IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF WISCONSIN, THE COMMONWEALTH OF MASSACHUSETTS, THE COMMONWEALTH OF VIRGINIA, THE DISTRICT OF COLUMBIA, THE CITY OF CHICAGO, THE CITY OF NEW YORK, THE STATE OF CONNECTICUT, THE STATE OF COLORADO, THE STATE OF MARYLAND, THE STATE OF IOWA, and THE STATE WASHINGTON ex rel. SALLY SCHIMELPFENIG and JOHN SEGURA Plaintiffs, vs. Dr. Reddy's Laboratories Limited and Dr. Reddy's Laboratories, Inc. 200 Somerset Corporate Boulevard (Bldg II) Bridgewater, New Jersey 08807 and CVS Caremark Corporation, Walgreen Co., and Wal-Mart Stores, Inc. Defendants.	§	**Docket No. 11-CV-4607** **FILED UNDER SEAL**

RELATORS SECOND AMENDED QUI TAM COMPLAINT

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I. INTRODUCTION

1. Plaintiffs/Relators hereby file this Second Amended Complaint[1] pursuant to The False Claims Act, Section 31 U.S.C. Title 3729 and 3730, under which a civil action may be brought for violations of 31 U.S.C. Section 3729 ("FCA") regarding false claims on behalf of the United States Government and the various States and municipalities listed herein ("State Plaintiffs") under their own False Claims Acts.

The purposes of this Second Amended Complaint are to clarify (i) that the products of Defendant Dr. Reddy's Laboratories Limited and Dr. Reddy's Laboratories (defined and described herein collectively as "DRL Drug Products") were knowingly illegally dispensed by the Defendant Pharmacies and (ii) knowingly misbranded under the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C.A. § 352(p) which is a prohibited act under 21 U.S.C.A. § 331(a) and remove the State of New Hampshire as a party in that Relators do not believe that New Hampshire is a proper party under the terms of it's False Claims Act.[2]

2. Relators allege that Defendant Dr. Reddy's Laboratories Limited is packaging, selling and distributing certain prescription drugs, deemed *"household substances*[3]*,"* and has violated the Consumer Product Safety Improvement Act of 2008 ("CPSIA") by failing to test and then certify compliance or exclusion from compliance, with applicable Consumer Product Safety Commission ("Commission" or "CPSC") rules,

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[1] The Original Complaint was filed under seal on July 21, 2011

[2] The New Hampshire False Claim Act allows an individual, hereafter referred to as "relator," to bring a civil action for a violation of RSA 167:61-b, if . . . during the 12-month period immediately preceding the date the action is filed, Defendant received reimbursement from the Medicaid program of this state, as defined under RSA 167:63, V, equal to 10 percent or more of the defendant's aggregate reimbursement from all state medical assistance programs governed by Title XIX of the Social Security Act.

[3] Poison Prevention Packaging Act, Title 15 § 1471(2)(B), 1472(a)(1) which defines a "drug" covered by Title 21 § 321 as a household substance requiring "special packaging".

standards, or bans, including the *"special packaging"* requirements of the Poison Preventive Packaging Act ("PPPA") of 1970 and regulations thereunder.

3. DRL's failure to comply with these testing and certification mandates results in the DRL Covered Drug Products (hereinafter defined) being *(i) "misbranded"* under the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C.A. § 352(p) which is a prohibited act under 21 U.S.C.A. § 331(a) and (ii) illegally dispensed by the Pharmacy Defendants because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards.

If DRL had notified the States and/or the federal government that they were noncompliant to CPSIA and PPPA, the noncompliant drug products identified by their National Drug Code (NDC's) would be, as a matter of law, excluded from "Covered Drugs." The drugs could have been refused entry by Customs officials and no government payments would legally be allowed against any claims related to these NDCs.

4. As a result, DRL has caused, during the relevant time period herein, its contract partners[4] to submit false claims. The alleged FCA violation arises from the knowing submission of claims to a Federal Payer (hereinafter defined) for uncovered drugs caused by DRL's fraudulent conduct which drugs were illegally dispensed drugs by the Pharmacy Defendants, thereby rendering the claims to be "false." A pharmacist or pharmacy has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA. In addition to the above, DRL has further caused its

[4] The Complaint herein identifies three such contract partners as Defendants (Walgreens, CVS/Caremark and Walmart) based on Relator's knowledge of the express representations in Supply Agreement that DRL made to them. Relator reserves the right to add similar like parties should discovery result in finding that such representations and warranties had been made to other such retail pharmacies.

primary customers who are its contract partners to submit false claims because it has expressly represented and warranted to such partners that it has complied with all Federal and State laws and that it's Drug Products were not misbranded as defined by the FFDCA, meaning that they could be legally dispensed.

5. In order to be compliant manufacturers, such as DRL, must perform testing and pass and then issue a certification assuring that the product complies with all applicable rules. Moreover, DRL did not even have the capacity or ability to test the products in India, (the Country of manufacture).

6. The DRL products in question are all drugs that it packages in *"units of use"* or *"unit dose"* packages or which could reasonably have the potential to be dispensed at a pharmacy in the original manufacturer's packaging. These products include all "blister packages," bottled packaging with 100 units or less and any other drug product that DRL has concluded requires or is manufactured[5] with a child resistant cap, otherwise referred to as a "CRC" (collectively, "DRL Drug Products"[6]).

7. DRL's Drug Products are untested with no certification being provided, and were being marketed with ultimate distribution to consumers through retail pharmacies and other providers who distribute to the consumer. DRL was not compliant with the CPSIA for any of the DRL Drug Products[7] set forth herein. DRL has packaged, sold and distributed and continued to do so as set forth herein.

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[5] Bottles with CRC are presumed to have the intent of direct dispensing to consumers

[6] The DRL Drug Products are more particularly described herein in ¶ 133, ¶ 136 and ¶ 139.

[7] To the extent that any DRL products are "exempt' from the testing requirements, a Certificate of Exemption is required under the CPSIA which must be included with the distribution of the product. Failure to do so also results in the "misbranding" of the drug.

8. There are several reported cases that DRL[8] is of aware of children accessing drugs which has resulted in overdoses in children causing periods of unconsciousness, seizures, hepatotoxicity, prolongation and a serotonin syndrome that required endotracheal intubation and intensive care unit management (see ¶ 188 herein).

9. From May 1, 2010 through April 30, 2011, DRL had overall net sales in the United States of 3,766,341,828.00 extended units[9] (EU) or an average of 125,544,728 EU per month. This resulted in net sales excluding cash discounts of $426,700,117.00 dollars. Relators believe that the Federal Payers are responsible for reimbursing providers approximately thirty per cent (30%) of these EU's.

10. Relators estimate that (i) Defendant Walgreens purchased approximately $24,249,856.68 of DRL Drug Products directly from DRL during the relevant period that were PPPA noncompliant and therefore misbranded and dispensed illegally, (ii) Defendant CVS Caremark purchased approximately $74,472,638.93 of DRL Drug Products directly from DRL during the relevant period that were PPPA noncompliant and therefore misbranded and dispensed illegally and (iii) Defendant Walmart purchased approximately $636,499.15 of DRL Drug Products directly from DRL during the relevant period that were PPPA noncompliant and therefore misbranded and illegally dispensed. Relators believe that the Federal Payers reimbursed these providers for approximately thirty per cent (30%) of these DRL Drug products.

II. THE PLAINTIFF / RELATORS

11. Sally Schimelpfenig (Schimelpfenig) resides at 2131 Old McKlinney Road,

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[8] These stories are referenced here as evidence that DRL was aware of the risks of these events occurring or could occur, not for the proposition that DRL actually caused these specific occurrences.

[9] Extended Units equals tablets and capsules, absolute values (i.e. packaged units x unit count per package)

York, SC 29745. Schimelpfenig has more than 15 years of experience in pharmaceutical industry in health care marketing, product management and other related fields. Her position with the Defendant DRL was North America Generics Marketing Director.

12. John Segura (Segura) was Senior Director, OTC Marketing and he was the former Senior Director of North American Generics (Rx) from December 2005 to April 2007. His employment terminated sometime in June 2011. Collectively, Schimelpfenig and Segura are referred to as Relators.

III. DEFENDANTS

13. There are multiple defendants that are included in this action. According its own publicly filed documents, DRL sells its products to customers that include chain drug stores, health maintenance organizations, mail service pharmacies, pharmacy buying groups and drug wholesalers[10]. By its actions described herein, DRL has caused these customers to submit a false claim when they seek reimbursement from Federal payers.

14. The Defendant's are identified in two separate groups based on their respective roles and liability. The first group, (Manufacturer), consists of Dr. Reddy's Laboratories (DRL or Dr. Reddys) and it's United States subsidiaries (DRLUS) and any other DRL subsidiary that may be responsible for the manufacture of the products herein and the mandated testing and certification on which this cause of action is based. (collectively DRL or Dr Reddys)

15. The second group, retailers and ultimate providers, (herein referred to as Pharmacy Defendants) consists of those parties who either purchase drug products

[10] RDL's Form 20-F for fiscal year ended March 31, 2010, page 26, 30.

directly from DRL and who then sells to the ultimate beneficiary and thereafter seeks reimbursement from a Federal Health Care Program. This Group includes, inter alia[11], CVS/Caremark, Walgreens and Wal-Mart, who then submit claims for reimbursement from a Federal Health Care Program of the "misbranded" and illegally dispensed DRL Covered Drugs.

A. MANUFACTURER (DRL and DRLUS)

16. Dr. Reddy's Laboratories Limited ("parent company"), together with its subsidiaries (collectively, "DRL" or "Dr Reddys"), is a leading India-based pharmaceutical company headquartered in Hyderabad, India. DRL's principal areas of operation are in (i) pharmaceutical services and active ingredients, (ii) global Generics, and (iii) proprietary products. The global Generics segment consists of finished pharmaceutical products ready for consumption by the patient, marketed under a brand name (branded formulations) or as generic finished dosages with therapeutic equivalence to branded formulations (Generics).

17. The Company's principal research and development facilities are located in Andhra Pradesh, India; its principal manufacturing facilities are located in Andhra Pradesh, India, Himachal Pradesh, India and Cuernavaca-Cuautla, Mexico; and its principal marketing facilities are located in India, Russia and other countries of former Soviet Union, the United States, the United Kingdom and Germany. The Company's shares trade on the Bombay Stock Exchange and the National Stock Exchange in India and, since April 11, 2001, also on the New York Stock Exchange in the United States.

18. Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of DRL in the

[11] The Complaint herein identifies three such contract partners as Defendants (Walgreens, CVS/Caremark and Walmart) based on Relator's knowledge of the express representations in Supply Agreement that DRL made to them. Relators believe that the same or similar representations and warranties are contained in all of DRL's Supply Agreements with retailers and reserves the right to add similar like parties should discovery result in finding that such representations and warranties had been made to other such retailers.

United States. ("DRLUS"). DRLUS markets DRL Covered Drug Products in the United States and North America. DRL and DRLUS along with any DRL subsidiaries any other DRL subsidiary that may be responsible for the manufacture of the products herein and the mandated testing and certification on which this cause of action is based are hereinafter referred to as DRL.

19. The DRL Drug Products are primarily manufactured in India. The shipping of the products come into the third party logistics distribution facility in Louisville, Kentucky, which is a UPS managed facility. The primary ports of entry are Philadelphia, Pennsylvania and Charleston, South Carolina. Products delivered by airfreight arrive into Charlotte North Carolina. Thereafter, from the Louisville facility, distribution is made directly to the warehousing retail pharmacy chains and mail service pharmacies and to the wholesalers.

20. The DRL Drug Products are subject to the testing and certification requirements set forth in the Consumer Product Safety Improvement Act of 2008 ("CPSIA") and PPPA. All of the DRL Drug Products are "drugs" pursuant to 21 U.S.C.A. § 321(g)(1)[12].

B. RETAILERS and ULTIMATE PROVIDERS

21. These Defendants include, inter alia, the following:

a. CVS Caremark Corporation ("CVS Caremark") is a Delaware corporation (now known as CVS Health[13]) with its principal office located at One CVS

[12] The term "drug" means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and © articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or ©

[13] CVS Health includes the company's retail business, which continues to be called CVS/pharmacy; its pharmacy benefit management business, which is known as CVS/caremark; its walk-in medical clinics, CVS/minute clinic; and its growing specialty pharmacy services, CVS/specialty.

Drive, Woonsocket, Rhode Island 02895. Together with its subsidiaries, it is the largest pharmacy health care provider in the United States through its pharmacy benefit management, mail order and specialty pharmacy division, which includes approximately 7,200 CVS/pharmacy retail stores; a retail-based health clinic subsidiary, MinuteClinic; and online pharmacy, CVS.com.

b. Walgreen Co. ("Walgreen") is an Illinois Corporation whose principal address is located at 200 Wilmot Road, Deerfield, Illinois 60015. Together with its subsidiaries, Walgreen operates the largest drugstore chain in the United States with net sales of $67.4 billion in the fiscal year ended August 31, 2010. Walgreen pharmacy services include retail, specialty, infusion, medical facility, long term care and mail service, along with pharmacy benefit solutions and respiratory services.

c. Wal-Mart Stores, Inc. a Delaware corporation (Walmart), whose principal office is located at 702 S.W. 8th Street, Bentonville, Arkansas. Walmart has large retail operations in all 50 States and with a significant retail pharmacy business segment.

