all Regional Managers and District Managers, at which senior sales management laid out the sales messages with specific instructions how each product was to be sold and detailed.

**C. NEURONTIN®: THE POSTER CHILD FOR OFF-LABEL PROMOTION.**

44. Neurontin® (gabapentin) started life with a narrow scope under Parke-Davis, a division of Warner Lambert. The FDA approved it in 1993 as an anti-convulsant for epileptics when their regular drugs needed a boost and was intended to be used in conjunction with other medications. With such a limited market, it never had much market potential. Over time, Parke-Davis realized that if Neurontin® could be sold to treat other ills, it could reap substantial profits. It did. As did Pfizer, which purchased Warner Lambert in 2000. In 1994, Parke-Davis had estimated that lifetime sales for Neurontin®’s only approved indication as a supplemental drug

to treat epilepsy would be \$500 million. By 2003, Pfizer made that much in Neurontin® sales every two months, as worldwide sales reached \$2.7 billion per year.

45. What accounted for the explosive growth in sales? Off-label promotion. By late 1995, senior management at Parke-Davis had committed the company to promoting Neurontin® for off-label uses for which it had no intention of ever seeking FDA approval. Neurontin® became a self-styled magical cure-all, thanks to Parke-Davis' aggressive promotion. It was sold as a remedy for various kinds of pain; hot flashes with menopause; restless leg syndrome; partial seizures in adults and children older than three; drug- and alcohol-withdrawal seizures; attention deficit disorder; migraines; amyotrophic lateral sclerosis (Lou Gehrig's disease); and assorted psychiatric conditions, including bipolar disorder, panic disorder, post-traumatic stress disorder, and social phobia.

46. To spread the word about the off-label uses, since it could not legally promote Neurontin® either to the public or physicians for purposes other than those the FDA originally approved, Parke-Davis (and later Pfizer) launched a massive covert marketing campaign. It recruited "Key Opinion Leaders" in major teaching hospitals to serve as Neurontin® "champions." It paid tens of thousands of dollars to these select doctors to extol the wonders of Neurontin®. It paid other physicians to listen to the sales pitches in order to influence them to favor Neurontin® in their prescribing. It also made money available in these teaching hospitals for doctors to conduct research and clinical trials on Neurontin® in order to curry their favor.

47. Physicians were singled out as Neurontin® cheerleaders based on their potential to write prescriptions. Doctors received money to promote Neurontin®'s off-label uses in

teleconferences and to conduct studies confirming off-label uses. Parke-Davis sales representatives then could drop off the favorable articles at doctors' offices.

48. What the Parke-Davis sales force neglected to mention to doctors was that clinical trials (a number of them suppressed by the company) had raised serious doubts about the drug's efficacy. One trial concluded that Neurontin® "is probably no more effective than placebo in the treatment of painful diabetic neuropathy." Another study of Neurontin®'s use in treating depression and bipolar disorder produced similar results.

49. The off-label scheme for Neurontin® was wildly successful. Meredith Rosenthal, Associate Professor of Health Economics and Policy at the Harvard School of Public Health, has calculated (for only a portion of the total off-label Neurontin® prescriptions) that between 1994 and 2004 there were 43,415,904 off-label Neurontin® prescriptions in the United States for migraines, bipolar disorder, neuropathic pain, nociceptive pain, and excessive dosing beyond FDA-approved levels.

50. Finally, in May 2004, the U.S. Attorney's Office in Boston and the U.S. Department of Justice announced that Pfizer "has agreed to plead guilty and pay more than \$430 million to resolve criminal charges and civil liabilities in connection with its illegal and fraudulent promotion of unapproved uses for one its drug products [Neurontin]."

V. **PROMOTING LYRICA® FOR OFF-LABEL USES.**

51. Pfizer knew from its Neurontin® experience that promoting a drug product for as many indications as possible would result in dramatically increased sales. In the case of Neurontin®, over 90% of its sales were for off-label use (*i.e.*, for uses not approved by the FDA).

**A. THE DEVELOPMENT OF LYRICA® AS THE FOLLOW-ON PRODUCT TO NEURONTIN®.**

52. Pregabalin (marketed under the trade name Lyrica®) is an anticonvulsant drug used for the management of specific kinds of neuropathic pain (post herpetic neuralgia, diabetic peripheral neuropathy), as an adjunct therapy for partial seizures with or without secondary generalization in adults, and for the management of fibromyalgia. Pregabalin was designed by Pfizer as being the more potent successor to Neurontin® (gabapentin), which had been marketed first by Warner Lambert in 1993 and then by Pfizer since 2000.

53. Pfizer submitted its application for a New Drug Application (“NDA”) to the FDA on October 30, 2003, requesting that it approve the marketing of pregabalin.

54. Before it could launch Lyrica®, Pfizer faced a generic competitor for Neurontin®. On August 18, 2004, generic manufacturer Ivax announced it had launched “at risk” its generic version of Pfizer’s Neurontin®, gabapentin, in 100 mg, 300 mg and 400 mg strengths. Pfizer had originally intended to launch Lyrica® prior to generic competition for gabapentin. However, the Lyrica® NDA filing had been delayed at least three years by the FDA due to a number of issues, including carcinogenicity and toxicological data, the FDA’s determination that Lyrica® would be a Schedule V controlled drug (due to its potential for euphoric effects, abuse, and dependence), and whether the FDA would approve Lyrica® for generalized anxiety disorder (“GAD”).

55. On December 31, 2004, the FDA approved Lyrica® for treating two specific neuropathic pain conditions: (1) Diabetic Peripheral Neuropathy (“DPN” -- diabetic nerve pain); and (2) Post Herpetic Neuralgia (“PHN” -- pain associated with shingles). On June 13, 2005, Lyrica® was also approved by the FDA as an adjunct therapy (*i.e.*, used in combination with

other seizure medications) to treat partial onset seizures in adults with epilepsy. Lyrica® was then approved by the FDA for the management of fibromyalgia on June 21, 2007. The most common side effects of Lyrica® include dizziness, somnolence, dry mouth, peripheral edema, blurred vision, weight gain, and difficulty with concentration/attention.

56. As part of its original NDA for Lyrica®, Pfizer had also sought FDA approvals for a number of indications for which Neurontin® had been used off label, including generalized anxiety disorder (“GAD”). GAD is an anxiety disorder that is characterized by excessive and uncontrollable worry about everyday things. The FDA gave Lyrica® a “non-approvable” letter for GAD in August 2004.

57. When the FDA gave Lyrica® the “non-approvable” letter for GAD, and delayed approval of other Lyrica® indications, market analysts reacted with concern. “This is certainly not positive,” said David Moskowitz, an analyst for Friedman, Billings, Ramsey, who added that his 2004 pregabalin revenue projection of \$130 million was now at risk. “The fact that they got a non-approvable letter for generalized anxiety disorder is a negative since Lyrica® was expected to get approved for all the off-label indications that Neurontin is being used for.”

58. Not only did Pfizer face the challenge of getting physicians to prescribe Lyrica® instead of gabapentin (when most of its uses were off-label), it faced new challenges with the introduction by competitors of products in the category, particularly Eli Lilly’s drug Cymbalta®, which was approved by the FDA for major depressive disorder and diabetic peripheral neuropathy on August 3, 2004, for GAD in 2007, and for fibromyalgia in 2008. Another significant competitor UCB’s drug Keppra® was first approved in 1999 as adjunctive therapy for adults with partial onset seizures, and later for primary generalized tonic-clonic (PGTC) seizures

in adults and children 6 years of age and older with idiopathic generalized epilepsy and for myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy (JME). Keppra® quickly had become the most prescribed second-generation anti-epileptic drug used to treat epilepsy in the United States.

59. In addition, by 2004, Pfizer had experienced a series of what were viewed as “failed” drug product launches, beginning with the Geodon® launch in 2001, the Relpax® launch in 2003, the Inspra® launch in 2003 all failing to meet profit expectations. *See* “The Pink Sheet,” April 26, 2004, p. 6. Moreover, in December, 2004, the company faced a loss of \$14 billion due to loss of patents on key products during 2005 through 2007. In order to deal with these series of failed launches, as well as declining revenues, Pfizer began an austerity program, including closing manufacturing plants and laying off employees around the world.

60. It thus became critically important for Pfizer to have a successful launch of Lyrica®, not only to shore up sagging revenues and move market share from its loss of patent exclusivity for Neurontin®, but also to fend off the challenge from competitors such as Eli Lilly’s Cymbalta® and UCB’s Keppra®, particularly for new indications for which Pfizer had attempted, but failed, to receive FDA approval.

**B. THE LAUNCH OF LYRICA®: FRAUDULENT MARKETING SCHEME TO GROW OFF-LABEL USE OF LYRICA®.**

61. Pfizer first placed Lyrica® on the market in August 2005. However, given the limited indications approved by the FDA and faced with intense competition, Pfizer knew it had only limited market potential for Lyrica®’s approved uses. Nonetheless, the company made the calculated business decision to replicate Neurontin®’s success by the illegal, off-label marketing

and misbranding of Lyrica®. Pfizer implemented its Fraudulent Marketing Scheme beginning shortly before the formal launch of the drug in September 2005. Sales representatives were told to ask their “top Neurontin targets” (without regard to what type of physicians they were going after) to switch to Lyrica®.

62. During their details, sales representatives were to emphasize with doctors that the reason Lyrica® came in so many different pill strengths was that there were all sorts of future indications coming from the FDA, including pre- and post-surgical pain, fibromyalgia, GAD, bipolar disorder, urinary incontinence, depression, and others.

1. **Unsubstantiated Lyrica® Superiority Claims to Gabapentin (Neurontin®).**

63. One of Pfizer’s key goals was to increase sales of Lyrica® by converting as many gabapentin prescriptions as possible to Lyrica® prescriptions, including those prescriptions that had been written for off-label uses as a result of Pfizer’s prior illegal promotion of Neurontin®. To accomplish the Lyrica®-for-gabapentin conversion goal, Pfizer promoted Lyrica® as being more effective than gabapentin, when there were no adequate head-to-head efficacy studies comparing the two drugs.

64. Before it will approve a drug for a specific indication, the FDA requires that a drug’s effectiveness be demonstrated by “adequate and well-controlled clinical investigations.” 21 C.F.R. § 314. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. According to the FDA’s 1998 *Guidance to the Industry*, “it has been FDA’s position that Congress generally intended to require at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness.”

65. As a result of the FDA's clear policy requiring "substantial evidence" to support marketing claims, a drug maker may not make comparative efficacy claims to physicians based on comparing product inserts (a product's approved labeling), nor may a drug maker's promotion to physicians compare two non-comparative trials (due to differences in trial designs, inclusion criteria and other factors).

66. Despite the fact that there were (and still are) no adequate, well-controlled head-to-head clinical studies supporting a comparison of gabapentin (Neurontin®) and Lyrica®, Pfizer developed and distributed promotional materials for its sales representatives claiming that Lyrica® was superior to gabapentin (Neurontin®). These materials were prepared and used as part of its Fraudulent Marketing Scheme to convert gabapentin (Neurontin®) use to Lyrica®, including the millions of prescriptions written for off-label uses.

(a) **Pre-Launch Marketing Claims of Lyrica® Superiority.**

67. The Pfizer sales force began preliminary marketing of Lyrica® at or around August 23, 2005. From the outset, Pfizer's plan was to urge physicians to switch from gabapentin, claiming that Lyrica® was superior. For example, at the August 23, 2005 Plan of Attack ("POA") meeting at the Collins Plaza Hotel in Cedar Rapids, Iowa, District Manager Tracy Lucas instructed the sales force to talk about Lyrica®'s efficacy compared to gabapentin, and to talk about the bioavailability of Lyrica® as compared to gabapentin. Lucas instructed representatives they were to tout that Lyrica® was a "better agent" than gabapentin (Neurontin®) despite the lack of any head-to-head adequate, well-controlled clinical trials.

68. Access to government formularies was key for a successful launch of Lyrica®. Besides the additional sales this would garner, placement on government formularies -- including

the State of Iowa Medicaid formulary and the University of Iowa Hospitals and Clinics (“University Hospitals”) formulary -- were very influential in “bandwagon” promotion to other formularies and prescribers.

69. Representatives were immediately to undertake focused efforts to obtain formulary status on key government formularies – such as the University Hospitals and the State of Iowa Medicaid formularies.

**(b) Lyrica® Launch: Superiority Claims Over Gabapentin.**

70. On September 12-15, 2005, Pfizer formally launched Lyrica® for widespread sales and marketing. As part of the launch, Relators attended a meeting in Anaheim, California with all the APM (arthritis, pain and metabolic) representatives for the entire United States, some 4,000 Pfizer sales representatives.

71. Pfizer spared no expense for the Lyrica® launch, staging numerous elaborate presentations. On one stage at the Anaheim meeting there was a mammoth fountain of boiling water where singers sang about the “Power of Pain,” while Bruce Fleischman (APM Vice President) stood over the boiling water, his arms in the air, exhorting “The Power of Pain!!!” Throughout the meeting, speakers touted the comparison of Lyrica® to gabapentin, telling those present that Lyrica® is “so good it can sell itself.”

72. During the meeting Lyrica® launch binders were distributed customized with targeted marketing for each representative, listing particular physicians they were to call on, including:

- “Thought leaders” who included “Lyrica® speakers, Investigators, and Key Opinion Leaders who are experts” on the approved conditions;

- Top 20 account information, sorted by total market sales from May 2004 through April 2005 based on the sales of Neurontin®;
- “Insell” opportunities for sales to community hospitals – *i.e.*, which provide opportunities to sell off-label to hospitals without the sale being traceable in the Pfizer Sherlock database;
- Sales opportunities with governmental accounts such as correctional facilities, Medicaid programs and VA Hospitals;
- Pain clinics within the representative’s region; and
- An “opportunity report” of the top 25 specialty physicians, tracking the gabapentin (Neurontin®) usage for each.

73. The message from the Anaheim launch meeting to the Pfizer sales force was clear. Representatives were expected to work diligently to get Lyrica® on prominent formularies (especially government formularies) and sell Lyrica® to doctors who had been prescribing gabapentin.

74. The head of Pfizer Germany was in attendance at the Lyrica® launch and told the entire sales force that “through successful selling efforts, Pfizer had managed to convert over 60% of all Neurontin® prescriptions in Germany to Lyrica® in one year.” The goal was to do at least as well in the United States.

75. The Pfizer computer system that tracks the representative’s calling activity, “Sherlock,” includes pre-loaded information on each doctor’s name, location, phone number, license number, DEA number, specialty, prescribing patterns, and health plans in which the doctors participate (and targeting government-funded programs). The Sherlock database tracks a wealth of information on doctors’ prescribing patterns through data purchased from third party vendors who assemble this information for drug makers like Pfizer. This database is updated regularly, and provides representatives with the doctors they are to call on – their “call cycle.”