Walgreens, CVS Caremark and Walmart are hereinafter referred to as "Pharmacy Defendants." DRL and the Pharmacy Defendants are collectively referred to the "Defendants."

IV. JURISDICTION

22. This action arises under the FCA, 31 U.S.C. §§3729 et seq., and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§1331 and 1345.

23. This Court also has supplemental jurisdiction over the claims brought by Relator on behalf of the States under their state FCAs, pursuant to 28 U.S.C. §1367(a) and 31 U.S.C. §3732(b).

Relators are original sources of the allegations in this Complaint as well as the prior complaints and the allegations contained therein are not based upon publicly disclosed information. Prior to filing this Complaint and the prior complaints, Relators provided the United States and all the other States named herein with Disclosure Statements as part of Relator's obligation to provide the government with material information prior to filing a Complaint in accordance with 31 U.S.C. § 3730(b)(2). Copies of the filed original Complaint and First Amended Complaint have been served on the Federal Government and all State Plaintiffs.

V. VENUE

24. Venue in this district is proper pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) and © since one or more of the Defendants transact business in this district and/or one or more of the acts at issue occurred in this district.

VI. STATUTORY & REGULATORY BACKGROUND

A. The Poison Prevention Packaging Act (1970) and The Consumer Product Safety Act (1972)

1. Background and Legislative History of the Acts

25. The Poison Prevention Packaging Act (PPPA), 15 U.S.C. §§1471-77, was enacted in 1970 *"[t]o provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances . . ."*

26. The legislative history of the PPPA reflects that it was enacted because hundreds of children were dying in the United States annually and many thousands more were seriously and permanently injured from the accidental ingestion of

poisonous household substances, including drugs, which were responsible for about half of all cases.

27. In 1972, Congress passed the Consumer Product Safety Act, 15 U.S.C. § 2051, et seq., ("CPSA"), based upon findings that (1) an unacceptable number of consumer products presented unreasonable risks of injury, (2) consumers could not anticipate risks and safeguard themselves adequately, (3) the public must be protected against unreasonable risks of injury from consumer products, (4) state and local controls were inadequate to protect consumers, (5) existing Federal authority was also inadequate, and (6) additional regulation of consumer products was necessary. 15 U.S.C. § 2051(a).

28. The purposes of the CPSA were to (1) protect the public against unreasonable risk of injury from consumer products, (2) assist consumers in evaluating the comparative safety of consumer products, (3) develop uniform safety standards for consumer products and to minimize conflicting state and local regulations, and (4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries. 15 U.S.C. § 2051(b).

29. In 1972, Congress established the Consumer Protect Safety Commission ("CPSC") as an independent regulatory commission and empowered the CPSC to promulgate consumer product safety standards. 15 U.S.C. §§ 2053, 2056.

30. With the passage of the CPSA in 1972, Congress transferred the functions of the Secretary of Health and Human Services under the FDCA to the CPSC to the extent such functions relate to the administration and enforcement of 15 U.S.C. § 2079(a). As a result the CPSC, (not the FDA) enforces the PPPA and related regulations. 15 U.S.C. § 2079(a); 16 C.F.R. § 1700.2.

31. Drugs that are customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household are subject to the requirements of the PPPA. 15 U.S.C. § 1471(2)(B) (1970).

32. Under the PPPA, any drug for human use that is in a dosage form intended for oral administration and that is required by federal law to be dispensed only by or upon a prescription shall be packaged in accordance with the provisions of the PPPA, 16 C.F.R. § 1700.15(a), (b) and ©. 16 C.F.R. § 1700.14(a)(10).

33. The CPSC has determined that the hazard to children in the availability of prescription drugs, by reason of their packaging, is such that special packaging is required to protect children. 16 C.F.R. § 1700.14(a).

34. To protect children from serious personal injury or illness, prescription drug packaging must be designed and constructed to meet the standards of "special packaging." 16 C.F.R. § 1700.15.

35. "Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five to open or obtain a toxic or harmful amount within a reasonable time and not difficult for normal adults to use properly. 16 C.F.R. § 1700.1(b)(4).

36. “Special packaging” specifications and testing regime are codified in the PPPA regulations. [see ¶ 52 - ¶ 58 herein].

37. 16 C.F.R. §§ 1700.15(a) and (b) set forth the general requirements and effectiveness specifications for "special packaging" of prescription drugs.

38. "Special packaging" of unit dose prescription drugs, tested by the method described in the PPPA regulations (16 C.F.R. § 1700.20), must meet the following

"effectiveness specifications": (1) child-resistant effectiveness of not less than 80 percent; and (2) ease of adult opening. 16 C.F.R. § 1700.15(b).

2. Child - Resistant Packaging Under the PPPA

39. Per the legislative history of the PPPA, child resistant packaging is the default for all prescription drugs intended for household use. 16 C.F.R. § 1700.14

40. Non child-resistant packaging of prescription drugs for household use is noncompliant unless a statutory exception applies. 16 C.F.R. § 1700.14(a)(10)

41. There are only two exceptions to the requirement that prescription drugs for the household be in child-resistant packaging – upon the order of the prescribing doctor or a request by the purchaser. 15 U.S.C. §1473(b) ("Noncomplying packages for substances dispensed pursuant to orders of medical practitioners").

42. Thus, under federal law, a prescription drug intended for household use, by definition, must be in child-resistant packaging, unless the prescription calls for non-child resistant packaging or unless the consumer requests non-child resistant packaging. 16 C.F.R. § 1700.14(a)

43. Drug manufacturers distributing prescription drugs in packages intended to be dispensed directly to the consumer (rather than repackaged by the pharmacist, e.g., drugs in bulk packages) must use child-resistant packaging. 16 C.R.F. § 1701.1(b) and (c).

3. Illegal Dispensing of Drugs by Pharmacy Defendants

44. The pharmacy and the pharmacist (collectively, the "pharmacist") must be and are responsible for dispensing the drug in the proper package. 16 C.R.F. § 1701.1(b). This is consistent with all State Pharmacy laws and regulations.

45. If the pharmacist receives a request from the consumer or an order from the prescribing medical practitioner for conventional (noncomplying) packaging, the pharmacist may convert the package to conventional packaging or repackage the drug in conventional packaging. 16 C.R.F. § 1701.1(b).

46. The PPPA expressly precludes a manufacturer of prescription drugs intended to be dispensed directly to the consumer to opt out of using child-resistant packaging by placing a warning label on the package. 15 U.S.C. §1473(a); 16 C.R.F. § 1701.1(c). DRL knowingly violated this provision by placing inconspicious warnings or notices on a limited number of the DRL Drug products that the package "is not child resistant (See ¶ 172 herein).[14] This clearly demonstrates that DRL had actual knowledge of its lack of compliance.

47. Unit dose or "blister" packaging is a type of drug packaging that is intended to be dispensed directly to consumers, and not repackaged by the pharmacist. A non-unit dose package is considered a bottle and is tested as if opened, meaning that if the child can get access to any of the contents inside the package within a certain period of time. Non-unit or bottles of less than 100 are typically not repackaged by the pharmacist.

48. The pharmacist has no right, discretion or authority to dispense prescription drugs in noncompliant packaging. 15 U.S.C. 1471 et seq; Fed. Reg. Vol. 38, No. 72, p. 9432 (Apr. 17, 1973). The dispensing pharmacist is responsible for determining at the

[14] See, e.g. (1) Risperidone 100-ct, 4 mg tablets, NDC 55111-471-78; (2) Risperidone 30-ct, 2 mg tablets, NDC 55111-209-81; (3) Ondansetron 4 & 8 mg tablets, NDC 55111-0153-13 and NDC 55111-0154-13, January 2011; (4) Ciproflaxin 6 tablets - 100 mg, NDC 55111-125-06

retail level whether a prescription drug must be packaged in accordance with PPPA standards[15].

49. The PPPA requires that the pharmacist dispense regulated drugs in special packaging. The only exceptions are those instances when the consumer or prescribing physician stipulates that a noncomplying package be used. Pharmacists who violate the regulations may be criminally prosecuted. Individuals may be sentenced to 1 year imprisonment and fined up to $250,000. Organizations may be fined up to $500,000. *Consumer Product Safety Commission (CPSC) Office of Compliance POISON PREVENTION PACKAGING: A GUIDE FOR HEALTHCARE PROFESSIONALS Revised 2005. 2005 WL 3878500 (C.P.S.C.)*

50. A pharmacist is expected to act as the gate-keeper of prescription medication, monitoring the distribution and implementation of prescription drug orders. Thus, a pharmacist provides a service to the patient, the physician, and the community which is relied on. Moreover, the pharmacist provides a number of professional healthcare services, including utilizing professional skill and care to interpret and evaluate the prescription; educating patients as to the intended use of the medication and manner of ingestion; and maintaining necessary records for compounding, labeling, and storing pharmaceuticals. *Walton v. Bayer Corporation*, et al 692 F.Supp.2d 1012 United States District Court, S.D. Illinois. (Feb 2010).

51. The Federal Payers rely on and expect the pharmacist and Pharmacies to dispense prescription drugs in compliant packaging.

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[15] [t]he pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.)

4. Child Resistant Testing of Drug Packaging

52. The PPPA regulations set forth a detailed testing regime whereby panels of young children attempt to open packages of placebo drugs within a specific time frame. 16 § C.F.R. 1700.20. Et. Seq. A test failure occurs when any child opens or gains access to the number of units of the drug which may produce serious personal injury or illness, or a child who opens or gains access to more than eight individual units. 16 C.F.R. § 1700.20(a)(2)(ii).

53. The testing regime for child resistant packaging of drugs is expensive and time consuming. The Commission, depending on the type of "package" (i.e., bottle or blister), has determined the type of test dependent on whether the drug is contained in a "unit dose package" or a "non-unit dose package." There are two types of tests specified under the regulations; a unit dose package test and a non-unit dose package. Non-unit dose packages are considered bottles with a closure[16], i.e., a cap and is tested as if opened, meaning that if the child can get access to any of the contents inside the package within a certain period of time, it is considered a failure. The package must test out to be 94% or more effective or it is considered a failure.

54. A unit dose package is considered a blister package. There are many factors which determine when the package fails. First there is an F scale that ranges from Fl - F8. The F rating is determined by the number of product doses that it would take to produce serious personal injury or illness. This is based on a 11kg or 25lb child.

55. The F rating is determined by an independent and approved third party toxicology analysis. Fl is the most toxic and F8 is the least toxic. The F rating for a drug that contains more than one active ingredient (i.e., Fexofenadine pseudo) is determined

[16] Closures, or caps can also come with a heat sealed liner that covers the mouth of the bottle. This liner is easily defeated in child resistant testing and is used primarily as a tamper evident feature.

by the most toxic active ingredient. For example Fexofenadine PSE 24hr (180/240mg) the 180mg Fexofenadine F rating is F8 but the F rating for the 240mg Pseudoephedrine is FI, thus a FI rating is given to the combination drug.

56. An example of a test failure would be a child who gains access to one dose if it is a FI rated drug. If it is an F8 rated drug, a test failure would be a child who gains access to more than eight doses. An F8 drug tested where a child only gains access to seven doses would be considered a pass. The testing pass/fail criteria are highlighted below in the table. The first test consists of a 60-child panel. If there are 0. 5 failures, the testing is considered a pass. If there are 6 - 14, the test needs to go into a second panel of 50 children. If there are 15 or more failures, the test is a failure. A package can be tested up to 200 children in increments of 50 if needed. See the table below.

Sequential Testing

Test Panel	#Children Tested	Pass	Continue	Fail
1	50	0-5	6 - 14	15
2	100	6-15	16 - 24	25+
3	150	6-25	26 - 34	35+
4	200	26-40	-	41+

57. Following the completion of the testing, a report must be generated by the testing facility. If a product passes the child resistance test, compliance will be granted and marketing of the product may commence or continue. If a product fails the child resistance test, a change is required.

58. Should the product currently be out in the market, the manufacturer is required to submit the testing report with the corresponding toxicology report (F-value) to the CPSC. In this case, DRL did not do any of the testing in the manner required nor

has DRL notified CPSC or their customers' of their CPSIA noncompliance set forth in the PPPA.

B. The Food, Drug, and Cosmetic Act

1. Covered Outpatient Drugs

59. The Federal Food, Drug and Cosmetic Act ("FFDCA") prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use. 21 U.S.C. § 355 (a) and (d).

60. Under the Medicaid Drug Rebate Statute, federal financial participation is prohibited for a drug manufacturer's covered outpatient drugs unless there is a rebate agreement between the manufacturer and the Secretary under the statute. *See* 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan.

61. Under the FFDCA, a "covered outpatient drug" (unless it is "misbranded") includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 355 and 357.

62. When a drug is misbranded it is not covered for reimbursement by federal programs such as Medicare, Medicaid, The Civilian Health and Medical Program of the Uniformed Services (a/k/a Tricare), and The Federal Employees Health Benefits Program. 15 U.S.C. §1473(b) of the PPPA. 21 U.S.C. § 352(p)

63. Misbranding a drug while it was held for sale after shipment in interstate commerce violates 21 U.S.C. §§ 331(k) and 333(a)(1).

2. Consequences of Test Failures - Drugs are Considered to be "Misbranded Drugs"

64. In 1970, the Food, Drug and Cosmetic Act ("FDCA), was amended to address violations of the PPPA. Under the amendment, a drug is deemed "misbranded" if its packaging or labeling is in violation of section 15 U.S.C. §1473(b) of the PPPA. 21 U.S.C. § 352(p).

65. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded under the FDCA is a prohibited Act. 21 U.S.C. § 331.

66. Thus, prescription drugs manufactured with the intent that they are dispensed directly to the consumer are misbranded if the drugs are not in child resistant packaging that have tested in accordance with the PPPA..

67. As described and set forth in more detail herein, DRL is and has been aware of its obligation to do the testing as early as 2007, had not done any testing for the period relevant herein and was aware that some of their products, including those with known F1 toxicity, would fail the testing.

68. It is unlawful to sell, manufacture, distribute, or import into the United States any consumer product that is not in conformity with an applicable consumer product safety rule or any rule or regulation enforced by the CPSC. 15 USC § 2068(a)(1).

69. Thus, it is unlawful for a manufacturer of prescription drugs intended or packaged to be dispensed directly to the consumer to sell, distribute, manufacture or import to the United States any drug that does not meet the specifications and testing requirements for child resistant packaging

70. As set forth below, the manufacturer is required to include a "general conformity certificate" that has information on the identity of the manufacturer or private labeler of the product, the name of the drug, the testing laboratory, and the date and place of testing with the distribution of the drug products

71. A drug manufacturer who obtains information which reasonably supports the conclusion that the drug fails to comply with an applicable consumer product safety rule or other rule or regulation enforced by the CPSC, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death must immediately inform the CPSC of such failure to comply, defect, or risk, unless the manufacturer has actual knowledge that the CPSC has been adequately informed of such defect, failure to comply, or such risk. 15 U.S.C. § 2064(b).

72. Any state law which is not identical to federal law governing the packaging of prescription drugs for child resistance is preempted, unless the state law offers a greater degree of protection from risk of illness or injury than the federal law. 15 U.S.C. § 1476(a), (b); 15 USC §§ 2075(a), (b).

73. In addition, several states have laws which mirror the provisions of the Federal Poison Prevention Packaging Act, e.g., Illinois, Hawaii, California, Texas.

C. The Consumer Product Safety Improvement Act (2008) - 15 USC § 2051

74. In 2008, Congress passed the Consumer Product Safety Improvement Act ("CPSIA") as amendments to the CPSA.

75. The CPSIA requires manufacturers of imported drugs to issue "general conformity certificates" which certify, "based on a test of each product or upon a reasonable testing program," that the product complies with all rules and regulations

enforced by the CPSC (including the PPPA's child resistant packaging rules). 15 U.S.C. § 2063(a)(1).

76. In January 2009, the CPSC issued a stay of enforcement of the general conformity certificate requirement. This afforded manufacturers an additional year to ensure compliance. The requirement to issue general conformity certificates went into effect on February 10, 2010.

77. It is unlawful for prescription drug manufacturers to fail to furnish general conformity certificates. 15 U.S.C. § 2068(a)(6).

78. A drug manufacturer must immediately inform the CPSC of its noncompliance with the general conformity certificate requirement. 15 U.S.C. § 2064(b).

79. Any consumer product offered for importation into the United States must be refused admission into the United States if the product fails to comply with an applicable consumer product safety rule or is not accompanied by a general conformity certificate. 15 U.S.C. §§ 2066(a)(1), (2)

80. Products without the required certificate cannot be imported or distributed in commerce in the United States. The certificate must accompany the product or product shipment and must be available to CPSC and Customs and Border Protection upon request. Failure to furnish the certificate or furnishing a false certificate can subject the manufacturer or private labeler to civil and criminal penalties.

D. Federal Health Care Programs That Reimburse for DRL Covered Drug Products

81. The Government through the Department of Health and Human Services ("HHS") administers the Hospital Insurance Program for the Aged and Disabled established by Part A ("Medicare Part A Program") and the Supplementary Medical Insurance Program established by Part B ("Medicare Part B Program") Title XVIII of the

Social Security Act under 42 U.S.C. §§ 1395 et seq. There is also Part C (Medicare + Choice or Medicare Advantage) and Part D (Prescription Drug Program).

82. The Medicare Part A and Medicare Part B programs are federally financed health insurance programs for persons who are aged 65 and over and those who are disabled. HHS has delegated the administration of the Medicare Program to the Centers for Medicare and Medicare Services ("CMS"), a component of HHS.

83. Medicare part C, sometimes called Medicare+Choice-allows beneficiaries to obtain medical services through preferred provider organization plans, and other "managed care" arrangements offered by private health insurers. 42 U.S.C. §§ 1395w-21 to 1395w-28. Individuals are eligible for Medicare part C if they are "entitled to benefits under [Medicare] part A." 42 U.S.C. § 1395w-21(a)(3)(A) ("[T]he term 'Medicare + Choice eligible individual' means an individual who is entitled to benefits under [Medicare] part A...."). Individuals eligible for Medicare part C may elect to receive their Medicare benefits either "through the original medicare fee-for-service program under [Medicare] parts A and B or through enrollment in a Medicare+Choice plan under [Medicare part C]." 42 U.S.C. § 1395w-21(a)(1).

84. Medicare Part D is a prescription drug program for Medicare beneficiaries. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (M.A.) and went into effect on January 1, 2006. Individuals are eligible for prescription drug coverage under a Part D plan if they are entitled to benefits under Medicare Part A and/or enrolled in Part B. Beneficiaries can obtain the Part D drug benefit through two types of private plans: they can join a Prescription Drug Plan (PDP) for drug coverage only or they can join a Medicare Advantage plan (MA) that covers both medical services and prescription drugs (MA-P.D.). The latter type of plan is actually part of Medicare Part C and has several other differences relative to original Medicare. Approximately two-thirds of Part D

beneficiaries are enrolled in a PDP option. Dual eligibles (those also eligible for Medicaid benefits) were transferred from Medicaid prescription drug coverage to a Medicare Part D plan on January 1, 2006. They are automatically enrolled in one of the less expensive PEPS in their area, chosen at random. If the dual-eligible person is already enrolled in an MA-PD plan, then they are automatically removed from the MA plan upon enrollment in a PDP. Enrollment in Part D as of April 2010 was 27.6 million beneficiaries.

85. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

86. DRL has been an approved Medicaid provider since, at a minimum, July 1, 2003[17] by virtue of entering into a Medicaid Rebate Agreement with the Government under which they, inter alia, agreed to provide rebates to the States equal to 11.1 per cent[18] on generic brand prescription drugs that they manufactured.

87. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. secs. 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active

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[17] Medicaid Drug Program Release #123 effective July 1, 2003. This Release identifies DRL as an approved "labeler" with Labeler number 51111. This "label number" becomes part of the eleven digit NDC code assigned to every approved drug. The "label number" is the first five digits of the eleven digit NDC code. DRL added an additional new labeler code 43598 as of April 1, 2011

[18] The rebate amount has been increased to 13% effective January 1, 2010

duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

88. The federal government, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise.

89. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described above shall be referred to as "Federal Payers").

E. The Federal False Claims Act

90. The Federal FCA, 31 U.S.C. § 3729(1)(A) makes "knowingly" presenting or causing to be presented to the United States any "false" or fraudulent "claim" for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

91. The Federal FCA, 31 U.S.C. § 3729(1)(B) makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

92. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

1. The FCA and False Certification

93. The FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the government." *United States V. Neifert-White*, 390 U.S. 228, 232 (1968). Relators allege that Defendant DRL violated the FCA by causing the submission of false claims (and the Pharmacy Defendants by submitting a false claim) all in violation of 31 U.S.C. § 3729(a)(1)(A). This section imposes liability on any person who:

A. "Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval"; 31 U.S.C. § 3729(a)(1)(A), as amended May 20, 2009.[19]

"Knowingly" means the defendant (1) had actual knowledge that the claim is false; (2) acted with deliberate ignorance of the truth or falsity of the claims; or (3) acted with reckless disregard of the truth or false of the other claim. 31 U.S.C. § 3729(b)(1)(A)(1-3) and Section 2729(b)(1)(B).

94. A false certification establishes the "falsity" of a claim under the FCA. This was emphasized by Congress in the 1986 Amendments to the FCA stating "each and every claim submitted under a contract, loan guarantee or other agreement which was

[19] The Fraud Enforcement Recovery Act of 2009, Pub.L. No. 111-21, § 4, 123 Stat. 1616 (2009) modified and renumbered the subsections of § 3729(a) ("FERA").

originally obtained by means of false statements or other corrupt and fraudulent conduct, or in violation of any statute or appropriate regulation, constitutes a false claim." S.Rep. No. 99-345 at 9 (1986), reprinted in 1986 U.S.C.C.A.M. 5266, 5274.

95. The Third Circuit, in *Wilkins and Willis ex rel USA v. United Health Group*, (June 30, 2011)[20], adopted the implied certification theory under the False Claims Act. In addition, the Third Circuit also indicated in *Wilkins* that no specific claim need be identified at the pleading stage in an action under the FCA to state a cause of action under the implied certification theory.

96. To establish a claim under § 3729(a)(1)(A) of the FCA, a relator "must prove that '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.' " *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 304–05 (3d Cir.2011) (quoting United States ex rel. *Schmidt v. Zimmer, Inc.* ("Zimmer I "), 386 F.3d 235, 242 (3d Cir.2004)) (referring to previous codification of the statute as § 3729(a)(1)).

97. "Section 3729(a)(1)[(A) requires only that a claimant present a 'false or fraudulent claim for payment or approval' without the additional element of a 'false record or statement.' " *Id.*

98. Thus § 3729(a)(1)(A) allows a relator to bring a claim based on a defendant submitting a claim for government funds without explicitly making a false statement. *Id.*

99. The Third Circuit decided in *Wilkins* that "there are two categories of false claims under the FCA: a factually false claim and a legally false claim." *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir.2011) .

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[20] See Third Circuit Docket, Case No 10-2747, Document 003110580261 filed 6/30/2011

100. A claim is factually false when the claimant misrepresents what goods or services that it provided to the government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation which is a condition for government payment.

101. A legally false FCA claim is based on a 'false certification' theory of liability." *Id.*

102. Within the theory of false certification, there are two further categories: express and implied false certification.

103. A defendant violates the FCA under express false certification when, in conjunction with a request for Federal funds, it certifies that it is in compliance with regulations that are requirements for payment.

104. An FCA violation occurs under implied false certification when a defendant submits or causes to be submitted a request for payment without disclosing that it is in violation of a regulation that effect its eligibility for payment.

105. For a relator to succeed under this theory, the Third Circuit has required relators to show "that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Id.*

106. Under an implied false certification theory, the relator "must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government." *Id.*

107. DRL's actions in (i) knowingly distributing unsafe and misbranded drugs, and (ii) making express representations and warranties to the contrary was a "substantial factor" in influencing the Pharmacy Defendants and their pharmacists to

illegally dispense prescription drugs in noncompliant packaging, thereby causing them to file false claims.

108. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301–97, the Food and Drug Administration (FDA) has authority to approve drugs for sale in interstate commerce if the manufacturer can demonstrate that the drug is safe and effective for specific intended uses.

109. Under the false certification theory, the misbranded DRL Products distributed were (i) not *"reasonable and necessary for treatment," and* (ii) were illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards which makes those uses ineligible for reimbursement under Medicare and Medicaid regulations.

110. Because DRL, through its false and misleading express representations and warranties to its contract partners that its Drug Products complied with all Federal laws, including the PPPA, it knowingly caused its contract partners such as the Pharmacy Defendants (Walgreens, CVS/Caremark and Walmart) to submit claims for reimbursement for misbranded drugs and were illegally dispensed in noncompliant packaging under the PPPA, causing the submission of false claims under the FCA.

111. These actions make the claim for reimbursement "false" under the FCA because they are both (i) factually false in that dispensing misbranded drug the Pharmacy Defendants are misrepresenting what goods the Federal Payers are paying for because they expect that the drug is packaged in conformance with the PPPA and (ii) legally false as a result of a breach of an implied certification in that if the Government had been aware that of the violations that resulted in the drugs being illegally dispensed, it would not have paid the claim.

112. DRL's sale and distribution of the DRL Covered Drug Products were misbranded and illegally dispensed as a result of being not in compliance with the PPPA, which compliance is a condition of payment by the Federal Payers and State Plaintiffs as set forth and described herein in that it is clear that testing, compliance with the PPPA and illegal dispensing of the drugs are material conditions and are substantial factors in the Government decision to reimburse providers for prescription drugs such as the DRL.