The representatives are then to enter the results of their calls on Sherlock as part of the tracking system for each doctor, any free samples given to the doctor, and sales information provided to the doctor.

76. On sales representatives' call cycles for potential sales of Lyrica® were all the physicians who had been Neurontin® writers, including numerous physicians who would have had no occasion to treat patients for the on-label conditions for which Lyrica® was approved (such as orthopedists, psychiatrists, physiatrists, and rheumatologists), but on whom sales representatives were expected to market Lyrica® nonetheless. Relator Farber's Pfizer call cycle, for example, included over 50 orthopedists as well as numerous rheumatologists, psychiatrists, and physiatrists. The only possible use of Lyrica® for these physicians would thus be off-label uses. As such, Pfizer planned the sales representatives' call cycles by capturing its knowledge of historical off-label Neurontin® sales and recycling these as targeted off-label sales for Lyrica®.

77. In addition, the sales force was given a generous supply of side-by-side comparative Lyrica® v. gabapentin marketing materials called "Compare and Win" pieces. The marketing pieces presented each drug's indications, the bioavailability of each drug as compared to the other, and Lyrica®'s efficacy as opposed to gabapentin (Neurontin®), even though no adequate head-to-head studies comparing Lyrica®'s efficacy to gabapentin (Neurontin®) had ever been conducted. Sales representatives were trained to use the side-by-side materials to misrepresent the onset of action for Lyrica® in comparison to Neurontin®, and tell physicians that (in comparison to Neurontin®'s slow onset of action) many Lyrica® patients would see a dramatic reduction in pain or be pain-free after the first full day of treatment when there was no evidence this was true.

78. Pfizer sales executives directed representatives to use these side-by-side sales materials immediately because it was unclear how long they would remain “approved” by Pfizer. Thus, from the outset Pfizer sales management knew exactly that the use of these materials would likely soon be found to violate Pfizer compliance policy concerning false and misleading comparative marketing, but used them anyway because this was critical to the success of converting gabapentin prescriptions to Lyrica®.

**(c) Post-Launch Superiority Claims and the Use of Side-By-Side Promotional Materials With Unsupported Comparative Claims.**

79. Pfizer’s senior sales management from the outset insisted that representatives sell Lyrica®’s superiority to gabapentin “at any cost.” For example, on January 5, 2006, David Cogan, a senior sales manager from Pfizer headquarters in New York City, joined Relator Farber on a field ride. During this field ride, Cogan commented that Relator Farber was not aggressive enough in his sales presentations, and that he was not “going in for the kill” or “getting the sale at any cost.”

80. Later that day, Relator Farber and Cogan met over lunch in Cedar Rapids, Iowa with Dr. Winthrop Risk and his partner Dr. Mark Fortson, two key neurologists in the area who treated a high volume of Medicaid patients. During the lunch, Cogan commented that Lyrica® is more efficacious than gabapentin, and that Pfizer “believes in Lyrica®’s potency” compared with gabapentin. At the time, the Iowa Medicaid Pharmacy & Therapeutics (“P&T”) Committee had just approved use of Lyrica® without a prior authorization requirement, a point which Cogan emphasized to Drs. Risk and Fortson. In addition, Cogan promoted other investigational uses of

Lyrica® to Drs. Risk and Fortson, including for the management of fibromyalgia, at that time still an off-label use.

81. Senior sales executive Cogan's promotional statements to Drs. Risk and Fortson misbranded Lyrica® because (a) there were no peer-reviewed, pharmacokinetic studies which substantiate claims that Lyrica® was more efficacious than gabapentin, so Cogan's statements were false; (b) Lyrica® was not approved for fibromyalgia; and (c) The *Field Guide* instructs them not to mention any uses for drug products except for FDA-approved uses.

82. Following the launch of Lyrica®, sales representatives received numerous reports tracking sales figures showing the success in converting gabapentin prescriptions to Lyrica® nationally. The reports then drilled down regionally and to the sales representative's specific call cycle to show the success in getting specific physicians to convert from prescribing gabapentin (Neurontin®) over to Lyrica®.

83. In addition, sales representatives received weekly "High Writers" reports showing every physician in their call cycles who was prescribing Lyrica® and gabapentin (Neurontin®) "opportunities." Included the "High Writers" reports were numerous psychiatrists, physiatrists, rheumatologists, and other physicians who did not have a reason to prescribe Lyrica® on-label to their patients, but who nonetheless were included on the list as potential "opportunity" for Lyrica®. One of the key "High Writers" reports tracked doctors who had written Neurontin® prescription for Medicaid patients.

84. In September of 2006, Pfizer issued a new, two-page side-by-side promotional detail pieces, PB271524A, including clinical studies in the pockets on each side. Inside on the left side of PB271524A was a list of the pharmacokinetic properties of Neurontin, including in

the pocket behind it two gabapentin clinical study reprints, one from the *Journal of the American Medical Association* authored by Rowbotham, et al., entitled “Gabapentin for the Treatment of Postherpetic Neuralgia,”<sup>1</sup> comparing the efficacy of gabapentin to a placebo. On the right side was a list of the pharmacokinetic properties of Lyrica, including in the pocket behind it three pregabalin (Lyrica®) clinical study reprints, including one authored by Dworkin, et al. from *Neurology*, entitled “Pregabalin for the Treatment of Postherpetic Neuralgia,”<sup>2</sup> comparing the efficacy of Lyrica® to a placebo.

85. Sales representatives were trained to use PB271524A in a “Pfizer Math” detail touting superior pain scores with Lyrica® to pain scores for gabapentin using the completely different, non-head-to-head *Dworkin* and *Rowbotham* studies. They were directed in their details to use the “Global Impression of Change” scores, also called “pain scores,” from these two completely different studies in order to tout Lyrica’s superiority. Not only were the *Dworkin* and *Rowbotham* studies not head-to-head, there was no evidence at all to suggest they used identical trial designs or inclusion criteria. As such, according to the *Field Guide*, “it is not permissible to compare results from two non-comparable trials.” *Field Guide* at 22.

86. A contemporaneous voice mail from District Manager Lucas explains how sales representatives were to use the sales materials to develop a “Pfizer Math” detail using non-comparable *Dworkin* Lyrica® study with its 84% pain scores and the *Rowbotham* gabapentin

---

<sup>1</sup> Rowbotham, et al., “Gabapentin for the Treatment of Postherpetic Neuralgia: A Randomized Controlled Trial,” *JAMA*, 280:1837-1842 (1998).

<sup>2</sup> Dworkin, et al., “Pregabalin For The Treatment Of Postherpetic Neuralgia: A Randomized, Placebo-Controlled Trial,” *Neurology*, 60(8): 1274-1283 (2003).

study with its 60% pain scores to emphasize that “Lyrica is better, Lyrica is more effective than gabapentin”:

Hey, Team, it’s Tracy here. Hey, I received a couple of questions over a detail from the conference call this morning, and wanted to just try and go over things...over these few minutes on voice mail. First of all, the first spread, again, is *Dworkin* on the left and on the right it is going to be *Rowbotham*. So, it is [page] 1277 is *Dworkin*, [page] 1840 at *Rowbotham*. That’s the spread. On *Dworkin*, what you are pointing out is that 84%. Eighty-four percent of the patients said that their pain had been improved from the previous assessment. What we are looking at on the scale is the “PGIC,” which is Patient’s Global Impression of Change, and their pain score. That is also what we are looking at on the right side of your detail on [page] 1840—that’s *Rowbotham*, Figure 3. That is where we get the 60% from....that’s adding 43% plus 17%, equals 60% improvement on that subject’s Global Impression of Change or the patient’s Global Impression of Change. So the difference there in the studies is 84% improvement with Lyrica using the same scale, and 60 or 61% with gabapentin. So, as many times as we can say it... “Lyrica is better, Lyrica is more effective than gabapentin ...”.

The information Lucas instructs sales representatives to provide to doctors in the detail was thus intended to misrepresent that the pain scores demonstrate Lyrica®’s superiority to gabapentin (Neurontin®).

87. In another voicemail a short time later, Lucas explained “we really can’t say this enough: that Lyrica is better than, or more efficacious than, gabapentin/Neurontin.... Our share I know will rise if we keep with the strategy of Lyrica is better than gabapentin/ Neurontin.”

88. And, several weeks later, Lucas explained in a sales meeting how they were to use the two non-comparable studies in their details with doctors to create the impression that Lyrica® is better: “So, again, the comparison is 84% with Lyrica, 60% with gabapentin. We really can’t—it’s not possible to say that too much in a presentation. So, the conclusion would be Lyrica works better than gabapentin.”

(d) **Pfizer Withdraws Misleading Lyrica® Marketing Materials on November 27, 2006.**

89. Beginning as early as the launch in August 2005, both Relators had made numerous complaints concerning Pfizer's use of improper comparative claims touting the superiority of Lyrica® to gabapentin (Neurontin®). Not only were Relators' complaints ignored for months, as discussed in more detail below, Pfizer retaliated against them for their whistleblowing through the use of trumped-up "Open Door" complaints and compliance violations.

90. At the High Plains POA on November 9, 2006 held in Denver, Colorado there was a presentation given entitled "Learning from Our History," discussing among other issues that Pfizer had entered into the Neurontin® settlement and Corporate Integrity Agreement ("CIA"), and that the company intended to take the lessons learned to strictly enforce compliance violations. Among other practices specifically discussed at the Denver meeting was that sales representatives could no longer make comparisons of drugs without adequate, head-to-head studies supporting the comparison.

91. On November 27, 2006, in an e-mail to all APM sales representatives, Kathleen Dowd, the Pfizer Lyrica® team leader, announced that the side-by-side comparisons (including the use of the *Dworkin* and *Rowbotham* studies) were to be withdrawn:

**APM RMs, DMs, PHRs, and TSRs,**

As we recently communicated to you, product features reflected in the side-by-side Lyrica/Neurontin chart in the Lyrica promotional materials are the only appropriate bases for comparing Lyrica to Neurontin/gabapentin. These product features are molecular structure, FDA-approved indications, oral bioavailability, dose potency, time to reach an effective dose, and dosing schedule. Statements comparing the efficacy or safety of Lyrica to Neurontin/gabapentin are not substantiated by head-to-head studies and, therefore, are not acceptable.

In order to ensure that we stay focused on promoting the approved benefits of Lyrica while at the same time maintaining an unimpeachable focus on compliance, we have decided to cease using and distributing the stand-alone side-by-side Lyrica/Neurontin profiler containing the following Neurontin clinical reprints: "Gabapentin as add-on therapy in refractory partial epilepsy -- A double-blind, placebo-controlled, parallel-group study" (reprinted from Neurology) and "Gabapentin for the treatment of postherpetic neuralgia -- A randomized controlled trial" (reprinted from JAMA). AS A RESULT, EFFECTIVE IMMEDIATELY, YOU ARE TO STOP USING AND DISTRIBUTING THE PROMOTIONAL PIECES WITH THE FOLLOWING CONTROL NUMBERS PRINTED ON THE BACK:

PB271524  
PB271524A

The Neurology and JAMA clinical reprints discussing Neurontin, which were included in the pocket of the side-by-side Lyrica/Neurontin profiler, are no longer approved and are not to be used.

92. In the face of the Relators' numerous complaints about Pfizer's use of the improper side-by-side promotional materials and unsubstantiated superiority claims, Dowd's statement concerning the company's "unimpeachable focus on compliance" is not only blatantly false, it demonstrates a remarkably cynical view of what it means to comply with the law. Moreover, the e-mail refers to the *Dworkin* and *Rowbotham* reprints as having formerly been "approved," when they were never included in the OLOS list of approved reprints in the first instance.

93. On December 9, 2006, District Manager Lucas left a voicemail reiterating Dowd's message that they could no longer compare Lyrica® and Neurontin®: "I wanted to let you all know I am sending over an e-mail tonight just to reinforce . . . one item from our POA and that is the POA presentation. It was 'Learning from our History.' It was the presentation that was on the comparison between Lyrica and Neurontin. In fact, we cannot do that. Anyway, you'll see it over tonight. It's pretty self-explanatory but it just reinforces the fact that we cannot

make any efficacy or safety comparisons between Lyrica and Neurontin.” An email that Lucas sent to the sales team that night retracts Pfizer’s insistence that sales representatives were to market Lyrica® using comparative statements: “To be absolutely clear, it is not appropriate to compare pharmacokinetic features and then ask the physician to agree that based on those features Lyrica is more efficacious than Neurontin/gabapentin. I realize that this is a departure from direction I provided earlier this fall when we set up our new Lyrica details.”

94. While Pfizer internally communicated that it was no longer acceptable for sales representatives to make such comparisons, no such communication was ever made to any of the doctors it had pitched Lyrica®’s superiority to for over a year. Nor was such information ever provided to any government programs.

95. Even though Pfizer had officially withdrawn the side-by-side marketing materials, the damage had largely been done. By late 2006, Pfizer had successfully completed much of its goal of converting as many gabapentin (Neurontin®) sales to Lyrica® as possible. Having convinced much of the marketplace that Lyrica® was superior to gabapentin (even though Pfizer had no substantial evidence to support these claims) by the end of 2006 Lyrica® was the blockbuster drug Pfizer needed to shore up its sagging profits, with sales revenue of \$1.2 billion, and became the first new Pfizer drug in more than a decade to earn more than \$1 billion in a year. The success of the gabapentin conversion scheme set the stage for Pfizer to generate even more revenue in 2007, \$1.8 billion, a 58% increase over 2006 sales of Lyrica®.

## 2. **Unsupported Superiority Claims to Keppra®.**

96. Another strategy employed by Pfizer in the Fraudulent Marketing Scheme involved false comparisons of Lyrica® superiority to a competing drug, Keppra®. Shortly after

the Lyrica® launch, Pfizer had realized that neurologists who were the most likely to be prescribing Lyrica® on-label for treatment of epilepsy were rarely prescribing the drug and instead were using Keppra®, which was the drug of choice among many treating neurologists. Pfizer thus developed specific sales strategies aimed at unseating Keppra® as the leading treatment for seizures and increasing Lyrica®'s market share through the unsubstantiated comparisons of the two drugs.

97. In furtherance of this scheme, on May 9, 2006, at the Technology Park Hilton in Denver, Colorado, Pfizer's senior sales management directed the Therapeutic Specialty Representatives ("TSRs") that they were to undertake a "Compare and Win" detail, comparing the purported efficacy of Keppra® to Lyrica®. Pfizer instructed representatives they were to use seizure reduction data from two non-comparable studies (one for Lyrica® and one for Keppra®) to illustrate Lyrica®'s purported superiority. According to the directives given, even though there had never been a head-to-head trial of the two drugs, sales representatives were to create the impression for doctors that there had been such a head-to-head trial. Not only were these studies not head-to-head, there was no evidence to suggest comparable dosing regimens, common study protocols, trial designs, or inclusion criteria.