113. DRL expressly represents and warrants compliance with all Federal medicaid and medicare related laws, rules and regulations to its Contract partners and the Pharmacy Defendants, knowing full well that in many cases, they will be seeking reimbursement from the States and/or Federal Government. If DRL had notified the States and/or Consumer Product Safety Commission[21] that they were noncompliant with the requirements of the CPSIA and PPPA, the noncompliant NDC's would be excluded from "Covered Drugs" and no government payments would be allowed against any claims related to these NDC's. In addition, If DRL notified its customers of its noncompliance, it is likely that DRL noncompliant products would be removed from their respective contracts. Clearly, compliance with this mandate is a "condition of payment."

2. Liability Under the FCA Is Appropriate When A Party Causes the Submission of a False Claim

114. The FCA expressly imposes liability on individuals who knowingly cause someone else to submit a false claim for payment. 31 U.S.C. § 3729(a)(1). In interpreting the statute, courts have imposed FCA liability on defendants who caused others to submit false claims for payment, even if the party submitting the claim was

[21] With the passage of the CPSA in 1972, Congress transferred the functions of the Secretary of Health and Human Services under the FDCA to the CPSC to the extent such functions relate to the administration and enforcement of 15 U.S.C. § 2079(a). As a result the CPSC, (not the FDA) enforces the PPPA and related regulations. 15 U.S.C. § 2079(a); 16 C.F.R. § 1700.2.

unaware of its falsity. *See, e.g., United States v. Bornstein*, 423 U.S. 303 (1976) (imposing liability on subcontractor whose faulty electron tubes were incorporated into radio kits sold to United States); *United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) (imposing liability on defendant who knowingly caused third party to unwittingly submit false claims).

115. DRL is and was aware that it's fraudulent conduct would cause its customers to submit false claims for reimbursement. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d. Cir. 2004) (knowingly assisting in causing the government to pay claims grounded in fraud actionable under FCA); *See also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S.662 (2008) (noting that a defendant is responsible for the "natural, ordinary and reasonable consequences of his conduct").

116. DRL, who fraudulently introduced drug products to market that are "misbranded" because they are not in compliance with the testing and certification mandates of the CPSIA and PPPA, and therefore cannot be legally dispensed, has knowingly caused the Pharmacy Defendants to submit a false claim for reimbursement by the Federal Payers and State Plaintiffs.

VII. FACTS AND ALLEGATIONS

A. Dr. Reddy's

117. Dr. Reddy's is an India-based manufacturer of generic drugs. It began its operations in the mid-1980s.

118. It is one of the largest generic drug manufacturers in the world. Its current market value is over eight billion dollars.

119. Dr. Reddy's has been selling generic drugs in the United States since about 2000.

120. Dr. Reddy's is ranked seventh among generic companies in the United States based on prescriptions dispensed. IMS Health, National Prescription Audit, March 2014.

B. Dr. Reddy and Its Contract Partners

121. DRL contracts with various pharmacies, including several large and national pharmacy chains to distribute its generic drugs in the United States. These contract partners include, inter alia, Walgreens, CVS/Caremark, Wal-Mart (Pharmacy Defendants).

122. Pharmacists and Pharmacies are responsible for ensuring the packaging of required drugs is in child-resistant packaging as required under the PPPA. DRL is aware of this responsibility of pharmacies and pharmacists.

123. The Group Defendants all rely on the express representations and promises made by DRL in their respective contracts that the DRL products are not misbranded as follows:

1. Walgreens

124. DRL and Walgreens Corporation (Walgreen) [redacted]

[redacted]

[22] Relators believe and allege that any renewal or subsequent supply agreement contains the same or substantially identical representations and warranties relating to "misbranding" as set forth herein that would have been in effect during the relative time period.

125. Walgreens operates retail pharmacy store and submits claims for reimbursement directly to Federal payers and relied on DRL's express representation that it was in compliance with all Federal laws, which included the testing under the PPPA .

126. The express representations by DRL to Walgreens that it's Drug Products were in compliance with Federal laws, which would include the PPPA, was a "substantial factor[23]" in Walgreens submitting claims for reimbursement to the Federal Payers because under the PPPA, it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers. Without this express representation, Walgreens would not have submitted DRL Products for reimbursement.

2. CVS/Caremark

127. DRL and CVS/Caremark Corporation (CVS)

[23] To demonstrate that this was a "substantial factor," Plaintiff does not have to show "but-for" causation. Furthermore, "substantial factor" does not mean the "dominant" or "primary" factor. Therefore, the activity may be a substantial factor even if a defendant shows some other factor was the but-for cause. *Lohman v. Duryea Borough* WL 4260943, United States District Court, M.D. Pennsylvania (2007), Civil Action No. 3:05-CV-1423.Nov. 29, 2007. quoting *Suppan v. Dadonna*, 203 F.3d 228, 234-35 (3d Cir.2000) (citing *Rutan v. Republican Party*, 497 U.S. 62, 76 n. 8, 110 S.Ct. 2729, 111 L.Ed.2d 52 (1990)))

[redacted]

128. CVS operates retail pharmacy stores and submits claims for reimbursement directly to Federal payers and relied on DRL's express representation that it was in compliance with all Federal laws

129. The express representations by DRL that it's Drug Products were in compliance with Federal laws, which would include the PPPA, was a substantial factor in CVS Caremark submitting claims for reimbursement to the Federal Payers because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers. Without this express representation, CVS/Caremark would not have submitted DRL Products for reimbursement.

3. Wal-Mart Stores

130. [redacted]

[24] Relators believe and allege that any renewal or subsequent supply agreement contains the same or substantially identical representations and warranties relating to "compliance with the FFDCA as set forth herein that would have been in effect during the relative time period.

[25] Relators believe and allege that any renewal or subsequent supply agreement contains the same or substantially identical representations and warranties relating to "misbranding" as set forth herein that would have been in effect during the relative time period.

131. Walmart operates retail pharmacy stores and submits claim for reimbursement directly to Federal payers and relied on DRL's express representation that it was in compliance with all Federal laws

132. The express representations by DRL that it's Drug Products were in compliance with Federal laws, which would include the PPPA, was a substantial factor in Walmart submitting claims for reimbursement to the Federal Payers because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers. Without this express representation, Walmart would not have submitted DRL Products for reimbursement.

C. The Drugs

1. The Blister Packs

133. Between 2004 and 2012, Dr. Reddy's manufactured and imported to the United States, and distributed five generic prescription drugs – Ciprofloxacin, Fluoxetine, Ondansetron, Risperidone, and Sumatriptan – in unit dose or "blister" packages as follows:

NDC	Count	Drug Name
55111-0125-06	6	Ciprofloxacin Tablets 100mg, 6
55111-0284-48	4	Fluoxetine DR Capsules USP 90mg,4
55111-0207-81	30	Risperidone ODT 0.5mg, 30
55111-0208-81	30	Risperidone ODT 1mg, 30
55111-0209-81	30	Risperidone ODT 2mg, 30
55111-0470-81	30	Risperidone ODT 3mg, 30

55111-0471-81	30	Risperidone ODT 4mg, 30
55111-0293-09	9	Sumatriptan Succinate Tablets 100mg, 9
55111-0291-09	9	Sumatriptan Succinate Tablets 25mg, 9
55111-0292-09	9	Sumatriptan Succinate Tablets 50mg, 9

134. With the exception of Ciprofloxacin, all these drugs are toxic or highly toxic to a child who ingests just a few or even a single pill. DRL and the Pharmacy Defendants knew this.

135. DRL, during the period at issue herein, never tested its blister packages for child resistance.

2. The Bottle Packages

136. Between 2004 and 2012, DRL manufactured, imported to the United States, and distributed, in addition to the blister packs, approximately thirty-eight prescription drugs in a non-unit dose or "bottle" packages as follow:

Non-unit dose packages or bottles.

NDC	Count	Drug Name
55111-0729-01	100	Allopurinol 100mg 100's
55111-0730-01	100	Allopurinol 300mg 100's
55111-0341-01	100	Amlo Besy&Benz HCl Cap 10mg/20mg 100
55111-0338-01	100	Amlo Besy&Benz HCl Cap 2.5mg/10mg 100
55111-0339-01	100	Amlo Besy&Benz HCl Cap 5mg/10mg 100
55111-0340-01	100	Amlo Besy&Benz HCl Cap 5mg/20mg 100
55111-0254-01	100	Carvedilol Tablets 12.5mg, 100
55111-0255-01	100	Carvedilol Tablets 25mg, 100
55111-0252-01	100	Carvedilol Tablets 3.125mg, 100
55111-0253-01	100	Carvedilol Tablets 6.25mg, 100
55111-0423-30	30	Ciprofloxacin ER Tablets 1000mg, 30
55111-0422-30	30	Ciprofloxacin ER Tablets 500mg, 30
55111-0126-01	100	Ciprofloxacin Tablets 250mg, 100
55111-0127-01	100	Ciprofloxacin Tablets 500mg, 100
55111-0128-50	50	Ciprofloxacin Tablets 750mg, 50
55111-0342-01	100	Citalopram Tablets 10mg, 100

55111-0342-30	30	Citalopram Tablets 10mg, 30
55111-0343-01	100	Citalopram Tablets 20mg, 100
55111-0343-30	30	Citalopram Tablets 20mg, 30
55111-0344-01	100	Citalopram Tablets 40mg, 100
55111-0344-30	30	Citalopram Tablets 40mg, 30
55111-0532-01	100	Divalproex Sodium Sprinkles 125mg, 100
55111-0119-01	100	Famotidine Tablets 20mg, 100
55111-0120-01	100	Famotidine Tablets 40mg, 100
55111-0194-01	100	Fexofenadine Tablets 180mg, 100
55111-0194-90	90	Fexofenadine Tablets 180mg, 90
55111-0192-01	100	Fexofenadine Tablets 30mg, 100
55111-0192-90	90	Fexofenadine Tablets 30mg, 90
55111-0193-01	100	Fexofenadine Tablets 60mg, 100
55111-0193-90	90	Fexofenadine Tablets 60mg, 90
55111-0572-01	100	Fexo/Pseudo 180/240mg ER Tabs 100
55111-0172-30	30	Finasteride Tab USP 5mg 30s (2010)
55111-0172-90	90	Finasteride Tab USP 5mg 90s (2010)
55111-0554-30	30	Finasteride Tablets AG 5mg, 30
55111-0554-90	90	Finasteride Tablets AG 5mg, 90
55111-0147-01	100	Fluoxetine Capsules 10mg, 100
55111-0148-01	100	Fluoxetine Capsules 20mg, 100
55111-0149-01	100	Fluoxetine Capsules 40mg, 100
55111-0149-30	30	Fluoxetine Capsules 40mg, 30
55111-0320-01	100	Glimepiride Tablets 1mg, 100
55111-0321-01	100	Glimepiride Tablets 2mg, 100
55111-0322-01	100	Glimepiride Tablets 4mg, 100
55111-0648-01	100	Glycopyrrolate Tablets 1mg, 100
55111-0649-01	100	Glycopyrrolate Tablets 2mg, 100
55111-0682-01	100	Ibuprofen Tablets 400mg, 100
55111-0682-09	90	Ibuprofen Tablets 400mg, 90's
55111-0683-01	100	Ibuprofen Tablets 600mg, 100
55111-0683-30	30	Ibuprofen Tablets 600mg, 30
55111-0683-50	50	Ibuprofen Tablets 600mg, 50
55111-0683-09	90	Ibuprofen Tablets 600mg, 90's
55111-0684-01	100	Ibuprofen Tablets 800mg, 100
55111-0684-30	30	Ibuprofen Tablets 800mg, 30
55111-0684-50	50	Ibuprofen Tablets 800mg, 50
55111-0684-60	60	Ibuprofen Tablets 800mg, 60
55111-0684-09	90	Ibuprofen Tablets 800mg, 90's
55111-0226-01	100	Lamotrigine Chewable Tablets 25mg, 100