98. Pfizer instructed representatives they were not to mention, nor in any way draw attention to, the fact that the Lyrica® study on which Pfizer relied to make its unsubstantiated and deliberately misleading head-to-head comparisons was a study for partial onset seizures in adults, the only epileptic condition for which Lyrica® is an FDA-approved treatment. In this way, Pfizer used deception to mislead doctors and other healthcare professionals to believe that Lyrica® treated the same types of epilepsy as Keppra®. Thus, Pfizer representatives were

trained to, and did, use what they called internally “Pfizer Math” to intentionally create the false impression that there had been head-to-head comparisons between Keppra® and Lyrica® showing Lyrica®’s superiority when there were no such studies.

99. Moreover, by promoting Lyrica® as more efficacious than Keppra®, Pfizer was representing that the 51% reduction in seizures in patients being treated with Lyrica® was across the board, meaning the same results would be experienced by *any* patient who was currently taking Keppra®, even if that patient was taking Keppra® for one of the seizure indications for which Lyrica® was not approved. As a result, Pfizer was instructing its sales representatives to off-label promote Lyrica® for treatment of numerous kinds of seizures for which it had no such approval from the FDA.

100. Later, during a conference call with TSRs in October 2006, Pfizer senior sales managers again instructed their sales representatives to emphasize the 51% vs. 37% seizure reduction as a means to tout Lyrica®’s improved “efficacy” as opposed to its competitor, Keppra®. Pfizer Medical also participated in this conference call and articulated the company’s position that, while Pfizer sales representatives could not “officially” tell doctors that Lyrica® was more efficacious than Keppra®, they could imply it by using the 51% vs. 37% seizure reduction rate information.

101. Pfizer thus engaged in a scheme of deliberate, misleading comparisons between Keppra® and Lyrica® when there were no such head-to-head studies available, in violation of Pfizer policy and FDA “substantial evidence” regulations. These unsubstantiated, comparative claims of Lyrica®’s superiority to Keppra® were (and are) prohibited by the Federal Food, Drug

and Cosmetic Act, 21 U.S.C. §§ 352, and 21 CFR 202.1(e)(6), as well as Pfizer's own internal sales policies.

**3. Marketing Lyrica® For All Neuropathic Pain and Nociceptive Pain Indications.**

**102.** As part of the Fraudulent Marketing Scheme to convert Neurontin® prescribers to Lyrica®, Pfizer intended that Lyrica also be prescribed not just for its two approved pain indications, DPN and PHN, but also for all neuropathic pain (“neuropathic pain”) and nociceptive pain conditions.

**103.** Following the launch of Lyrica® in 2005, Pfizer's challenge was how to convert all the off-label use of Neurontin® for the treatment of neuropathic pain and nociceptive pain over to Lyrica®, when Lyrica® had no such broad pain indications.

**104.** Pfizer's intent in converting the off-label use of Neurontin® to Lyrica® was to widen Lyrica®'s market by selling the drug with the completely unsubstantiated subtext that Lyrica® could be used to treat all forms of pain. According to Pfizer, many patients have “NON-painful” neuropathy, or simply nerve damage. While the original Lyrica® marketing pieces specifically said its indication was only for “painful neuropathy,” sales representatives were told to simply say Lyrica® was indicated for “neuropathy,” and imply it was included for non-painful neuropathy and nociceptive pain as well.

**105.** Pfizer provided specific training to its sales force to refine the off-label pain pitch during the POA Meeting on May 30-31, 2006. During the second day of the POA, when the meeting focused on Lyrica® sales and marketing strategies, sales representatives were given a training document prepared by Pfizer Corporate Sales that required the sales force to “gain

agreement that Lyrica® is different and more potent as an anti-epileptic drug when compared to gabapentin and others” when meeting and pitching Lyrica® to neurologists.

106. Sales representatives were told that the goal of the promotions was to “gain commitment from the physician that Lyrica® is better than gabapentin.” During this meeting the sales force was also directed to close details by gaining a commitment from the doctor to prescribe Lyrica® to any new patients who present with DPN or PHN and “for those patients on other therapies who are not pain-free or who are suffering side effects that limit their ability to enjoy a reasonable quality of life.”

107. At this May 2006 POA, sales representatives were given stacks of side-by-side comparison brochures with the heading “The pharmacology facts” and the statement, “Welcome to predictability and consistency.” While the side-by-side materials implied Pfizer had “facts” to support the broad pain claims, no substantial evidence existed for these promotional claims.

108. Pfizer’s message was clear: convert the Neurontin® off-label pain uses by getting doctors to choose Lyrica® for all pain conditions, not just for DPN or PHN.

#### 4. **Marketing Lyrica as Monotherapy for Treatment of Epilepsy.**

109. The FDA’s approval of Lyrica® (like it had been for Neurontin® as well) was limited to adjunctive use in combination with other seizure medications for the treatment of partial onset seizures. Like Neurontin®, Lyrica® was never approved for monotherapy use in the treatment of seizures, but only as a secondary (i.e., adjunctive) agent.

110. At the time of the launch of Lyrica®, Pfizer’s quandary was that, because it (and Parke-Davis before it) had been marketing Neurontin® off-label as a monotherapy treatment for all types of seizures (not just partial onset seizures), it needed a story to respond to doctor’s

inquiries about whether Lyrica® could also be used as a monotherapy for treatment of all forms of epilepsy, especially because there were a number of other on-label monotherapy agents available.

111. To get around the same monotherapy limitations as had been imposed on Neurontin®, Pfizer sales representatives were instructed what to say if a doctor asked whether Lyrica® could be used as a monotherapy agent. Sales representatives were instructed that, although Lyrica® was indicated as a secondary agent, they should nonetheless tell doctors: “You are an expert. It is within your clinical judgment to use it as a monotherapeutic agent.”

112. Sales representatives were extensively trained on a district, regional and national level to tell doctors asking about using Lyrica® as a monotherapy agent that, for Lyrica® to get an anti-epileptic drug approval from the FDA with so many other anti-epileptic drugs already on the market, it needed to have demonstrated that it was a novel drug product – i.e., that it was better than Neurontin®.

113. Sales representative were also trained to encourage physicians to experiment with the use of Lyrcia® as a monotherapy by saying that Pfizer was “actively working on a monotherapy indication, but the FDA wanted to drug to be on the market for a few years first.”

114. These representations about Lyrica®’s efficacy as a monotherapy agent violated Pfizer’s marketing policy as well as FDA marketing regulations, and effectively misbranded it beyond its product labeling.

##### **5. Using Secondary Endpoints to Off-Label Promote Lyrica®.**

115. One of the most aggressive off-label schemes developed shortly after the launch was the promotion of the “secondary endpoints” from several Lyrica® studies and the

unapproved uses of Lyrica® from those studies. At the launch meetings in September 2005, Pfizer senior sales executives instructed its sales force, including Relators, to market Lyrica®'s purported "secondary endpoints." These secondary endpoints had been mentioned in two Pfizer-sponsored studies of Lyrica®, *Dworkin*<sup>3</sup> and *Rosenstock*,<sup>4</sup> as possible additional beneficial endpoints reached other than those intended in the study. These secondary endpoints included sleep medication, and for its use in reducing anxiety and total mood improvement. These secondary endpoints indications are not FDA-approved.

116. This marketing of Lyrica®'s secondary endpoints became pivotal in the Fraudulent Marketing Scheme. For example, at a POA meeting in Cedar Rapids, Iowa at the end of October 2005, District Manager Lucas directed the sales representatives to include secondary endpoints when marketing Lyrica® to health care professionals. Lucas responded to off-label concerns by saying that it was okay to proceed with marketing secondary endpoints, and if anyone got in trouble, the sales team could "blame it on Stuart," meaning Stuart Smith, the Regional Manager, who had directed the sales representatives to use the secondary endpoints as part of the marketing pitch.

---

<sup>3</sup> Dworkin, et al., "Pregabalin for Treatment of Postherpetic Neuralgia: A Randomized, Placebo-Controlled Trial," *Neurology*, 60(8): 1274-1283 (2003). According to the *Dworkin* study, the secondary endpoints included additional pain ratings, sleep interference, quality of life, mood, and patient and clinician ratings of global improvement.

<sup>4</sup> Rosenstock, et al., "Pregabalin for the Treatment of Painful Diabetic Peripheral Neuropathy: A Double Blind, Placebo-Controlled Trial," *Pain*, 110:628-38 (2004). According to the *Rosenstock* study, the secondary endpoints included additional pain ratings, sleep interference, quality of life, mood, and patient and clinical ratings of global improvement.

117. On April 17, 2006 Pfizer circulated the *Freeman, et. al* abstract<sup>5</sup> presented at the 58th American Academy of Neurology (“AAN”) meeting as a “Do Not Detail” marketing aid to sales representatives. In an e-mail dated April 17, 2006, Regional Manager Smith sent the *Freeman* abstract to the sales team with an admonition “Do Not Detail.” While this was made to appear that Pfizer was instructing sales representatives to stay on-label, instead the use of “Do Not Detail” was meant by Pfizer to be exactly the opposite: Pfizer intended that its sales representatives use the materials in promoting Lyrica® off label for sleep disturbance. Representatives were to report “areas of continued investigation with Lyrica” as part of their details.

118. In addition to discussing the fact that the study’s secondary endpoints message about sleep disturbance, the *Freeman* abstract also discussed the fact that Lyrica® had “demonstrated efficacy” for treating pain associated with fibromyalgia, osteoarthritis, and spinal cord injury – all off-label.

**6. Failure to Engage in Fair and Balanced Promotion of Lyrica®’s Side Effects.**

119. FDA regulations require Pfizer sales representatives to provide fair and balanced information when promoting Lyrica®, including explaining safety issues. However, from the outset of the launch of Lyrica®, sales representatives were told to tout the fact that, by comparison to gabapentin, which required titration of up to three weeks to reach an effective dose, Lyrica® was effective immediately. This ability to titrate patients immediately on Lyrica® was an important selling point for Lyrica® in getting doctors to switch from gabapentin, which

---

<sup>5</sup> Freeman R, et al., “Pregabalin Rapidly and Significantly Improves Sleep Disturbances in Chronic Pain Syndromes and Is Associated With Sleep Improvements in Health Volunteers,” Abstract EV1.014, poster presented on April 2, 2006 at the 58th American Academy of Neurology (“AAN”) meeting.

required more active involvement of doctors titrating patients to an effective dose. The titration difference became a key selling point in driving the launch of Lyrica®, and one which the sales force was told should be marketed heavily to doctors.

120. Shortly after the launch Relators and other sales representatives began receiving reports from doctors that patients were suffering from serious side effects when they started on Lyrica®, complaining their patients starting out on Lyrica® suffered from severe dizziness and edema (weight gain).

121. There were numerous complaints. One doctor complained that a patient reported a weight gain of over 30 pounds after suffering from peripheral edema caused by starting on Lyrica®. In another example, a doctor raised concerns that one of his patients became extremely hostile, agitated, and delusional after starting on Lyrica®. Another doctor was concerned because one of his patients described the feeling of being on Lyrica® as “being glued to the wall.” And, another doctor reported that one of his patients almost died due to taking Lyrica®. These and other complaints were reported to senior Pfizer management.

122. In response to the reports of side effects and doctor pushback (because it needed to keep up the “message” about superiority claims with regard to Lyrica®’s immediate onset of action in comparison to Neurontin®), Pfizer Corporate directed that sales representatives should tell doctors to continue the recommended dosing and the side effects go away.

**7. Falsified Call Notes to Support Unsolicited Medical Inquiry Requests for Lyrica® Off-Label Information.**

123. One of the more flagrant ways that Pfizer dramatically increased the off-label promotion of Lyrica® was by manipulating requests for Medical Inquiry letters from the Pfizer

Medical Information Department. A “Medical Inquiry” is Pfizer’s in-house term for a physician request for off-label information for one of Pfizer’s drugs, in this case Lyrica®.

124. Abuses related to Medical Inquiries had been a specific concern in the government’s Neurontin® investigation and were specifically included in the Neurontin® Corporate Integrity Agreement (“CIA”), *see* CIA at 9, and were against Pfizer’s policies.

125. To evade detection under the Neurontin CIA and get around Pfizer’s Medical Inquiry policy, senior sales management directed representatives to falsify their call notes to make it appear that physicians had requested this information be sent at the physician’s request even though physicians had never made the request.

126. Pfizer management has condoned, in fact encouraged, this practice for years for Lyrica® and other drug products, and even has instructed sales representatives how to avoid detection by warning that submitting too many phony Medical Inquiries all at once would cause red flags to come up. In addition, sales managers would particularly push sales representatives to increase the number of Medical Inquiry requests just before the end of the sales year in order to increase their sales numbers. As a result, the volume of Medical Inquiries would regularly spike just before the end of the sales year, at the end of September.

127. Pfizer knew the phony Medical Inquiry requests constituted off-label promotion, was prohibited from doing so by law, but nonetheless did so because it would increase sales of Lyrica®. The use of falsified Medical Inquires as a way to promote off label and to avoid detection is a widespread, systemic problem at Pfizer and part of the corporate culture which encourages increasing sales by any means.

8. **Quota System to Induce Marketing to Doctors and Facilities Who Do Not Treat Patients With Conditions Requiring the On-Label Use of Lyrica®.**

128. Yet another off-label marketing scheme employed by Pfizer as part of the Fraudulent Marketing Scheme was to market Lyrica® to doctors who do not treat patients for any of its on-label uses, but may be influenced by Pfizer to prescribe Lyrica® off-label.

129. Pfizer's national Lyrica® sales strategy included quota and credit programs that both penalized and incentivized the sales force to sell to doctors who could not treat their patients using Lyrica® on-label. Pfizer knew that these programs created a working environment that was conducive to promoting Lyrica® for as many uses and as wide a patient base as possible. The quota and credit programs were instituted immediately upon Lyrica®'s launch in 2005, and applied to sales representatives, District Managers, Regional Managers and Vice Presidents.

130. Pfizer's quota system required Lyrica® sales representatives to detail any physician on their call list (regardless of specialty) and awarded them with bonuses based on sales of Lyrica®. Lyrica® sales representatives that exceeded quota would be paid additional bonus dollars and additional chances of winning award trips. The prescribers Pfizer included in its quota and credit programs were doctors that would not normally treat patients with Lyrica®'s approved indications. These doctors included psychiatrists, orthopedists, rheumatologists, physiatrists, spine surgeons, and general surgeons.

131. The solicitation of psychiatrists, orthopedists, rheumatologists, physiatrists, spine surgeons, general surgeons, etc. who did not treat patients with conditions related to Lyrica®'s FDA-approved uses was common.

132. For example, in November 2005, District Manager Lucas left a voicemail for Relator Farber requesting that he leave marketing materials, including the *Dworkin* and *Rosenstock* studies, with Dr. Michael Flaum, a psychiatrist at the University of Iowa Hospital who chairs the Iowa Medicaid P&T committee. District Manager Lucas specifically informed Relator Farber that he should not record his call to Dr. Flaum in Pfizer's Sherlock system, and that he should not "leave a business card or anything like that."