55111-0225-01	100	Lamotrigine Chewable Tablets 5mg, 100
55111-0221-01	100	Lamotrigine Tablets 100mg, 100
55111-0222-60	60	Lamotrigine Tablets 150mg, 60
55111-0223-60	60	Lamotrigine Tablets 200mg, 60
55111-0220-01	100	Lamotrigine Tablets 25mg, 100
55111-0398-30	30	Lansoprazole DR Cap 15mg 30
55111-0398-90	90	Lansoprazole DR Capsules USP 15mg 90
55111-0399-90	90	Lansoprazole DR Capsules USP 30mg 90 USA
55111-0248-60	60	Levetiracetam Tabs 1000mg,60
55111-0181-04	120	Levetiracetam Tabs 250mg,120
55111-0182-04	120	Levetiracetam Tabs 500mg,120
55111-0183-04	120	Levetiracetam Tabs 750mg,120
55111-0282-90	90	Levocetirizin DiHCl Tab 5mg 90s HDPE USA
55111-0640-01	100	Meprobamate Tablets 200mg, 100
55111-0641-01	100	Meprobamate Tablets 400mg,100
55111-0639-60	60	Minocycline Tablets 100mg, 60
55111-0637-01	100	Minocycline Tablets 50mg, 100
55111-0638-01	100	Minocycline Tablets 75mg, 100
55111-0329-90	90	Nateglinide Tablets 120mg, 90
55111-0328-90	90	Nateglinide Tablets 60mg, 90
55111-0310-60	60	Nizatidine Capsules 150mg, 60
55111-0311-30	30	Nizatidine Capsules 300mg, 30
55111-0160-50	50	Ofloxacin Tablets 200mg, 50
55111-0161-50	50	Ofloxacin Tablets 300mg, 50
55111-0162-01	100	Ofloxacin Tablets 400mg, 100
55111-0157-01	100	Omeprazole DR Capsules USP 10mg,100
55111-0157-30	30	Omeprazole DR Capsules USP 10mg,30
55111-0158-01	100	Omeprazole DR Capsules USP 20mg,100
55111-0158-30	30	Omeprazole DR Capsules USP 20mg,30
55111-0159-01	100	Omeprazole DR Capsules USP 40mg,100
55111-0159-30	30	Omeprazole DR Capsules USP 40mg,30
55111-0153-13	3	Ondansetron Tablets 4mg, 3
55111-0153-30	30	Ondansetron Tablets 4mg, 30
55111-0154-13	3	Ondansetron Tablets 8mg, 3
55111-0154-30	30	Ondansetron Tablets 8mg, 30
55111-0170-01	100	Oxaprozin Tablets 600mg, 100
55111-0332-90	90	Pantopraz Sod DR TabUSP 20mg 90sHDPE USA
55111-0333-90	90	Pantopraz Sod DR TabUSP 40mg 90sHDPE USA
55111-0229-90	90	Pravastatin Tablets 10mg, 90
55111-0230-90	90	Pravastatin Tablets 20mg, 90

55111-0231-90	90	Pravastatin Tablets 40mg, 90
55111-0274-90	90	Pravastatin Tablets 80mg, 90
55111-0129-60	60	Ranitidine Capsules 150mg, 60
55111-0130-01	100	Ranitidine Capsules 300mg, 100
55111-0130-30	30	Ranitidine Capsules 300mg, 30
55111-0198-30	30	Simvastatin Tablets 10mg, 30
55111-0198-90	90	Simvastatin Tablets 10mg, 90
55111-0199-90	90	Simvastatin Tablets 20mg, 90
55111-0200-90	90	Simvastatin Tablets 40mg, 90
55111-0197-30	30	Simvastatin Tablets 5mg, 30
55111-0197-90	90	Simvastatin Tablets 5mg, 90
55111-0268-30	30	Simvastatin Tablets 80mg, 30
55111-0268-90	90	Simvastatin Tablets 80mg, 90
55111-0293-36	36	Sumatriptan Succinate Tablets 100mg, 36
55111-0291-36	36	Sumatriptan Succinate Tablets 25mg, 36
55111-0292-36	36	Sumatriptan Succinate Tablets 50mg, 36
55111-0525-01	100	Tacrolimus Capsules 0.5mg 100
55111-0526-01	100	Tacrolimus Capsules 1mg 100
55111-0527-01	100	Tacrolimus Capsules 5mg 100
55111-0250-30	30	Terbinafine 250mg 30
55111-0250-90	90	Terbinafine Tablets 250mg, 90
55111-0179-15	150	Tizanidine Tablets 2mg, 150
55111-0180-15	150	Tizanidine Tablets 4mg, 150
55111-0553-30	30	Valacyclovir HCl Tabs 1g 30s HDPE USA
55111-0552-30	30	Valacyclovir HCl Tabs 500mg 30s HDPE USA
55111-0549-90	90	Venlafaxine Tablets 100mg, 90
55111-0545-90	90	Venlafaxine Tablets 25mg, 90
55111-0546-90	90	Venlafaxine Tablets 37.5mg, 90
55111-0547-90	90	Venlafaxine Tablets 50mg, 90
55111-0548-90	90	Venlafaxine Tablets 75mg, 90
55111-0625-60	60	Zafirlukast Tab 10mg, USA, HDPE, 60
55111-0626-60	60	Zafirlukast Tab 20mg, USA, HDPE, 60

137. Many of all these drugs are toxic or highly toxic to a child who ingests just a few or even a single pill. DRL and the Pharmacy Defendants knew this.

138. DRL, during the period at issue herein, did not test its bottle packages for child resistance.

139. In addition to above, the following generic drugs received approval after 2012 for which there was no certification or testing done at the time of FDA approval.

NDC	Count	Drug Name
55111-587-01	100	Amlodipine Besylate and Benazepril Hydrochloride Capsules 5mg/40mg
55111-659-30	30	Ropinirole Extended-Release Tablets 2mg
55111-661-30	30	Ropinirole Extended-Release Tablets 4mg
55111-727-30	30	Ropinirole Extended-Release Tablets 6mg
55111-662-30	30	Ropinirole Extended-Release Tablets 8mg
55111-728-30	30	Ropinirole Extended-Release Tablets 12 mg
55111-453-30	30	Venlafaxine XR Capsule 37.5mg
55111-453-90	90	Venlafaxine XR Capsule 37.5mg
55111-454-30	30	Venlafaxine XR Capsule 75mg
55111-454-90	90	Venlafaxine XR Capsule 75mg
55111-455-30	30	Venlafaxine XR Capsule 150mg
55111-455-90	90	Venlafaxine XR Capsule 150mg

140. Many of these drugs are toxic or highly toxic to a child who ingests just a few or even a single pill. DRL and Pharmacy Defendants knew this.

141. DRL never tested these packages for child resistance prior to commercial distribution of these products.

3. DRL Distributed Without Required CRC Testing

142. DRL Regulatory and Compliance officials had awareness of the PPPA and CPSIA legislation as early as 2007 and the proposed requirements prior to the Congressional vote executing the regulations into law.

143. As early as February 2009 DRL Regulatory officials had received a request from CHPA (Consumer Health Products Association) for comment to the proposed regulations prior to final Congressional approval.

144. On February 10, 2010, the CPSIA certification mandates went into effect. DRL was well aware of this coming mandate. In addition to the above, representatives of the "over the counter" (OTC) side of DRL[26] attended a "Bird Dog" Seminar in August 2009 with respect to CPSIA compliance and thereafter initiated a program for testing on the OTC side of the business.

145. No one from the prescription side (Rx) of the business attended even though they were aware of the Seminar being held. Bird Dog is a CPSC accredited testing company.

146. Despite the foregoing, no significant compliance efforts were made on DRL Products on the Rx side of the business prior to the deadline. In October 2010, another Bird Dog Seminar was held which included Rx side and still no significant compliance effort has been made.

147. While there are limitations in the collection of data related to children's ingestion of prescription drugs, there have been many cases reported in the medical literature of children being hospitalized after accidental ingestion of toxic doses of prescription drugs, including some that are DRL Products.

148. DRL distributed these drugs to wholesalers and/or retail pharmacies with the knowledge and intention that the drugs would be dispensed directly to individual consumers for use in the household, without repackaging by the pharmacist.

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[26] Josh Lee, Manager OTC Marketing, packaging engineer and Reena Zade, Associate Manager, Regulatory Affairs attended.

149. DRL at all times, knew with certainty, that its blister packages and bottle packages had not gone through the required testing and were not, in fact, child resistant.

150. It was not until 2011, when, in the face of regulatory action by the CPSC, DRL implemented a testing program to ensure that the drugs' packaging going forward met the child resistance specifications set forth in the PPPA.

D. The Fraud

1. Customers Complaints

151. DRL manufactured and packaged its Drug Products in India.

152. When the CPSIA was passed in 2008, Dr. Reddy's U.S. subsidiary began to receive inquiries from pharmacies as to the child resistance of Dr. Reddy's drugs because of the new requirement to issue general conformity certificates certifying compliance with a child resistant testing regime. As an example, on September 23, 2010 (more than seven months after the mandate went into effect) DRL received its first complaint from a DRL customer about the lack of compliance. This came from HEB Grocery chain in Texas. Relator Schimelpfenig heard about this and brought it to the attention of John Adams (vice president - RX sales and marketing and Kumara Sekar (senior director, Regulatory Affairs), and also requested information regarding the status of DRL compliance with CPSIA mandates.

2. DRL Management was Aware of Lack of Testing

153. On September 29, 2010 an internal meeting was held which included Relator Schimelpfenig, Kumara Sekar, and Matt Prokopczk (Director, Quality Assurance) to discuss status and requirements to become PPPA compliant. There was zero compliance on the Rx side with no activities, resources or plans in place.

154. These inquiries sparked an internal investigation by several U.S. based Dr. Reddy's employees who discovered that, contrary to law, the company's drugs,

including the DRL Products were not properly tested or packaged for child resistance and, as a result, exposed children to a greater risk of harm from accidental ingestion.

155. In order for Dr. Reddy's prescription drugs to be tested for child resistance, placebos had to be made for the blister packs and packaged in India, then sent to the U.S. for testing.

156. On November 1, 2010 Tricia Wetzel emailed Relator Schimelpfenig asking for an update on CPSIA status in connection with the HEB complaint. Relator forwarded this email to Matt Prokopczyk and Subbareddy Inta requesting a report. Matt Prokopczyk indicated that the compliance activities were "just beginning" and that he hoped to have some progress by the end of the year.

157. On December 1, 2010 at a sales and marketing meeting presentation, DRL officials included a "watch out" for the CPSIA non-compliance as a threat to the business. This presentation which was made by Relator Schimelpfenig to Abhijit Mukherjee (President, Global Generics). Also in attendance were, among others, Relator, John Adams, Amit Patel (Senior Vice President of North America for DRL), and other sales directors for national accounts.

158. On or about December 15, 2010 there were repeated requests from DRLUS to DRL in India to begin the supply of sample packaging components for compliance testing purposes, but there was still no compliance. Sample bottles began to arrive in the United States sometime after January 2011.

3. The Rx Blister Pack - Internal Risk Analysis - "The Smoking Gun"

159. On February 25, 2011 (over one year after the compliance deadline for certification went into effect) a "risk analysis" meeting on the lack of compliance in

general and the Rx blister packs specifically was held[27]. In attendance was Greg Longabucco, John Adams, possibly Matt Prokopczyk, Relator Schimelpfenig, Josh Lee and Sridhar Balasuvramanian. This meeting was held to discuss the risk of non-compliance of the DRL Covered Drug Products. A decision was made to "not test those packages at high risk of testing failure" in as much as a test failure would have required DRL to notify the Consumer Product Safety Commission and increased the legal and commercial risks to DRL.

160 [redacted]

[redacted]

161. It was at the direction of John Adams that there should be no email or electronic document transmission regarding this subject (and then continued by saying *"safety first"*). The Report went onto state:

[redacted]

[27] Josh Lee and Relator Schimelpfenig were in Charlotte, North Carolina. The others were in the Bridgewater, New Jersey Office

162. On April 11, 2011, the first placebo for blister testing arrived in U.S. but untested products still remained in the market. Relator was shortly thereafter terminated as a result of her business unit being relocated.

163. For years after the CPSIA was passed, several U.S. based Dr. Reddy's employees tried to convince their colleagues in India who were responsible for drug packaging to implement a child resistant packaging testing program or to facilitate the implementation of a testing program for child resistance by sending placebo for testing in the United States.

164. The U.S. based Dr. Reddy's employees also agitated for years with the highest levels of the company's management to implement a testing program that would rectify the unsafe packaging.

165. Dr. Reddy's U.S. based leadership also raised the issue on various occasions with the company's leaders in India.

166. Notwithstanding these efforts, from 2008 to 2012, Dr. Reddy's India based personnel did not test its Drug Products nor did they facilitate the testing of these products in the United States by making and sending placebo to be tested.

167. It was not until 2012, several months after the CPSC intervened with the company, that placebos were received in the U.S. for testing.

168. Up until January or February of 2011, Dr. Reddy's management chose not to incur the costs of implementing a testing program or of having their products tested by a third party. Bottle testing began in January or February of 2011 and blister pack testing did not commence until after August 2011.

169. Also, Dr. Reddy's management chose not to interrupt the company's manufacturing, sale and distribution of their noncompliant products for the time

necessary to test its packaging and implement new packaging, as this would have cost Reddy's significant revenue and profit.

170. As a result, between 2004 and March or May of 2012, Dr. Reddy's distributed in the United States the above-named drugs which were at certain times this period noncompliant with child resistant packaging requirements. As of 2008, Dr. Reddy's knew that its distribution and sale of these drugs would be subject to the impending requirement or would be unlawful without compliance.

171. Dr. Reddy's was also aware in 2007 of the impending requirements imposed by the CPSIA (effective February 10, 2010) to issue general conformity certificates certifying compliance with the child resistant packaging rules based upon a testing regime.

172. Notwithstanding, Dr. Reddy's failed to issue general conformity certificates for the above-named drugs in some cases, as required by law, until 2012, after the CPSC's intervention with the company and after the company had withdrawn the non-child resistant drugs from the market and replaced them with properly packaged and tested drugs. Not only did DRL not provide general conformity certificates as required, in a shallow and meaningless attempt to shield themselves from liability, DRL brazenly placed inconspicious warnings or notices on many of the DRL Drug products that the package "is not child resistant."[28]

173. Between February 10, 2010 and 2011, Dr. Reddy's chose not to issue the certificates because they knew that they could not certify as a matter of fact that their Drug Products were compliant with child resistant packaging rules.