133. Pfizer provided various annual and "spot" bonuses to reward sales representatives for meeting goals set for Lyrica® sales. One such spot program was a bonus program called "Awards Celebrating Excellence" or "ACE" under which representatives could win points for exceeding their short-term goals in specific sales promotions. These points could then be exchanged for awards including stereo equipment and other items in an ACE catalogue.

134. As an example of a promotion in which sales representatives could receive ACE points for off-label promotion of Lyrica®, at the May 31, 2006 POA, Pfizer announced the "Gaba is Going, Going, Gone" contest for sales representatives, aimed at rewarding ACE points for sales representatives who successfully converted gabapentin (Neurontin®) scripts to Lyrica®. In order to win ACE points, representatives had to exceed their quota for sales to physicians included on their call lists, including sales to numerous psychiatrists, rheumatologists, and physiatrists. The off-label "Gaba is Going, Going, Gone!" message was explicit: representatives were to "[t]ake market share from gabapentin" and detail the fact that "Lyrica is a better option vs. gabapentin."

9. **Using "Insell" to Hospitals to Avoid Detection of Off-Label Promotion.**

135. Another key to Pfizer's Lyrica® success was the concept of "insell" – *i.e.*, sales of Pfizer drugs for prescriptions filled at a hospital pharmacy as opposed to an external pharmacy like CVS. "Inselling" a product at a hospital allowed a sales representative to market off-label without Pfizer Legal becoming aware of the sale because there was no record to trace the off-label sale other than a general record of a sale to a hospital. The benefit of "inselling" a drug at a hospital is that it is very easy to off-label market a drug like Lyrica® within the hospital because the department that dispenses the drug is not tracked on Pfizer's Sherlock system. This is because, when the sale is recorded, the hospital will be listed as the purchaser, but the department will not be listed.

136. District Manager Lucas talked extensively about how to use "inselling" as a means to increase Lyrica® sales at hospitals as a means to avoid detection of off-label promotion. For example, Lucas directed Relator Farber, while he was at the University Hospitals making his normal sales visits, to stop at the Psychiatric Clinic to encourage the doctors there to write Lyrica® scripts. He advised Relator Farber not to log such visits into Sherlock (as every sales representative was required to do) because psychiatrists would have no reason to prescribe Lyrica® as the drug is not indicated for any psychological conditions, such representations were off-label. While Farber would still receive sales credit for a sale to the University Hospitals, since this was an "insell" situation there was no opportunity that the promotion to the Psychiatric Clinic would thus be detected.

137. In another "insell" example in the fall of 2006, Pfizer sponsored a Continuing Medical Education ("CME") talk on Arthritis and Pain at Los Angeles Metropolitan Hospital ("L.A. Metro"). L.A. Metro's primary focus for Pfizer was its large inpatient psychiatric unit

and outpatient orthopedic surgery department. District Manager Ciccarelli directed Relator Schildhauer to market Lyrica® to L.A. Metro psychiatrists off-label, and told him that (since these in-sell sales would not be traceable off-label sales) the L.A. sales team would nonetheless be compensated by Pfizer as in-sell sales.

**10. The Lyrica® “Upgrade” Scheme to Defraud the Medi-Cal Program.**

138. Although Pfizer’s strategy for off-label and deceptive marketing of Lyrica® was company-wide, different sales regions developed unique ways to work around state and federal Medicaid regulations, thereby, defrauding those programs.

139. For example, during a team conference call and also in a broadcast voicemail message, District Manager Ciccarelli instructed representatives how to use a false prescription scheme, euphemistically referred to as “the Lyrica® upgrade strategy,” to ensure Lyrica® was reimbursed by Medi-Cal (the Medicaid program for the State of California).

140. At that time, Medi-Cal had not placed Lyrica® on its formulary and required patients to have failed on gabapentin before Medi-Cal would approve the use of Lyrica®. To get around this prior authorization requirement, sales representatives were directed to encourage prescribing doctors to write two prescriptions whenever gabapentin was prescribed. One prescription would be for gabapentin, the other for Lyrica®. The sales representatives were then directed to request that the doctor date the Lyrica® prescription for exactly one week or seven (7) days following the date written on the gabapentin prescription. Further, the doctor was to give the patient a coupon for a free seven (7) day trial of Lyrica® and send the patient to the pharmacist, instructing the patient to give the pharmacist both the gabapentin and Lyrica® prescriptions. The sales representatives would then talk to those pharmacists with whom they

were most closely aligned and instruct them to fill both prescriptions. The patient would come back to the pharmacist to pick up the Lyrica® prescription and although it was filled, never take the gabapentin.

141. Once put into use, this sham gabapentin prescription strategy was so effective that the L.A. Confidential team began to use it for managed care patients as well.

11. **Using Pfizer-Sponsored Presentations by “Key Opinion Leaders” to Promote Off-Label Use of Lyrica®.**

142. Pfizer used speeches by retained “Key Opinion Leaders” to drive sales of Lyrica®. Many of these speakers promoted Lyrica® for off-label uses.

143. One such speaker was Dr. Loralu Raburn, a geriatric neurologist specializing in Alzheimer’s disease and an adjunct professor at Texas Tech University School of Pharmacy. Although her Texas medical license is active, Dr. Raburn does not actively practice medicine. She has been a national speaker for Pfizer since 1998 and for Lyrica® specifically since 2005, and has spoken about Lyrica® on numerous occasions, charging \$3,000 per day. Her annual speaker’s cap is \$150,000 per year.

144. For example, Dr. Raburn gave a Pfizer-sponsored speech to a group of doctors at the CU Restaurant in Waterloo, Iowa, which included unsolicited off-label representations of using Lyrica® to treat migraine headaches. Dr. Raburn later admitted to Relator Farber that the only apparent evidence she had to support the off-label use of Lyrica® for migraines was anecdotal information that her husband was using it for his migraines.

145. Migraine had been one of the largest off-label uses for Neurontin®. Dr. Rosenthal’s analysis found that between September 2005 and December 2004 there were 679,075 off-label Neurontin® prescriptions for migraine. Thus, Dr. Raburn’s off-label promotion

for use of Lyrica® to treat migraines was consistent with the ongoing efforts by Pfizer to convert off-label Neurontin® (gabapentin) use to Lyrica®.

146. Because Dr. Raburn's off-label remarks at the CU Restaurant were not in response to specific, unsolicited questions, her statements were impermissible off-label promotion.

147. Later, in the fall of 2007 Pfizer sales representative Jennifer Bohr took Dr. Raburn on a sales call to visit Dr. Winthrop Risk in Cedar Rapids, Iowa to talk about Lyrica®. During the visit Dr. Raburn again discussed Lyrica® for off-label use to treat migraines.

148. As a result of the off-label migraine promotional claims made by Dr. Raburn, Dr. Risk (a neurologist from Cedar Rapids who treats a large number of Medicaid patients for pain and migraine), began prescribing Lyrica® off-label as a first-line medicine for the treatment of migraines, including to numerous of his Medicaid patients.

**12. Use of Regional Medical Research Specialists to Promote Lyrica® Off-Label.**

149. Another Pfizer strategy to promote Lyrica® for non-approved uses is the use of Pfizer Regional Medical & Research Specialists ("RMRSs") as an end-around sales representatives' duty to lawfully promote Lyrica®. Pfizer's use of RMRSs in this manner was against Pfizer policy and was a way for Pfizer to make the unlawful promotional activities for Lyrica® appear lawful. Indeed, senior sales managers in 2006 announced that they were undertaking an aggressive national initiative to use RMRSs to promote Lyrica® because they are allowed to talk with physicians about off-label uses.

(a) **RMRS Bart Brown, R.Ph.**

150. In July 2006 Relator Farber was directed by his Regional Manager, Stuart Smith, that he was to use RMRS Bart Brown, R.Ph., to gain access to influential doctors at the University Hospitals, to influence their prescribing of Lyrica®.

151. One such meeting was with Dr. Erik St. Louis, a Professor at the University of Iowa School of Medicine specializing in clinical neurophysiology, neurology, psychiatry, and neurology sleep medicine at the University Hospitals. Dr. St. Louis was well recognized throughout the country in his field, was a Pfizer “Key Opinion Leader” with regard to the promotion of Lyrica®, and a frequent Lyrica® speaker.

152. The meeting specifically violated Pfizer policy in that representatives were not to be present on these RMRS calls, but Relator Farber was directed by District Manager Lucas to be there. As a result, before the meeting Brown told Relator Farber that, if he was ever asked, he was to deny that he was in attendance at the meeting. In addition, the meeting with Dr. St. Louis was set up in violation of Pfizer rules as it had not been solicited by Dr. St. Louis, but was initiated by Pfizer. As a result, the meeting was entirely promotional.

153. Brown began the meeting by asking what Dr. St. Louis’ experience had been treating patients with Lyrica®. Dr. St. Louis raised the fact that his refractory epilepsy patients sometimes were not getting enough of a response using Lyrica® at the FDA-approved limits of 600 mg per day, and that he was then treating them with Keppra®. In response, Brown insisted that Lyrica® was superior to Keppra®, even for refractory patients. He then openly promoted the use of Lyrica® above the FDA-approved doses of 600 mg per day, explaining that doctors were successfully using Lyrica® at doses as high as 900 mg/day.

154. Brown then asked Dr. St. Louis if he had any research projects where he needed financial help from Pfizer. St. Louis stated he was looking for some funding for a residency project, and discussed possible funding from Pfizer in the amount of \$22,000.

155. The clear implication of the discussion between Brown and Dr. St. Louis was that, if Dr. St. Louis would help Pfizer push up Lyrica® sales, even with off-label uses exceeding FDA approved dosing, Pfizer in turn would line up financial support for his research projects.

156. Following the meeting, Brown instructed Relator Farber that, if he was ever asked, he was to conceal what happened and again reiterated he was to say he “wasn’t there.”

(b) **RMRS Bernard Effertz, Ph.D.**

157. In another instance, in August 2006 Pfizer RMRS Bernard Effertz, Ph.D. called upon Dr. Richard Rosenquist, at the time Clinical Professor of Anesthesia as well as Director of the Pain Medicine Division at the University Hospitals. Dr. Rosenquist had been a Lyrica® investigator, and was considered a “Key Opinion Leader” for Lyrica®.

158. The Rosenquist meeting had been requested by Pfizer. Because an RMRS can only respond to unsolicited requests for medical information, the meeting with Dr. Rosenquist was thus entirely promotional.

159. During the meeting, Dr. Rosenquist stated that he wanted Pfizer to have “more of a presence” at the University Hospitals in terms of financial support. He also requested that Effertz line up Pfizer financial support for a “journal club” presentation. Sponsoring journal clubs with a grant is not allowed under Pfizer policy.

160. While it was against Pfizer policy to provide grants for University Hospitals’ journal clubs, this policy had been routinely ignored by Pfizer because of how important it

viewed supporting such activities was to currying favor with these influential University Hospitals' physicians. The journal clubs conducted by the University Hospitals' physicians were nearly always held at their homes where Pfizer would supply large amounts of food and alcohol, in violation of Pfizer policy.

161. After the meeting between Dr. Rosenquist and RMRS Effertz, Relator Farber received an e-mail from both District Manager Lucas and Regional Manager Smith, chastising him for not being more involved in Dr. Rosenquist's department by giving the "support" Rosenquist was looking for -- *i.e.*, journal clubs. Relator Farber refused to arrange the journal club, and instead contacted Pfizer's Compliance Department to describe the activity that was taking place, and was explicitly informed that the University Hospitals' journal clubs were not allowed.

162. Relator Farber also raised concerns about the University Hospitals' journal clubs with the sales representative who had been coordinating them, Jennifer Bohr. He told her that he had spoken with the Compliance Department and had been told they could not do the journal clubs anymore. Consistent with Pfizer's pattern of retaliating against the messenger, two days later Relator Farber received an "Open-Door" complaint from both Bohr's District Manager (Luke Esslinger) and her Regional Manager (Dale Anon), neither of whom he worked with (he had never met Anon), but who were both upset that Relator Farber had blown the whistle on the illegal journal clubs with the University Hospitals' physicians. The Open-Door complaints were later withdrawn.

(c) **Carl Wilbanks' April 28, 2008 E-mail Admits RMRS Abuses.**

163. RMRS abuses at Pfizer became so widespread that on April 28, 2008, Carl Wilbanks, Pfizer's Executive Vice President of Sales, deemed it necessary to send a mass intra-company e-mail to "clarify" the role of RMRSs. Wilbanks explained that Pfizer had decided "to clarify the role of RMRS colleagues to focus solely on non-promotional scientific exchange. While this has always been the primary focus of RMRS colleagues, over time there has been some blurring of responsibilities and our physician stakeholders have expressed confusion and concern around their interactions with RMRS colleagues." Wilbanks E-mail at 1.

**VI. MANIPULATION OF FIBROMYALGIA INDICATION TO GROW OFF-LABEL USE OF LYRICA®.**

164. In the fourth quarter of 2006, Pfizer had submitted an sNDA to the FDA for approval to market Lyrica® for the management of fibromyalgia based on two studies, a 14-week, double-blind, controlled clinical trial and a six-month randomized withdrawal study that included 1800 patients. After a priority review by the FDA, on June 21, 2007, Lyrica® was approved by the FDA as the first medication specifically for the treatment of fibromyalgia. *See* U.S. Food and Drug Administration, "FDA Approves First Drug for Treating Fibromyalgia," (June 21, 2007).

165. Fibromyalgia is a common condition characterized by long-term, body-wide pain and tender points in joints, muscles, tendons, and other soft tissues. Fibromyalgia has also been linked to fatigue, morning stiffness, sleep problems, headaches, numbness in hands and feet, depression, and anxiety. The overwhelming characteristic of fibromyalgia is long-standing, body-wide pain with defined tender points. Fibromyalgia pain can mimic the pain that occurs with various types of arthritis. However, the significant swelling, destruction, and deformity of

joints seen in diseases such as rheumatoid arthritis does not occur with fibromyalgia syndrome alone. Diagnosis of fibromyalgia requires a history of a least three months of widespread pain, and pain and tenderness in at least 11 of 18 tender-point sites. These tender-point sites include fibrous tissue or muscles of the: neck, shoulders, chest, rib cage, lower back, thighs, knees, arms (elbows), buttocks.