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[28] See, e.g. (1) Risperidone 100-ct, 4 mg tablets, NDC 55111-471-78; (2) Risperidone 30-ct, 2 mg tablets, NDC 55111-209-81; (3) Ondansetron 4 & 8 mg tablets, NDC 55111-0153-13 and NDC 55111-0154-13, January 2011; (4) Ciproflaxin 6 tablets - 100 mg, NDC 55111-125-06

174. Between February 10, 2010 and 2011, Dr. Reddy's sold and distributed the above-named drugs which were noncompliant with child resistant packaging rules and which lacked general conformity certificates. Dr. Reddy's knew that this too was unlawful.

175. Prior to CPSC's intervention with Dr. Reddy's in 2011-2012, at no time did Reddy's disclose to the CPSC that its Drug Products did not meet the specifications in the PPPA for child resistant packaging or lacked general conformity certificates, in spite of their obligations pursuant to 15 U.S.C. § 2064(b) to immediately report such information.

176. Despite it's illegal and inconspicious attempt to place a warning on a small number of products, Dr. Reddy's did not at any time formally or officially disclose to pharmacists, to prescribing doctors, to consumers or to State and/or federal payers that its drugs did not meet or had not been tested to meet the specifications for child resistant packaging set forth in the PPPA or that its drugs were being sold in violation of law.

E. Effects of the Fraud

1. Impact on Consumers and Physicians

177. As a result of Dr. Reddy's failure to comply with the child resistant packaging specifications of the PPPA, pharmacists illegally dispensed drugs in non-child resistant packages to consumers who had not requested non-child resistant packaging and who had no prescription from their doctor to obtain non-child resistant packaging.

178. The doctors who prescribed these drugs had no way of knowing that the drugs they prescribed were being dispensed to their patients in non-child resistant packaging.

179. Because in most or all cases the doctors' prescriptions did not specifically order non-child resistant packaging (and the consumer had not requested non-child resistant packaging), these prescriptions could not lawfully be used, under federal or state law, to obtain DRL's noncompliant drugs, per 15 U.S.C. §1473(b) which state:

> (b) **Noncomplying packages for substances dispensed pursuant to orders of medical practitioners**. In the case of a household substance which is subject to such a standard and which is dispensed pursuant to an order of physician, dentist, or other licensed medical practitioner authorized to prescribe, ***such substance may be dispensed in noncomplying packages only when directed in such order or when requested by the purchaser.***

180. The consumers of these drugs in many or all cases also did not know or had no way of knowing that the drugs they were being dispensed were not in child resistant packaging.

181. In many or all cases, they had not requested non-child resistant packaging and did not have a prescription from their doctor to obtain non-child resistant packaging.

182. DRL's undisclosed failure to use child resistant packaging, as required by law, deprived doctors and consumers of their choice provided by 15 U.S.C. §1473(b) and instead imposed upon all consumers untested and uncertified non child-resistant packages which, in many or all cases, neither the consumer had requested or the doctor had ordered.

183. DRL's version of the drugs was not only undesirable but also inferior to other manufacturers' generic versions of the same drugs which did comply with the PPPA's child resistance specifications.

184. DRL's drugs were inferior because, due to their non-compliance with child resistance specifications in the PPPA, they posed a greater risk of serious illness and

injury to children than drugs which did comply with the PPPA's specifications for child resistant packaging.

185. In many cases, the consumers had young children living in or visiting their homes, or they took their medications with them when they visited friends or family with young children.

186. As a result of DRL's failure to use child resistant packaging, children have been and continue to be exposed to great risk of serious injury or illness from accidental ingestion of the drugs. The risk is greater because consumers in many or all cases do not know that the drugs are not in child-resistant packaging.

2. DRL's Individual Risk Assessment on Certain Products

187. As part of it's "risk assessment" DRL evaluated certain specific products as set forth below. As discussed herein F-8 is the least toxic and F-1 is the most toxic.

- Ciprofloxacin Tablets 100mg. Ciprofloxacin Tablets 100 mg. The toxicology report showed that this product was ranked at an F-8.

- Fluoxetine Capsules 90mg. Fluoxetine Capsules 90 mg. The toxicology report showed that this product was ranked at an F-3.

- Ondansetron Tablets 4mg. Onclansetron Tablets 4 mg: The toxicology report showed that this product was ranked at an F-8.

- Ondansetron Tablets 8mg. Ondansetron Tablets 8 mg: The toxicology report showed that this product was ranked at an F-5.

- Risperidone ODT .5mg. Risperldone ODT 0.5 mg: The toxicology report showed that this product was ranked at an F-6.

- Risperidone ODT lmg. The toxicology report showed that this product was ranked at an F-3.

- Risperldone CDT 2mg. Risperidone ODT 2 mg: The toxicology report showed that this product was ranked at an F-2.

- Risperldone CDT 3mg. Risperldone CDT 3 mg: The toxicology report showed that this product was ranked at an F-1.

- Risperidone CDT 4mg. Risperidone CDT 4 mg: The toxicology report showed that this product was ranked at an F-1.

- Sumatriptan Tablets 25mg. Sumatriptan Tablets 25mg: The toxicology report showed that this product was ranked at an F-4.

- Sumatriptan Tablets 50mg. Sumatriptan Tablets 50mg; The toxicology report showed that this product was ranked at an F-2.

- Sumatriptan Tablets 100mg. Sumatriptan Tablets 100mg: The toxicology report showed that this product was ranked at an F-1.

3. Reported Incidents of Overdoses

188. Set forth below are a sample of the reported incidents of "over dose" that were detailed in the Risk Analysis Report.

- Fluoxetine Capsules 90 mg - A single case of ingestion of 700 mg of fluoxetine by a 4-year old girl [16.3kg] (43 mg/kg) was reported. The ingested resulted in agitation, dyskinesia, sinus tachycardia and transient periods of unconsciousness within 3 hours of ingestion from which the patient recovered within 1 hour of arrival at an emergency room.

- Ondansetron Tablets 6.4 mg - A infant weighing [10 kg] ingested seven to eight tablets of 8 mg Ondansetron ODT, an estimated dose of 5.6 to 6.4 mgs. The infant developed somnolence and intermittent jerking movement of the extremities within 20 minutes of the ingestion. The infant was taken to the emergency room where he developed seizures, hepatotoxicity, prolongation and a serotonin syndrome that required endotracheal intubation and intensive care unit management. The clinical status of the infant improved over the next 24 hours with supportive care and ultimately the child was discharged with no sequelae.

- Risperidone ODT 4mg - A 3.5-year-old boy [15kg] accidently ingested a single 4 mg risperidone tablet. His dose was estimated to be 0.268mg/kg1. He was taken to the ER with extrapyramidal symptoms including bilateral upward eye gaze, jerky extremity movement and motor restlessness. He was treated and discharged 33 hours later with continued at home treatment for hand tremor, body shivering and eye wandering which resolved after 24 hours'. Risperidone is completely absorbed after oral administration, reaching peak plasma concentrations within 1 to 2 hours. Absorption is not affected by food.

F. DRL Product Distribution

189. For the period May 1, 2010 through April 2011 an analysis of the DRL Covered Drug Products based at the NDC level by chain of distribution shows the following:

a. Extended Units (EU's) representing approximately 10,788,098 prescriptions. In total this represented sales, net of cash discount[29], of approximately $204,047,657.00 dollars.

b DRL had overall sales of approximately 2,165,882,872 EU's of drugs sold to retailers. The Federal reimbursement of these EU's, estimated to be twenty (20%) is 433,176,574 EU's representing approximately 14,439,219 prescriptions. In total this represented sales, net of cash discount, of approximately $198,430,817.00 dollars.

c. Combined, DRL had overall sales of 3,766,341,828 EU's, representing $426,700,117 in sales excluding cash discount. The Federal reimbursement (estimated at 20%), is 24,803,679 prescriptions during this period.

d. By its own account, DRL acknowledges that it participates in the Medicaid Rebate Program and reimburses States for covered drugs that it had manufactured. In the fiscal year ended March 31, 2010, this amounted to 9 million dollars in payments to States under the Medicaid Rebate Program[30]. Assuming that DRL was reimbursing at 11%, this equates to approximately $82,000,000 dollars in sales from medicaid recipients alone.

e. Walgreens purchased $24,249,856.68 of DRL Covered Drug Products directly from DRL during the relevant period that were PPPA noncompliant.

f. CVS Caremark purchased $74,472,638.93 of DRL Covered Drug Products directly from DRL during the relevant period that were PPPA noncompliant.

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[29] Cash discount for wholesalers is typically calculated as 2% of invoice price (Wholesale Acquisition Cost "WAC"). As an example, the WAC may be $100 while the contract price net of all discounts and rebates is $20.00. The cash discount is 2% of $100, not $18.00. It is not difficult to precisely calculate a straight % cash discount against sales to arrive at a true net sales. As a result, the estimated sales herein is slightly overstated.

[30] DRL 20-F SEC filings as of March 31, 2010, page 57.

g. Walmart purchased $636,499.15 of DRL Covered Drug Products directly from DRL during the relevant period that were PPPA noncompliant

190. It is likely that the Federal payers are reimbursing providers a cost that is greater than the sales price of the product to the pharmacy chain by a ratio that is much higher than a brand product, as opposed to DRL as a Generics product. As an example DRL may sell Product XXXX to National Chain A for $0.80 while the published Federal Upper Limit is $6.00 (set in 2008) based on a per tablet FUL of $0.20. As a result, the harm to the Federal fisc is much greater than the acquisition cost by the pharmacies.

VIII. The Lack of Testing and Compliance With the PPPA and Illegal Dispensing are a Material and Substantial Factor to the Government Decision to Pay for the DRL Products

191. The 'misbranding," lack of testing and illegal dispensing of the drugs are "material" if it *has a "natural tendency to influence or was capable of influencing the government's funding decision.* In *USA, ex rel. Thomas v. Siemens AG, et al.*, 708 F.Supp.2d 505, United States District Court, E.D. Pennsylvania (2010) the Court stated that *"A statement or claim is material if it has a "natural tendency to influence or was capable of influencing the government's funding decision."* See, e.g., *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 446 (6th Cir.2005); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917 (4th Cir.2003). This definition of "materiality" has been codified into the law with the enactment of FERA in 2009.

192. There is no doubt that childproof packaging in prescription medication has been effective in saving lives. Ever since the development of the child-resistant closure (CRC) for aspirin packaging, child mortality rates from inadvertent poisoning have dramatically declined. In the early stages of the history of CRC's, research and

population trials indicated that the incidence of poison by prescription drugs had been diminishing between 75 and 90 percent.[31]

193. As the research continued to point to dramatic statistical improvements with the introduction of CRC's, Congress passed the PPPA and mandated safety packaging for aspirin and prescription drugs. A 1977 study showed aspirin related deaths dropped 50 percent after the implementation of the legislation.[32] The Government itself, through the Commission, determined through a 1973-1990 study period that aspirin packaging with CRC's revealed a reduction of the aspirin-related mortality rate by 34 percent, or about 90 fewer child deaths overall just from incidental digestion of aspirin alone.[33]

194. A 1996 study by GB Roberts exhibited that CRC's were associated with reduction of the prescription drug mortality rate of 1.4 deaths per million children younger than five years, or equivalent to roughly 460 child deaths since 1974. Overall Roberts pointed to a mortality rate reduction of about 45 percent from levels projected without the implementation of mandatory CRC requirements in that time frame.[34] This number additionally equates to about 24 fewer child deaths annually.[35]

195. In the time since the aforementioned studies, more and more data displayed the success of the child-restraint packaging measures. A 2002 study researching acetylsalicylic acid (ASA) indicates a 34 percent reduction in accidental overdoses of ASA since child-restraint packaging was required by law. The number of

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[31] LK Garretson, "The Child Restraint Container: A Success and a Model for Accident Prevention," *American Journal of Public Health* 67, no. 2 (1977): 136.

[32] Ibid.

[33] US Consumer Product Safety Commission, "Poison Prevention Packaging: A Guide for Healthcare Professionals," (2005).

[34] GB Roberts, "The Safety Effects of Child-Restraint Packaging for Oral Prescription Drugs: Two Decades of Experience," *Journal of the American Medical Association* 275, no. 21 (1996): 1661-1665.

[35] US CPSC, "Poison Prevention Packaging".

deaths due to inadvertent poisoning from ASA and other similar toxic substances has diminished from seven deaths per million in the 1960's to less than 0.1 per million in the 1990's.[36]

196. In 2005, the Consumer Product Safety Commission estimated that special packaging on prescription medication saved the lives of more than 900 children since the initial legislation in the Poison Prevention Act. A 2011 analysis now puts that figure well over 1000 child deaths and numerous injuries prevented from the implementation of CRC's.[37] That figure additionally does not even account for the countless number of other household products that now require child-restraint closures and the number of deaths prevented from their requirements.[38]

197. Furthermore, a study in the Journal of Pediatrics and Child Heath in 2003 warned that medication not required to have CRC's may lead the public to perceive the contents as less toxic and therefore be less careful in their storage.[39] The exhaustive amount of data clearly indicates that special packaging for children on toxic products has saved many invaluable lives of children and has the potential to protect even more.