166. The validity of fibromyalgia as a unique disease is a matter of some contention among researchers in the field. The New York Times on January 14, 2008, reported on Pfizer's marketing of Lyrica® for treatment of fibromyalgia and that there is considerable debate whether fibromyalgia is actually a disease. *See* Alex Berenson, "Drug Approved. Is Disease Real?", New York Times, January 14, 2008. For example, Dr. Frederick Wolfe, the director of the National Databank for Rheumatic Diseases and the lead author of the 1990 paper that first defined the diagnostic guidelines for fibromyalgia, was quoted as saying he had become cynical and discouraged about the diagnosis and now considered the condition a physical response to stress, depression, and economic and social anxiety. "Some of us in those days thought that we had actually identified a disease, which this clearly is not," Dr. Wolfe said. "To make people ill, to give them an illness, was the wrong thing." *Id.*

**A. USE OF "FREEDOM" TRIAL RESULTS TO MARKET LYRICA® FOR FIBROMYALGIA BEFORE FDA APPROVAL.**

167. Well before receiving the fibromyalgia indication from the FDA, Pfizer had already begun promoting Lyrica® off-label for this condition. From the launch of Lyrica® forward, Pfizer had sales representatives call on rheumatologists about the use of Lyrica®.

While rheumatologists did not treat any on-label conditions for which they might prescribe the use of Lyrica®, they regularly do diagnose and treat fibromyalgia patients.

168. By the May 30, 2006 POA meeting, Pfizer presented sales results, which showed a significant number of Lyrica® prescriptions were already being written for fibromyalgia throughout the United States.

169. In furtherance of its scheme to off-label market Lyrica® for fibromyalgia, Pfizer regularly used the so-called “FREEDOM Trial” (or the “Fibromyalgia Relapse Evaluation and Efficacy for Durability of Meaningful Relief” study)<sup>6</sup> results in marketing Lyrica® for the treatment of fibromyalgia before the FDA approved it for this use on June 21, 2007. The study results were first announced in November 2006 at the American College of Rheumatology meeting. As a result of Pfizer’s publicity of the FREEDOM Trial, there were numerous news articles, touting the fact that the FREEDOM Study showed that Lyrica® may offer extended pain relief for people with fibromyalgia. *See* Mann, “Lyrica May Relieve Fibromyalgia,” WebMD, <http://www.medscape.com/viewarticle/547832> (November 14, 2006).

170. On November 27, 2006, Pfizer included a story on the employee intranet magazine, PfizerWorld, discussing the FREEDOM Trial results. According to the PfizerWorld article, Lyrica®’s reputation was growing due to results showing it could be used to treat fibromyalgia: “The reputation of Lyrica as a powerful pain agent continues to grow with the latest data showing it provides long-term relief in patients with the often debilitating condition of fibromyalgia.” The article tells readers (including Pfizer sales representatives) that Lyrica®

---

<sup>6</sup> The FREEDOM Trial was not published until June 2008. *See* Crofford, et al., “Fibromyalgia Relapse Evaluation and Efficacy for Durability of Meaningful Relief,” (“FREEDOM”): A 6-Month, Double-Blind, Placebo-Controlled Trial With Pregabalin,” *Pain*, 136(3):419-31 (2008).

“became the first drug to demonstrate long-term improvement in patients suffering from fibromyalgia, based on clinical data presented at a late-breaking presentation at the recent American College of Rheumatology meeting.” The article includes “Quick Facts” stating that there are no known drugs which have been approved to treat fibromyalgia and the FREEDOM Trial data “reinforces the clinical versatility of Lyrica.”

171. In addition, in the “Colleague Insights” section of the PfizerWorld article there is a telling November 28, 2006 quote from Pfizer U.K. District Manager Peter Cullum: “It is fantastic news that Lyrica is proven to have great benefit in fibromyalgia. Not only will this news enhance the reputation of the drug, but it will also has [sic] a very motivating impact on the sales force.”

172. Evidence shows that state Medicaid programs reimbursed numerous Lyrica® prescriptions for the treatment of fibromyalgia before it was approved by the FDA. The Idaho Medicaid program in July 2008 published a retrospective analysis which studied various treatments for fibromyalgia with a focus on the impact of the introduction of Lyrica®. *See* “Treatment of Fibromyalgia,” Idaho Drug Utilization Review Program Quarterly Board Meeting, July 10, 2008. The report found that the Idaho Medicaid program reimbursed for off-label use for management of fibromyalgia in 2005, following the launch of Lyrica®, and that during 2006 over a third of all Lyrica® Medicaid claims incurred were for the off-label treatment of fibromyalgia.

173. Similarly, a retrospective study prepared by the Oregon State University for the Oregon Department of Human Services examining the use of anti-epileptic drugs found that in

2006 15.1% of Oregon Lyrica® Medicaid prescriptions were for the off-label management of fibromyalgia.

174. It is thus clear that, due to Pfizer's calculated strategy to off-label market Lyrica® for the management of fibromyalgia, a number of physicians were already prescribing Lyrica® for the treatment of fibromyalgia well in advance of the FDA approval on June 21, 2007.

**B. OFF-LABEL MARKETING OF LYRICA® FOR CHRONIC WIDESPREAD PAIN.**

175. After Lyrica® had been FDA-approved for the treatment of fibromyalgia, Pfizer implemented a new strategy to use the fibromyalgia approval as a gateway to open up sales even further for the management of all chronic widespread pain. Representatives were instructed by Pfizer sales managers to specifically not use the term "fibromyalgia" in their marketing of Lyrica® to physicians, but instead use the term "chronic widespread pain" to so as to avoid any negative connotations associated with fibromyalgia, thereby allowing off-label promotion to physicians at the same time.

176. Pfizer's strategy was to market the use of Lyrica® for the treatment of chronic widespread pain, a more general description of a set of symptoms that does not carry the negative connotations that come with Fibromyalgia. It knew that many doctors did not believe fibromyalgia was a real disease and, therefore, instead promoted Lyrica® for any symptoms of chronic widespread pain.

177. For example, in September 2007 Pfizer sales representative Jennifer Bohr set up a meeting between Dr. Winthrop Risk, a Cedar Rapids, Iowa neurologist who treated a high percentage of Medicaid patients, and an outside Pfizer speaker, Dr. Basem Hamid. Dr. Hamid is an Assistant Professor, Anesthesiology and Pain Medicine at M.D. Anderson Cancer Center in

Houston and a frequent Pfizer speaker. Dr. Hamid was formerly on the faculty at the University of Iowa School of Medicine.

178. During the meeting with Dr. Risk, Dr. Hamid discussed that Lyrica® had gotten a new indication for fibromyalgia, but that Lyrica® would obviously also be effective for many other types of chronic pain as well since it acts on the central nervous system, and the body obviously cannot tell what type of pain it is having.

179. Pfizer is thus using the fibromyalgia indication to widen the scope of Lyrica® prescriptions and off-label market the drug for all types of chronic pain, including for off-label indications.

**VII. PAYMENT OF SPEAKER FEES TO INDUCE PHYSICIANS TO PRESCRIBE LYRICA® AND TO INCLUDE LYRICA® ON GOVERNMENT FORMULARIES.**

180. Pfizer's illegal promotion also included off-label promotion of Lyrica® through the use of various speaker programs. These programs included payments to speakers and Pfizer medical specialists to promote the use of Lyrica® off-label and induce inclusion of Lyrica® on government formularies.

181. To bolster its illegal promotion of Lyrica® to physicians, Pfizer paid monies to its identified "Key Opinion Leaders" – *i.e.*, "High Writer" Neurontin® prescribers who were also Pfizer speakers in order to induce them to recommend Lyrica® for addition to formularies, including Medicaid formularies.

182. The federal Medicare and Medicaid Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) regulates the promotion of prescription drugs that are reimbursed by Federal Programs. Under the Anti-Kickback Act, any form of remuneration, in cash or in kind, paid by Pfizer to an

individual such as a physician to induce the use of Pfizer drug products that are reimbursed by Federal Programs, including Medicare or Medicaid, is illegal. But for the payment of a kickback, government programs would not have otherwise paid for the product tainted by the kickback, thereby causing financial loss to the United States.

**A. PFIZER SPEAKER FEES TO DR. UDAYA KABADI TO INFLUENCE PRESCRIBING OF LYRICA® AT THE VA HOSPITAL AND THE ADDITION OF LYRICA® TO THE UNIVERSITY HOSPITALS' FORMULARY.**

183. The University of Iowa Hospitals and Clinics ("University Hospitals") is the one of the largest teaching hospitals in the world and is one of the largest medical centers in the Midwest. The University Hospitals treats a significant number of Medicaid patients, and thus is not only a large consumer of prescription drugs, its formulary is viewed as being extremely influential throughout the United States. Thus, it was key to Pfizer in the Lyrica® launch to gain access to the University Hospitals' formulary.

184. Pfizer not only gave significant monies to the University Hospitals, it has had very close relationships with many physicians at the University Hospitals, a number of whom are accorded "Key Opinion Leader" status by Pfizer. Many of these physicians are recognized as leaders in their fields and have regularly participated in Pfizer-sponsored research grants and as speakers for Pfizer products. In addition, a number of these physicians (a) serve on Pharmacy & Therapeutics Committees ("P&T Committees") for the University Hospitals and/or the State Medicaid formularies, (b) make recommendations to the P&T Committees for the addition of specific drug products, or (c) have dual responsibilities at the University Hospitals and at the Iowa City VA Medical Center

185. One such “Key Opinion Leader” was Dr. Udaya Kabadi, an endocrinologist at both the Iowa City VA Medical Center and the University Hospitals and a frequent speaker for a number of Pfizer drugs, including Lyrica®. Pfizer used its payment of speaker fees to Dr. Kabadi in order gain his support for using Lyrica® at the VA Medical Center and in getting access for Lyrica® to the University Hospitals’ formulary.

186. In short, Pfizer engaged in influence-pedaling to increase use of Lyrica® at the VA Medical Center and in getting Lyrica® on the University Hospitals’ formulary. In exchange for Dr. Kabadi’s Lyrica® support and assistance, Dr. Kabadi was trained as a Lyrica® speaker. Further, as a reward for his help, Dr. Kabadi’s speaker’s honorarium cap was raised to \$150,000 per year. Not only does this exchange of a favor for a favor violate the federal Anti-Kickback Act, such transactions are strictly forbidden by Pfizer policies.

**B. RECRUITING PHYSICIANS AS SPEAKERS TO INDUCE THEIR PRESCRIBING OF LYRICA®.**

187. Additionally, Pfizer also employed a strategy in which it required sales representatives to recruit doctors who were not prescribing Lyrica® and entice those doctors to become paid Pfizer speakers in exchange for prescribing Lyrica®. The strategy required sales representatives to enlist doctors as speakers, many of whom were heavy Medicaid prescribers. Once the speakers were accepted into Pfizer’s speaker program, they were then trained by Pfizer to speak on a variety of drugs and paid an honorarium for each speaking engagement. In exchange for the opportunity to make additional money through speaking events, the doctors would tacitly agree to increase their prescribing of Lyrica®.

188. One instance involved Dr. Nidel Alkurdy, a neurologist in Burlington, Iowa, and a very influential doctor in southeastern Iowa. Based on research conducted by Pfizer, District Manager Lucas had learned that Dr. Alkurdy wrote very few Lyrica® prescriptions, although he treated conditions for which Lyrica® is indicated and FDA-approved. At the time, Dr. Alkurdy was a heavy prescriber of generic gabapentin.

189. During telephone conversations, POA meetings, and in emails, District Manager Lucas directed the Relators that he wanted Dr. Alkurdy to become a Lyrica® speaker in order to increase the number of prescriptions Dr. Alkurdy and the doctors at Alkurdy's clinic wrote.

190. In notes dated March 13, 2006 to Relator Farber, Lucas stated that Dr. Alkurdy was "ready to move to the next level." Later, on July 12, 2006, Lucas sent Relator Farber an email responding to what actions Farber needed to take for his upcoming performance review: "An example of an action to improve sales performance would be a speaker program or developing a local speaker [Alkrudy]."

191. Moreover, pursuant to Lucas' instructions, Relator Schildhauer met with Dr. Alkurdy in Fort Madison, Iowa and gained Dr. Alkurdy's agreement to become a Lyrica® speaker in exchange for his agreement to prescribe more Lyrica®.

192. In exchange for being nominated to become a Pfizer speaker on Lyrica®, Dr. Alkrudy dramatically increased his prescribing of Lyrica® for his patients, many of whom were Medicaid patients. This use of speaker fees to influence Lyrica® prescribing is an express violation of the Anti-Kickback Act and Pfizer policy.

**VIII. PFIZER'S FRAUDULENT MARKETING SCHEME VIOLATED FEDERAL PROGRAM LIMITATIONS.**

193. Pfizer could lawfully market Lyrica® in a number of ways, including the dissemination of truthful information that complies with federal law. Once a drug is approved by the FDA for a certain use (or “indication”), it can be promoted by the manufacturer for that use, and that use only. Lyrica® was initially FDA approved to treat DPN and PHN and later as an adjunct for partial seizures and for management of fibromyalgia. Pfizer could only promote Lyrica® to treat the then FDA-approved conditions. At the official launch, Lyrica® was approved for DPN, PHN and adjunct for partial onset seizures.

194. Government programs, including the Medicaid program, also rely on the FDA’s findings regarding what uses for approved drugs are safe and effective. Whether a drug that is FDA-approved for a particular use will largely determine whether a prescription for that drug will be reimbursable under Federal Programs, including the Medicaid program.

195. In 1990, Congress passed the Budget Reconciliation Act which limited reimbursement for prescription drugs to “covered outpatient drugs.” Covered outpatient drugs only include drugs used for “medically accepted indications.” A medically-accepted indication is a use which has been approved by the FDA or one which is supported by specific drug reporting compendia set forth in the Medicaid statute, 42 U.S.C. § 1396r-8(k)(6). Reimbursement by Medicaid is, generally, prohibited if the drug is not being used for a medically-accepted indication. 42 U.S.C. § 1396r-8(k)(3).

196. Congress has adopted a compendia-based system for determining appropriate Medicaid reimbursements for off-label uses of a “covered outpatient drug.” Soc. Sec. Act § 1927(g)(1)(B)(i) and (k)(6) (permitting reimbursements for drug uses that “(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results”). Thus,

(in the absence of FDA approval for the particular indication,) the only way a prescription could be allowed under the Medicaid statute was if it had been approved in one of the compendia identified in § 1927(g)(1)(B)(i) to be eligible for reimbursement under Medicaid and other federal programs.

197. Of the approved compendia, only Drugdex discusses off-label uses of Lyrica®. The Drugdex listing for Lyrica® dated October 2007 includes a discussion of four off-label indications for Lyrica® found in section 4.5, entitled “Therapeutic Uses.” For three of these off-label indications (dental pain, osteoarthritis and social phobia) Drugdex notes that the evidence of efficacy is “inconclusive.” For the fourth, generalized anxiety disorder (“GAD”), Drugdex states that “evidence favors efficacy.” Despite the Drugdex suggestion that the evidence “favors efficacy” for GAD, this reference is questionable because the FDA had specifically given a “non-approvable” letter for this indication in 2004.

198. With regard to the comparative claims which Pfizer used to convert gabapentin prescriptions to Lyrica®, there is no mention in Drugdex of any comparative studies between Lyrica and gabapentin. In fact, the only mention of comparisons between gabapentin and Lyrica is in 4.5.H, discussing social phobia, with a statement that “direct comparisons [presumably with Lyrica®] are warranted.” Nor does Drugdex discuss any comparative studies between Lyrica® and Keppra®.

199. In violation of federal law, Pfizer promoted Lyrica® for non-FDA approved uses (“off-label” uses) and for uses not supported in the compendia that led to violations of federal Medicaid statutes and regulations designed to restrict reimbursement to government programs such as Medicaid.

**IX. PFIZER'S PROMOTION OF LYRICA® CAUSED SUBMISSION OF OFF-LABEL CLAIMS TO GOVERNMENT PROGRAMS.**

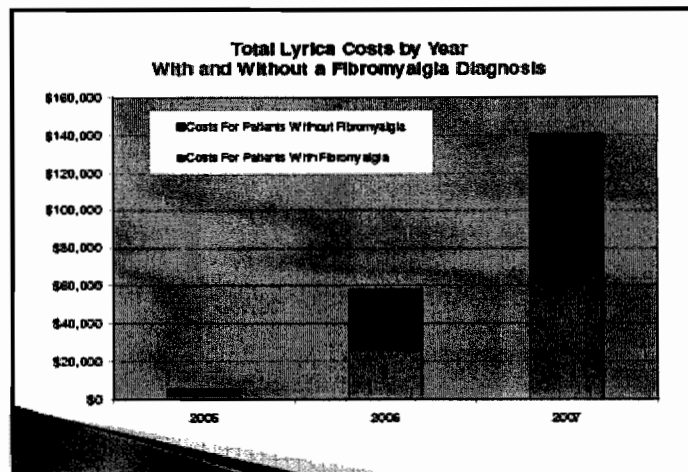
200. Defendant Pfizer promoted off-label indications of Lyrica®, knowing they were not eligible for reimbursement because the indication or dosage was neither supported in the drug compendia, nor was it included on Lyrica®'s FDA-approved product labeling. Furthermore, Defendant Pfizer illegally promoted numerous off-label uses of Lyrica® without meeting the FDA requirements, and without resubmitting Lyrica® to the FDA testing and approval process as required by 21 U.S.C. § 360aaa *et seq.* Thus, claims for reimbursement of off-label Lyrica® prescriptions fail to meet the eligibility requirements of government programs.

201. Pfizer's off-label promotion of Lyrica® resulted in reimbursement by government programs for numerous false claims. For example, a retrospective study prepared by the Oregon State University for the Oregon Department of Human Services examining the use of anti-epileptic drugs found that in 2006 of the Lyrica® Medicaid prescriptions 43.5% of the prescriptions were clearly for off-label uses.

202. The Oregon State University Study investigated the 1,689 chronic users of anti-epileptic drugs within the Oregon Medicaid Program in 2006. Of the total studied, 195 (or 11.5%) were prescribed Lyrica®. When eliminating those patients from the study who were on more than one medication, there remain 152 chronic anti-epileptic drug users whose claims were reimbursed by Oregon Medicaid. Using these 152 Medicaid patients' claims, just under a half of the claims, or some 43.5% of the Lyrica® prescriptions, were for clearly off-label uses, including bipolar disorder (6.6%), migraine (8.6%), anxiety disorder (13.2%), and fibromyalgia (15.1%). The other two categories of diagnosis identified in the Oregon study, seizures and neuropathic

pain, which account for 67.1% of the total diagnoses may include numerous off-label prescriptions as well.<sup>7</sup>

203. In another study, the Idaho Medicaid program in July 2008 published a retrospective analysis of various treatments for fibromyalgia from 2005 through 2007. See “Treatment of Fibromyalgia,” Idaho Drug Utilization Review Program Quarterly Board Meeting, July 10, 2008. The report includes the following table of Lyrica® costs broken down by year:



The Idaho study found that off-label use for management of fibromyalgia began immediately in 2005, following the launch of Lyrica®, and that during 2006 over a third of the Lyrica® Medicaid claims incurred were for the off-label treatment of fibromyalgia.

204. As a result of Pfizer’s illegal marketing practices, physicians and pharmacists routinely and necessarily filed claims with government programs for reimbursement for Lyrica® prescriptions. But for Pfizer’s illegal promotion, these off-label and misbranded prescriptions for Lyrica® would not have been written. As a result, Pfizer caused the submission of false claims

<sup>7</sup> When added, the six diagnoses identified in this study equal 110.6% (43.5% + 67.1%). The reason for this is that there were a total of 152 chronic AED users in the study; however, some of the patients were diagnosed with multiple diseases and both diagnoses were identified, which led to a total of 168 diagnosis claims.

to government programs for reimbursement of Lyrica®. Pfizer was the beneficiary of these false claims for reimbursement of Lyrica® prescriptions.

**X. PFIZER'S FALSE REPORTING IN CONNECTION WITH THE NEURONTIN® CORPORATE INTEGRITY AGREEMENT.**

205. Pfizer is well aware of the legal restrictions placed on drug promotion. In the governments' Neurontin® settlement in 2004, Pfizer paid \$430 million – the largest settlement for an off-label promotion case – to resolve charges related to off-label marketing practices for Neurontin®. According to the Neurontin® guilty plea: “After previously having been convicted of violating the FD&C Act, Warner-Lambert distributed Neurontin® intended for unapproved uses, causing the drug to be misbranded.”

206. As part of the Neurontin® settlement and guilty plea with the United States, Pfizer entered into a five-year Corporate Integrity Agreement, dated May 11, 2004 (“CIA”). Under the terms of the CIA, Pfizer stated that it had implemented written Policies and Procedures regarding the operation of its compliance program.

207. As stated herein, there have been numerous, material breaches of the CIA by Pfizer in the marketing of Lyrica®, material breaches which were at the direction and supervision of Pfizer sales management throughout the organization, including a number of the most senior sales management in the company, many of which had been reported by Relators to Pfizer's Compliance Department. Rather than rectify the problems, Pfizer engaged in a systematic harassment of the Relators.

208. As a result of Pfizer's conduct, government programs have been damaged, and continue to be damaged, causing government program payments for off-label and falsely

promoted Lyrica® prescriptions. Upon information and belief, Lyrica® off-label prescription payments made by government programs total in the hundreds of millions of dollars.

**XI. PFIZER'S RETALIATION AGAINST EMPLOYEES WHO RAISE CONCERNS ABOUT COMPLIANCE VIOLATIONS.**

209. From the outset, Pfizer knew it was only a matter of time until its out-of-control, off-label marketing of Lyrica® could continue before it had to stop. However, the prevailing attitude was (and has been) get away with what you can for as long as you can.

210. As just one example, in March 2006 at a meeting for newly hired sales representatives at Pfizer's Arrowwood training facility in upstate New York, Pfizer Sales Trainer in New York Nick Corsine instructed the trainees that they were to use the Lyrica® sales materials with unsubstantiated side-by-side comparisons of Lyrica®'s superiority to gabapentin immediately because Pfizer had compliance concerns with them and would likely withdraw the materials very soon. Corsine instructed the class to "use 'em while you got 'em," referring to the illegal side-by-side comparison pieces, because "Legal may have issues with them and they may not be around much longer."

211. These are the same Lyrica® side-by-side sales pieces that Relators complained of on numerous occasions to Pfizer management, beginning with the launch in 2005, and which were eventually withdrawn in November 2006. Rather than immediately cease the illegal and unsubstantiated comparisons between Lyrica® and Neurontin® (gabapentin), Pfizer chose instead to retaliate against the Relators.

212. Pfizer claims that its "Open Door Policy" encourages employees to "discuss any issues, concerns, problems and suggestions with their immediate supervisor or other manager without fear of retaliation." Its stated policy has often been ignored. Despite this stated policy,

the Pfizer culture has been to retaliate against employees who come forward with compliance concerns. Even Pfizer CEO Jeff Kindler during a December 2006 employee meeting in St. Louis admitted this is a widespread problem within the company: “I’d like to see a culture [within Pfizer] where people feel freer than I think they do today, to be perfectly candid, to be open and frank and express their points of view, . . . without fear of some consequences to them. . . . I think in different parts of the company that kind of culture exists, but I see a lot of evidence where it doesn’t exist.”

**A. SENIOR VP IAN READ AUGUST 16, 2007 E-MAIL ADMITS COMPLIANCE VIOLATIONS, INCLUDING “USE OF UNAPPROVED MATERIALS” AND OFF-LABEL PROMOTION.**

**213.** On August 16, 2007, Pfizer’s Senior Vice President and President of Worldwide Pharmaceutical Operations Ian Read sent a mass e-mail message to all employees in the company with the subject heading “Pfizer Compliance Policies.” In the e-mail, Read announced that he had become aware of “violations of our compliance standards” and claimed that the company had been “swift and vigilant” in addressing these violations. Most notably, Read states the company had uncovered the “use of unapproved materials and discussion of products and indications before approval.”

**214.** Read’s e-mail also implored Pfizer employees who witness such violations of Pfizer’s own compliance policies to come forward and report them. “[I]naction is not an option,” Read declared. Read assured if employees notify their manager of violations, “you will not be retaliated against,” as retaliation is also against Pfizer policy.

**215.** Read’s e-mail ignores the fact that in the marketing of Lyrica® the company developed the very kind of “approved” off-label sales materials and discussion that he later

would pass off as only caused by purportedly rogue employees using unapproved marketing materials. In the case of the Lyrica® compliance violations, not only were the violations deliberately planned and executed by the company, the only “swift and vigilant” action was the retaliation on the Relators.

**B. RETALIATION AGAINST RELATORS FOR BLOWING THE WHISTLE.**

216. Although Read’s e-mail insisted that no one would be retaliated against for coming forward, the experience of the Relators was otherwise. Rather, Relators were subjected to months of intense scapegoating after informing Pfizer of the illegal promotion of Lyrica®. Moreover, what the Read e-mail fails to recognize is that in Pfizer’s culture of sales “at any cost” the admonition most often is “don’t get caught.”

217. Relators had informed Pfizer of Lyrica®’s illegal promotion on numerous occasions. Pfizer’s response was aimed at containing any adverse impact caused by Relators’ whistle-blowing, rather than seeking to uncover and remedy the illegal conduct. As a result of Relators’ whistle-blowing activities, each has been the subject of retaliation. Pfizer has discharged, demoted, suspended, threatened, harassed and/or discriminated against Relators by virtue of their lawful acts in bringing to light Pfizer’s illegal and potentially harmful actions.

**1. Relator David Farber**

218. Relator Farber informed Pfizer of its illegal activity, including misleading efficacy promotion of Lyrica®, as well as illegal off-label promotion. This illegal activity included: (1) directives from his district manager, Tracy Lucas, including a voicemail message left on his telephone to leave sales materials for a doctor who would never prescribe Lyrica® in the normal course of business; (2) directives from Pfizer management to market non-FDA

approved indications known as “secondary endpoints”; (3) directives from his district manager to never discuss reports of the drug’s side effects; (4) sales calls involving the discussion of secondary endpoints with physicians; and (5) use of side-by-side promotional materials to demonstrate the comparative advantages of Lyrica® as opposed to gabapentin or Keppra®, absent supporting, peer-reviewed studies.

**219.** Relator Farber made his first report of off-label marketing on or about March 2006, principally related to the off-label marketing of Pfizer’s drug Bextra®. Over the course of the next several months, Farber expressed numerous concerns to his district manager, Pfizer Human Resources (“HR”) representatives, Compliance, as well as others, not only about Bextra®, but about Lyrica® as well.

**220.** As a result of Relator Farber expressing concerns to Pfizer, Pfizer retaliated against him by making false Open Door complaints against him (which were later dismissed by Pfizer), launching compliance investigations out of desperation to frame him, and causing him to be isolated in his profession.

**221.** During the following months, Relator Farber continued to inform Pfizer of off-label marketing activities in which the sales force was being directed by Pfizer management to participate. The activities Relator Farber complained of were not just the actions of a “select few,” but were widespread throughout the company.

**222.** As a result of Relator Farber’s whistle-blowing activities, on or about January 19, 2007, he was constructively discharged by Pfizer.

## **2. Relator Casey Schildhauer**

**223.** Relator Schildhauer had first complained to Pfizer management regarding Pfizer's promotion of Lyrica® in or around the time of Lyrica®'s launch, including at a meeting in Denver, Colorado on February 23, 2006. These complaints were made to Pfizer management, including Schildhauer's district managers, Pfizer Human Resources, Pfizer Corporate, Compliance, and others.

**224.** For example, at a meeting held at Pfizer's Denver office on February 23, 2006, Relator Schildhauer informed Pfizer management of illegal sales activity, including the off-label promotion of Lyrica®, the unsubstantiated comparison promotion of Lyrica® with gabapentin and Keppra®, as well as the excessive payment of speakers.

**225.** Subsequent to the Denver meeting, Relator Schildhauer was accorded pariah treatment, including additional false accusations that he had violated Pfizer policies.

**226.** In September, 2006, Pfizer initiated a relocation of Relator Schildhauer to one of Pfizer's Los Angeles-based sales teams, where he witnessed many of the same Fraudulent Marketing Scheme activities he had complained of earlier. Finally, on March 27, 2007 he was terminated for refusing to subject himself to further retaliation stemming from his whistleblowing activities.

### **COUNT I** **VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, ET SEQ.**

**227.** Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

228. This is a civil action brought by Plaintiffs/Relators, on behalf of the United States of America against Defendant under the False Claims Act, 31 U.S.C. §§ 3729(a)(1) and (2).

229. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented, and may still be presenting or causing to be presented, to government programs, false or fraudulent claims for payment, in violation of, *inter alia*, 31 U.S.C. § 3729(a)(1).

230. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, made, caused, or caused to be used, and may still be using or causing to be used, false or fraudulent records and/or statements to get false or fraudulent claims paid in violation of, *inter alia*, 31 U.S.C. § 3729(a)(2).

231. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information which supported claims to government programs, with actual knowledge of the falsity of the information that supported these claims, caused, and may still be causing, the use of false or fraudulent materials or information to support claims paid by the government.

232. The United States of America, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Lyrica® prescribed to patients enrolled in government programs.

233. As a result of Defendant's actions as set forth above in this complaint, the United States of America has been, and may continue to be, severely damaged.

**COUNT II**  
**VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, ET SEQ.**

234. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

235. Pfizer's failure to report, or false reporting to the United States in accordance with the Neurontin CIA, was done deliberately, or in reckless disregard of the truth, and as a result, caused, and may still be causing, false or fraudulent records and/or statements resulting in false or fraudulent claims paid by the United States in violation of, inter alia, 31 U.S.C. § 3729 et seq.