198. The aforementioned facts are precisely why the United States Congress passed and continues to enforce the PPPA. Pharmaceutical products that are not manufactured with adequate packaging that pass the mandated requirements by the legislation are "misbranded" and thus violate the Food Drug and Cosmetic Act.

199. As the United States has an unequivocal interest in the regulation of uniform interstate commerce, "deficiencies where the Poison Prevention Packaging Act

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[36] "Child-Proof Caps Prevent Deaths." *Pharmacy Post* 10, no. 11 (2002): 22.

[37] G. Randall Bond et al, "The Growing Impact of Pediatric Pharmaceutical Poisoning," *The Journal of Pediatrics* 160, no. 2 (2012): 265-270.

[38] US CPSC, "Poison Prevention Packaging".

[39] C. Chien et al, "Unintentional Ingestion of Over-the-Counter Medications in Children less than 5 years old," *The Journal of Pediatrics and Child Health* 39 (2003): 264-269.

requires special packaging"[40] results in a misbranding violation, for the product would contain "false or misleading" packaging[41].

200. By it's own action in regulating this important area of child safety, the United States has demonstrated by word and deed that drugs which were misbranded and illegally dispensed because of violations of the PPPA would have a natural tendency to influence or was capable of influencing their funding decision.

201. Based on the foregoing, it is clear that testing, compliance with the PPPA and illegal dispensing of the drugs is a material condition and substantial factor in the Government decision to reimburse providers for prescription drugs such as the DRL Drug Products because it has been shown that unapproved packaging of prescription drugs can be precarious for the safety of children who can access the product, and additionally disrupts the uniformity of the exchange of goods passing through interstate commerce. A market possessing potentially dangerous products can harm the consumer as well as impede the government's regulation of the pharmaceutical products market.

202. Under the FFDCA, drugs must demonstrate that they are safe for specific intended uses. As a result of knowing violations of the PPPA, DRL drug products must be considered not safe.

203. DRL, through its false and misleading express representations and warranties to its contract partners that its Products complied with all Federal laws, including the PPPA, it knowingly caused its contract partners such Walgreens, CVS/Caremark and Walmart to illegally dispense prescription drugs and submit claims for reimbursement for illegally dispensed and misbranded uses that did not meet the

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[40] US Food and Drug Administration, *Key Legal Concepts: "Interstate Commerce," "Adulterated," and "Misbranded,"* http://www.fda.gov/ cosmetics/guidancecomplianceregulatoryinformation /ucm074248.htm.

[41] Nicholas Freitag, "Federal Food and Drug Act Violations," *American Criminal Law Review* 41, no. 2 (2004): 647

requirement for payment, it is liable for causing the submission of false claims under the FCA.

204. In addition to the above, TRICARE Regulations, 32 C.F.R. § 199.4(g)(15)(i)(A) and § 199.4(g)(15)(i)(B)-(D) state that prescriptions are not covered unless it is for a *medical necessity, in which the safety, inter alia, has been demonstrated* in accordance with nationally accepted standards of practice in the medical community. FEHBP has similar regulations denying coverage for off-label uses unless proven medically necessary. These strict regulations for TRICARE and FEHBP, make a strong chain of causation between the misbranding and illegal dispensing and the submission of claims for reimbursement for uses that violate a condition of payment.

IX. CAUSE OF ACTIONS

205. With respect to each of the causes of action set forth herein, all of the allegations set forth herein in paragraphs 1 - 204 are incorporated into each of these counts as if they were fully set forth therein.

A. COUNT ONE

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. § 3729(a)(1)(A)

Relators ex rel USA et al v. DRL

206. Relators allege that DRL violated the FCA by submitting or causing the submission of legally and factually false claims in violation of 31 U.S.C. § 3729(a)(1)(A). This section imposes liability on any person who:

A. "Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A) as amended May 20, 2009.

207. Under § 3729(a)(1)(A), civil liability is imposed on any person who knowingly presents or causes to present a false claim to the government for payment or approval. 31 U.S.C. § 3729(1)(A). There are three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false.

208. DRL caused claims for payment to be presented to the United States for DRL Covered Drug Products as set forth herein which were knowingly false, both factually and legally, because they were:

(1) "misbranded" under the FFDCA and therefore not a "covered drug" and

(2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, and

(3) Defendants also made an implied certification that they were in compliance with the PPPA which was a material and substantial factor to the Government's decision to make payment and a condition of such payment, and

(4) DRL made express representations to its contract partners such as Walgreens, CVS/Caremark and Walmart that it's Drug Products were in compliance with Federal laws, which would include the PPPA, knowing that it was substantial factor in their respective decisions in submitting claims for reimbursement to the Federal Payers because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement.

B. COUNT TWO

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. § 3729(1)(A)

Relators ex rel USA et al v. Walgreens

209. Relators allege that Walgreens violated the FCA by submitting or causing the submission of false claims in violation of 31 U.S.C. § 3729(a)(1)(A). This section impose liability on any person who:

A. "Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(B) as amended May 20, 2009.

210. Under § 3729(a)(1)(A), civil liability is imposed on any person who knowingly presents a false claim to the government for payment or approval. 31 U.S.C. § 3729(1)(A). There are three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false.

211. Defendant Walgreens submitted claims for payment that were presented to the United States for DRL Covered Drug Products as set forth herein which were knowingly false, both legally and factually as set forth below:

A. The claims were "false" under the FCA because they were:

(1) "misbranded" under the FFDCA and therefore not a "covered drug" and

(2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards and

(3) Defendant Walgreens made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA.

B. The false claims were submitted "knowingly" under the FCA because (1) Walgreens, as a pharmacist who was dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers[42], (2) Walgreen knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; (3) Walgreens was on actual notice of the lack of compliance because DRL brazenly placed disclaimers on some of the packaging that the package was "not child resistant" and (4) Walgreens knew that the testing and compliance with the PPPA is a material condition and would be a substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

C. COUNT THREE

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. § 3729(1)(A)

Relators ex rel USA et al v. CVS/Caremark Corporation

212. Relators allege that CVS/Caremark violated the FCA by submitting or causing the submission of false claims in violation of 31 U.S.C. § 3729(a)(1)(A). This section impose liability on any person who:

A. "Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(B) as amended May 20, 2009.

213. Under § 3729(a)(1)(A), civil liability is imposed on any person who knowingly presents a false claim to the government for payment or approval. 31 U.S.C. § 3729(1)(A). There are three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false.

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[42] [t]he pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.)

214. Defendant CVS Caremark submitted claims for payment that were presented to the United States for DRL Covered Drug Products as set forth herein which were knowingly false, both factually and legally as set forth below:

A. The claims were "false" under the FCA because they were

(1) "misbranded" under the FFDCA and therefore not a "covered drug" and

(2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards and

(3) Defendant CVS Caremark made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA.

B. The false claims were submitted "knowingly" under the FCA because (1) CVS Caremark, as a pharmacist who was dispensing the drugs is responsible under the PPPA[43] for ensuring packaging of required drugs in child-resistant containers, (2) Walgreen knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; (3) CVS Caremark was on actual notice of the lack of compliance because DRL brazenly placed disclaimers on the packaging that the package was "not child resistant" and (4) CVS Caremark knew that the testing and compliance with the PPPA is a material condition and would be a substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

[43] [t]he pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.)

D. COUNT FOUR

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. § 3729(1)(A)

Relator ex rel USA et al v. Walmart

215. Relators allege that Walmart violated the FCA by submitting or causing the submission of false claims in violation of 31 U.S.C. § 3729(a)(1)(A). This section impose liability on any person who:

A. "Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A) as amended May 20, 2009.

216. Under § 3729(a)(1)(A), civil liability is imposed on any person who knowingly presents a false claim to the government for payment or approval. 31 U.S.C. § 3729(1)(A). There are three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false.

217. Defendant Walmart submitted claims for payment that were presented to the United States for DRL Covered Drug Products as set forth herein which were knowingly false, both factually and legally as set forth below:

A. The claims were "false" under the FCA because they were

(1) "misbranded" under the FFDCA and therefore not a "covered drug" and

(2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards and

(3) Defendant CVS Caremark made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA.

B. The false claims were submitted "knowingly" under the FCA because (1) Walmart, as a pharmacist who was dispensing the drugs is responsible under the PPPA[44] for ensuring packaging of required drugs in child-resistant containers, (2) Walgreen knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; (3) Walmart was on actual notice of the lack of compliance because DRL brazenly placed disclaimers on the packaging that the package was "not child resistant" and (4) Walmart knew that the testing and compliance with the PPPA is a material condition and would be a substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

E. COUNT FIVE

Violations of the California FCA by Defendants

Relators ex rel State of California v. Defendants

218. Defendants violated the California FCA in the following respects:

a. California Government Code §12651(a)(1) prohibits a person from knowingly presenting or causing to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.

219. California Health & Safety Code § 111440 entitled Manufacture, sale, delivery, or holding of misbranded drug or device, states that "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded." Pursuant to Cal. Health & Safety Code § 108700, the State of California adopted the regulations under the CPSIA and PPPA.

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[44] [t]he pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.)

1. DRL Defendants

220. DRL caused claims for payment to be presented to the State of California for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and California Health & Safety Code § 111440 and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in Pharmacy defendants submitting claims for reimbursement to the State because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

221. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of California for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the

pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, or should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

F. COUNT SIX

Violations of the Delaware FCA by Defendants

Relators ex rel State of Delaware v. Defendants

222. Defendants violated the Delaware FCA in the following respects:

a. The Defendants violated the Delaware FCA §1201(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Delaware a false or fraudulent claim for payment or approval;

223. Pursuant to 16 Del.C. § 3308, Misbranding of drugs. States that a drug is deemed to be misbranded:. . .

> (4) If it is included in the definition of misbranding in the Federal Food, Drug and Cosmetic Act.

1. DRL Defendants

224. DRL caused claims for payment to be presented to the State of Delaware for DRL Covered Drug Products as set forth herein which were knowingly false because

they were (1) "misbranded" under the FFDCA and 16 Del.C. § 3308 and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in Walmart submitting claims for reimbursement to the State because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

225. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Delaware for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied

certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, or should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

G. COUNT SEVEN

Violations of the Florida FCA by Defendants

Relators ex rel State of Florida v. Defendants

226. Defendants violated the Florida FCA in the following respects:

a. Defendants violated §68.082(2)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Florida a false or fraudulent claim for payment or approval;

1. DRL Defendants

227. DRL caused claims for payment to be presented to the State of Florida for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and 16 Del.C. § 3308 and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to

make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in Walmart submitting claims for reimbursement to the State because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

228. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Florida for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Walmart knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the

Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

H. COUNT EIGHT

Violations of the Georgia FCA by Defendants

Relators ex rel State of Georgia v. Defendants

229. Defendants violated the Georgia FCA in the following respects:

a. Defendants violated O.C.G.A. §49-4-168.1(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Georgia a false or fraudulent claim for payment or approval;

1. DRL Defendants

230. DRL caused claims for payment to be presented to the State of Georgia for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and 16 Del.C. § 3308 and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in Walmart submitting claims for reimbursement to the State because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for

reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

231. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Georgia for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Walmart knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

I. COUNT NINE

Violations of the Hawaii FCA by Defendants

Relators ex rel State Hawaii v. Defendants

232. Defendants violated the Hawaii FCA in the following respects:

a. Defendants violated H.R.S. Section 661.21(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Hawaii a false or fraudulent claim for payment or approval;

233. Under the "Hawaii Poison Prevention Packaging Act," § 330C-6(a) et seq. *"All rules prescribing standards for the special packaging of household substances now or hereafter adopted under authority of the Federal Act shall be the regulatory standards for special packaging of household substances in this State."*

1. DRL Defendants

234. DRL caused claims for payment to be presented to the State of Hawaii for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and Hawaii Poison Prevention Packaging Act," § 330C-6(a) et seq. and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in Walmart submitting claims for reimbursement to the State of Hawaii because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor

in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

235. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Hawaii for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Walmart knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

J. COUNT TEN

Violations of the Illinois FCA by Defendants

Relators ex rel State of Illinois v. Defendants

236. Defendants violated the Illinois FCA in the following respects:

a. Defendants violated 740 ILCS 175/3(a)(1)(A) by knowingly presenting or causing to be presented to an officer or employee of the State of Illinois a false or fraudulent claim for payment or approval;

237. Illinois has its own act, known and may be cited as the "Illinois Poison Prevention Package Act 430 ILCS 40/5, Formerly cited as IL ST CH 111, 40/5. It states at § 5(a), that all regulations adopted under federal Poison Prevention Packaging Act are adopted as regulations in the State of Illinois.