236. As a result of Defendant's actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

**COUNT III**  
**VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3730(H)**

237. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

238. As a result of Plaintiffs/Relators' whistle-blowing activities, Pfizer has discharged, demoted, suspended, threatened, harassed, and discriminated against Plaintiffs/Relators by virtue of his lawful acts.

239. Plaintiffs/Relators are entitled to all the relief afforded by 31 U.S.C. § 3730(h), including, without limitation, double back pay, front pay, and special damages.

**COUNT IV**  
**ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT, ARK. CODE ANN. § 20-77-901, ET SEQ.**

240. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

**241.** This is a civil action brought by Plaintiffs/Relators, in the name of the State of Arkansas, against Defendant pursuant to the State of Arkansas Medicaid Fraud False Claims Act, ARK. CODE ANN. § 20-77-901, *et seq.*

**242.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Arkansas Medicaid program, in violation of ARK. CODE ANN. § 20-77-902(1).

**243.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of ARK. CODE ANN. § 20-77-902(2).

**244.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of ARK. CODE ANN. 20-77-902(3).

**245.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly

or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of ARK. CODE ANN. § 20-77-902(7)(A)(ii).

246. The State of Arkansas or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

247. As a result of Defendant' actions, as set forth above, the State of Arkansas or its political subdivisions has been, and may continue to be, severely damaged.

**COUNT V**  
**VIOLATION OF THE STATE OF CALIFORNIA FALSE CLAIMS ACT, CAL GOV'T**  
**CODE § 12650, ET SEQ.**

248. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

249. This is a civil action brought by Plaintiffs/Relators on behalf of the State of California against Defendant under the California False Claims Act, CAL. CODE § 12652(c).

250. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of California or its political subdivisions false or fraudulent claims for payment, in violation of CAL. CODE § 12651(a)(1).

251. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of CAL. CODE § 12651(a)(2).

252. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California or its political subdivisions in violation of CAL. CODE § 12651(a)(7).

253. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

254. As a result of Defendant's actions as set forth above, the State of California, including its political subdivisions, has been, and may continue to be, severely damaged.

**COUNT VI**  
**VIOLATION OF THE STATE OF DELAWARE FALSE CLAIMS AND REPORTING**  
**ACT, DEL. CODE ANN. TIT. 6, § 1201, ET SEQ.**

255. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

**256.** This is a civil action brought on behalf of Plaintiffs/Relators on behalf of the Government of the State of Delaware against Defendant under the State of Delaware's False Claims and Reporting Act, DEL. CODE ANN. tit. 6, § 1203(b).

**257.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, directly or indirectly, to an officer or employee of the Government of the State of Delaware false or fraudulent claims for payment or approval, in violation of DEL. CODE ANN. tit. 6, § 1201(a)(1).

**258.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved, in violation of DEL. CODE ANN. tit. 6, § 1201(a)(2).

**259.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the Government of Delaware, in violation of DEL. CODE ANN. tit. 6, § 1201(a)(7).

**260.** The Government of the State of Delaware, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or

statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the Government of the State of Delaware.

261. As a result of Defendant's actions, the Government of the State of Delaware has been, and may continue to be, severely damaged.

**COUNT VII**  
**VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT, D.C. CODE**  
**ANN § 2-308.13, ET SEQ.**

262. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

263. This is a civil action brought by Plaintiffs/Relators, in the name of the District of Columbia against Defendant under the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.15(b).

264. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, a false or fraudulent claim for payment or approval, in violation of D.C. CODE ANN. § 2-308.14(a)(1).

265. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records and/or statements to get false claims paid or approved by the District, in violation of D.C. CODE ANN. § 2-308.14(a)(2).

266. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, in violation of D.C. CODE ANN. § 2-308.14(a)(7).

267. The District of Columbia, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

268. As a result of Defendant's actions, as set forth above, the District of Columbia has been, and continues to be, severely damaged.

**COUNT VIII**  
**VIOLATION OF THE STATE OF FLORIDA FALSE CLAIMS ACT, FLA. STAT. 68-081, ET SEQ.**

269. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

270. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Florida against Defendant under the State of Florida's False Claims Act, FLA. STAT. ANN. § 68.083(2).

271. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to

officers or employees of the State of Florida or one of its agencies false or fraudulent claims for payment or approval, in violation of FLA. STAT. ANN. § 68.082(2)(a).

272. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082(2)(b).

273. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082(2)(g).

274. The State of Florida and its agencies, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

275. As a result of Defendant's actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

**COUNT IX**  
**VIOLATION OF STATE OF GEORGIA FALSE MEDICAID**  
**CLAIMS ACT, GA. CODE ANN. § 49-4-168 (2007), ET SEQ.**

**276.** Plaintiffs incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

**277.** This is a civil action brought by Plaintiffs, in the name of the State of Georgia, against Defendant pursuant to the State of Georgia False Medicaid Claims Act, GA. CODE ANN. § 49-4-168 (2007), *et seq.*

**278.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval, in violation of GA. CODE ANN. § 49-4-168.1(a)(1) (2007).

**279.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program, in violation of GA. CODE ANN. § 49-4-168.1(a)(2) (2007).

**280.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally conspired, and may still be conspiring to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid, in violation of GA. CODE ANN. § 49-4-168.1(a)(3) (2007).

281. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia, in violation of GA. CODE ANN. § 49-4-168.1(a)(7) (2007).

282. The State of Georgia or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

283. As a result of Defendant' actions, as set forth above, the State of Georgia or its political subdivisions has been, and may continue to be, severely damaged.

**COUNT X**  
**VIOLATION OF THE STATE OF HAWAII**  
**FALSE CLAIMS ACT FALSE CLAIMS TO THE STATE, HAWS REV. STAT. § 661-21,**  
**ET SEQ.**

284. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

285. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Hawaii and its political subdivisions against Defendant under the State of Hawaii's False Claims Act – False Claims to the State, HAW. REV. STAT. § 661-25.

286. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of HAW. REV. STAT. § 661-21(a)(1).

**287.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(2).

**288.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(7).

**289.** The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

**290.** As a result of Defendant's actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XI**  
**VIOLATION OF THE STATE OF INDIANA FALSE CLAIMS AND**  
**WHISTLEBLOWER PROTECTION ACT, IND. CODE § 5-11-5.5, ET SEQ.**

**291.** Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

**292.** This is a civil action brought by Plaintiffs/Relators on behalf of the State of Indiana against Defendant under the State of Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-4(a).

**293.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(1).

**294.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain payment or approval of false claims by the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(2).

**295.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(6).

**296.** The State of Indiana, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and may

continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

297. As a result of Defendant's actions, as set forth above, the State of Indiana has been, and may continue to be, severely damaged.

**COUNT XII**  
**VIOLATION OF THE STATE OF ILLINOIS**  
**WHISTLEBLOWER REWARD AND PROTECTION ACT, 740 ILL. COMP. STAT.**  
**ANN. 175/1, ET SEQ.**

298. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

299. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Illinois against Defendant under the State of Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. 175/4(b).

300. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Illinois or a member of the Illinois National Guard a false or fraudulent claim for payment or approval, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(1).

301. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made

or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(2).

302. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(7).

303. The State of Illinois, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

304. As a result of Defendant' actions, as set forth above, the State of Illinois has been, and may continue to be, severely damaged.

**COUNT XIII**  
**VIOLATION OF THE STATE OF LOUISIANA**  
**MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, LA. REV. STAT. § 46:437.1,**  
**ET SEQ.**

305. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

306. This is a civil action brought by Plaintiff, Relator, on behalf of the State of Louisiana's medical assistance programs against Defendant under the State of Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. § 46:439.1.

307. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of LA. REV. STAT. § 46:438.3(A).

308. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of LA. REV. STAT. § 46:438.3(B).

309. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of LA. REV. STAT. § 46:438.3 (D).

310. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendant, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendant's claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

311. As a result of Defendant's actions, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

**COUNT XIV**  
**VIOLATION OF THE STATE OF MASSACHUSETTS FALSE CLAIMS ACT, MASS**  
**LAWS ANN. CH. 12, § 5A, ET SEQ.**

312. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

313. This is a civil action brought by Plaintiffs/Relators on behalf of the Commonwealth of Massachusetts against Defendant under the Massachusetts False Claims Act, MASS. LAWS ANN. ch. 12, § 5C(2).

314. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MASS. LAWS ANN. ch. 12, § 5B(1).

315. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts or its political subdivisions in violation of MASS. LAWS ANN. ch. 12, § 5B(2).

316. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts or one of its political subdivisions, in violation of MASS. LAWS ANN. ch. 12, § 5B(8).

317. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

318. As a result of Defendant's actions, as set forth above, the Commonwealth of Massachusetts or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XV**  
**VIOLATION OF THE STATE OF MICHIGAN MEDICAID FALSE CLAIMS ACT,**  
**MICH. COMP. LAWS SERV. § 400.601, ET SEQ.**

319. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

320. This is a civil action brought by Plaintiffs/Relators in the name of the State of Michigan against Defendant under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(1).

321. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, a false statement or

false representation of a material fact in an application for Medicaid benefits, in violation of MICH. COMP. LAWS. SERV. § 400.603(1).

**322.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit, in violation of MICH. COMP. LAWS. SERV. § 400.603(2).

**323.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf Defendant has applied for or is receiving a benefit with intent to obtain a benefit to which Defendant is not entitled or in an amount greater than that to which Defendant is entitled, in violation of MICH. COMP. LAWS. SERV. § 400.603(3).

**324.** Defendant, in possession of facts under which it is aware or should be aware of the nature of its conduct and that its conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly presented or made or caused to be presented or made, and may still be presenting or causing to be presented a false claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, in violation of MICH. COMP. LAWS. SERV. § 400.607(1).

**325.** The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

326. As a result of Defendant's actions, as set forth above, the State of Michigan or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XVI**  
**VIOLATION OF STATE OF MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. §**  
**17-8-401, ET SEQ.**

327. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

328. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Montana against Defendant under the State of Montana False Claims Act, MONT. CODE ANN. § 17-8-406(1).

329. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MONT. CODE ANN. § 17-8-403(1)(a).

330. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of MONT. CODE ANN. § 17-8-403(1)(b).

331. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana or one of its political subdivisions, in violation of MONT. CODE ANN. § 17-8-403(1)(g).

332. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

333. As a result of Defendant's actions, as set forth above, the State of Montana or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XVII**  
**VIOLATION OF STATE OF NEW HAMPSHIRE MEDICAID FALSE CLAIMS ACT,**  
**N.H. REV. STAT. ANN. § 167:61-B, ET. SEQ.**

334. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

335. This is a civil action brought by Plaintiffs/Relators on behalf of the State of New Hampshire against Defendant under the State of New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-cII.(a).

336. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(a).

337. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(b).

338. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Hampshire or one of its political subdivisions, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(e).

339. The State of New Hampshire, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

340. As a result of Defendant's actions, the State of New Hampshire or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XVIII**  
**VIOLATION OF STATE OF NEW JERSEY**  
**FALSE CLAIMS ACT, N.J. STAT. ANN. § 2A:32C-3 (2007), ET SEQ.**

341. Plaintiffs incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

**342.** This is a civil action brought by Plaintiffs, in the name of the State of New Jersey, against Defendant pursuant to the State of New Jersey Fraud False Claims Act, N.J. STAT. ANN. § 2A:32C-3 (2007), *et seq.*

**343.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presents or caused to be presented, and may still be presenting or causing to be presented, to an employee, officer, or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of N.J. STAT. ANN. § 2A:32C-3(a) (2007).

**344.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State, in violation of N.J. STAT. ANN. § 2A:32C-3(b) (2007).

**345.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally conspired, and may still be conspiring, to defraud the State by getting a false or fraudulent claim allowed or paid by the State, in violation of N.J. STAT. ANN. § 2A:32C-3(c) (2007).

**346.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made

or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State, in violation of N.J. STAT. ANN. § 2A:32C-3(g) (2007).

347. The State of New Jersey or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

348. As a result of Defendant' actions, as set forth above, the State of New Jersey or its political subdivisions has been, and may continue to be, severely damaged.

**COUNT XIX**  
**VIOLATION OF STATE OF NEW MEXICO MEDICAID FALSE CLAIMS ACT, N.M**  
**STAT. ANN. § 27-14-1, ET SEQ.**

349. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

350. This is a civil action brought by Plaintiffs/Relators on behalf of the State of New Mexico against Defendant under the State of New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-7(B).

351. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false or fraudulent claim for payment under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4A.

352. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented, or caused to be presented, and may be continuing to present or causing to be presented a claim for payment under the Medicaid program that is not authorized or is not eligible for benefit under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4B.

**353.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false or fraudulent claim paid or approved, in violation of N.M. STAT. ANN. § 27-14-4C.

**354.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico or one of its political subdivisions, in violation of N.M. STAT. ANN. § 27-14-4E.

**355.** The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

**356.** As a result of Defendant's actions, as set forth above, the State of New Mexico or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XX**  
**VIOLATION OF THE STATE OF NEW YORK FALSE CLAIMS ACT, N.Y. CLS. ST.**  
**FIN. § 187 ET SEQ.**

357. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

358. This is a civil action brought by Plaintiffs/Relators on behalf of the State of New York against Defendant under the State of New York False Claims Act, N.Y. CLS St. Fin. § 190.2.

359. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.Y. CLS St. Fin. § 189(a).

360. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of N.Y. CLS St. Fin. § 189(b).

361. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York or one of its political subdivisions, in violation of N.Y. CLS St. Fin. § 189(g).

362. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

363. As a result of Defendant's actions, as set forth above, the State of New York or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XXI**  
**VIOLATION OF THE STATE OF NEVADA SUBMISSION OF**  
**FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT, NEV. REV. STAT.**  
**ANN. § 357.010, ET SEQ.**

364. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

365. This is a civil action brought by Plaintiff/Relators on behalf of the State of Nevada against Defendant under the State of Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. ANN. § 357.080(1).

366. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of NEV. REV. STAT. ANN. § 357.040(1)(a).

367. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to obtain payment or approval for false claims in violation of NEV. REV. STAT. ANN. § 357.040(1)(b).

368. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada or one of its political subdivisions, in violation of NEV. REV. STAT. ANN. § 357.040(1)(g).

369. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

370. As a result of Defendant's actions, as set forth above, the State of Nevada or its political subdivisions have been, and may continue to be, severely damaged.

**COUNT XXII**  
**VIOLATION OF STATE OF OKLAHOMA MEDICAID**  
**FALSE CLAIMS ACT, OKLA. STAT. TIT. 63, § 5053 (2007), ET SEQ.**

371. Plaintiffs incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

372. This is a civil action brought by Plaintiffs, in the name of the State of Oklahoma, against Defendant pursuant to the State of Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*

373. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval, in violation of OKLA. STAT. tit. 63, § 5053(B)(1) (2007).

374. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state, in violation of OKLA. STAT. tit. 63, § 5053(B)(2) (2007).

375. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally conspired, and may still be conspiring, to defraud the state by getting a false or fraudulent claim allowed or paid, in violation of OKLA. STAT. tit. 63, § 5053(B)(3) (2007).

376. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, in violation of OKLA. STAT. tit. 63, § 5053(B)(7) (2007).

377. The State of Oklahoma or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

378. As a result of Defendant' actions, as set forth above, the State of Oklahoma or its political subdivisions has been, and may continue to be, severely damaged.

**COUNT XXIII**  
**VIOLATION OF STATE OF RHODE ISLAND**  
**FALSE CLAIMS ACT, R.I. GEN. LAWS § 9-1.1-1 (2007), ET SEQ.**

379. Plaintiffs incorporates herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

380. This is a civil action brought by Plaintiffs, in the name of the State of Georgia, against Defendant pursuant to the State of Rhode Island Fraud False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2007), *et seq.*

381. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee or a member of the guard, a false or fraudulent claim for payment or approval, in violation of R.I. GEN. LAWS § 9-1.1-3(A)(1) (2007).

382. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state, in violation of R.I. GEN. LAWS § 9-1.1-3(A)(2) (2007).

383. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally conspired, and may still be conspiring, to defraud the state by getting a false or fraudulent claim allowed or paid, in violation of R.I. GEN. LAWS § 9-1.1-3(A)(3) (2007).

384. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, in violation of R.I. GEN. LAWS § 9-1.1-3(a)(7) (2008).

385. The State of Rhode Island or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

386. As a result of Defendant' actions, as set forth above, the State of Rhode Island or its political subdivisions has been, and may continue to be, severely damaged.

**COUNT XXV**  
**VIOLATION OF THE STATE OF TENNESSEE MEDICAID FALSE CLAIMS ACT,**  
**TENN. CODE ANN. § 71-5-181 ET SEQ.**

387. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

388. This is a civil action brought by Plaintiffs/Relators in the name of the State of Tennessee against Defendant under the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-183(a).

**389.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee a claim for payment under the Medicaid program knowing it was false or fraudulent, in violation of TENN. CODE ANN. § 71-5-182(a)(1)(A).

**390.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(1)(B).

**391.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, relative to the Medicaid program, with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(1)(D).

**392.** The State of Tennessee, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

393. As a result of Defendant's actions, as set forth above, the State of Tennessee has been, and may continue to be, severely damaged.

**COUNT XXVI**  
**VIOLATION OF THE STATE OF TEXAS HUMAN RESOURCES CODE, TEX. HUM.**  
**RES. CODE § 36.001 ET SEQ.**

394. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

395. This is a civil action brought by Plaintiffs/Relators in the name of the State of Texas against Defendant under the State of Texas Human Resources Code, Medicaid Fraud Prevention Chapter, TEX. HUM. RES. CODE § 36.101(a).

396. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for a contract, benefit or payment under a Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(1).

397. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact that is intended to be used, and has been used, to determine a person's eligibility for a benefit or payment under the Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(2).

398. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

or intentionally made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of TEX. HUM. RES. CODE § 36.002(4)(B).

399. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made a claim under the Medicaid program for a service or product that was inappropriate, in violation of TEX. HUM. RES. CODE § 36.002(7)(C).

400. The State of Texas, its political subdivisions or the Department, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

401. As a result of Defendant's actions, as set forth above, the State of Texas, its political subdivisions or the Department has been, and may continue to be, severely damaged.

**COUNT XXVII**  
**VIOLATION OF THE COMMONWEALTH OF VIRGINIA**  
**FRAUD AGAINST TAXPAYERS ACT, VA CODE ANN. § 8.01-216.1, ET SEQ.**

402. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

403. This is a civil action brought by Plaintiffs/Relators on behalf of the Commonwealth of Virginia against Defendant under the Commonwealth of Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.5, *et seq.*

**404.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the Commonwealth, a false or fraudulent claim for payment or approval, in violation of VA. CODE ANN. § 8.01-216.3(A)(1).

**405.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(2).

**406.** Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(7).

**407.** The Commonwealth of Virginia, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

**408.** As a result of Defendant' actions, as set forth above, the Commonwealth of Virginia, its political subdivisions or the Department has been, and may continue to be, severely damaged.

**COUNT XXVIII**  
**VIOLATION OF THE STATE OF WISCONSIN**  
**FALSE CLAIMS FOR MEDICAL ASSISTANCE, WIS. STAT. § 20.931 (2007), ET SEQ.;**

409. Plaintiffs/Relators incorporate herein by reference the preceding paragraphs of the Second Amended Complaint as though fully set forth herein.

410. This is a civil action brought by Plaintiffs/Relators on behalf of the State of Wisconsin against Defendant under the State of Wisconsin False Claims for Medical Assistance, WIS. STAT. § 20.931 (2007), *et seq.*;

411. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the state, a false or fraudulent claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(a) (2007).

412. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(b).

413. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly conspired, and may still be conspiring, to defraud the state by obtaining allowance or payment of a false claim for medical assistance; or knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to conceal,

avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program, in violation of WIS. STAT. § 20.931(2)(C).

**414.** The State of Wisconsin, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

**415.** As a result of Defendant' actions, as set forth above, the State of Wisconsin, its political subdivisions or the Department has been, and may continue to be, severely damaged.

**WHEREFORE,** Plaintiffs pray for judgment against Defendant as follows:

A. That Defendant be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729, *et seq.*; ARK. CODE ANN. § 20-77-901, *et seq.*, CAL. CODE § 12650, *et seq.*, DEL. CODE ANN. tit. 6, § 1201, *et seq.*, D.C. CODE ANN. § 2-308.13, *et seq.*, FLA. STAT. ANN. § 68.081, *et seq.*, GA. CODE ANN. § 49-4-168, *et seq.*, HAW. REV. STAT. § 661-21, *et seq.*, IND. CODE ANN. § 5-11-5.5, *et seq.*, 740 ILL. COMP. STAT. ANN. 175/1, *et seq.*, LA. REV. STAT § 437.1, *et seq.*, MASS. LAWS ANN. Ch. 12, §5A, *et seq.*, MICH. COMP. LAWS SERV. § 400.601, *et seq.*, MONT. CODE ANN. § 17-8-401, *et seq.*, N.H. REV. STAT. ANN. § 167:61-b, *et seq.*, N.J. STAT ANN. § 265, *et seq.*, N.M. STAT. ANN. § 27-14-1, *et seq.*, N.Y. CLS ST. FIN. § 187, *et seq.*, NEV. REV. STAT. ANN. § 357.010, *et seq.*, OKLA. STAT. tit. 63, § 5053, *et seq.*, R.I. GEN. LAWS § 9-1,1-1, *et seq.*, TENN. CODE ANN. § 71-5-181, *et seq.*, TEX. HUM. RES. CODE § 36.001, *et seq.*, VA. CODE ANN. § 8.01-216.1, *et seq.*, and WIS. STAT. § 20.931 (2007), *et seq.*

B. That judgment be entered in Plaintiffs' favor and against Defendant in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

C. That Plaintiffs be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and § 3730(h), ARK. CODE ANN. § 20-77-901, *et seq.*, CAL. CODE § 12650, *et seq.*, DEL. CODE ANN. tit. 6, § 1201, *et seq.*, D.C. CODE ANN. § 2-308.13, *et seq.*, FLA. STAT. ANN. § 68.081, *et seq.*, GA. CODE ANN. § 49-4-168, *et seq.*, HAW. REV. STAT. § 661-21, *et seq.*, IND. CODE ANN. § 5-11-5.5, *et seq.*, 740 ILL. COMP. STAT. ANN. 175/1, *et seq.*, LA. REV. STAT § 437.1, *et seq.*, MASS. LAWS ANN. Ch. 12, §5A, *et seq.*, MICH. COMP. LAWS SERV. § 400.601, *et seq.*, MONT. CODE ANN. § 17-8-401, *et seq.*, N.H. REV. STAT. ANN. § 167:61-b, *et seq.*, N.J. STAT ANN. § 265, *et seq.*, N.M. STAT. ANN. § 27-14-1, *et seq.*, N.Y. CLS ST. FIN. § 187, *et seq.*, NEV. REV. STAT. ANN. § 357.010, *et seq.*, OKLA. STAT. tit. 63, § 5053, *et seq.*, R.I. GEN. LAWS § 9-1,1-1, *et seq.*, TENN. CODE ANN. § 71-5-181, *et seq.*, TEX. HUM. RES. CODE § 36.001, *et seq.*, VA. CODE ANN. § 8.01-216.1, *et seq.*, and WIS. STAT. § 20.931, *et seq.*

D. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Arkansas or its political subdivisions multiplied as provided for in ARK. CODE ANN. § 20-77-903(a)(1), plus a civil penalty of not less than five

thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) per claim as provided by ARK. CODE ANN. § 20-77-903(a)(1), to the extent such multiplied penalties shall fairly compensate the State of Arkansas or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

E. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in CAL. CODE § 12651(a), plus a civil penalty of no more than ten thousand dollars (\$10,000) per claim as provided by CAL. CODE § 12651(a), to the extent such multiplied penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

F. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the Government of the State of Delaware multiplied as provided for in DEL. CODE ANN. tit. 6, § 1201(a), plus a civil penalty of not less than five thousand five-hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) for each act in violation of the State of Delaware False Claims and Reporting Act, as provided by DEL. CODE ANN. tit. 6, § 1201(a), to the extent such multiplied penalties shall fairly compensate the Government of the State of Delaware for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

G. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. CODE

ANN. § 2-308.14(a), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. CODE ANN. § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

H. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in FLA. STAT. ANN. § 68.082, plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) as provided by FLA. STAT. ANN. § 68.082, to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

I. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in GA. CODE ANN. § 49-4-168, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent of the proceeds per claim as provided by GA. CODE ANN. § 49-4-168.2, to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

J. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in HAW. REV. STAT. § 661-21(a), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) as provided by HAW. REV. STAT. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

K. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Indiana, multiplied as provided for in IND. CODE ANN. § 5-11-5.5-2, plus a civil penalty of at least five thousand dollars (\$5,000) as provided by IND. CODE ANN. § 5-11-5.5-2, to the extent such multiplied penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

L. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 ILL. COMP. STAT. ANN. 175/3(a), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000), and the costs of this civil action brought to recover such damages and penalty, as provided by 740 ILL. COMP. STAT. ANN. 175/3(a), to the extent such multiplied penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

M. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in LA. REV. STAT § 438.6(B)(2), plus a civil penalty of no more than ten thousand dollars (\$10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by LA. REV. STAT § 438.6(B)(1), plus up to ten thousand dollars (\$10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by LA. REV. STAT §. 438.6(C)(1)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of s. 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by LA. REV. STAT § 438.6(C)(1)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

N. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the Commonwealth of Massachusetts or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in MASS. LAWS ANN. ch. 12, § 5B, multiplied as provided for in MASS. LAWS ANN. ch. 12, § 5B, plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) for each false claim, pursuant to MASS. LAWS ANN. ch. 12, § 5B, to the extent such multiplied penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes

undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

O. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in MICH. COMP. LAWS SERV. §§ 400.603 – 400.606, 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

P. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in MONT. CODE ANN. § 17-8-403(2), multiplied as provided for in MONT. CODE ANN. § 17-8-403(2), plus a civil penalty of up to ten thousand dollars (\$10,000) for each false claim, pursuant to MONT. CODE ANN. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Q. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of New Hampshire or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in N.H. REV. STAT. ANN. § 167:61II, multiplied as provided for in N.H. REV. STAT. ANN. §

167:61II, plus a civil penalty of two thousand dollars (\$2,000) for each false claim, pursuant to N.H. REV. STAT. ANN. § 167:61II, to the extent such multiplied penalties shall fairly compensate the State of New Hampshire or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

R. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. STAT. ANN. § 265, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by N.J. STAT. ANN. § 265, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

S. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in N.M. STAT. ANN. § 27-14-4, multiplied as provided for in N.M. STAT. ANN. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

T. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.Y.

CLS St. Fin. § 189.1., multiplied as provided for in N.Y. CLS St. Fin. § 189.1., plus a civil penalty of not less than six thousand dollars (\$6,000) or more than twelve thousand dollars (\$12,000) for each false claim, pursuant to N.Y. CLS St. Fin. § 189.1., to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

U. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in NEV. REV. STAT. ANN. 357.040, multiplied as provided for in NEV. REV. STAT. ANN. § 357.040(1), plus a civil penalty of not less than two thousand dollars (\$2,000) or more than ten thousand dollars (\$10,000) for each act, pursuant to NEV. REV. STAT. ANN. § 357.040, to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

V. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in OKLA. STAT. tit. 63, § 5053, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by OKLA. STAT. tit. 63, § 5053.4, to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

W. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. GEN. LAWS § 9-1,1-1, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by R.I. GEN. LAWS § 9-1,1-4, to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

X. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in TENN. CODE ANN. 71-5-182, multiplied as provided for in TENN. CODE ANN. § 71-5-182(a)(1), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) pursuant to TENN. CODE ANN. § 71-5-182(a)(1), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Y. that judgment be entered in Plaintiffs' favor and against Defendant for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendant' unlawful acts, as provided for in TEX. HUM. RES. CODE § 36.052(a)(1), multiplied as provided for in TEX. HUM. RES. CODE § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to TEX. HUM. RES.

CODE § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than fifteen thousand dollars (\$15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars (\$1,000) or more than ten thousand dollars (\$10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to TEX. HUM. RES. CODE § 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Z. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in VA. CODE ANN. § 8.01-216.3(A), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) as provided by VA. CODE ANN. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

AA. that judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in WIS. STAT. § 20.931(2), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) as provided by WIS. STAT. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

BB. that Defendant be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

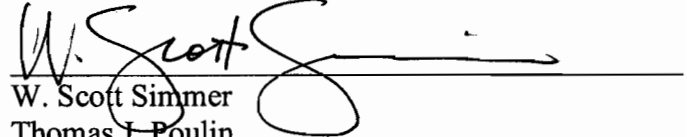
CC. that judgment be granted for Plaintiffs against Defendant for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Plaintiffs in the prosecution of this suit; and

DD. that Plaintiffs be granted such other and further relief as the Court deems just and proper.

**JURY TRIAL DEMAND**

Plaintiffs demand a trial by jury of all issues so triable.

Dated: November 13, 2008.



W. Scott Simmer  
Thomas J. Poulin  
Blank Rome, LLP  
600 Watergate New Hampshire Ave., NW  
Washington, D.C. 20037  
Telephone: (202) 772-5800  
Facsimile: (202) 772-5858

Anthony A. Froio  
Alan E. McKenna  
Robins, Kaplan, Miller & Ciresi L.L.P.  
800 Boylston Street  
Suite 2500  
Boston, MA 02199-7080  
Telephone: (617) 267-2300  
Facsimile: (617) 267-8288

*Counsel for Plaintiffs/Relators*