1. DRL Defendants

238. DRL caused claims for payment to be presented to the State of Illinois for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and Illinois Poison Prevention Packaging Act as described above and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Illinois because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a

material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

239. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Illinois for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

K. COUNT ELEVEN

Violations of the Indiana FCA by Defendants

Relators ex rel State of Indiana v. Defendants

240. Defendants violated the Indiana FCA in the following respects:

a. Defendants violated I.C.5-11-5.5-2(b)(1) by knowingly presenting a false claim to the State of Indiana for payment or approval;

1. DRL Defendants

241. DRL caused claims for payment to be presented to the State of Indiana for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Indiana because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

242. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Indiana for DRL Covered Drug Products as set forth herein

which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug";(2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

L. COUNT TWELVE

Violations of the Louisiana FCA by Defendants

Relators ex rel State of Louisiana v. Defendants

243. Defendants violated the Louisiana FCA in the following respects:

a. Defendants violated RS 46:438.3A by knowingly presenting or causing to be presented a false or fraudulent claim;

1. DRL Defendants

244. DRL caused claims for payment to be presented to the State of Louisiana for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the

dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Louisiana because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

245. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Louisiana for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible

under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

M. COUNT THIRTEEN

Violations of the Michigan FCA by Defendants

Relators ex rel State of Michigan v. Defendants

246. Defendants violated the Michigan FCA in the following respects:

a. Defendants violated MCL 400.607(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Michigan a claim under the social welfare act, upon or against the state, knowing the claim to be false;

1. DRL Defendants

247. DRL caused claims for payment to be presented to the State of Michigan for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart

("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Michigan because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

248. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Michigan for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition

and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

N. COUNT FOURTEEN

Violations of the Montana FCA by Defendants

Relators ex rel State of Montana v. Defendants

249. Defendants violated the Montana FCA in the following respects:

a. Defendants violated MCA 17-8-403(1)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Montana a false or fraudulent claim for payment or approval.

1. DRL Defendants

250. DRL caused claims for payment to be presented to the State of Montana for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the

PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Montana because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

251. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Montana for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

O. COUNT FIFTEEN

Violations of the Nevada FCA by Defendants

Relators ex rel State of Nevada v. Defendants

252. Defendants violated the Nevada FCA in the following respects:

a. Defendants violated NRS 357.040(1)(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;

1. DRL Defendants

253. DRL caused claims for payment to be presented to the State of Nevada for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Nevada because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

254. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Nevada for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

P. COUNT SIXTEEN

Violations of the New Jersey FCA by Defendants

Relators ex rel State of New Jersey v. Defendants

255. Defendants violated the New Jersey FCA in the following respects:

a. violated the New Jersey FCA §2A:32C-3a by knowingly presenting or causing to be presented to an officer or employee or agent of the State of New Jersey,

or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

1. DRL Defendants

256. DRL caused claims for payment to be presented to the State of New Jersey for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of New Jersey because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

257. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of New Jersey for DRL Covered Drug Products as set forth

herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

Q. COUNT SEVENTEEN

Violations of the New Mexico FCA by Defendants

Relators ex rel State of New Mexico v. Defendants

258. Defendants violated the New Mexico FCA in the following respects:

a. violated NMSA §27-14-4A by presenting or causing to be presented to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent.

1. DRL Defendants

259. DRL caused claims for payment to be presented to the State of New Mexico for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered

drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of New Mexico because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

260. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of New Mexico for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA;

(4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

R. COUNT EIGHTEEN

Violations of the New York FCA by Defendants

Relators ex rel State of New York v. Defendants

261. The Defendants violated the New York FCA in the following respects:

a. The Defendants violated State Fin. Law §189.1(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;

1. DRL Defendants

262. DRL caused claims for payment to be presented to the State of New York for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations

to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of New York because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

263. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of New York for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition

and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

S. COUNT NINETEEN

Violations of the Oklahoma FCA by Defendants

Relators ex rel State of Oklahoma v. Defendants

264. Defendants violated the Oklahoma FCA in the following respects:

a. Defendants violated Okla. Stat. §63-5053.1(B)(1) by knowingly 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;

1. DRL Defendants

265. DRL caused claims for payment to be presented to the State of Oklahoma for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Oklahoma because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and

compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

266. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Oklahoma for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

T. COUNT TWENTY

Violations of the Rhode Island FCA by Defendants

Relators ex rel State of Rhode Island v. Defendants

267. Defendants violated the Rhode Island FCA in the following respects:

a. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the state or member of the guard a false or fraudulent claim for payment or approval;

1. DRL Defendants

268. DRL caused claims for payment to be presented to the State of Rhode Island for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Rhode Island because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

269. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Rhode Island for DRL Covered Drug Products as set forth

herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

U. COUNT TWENTY ONE

Violations of the Tennessee FCA by Defendants

Relators ex rel State of Tennessee v. Defendants

270. Defendants violated the Tennessee FCA in the following respects:

a. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(A) by presenting or causing to be presented to the state a claim under the Medicaid program knowing such claim is false or fraudulent;

1. DRL Defendants

271. DRL caused claims for payment to be presented to the State of Tennessee for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a

"covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Tennessee because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

272. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Tennessee for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied

certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

V. COUNT TWENTY-TWO

Violations of the Texas FCA by Defendants

Relators ex rel State of Texas v. Defendants

273. Defendants knowingly or intentionally reported to the State of Texas' Medicaid Program false statements or misrepresentations regarding their pharmaceutical products. These actions were repeated and continuous violations of the Texas Medicaid Fraud Prevention Act ("TMFPA").

274. Defendants violated the TMFPA in the following respects:

a. Section 36.002(1) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program;

b. Section 36.002(2) prohibits a person from knowingly or intentionally concealing or failing to disclose an event that permits a person to receive a benefit or payment that is not authorized, or that permits a person to receive a benefit or payment that is greater than the benefit or payment that is authorized;

c. Section 36.002(4) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program;

1. DRL Defendants

275. DRL caused claims for payment to be presented to the State of Texas for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Texas because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

276. Defendants Walgreens, CVS Caremark and Walmart (individually and

collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Texas for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition

and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

W. COUNT TWENTY- THREE

Violations of the Wisconsin FCA by Defendants

Relators ex rel State of Wisconsin v. Defendants

277. Defendants violated the Wisconsin FCA in the following respects:

a. Defendants violated Wis. Stat. §20.931(2)(a) by knowingly presenting or causing to be presented to an officer, employee, or agent of the state a false claim for medical assistance;

1. DRL Defendants

278. DRL caused claims for payment to be presented to the State of Wisconsin for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Wisconsin because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

279. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Wisconsin for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging

under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

X. COUNT TWENTY-FOUR

Violations of the Massachusetts FCA by Defendants

Relators ex rel Commonwealth of Massachusetts v. Defendants

280. Defendants violated the Massachusetts FCA in the following respects:

a. Defendants violated Mass. Gen. Laws Ch. 12, §5B(1) by knowingly presenting or causing to be presented a false claim for payment or approval;

1. DRL Defendants

281. DRL caused claims for payment to be presented to the State of Massachusetts for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance

with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Massachusetts because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

282. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Massachusetts for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general

conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

Y. COUNT TWENTY- FIVE

Violations of the Virginia FCA by Defendants

Relators ex rel Commonwealth of Virginia v. Defendants

283. Defendants violated the Virginia FCA in the following respects:

a. Defendants violated Code of Virginia § 8.01-216.3A(1) by knowingly presenting, or causing to be presented, to an officer or employee of the Commonwealth a false claim for payment or approval;

1. DRL Defendants

284. DRL caused claims for payment to be presented to the State of Virginia for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Virginia

because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

285. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Virginia for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition

and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

Z. COUNT TWENTY-SIX

Violations of the District of Columbia FCA by Defendants

Relators ex rel District of Columbia v. Defendants

286. Defendants violated the District of Columbia (DoC) FCA in the following respects:

a. Defendants violated D.C. Code Ann., 2-308.14(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the District a false claim for payment or approval;

1. DRL Defendants

287. DRL caused claims for payment to be presented to the DoC for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the DoC because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition

and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

288. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the DoC for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

AA. COUNT TWENTY- SEVEN

Violations of the City of Chicago FCA by Defendants

Relators ex rel City of Chicago v. Defendants

289. Defendants violated the Chicago FCA in the following respects:

a. Defendants violated Mun. Code of Chicago 1-22-020(1) by knowingly presenting, or causing to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval;

1. DRL Defendants

290. DRL caused claims for payment to be presented to the City of Chicago for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the City of Chicago because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

291. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to

be presented to the City of Chicago for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

BB. COUNT TWENTY- EIGHT

Violations of the City of New York FCA by Defendants

Relators ex rel City of New York v. Defendants

292. The Defendants violated the City of New York FCA in the following respects:

a. The Defendants violated New York City Administrative Code § 7-803(a)(1) by knowingly presenting, or causing to be presented, to a city officer or employee a false claim for payment or approval by the city;

1. DRL Defendants

293. DRL caused claims for payment to be presented to the City of New York for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the City of New York because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

294. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the City of New York for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA,

which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

CC. COUNT TWENTY - NINE

Violations of the Connecticut FCA by Defendant

Relators ex rel State of Connecticut v. Defendants

295. Defendants violated the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301 through 17b-301p ("Connecticut FCA") in the following respects:

a. Defendants violated the Connecticut FCA by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

1. DRL Defendants

296. DRL caused claims for payment to be presented to the State of Connecticut for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states

that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Connecticut because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

297. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Connecticut for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible

under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

DD. COUNT THIRTY

Violations of the Maryland FCA by Defendant

Relators ex rel State of Maryland v. Defendants

298. Defendants violated the Maryland Health False Claims ACT, as amended by Maryland Laws Ch 66. Title 2, Subchapter 6, § 2-601 to § 2-610 ("Maryland FCA") in the following respects:

a. Defendants violated the Maryland FCA by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

1. DRL Defendants

299. DRL caused claims for payment to be presented to the State of Maryland for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to

make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Maryland because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

300. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Maryland for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy

Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

EE. COUNT THIRTY- ONE

Violations of the Washington FCA by Defendant

Relators ex rel State Washington v. Defendants

301. Defendants violated the Washington Medicaid Fraud False Claims Act, WASH. SESS. LAWS, LAWS OF 2012, ch. 241 §§ 201 through 214 ("Washington FCA") in the following respects:

a. Defendants violated the Washington FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

1. DRL Defendants

302. DRL caused claims for payment to be presented to the State of Washington for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the

Pharmacy Defendants submitting claims for reimbursement to the State of Washington because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

303. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Washington for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

FF. COUNT THIRTY-TWO

Violations of the Colorado FCA by Defendant

Relators ex rel State of Colorado v. Defendants

304. Defendants violated the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310 ("Colorado FCA") in the following respects:

a. Defendants violated, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

1. DRL Defendants

305. DRL caused claims for payment to be presented to the State of Washington for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart ("Pharmacy Defendants) that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Washington because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation,

they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

306. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Washington for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

GG. COUNT THIRTY THREE

Violations of the Iowa FCA by Defendant

Relators ex rel State of Iowa v. Defendants

307. Defendants violated the Iowa False Claims Act ("Iowa FCA") Iowa Code §§ 685.1 through 685.7 in the following respects:

a. Defendants violated Iowa FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State of Iowa a false or fraudulent claim for payment or approval;

1. DRL Defendants

308. DRL caused claims for payment to be presented to the State of Iowa for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug" and/or (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards (3) Defendants made an implied certification that they were in compliance with the CPSIA and PPPA which was material and a substantial factor to the Government's decision to make payment and a condition of such payment, (4) DRL made express representations to its contract partners such as Defendants Walgreens, CVS/Caremark and Walmart (collectively "Pharmacy Defendants") that it's Drug Products were in compliance with Federal and State laws, which would include the PPPA, knowing that it was substantial factor in the Pharmacy Defendants submitting claims for reimbursement to the State of Iowa because under the PPPA it is the pharmacist who is responsible for ensuring packaging of required drugs in child-resistant containers and without this express representation, they would not have submitted DRL Products for reimbursement and (5) that testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

2. Pharmacy Defendants

309. Defendants Walgreens, CVS Caremark and Walmart (individually and collectively referred to as the Pharmacy Defendants), submitted claims for payment to be presented to the State of Iowa for DRL Covered Drug Products as set forth herein which were knowingly false because they were (1) "misbranded" under the FFDCA and therefore not a "covered drug"; (2) illegally dispensed because the pharmacist has no discretion to dispense prescription drugs in noncompliant packaging under the PPPA, which states that the dispensing pharmacists is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards, (3) Pharmacy Defendants made an implied certification that the DRL Drug Products were in compliance with the CPSIA and PPPA; (4) Pharmacy Defendants, as pharmacists who were dispensing the drugs is responsible under the PPPA for ensuring packaging of required drugs in child-resistant containers. Pharmacy Defendants knew, should have known, or recklessly disregarded the fact the drugs were not compliant because they were delivered by DRL without the general conformity certificates for the above-named drugs, as required by law; and (5) Pharmacy Defendants knew that the testing and compliance with the PPPA is a material condition and substantial factor in the Government's decision to reimburse providers for prescription drugs such as the DRL Covered Drug Products.

X. RELIEF REQUESTED

310. Relators request the following relief be imposed against Defendants as it relates to each of the Counts set forth herein:

(a) That the United States be awarded three times the amount of damages which it sustained because of the acts of Defendants pursuant to §3729(a)(1) of the FCA under Counts One (1) and Three[45] (3); that the States of California, Delaware, Florida,

[45] Count three being against DRL and DRLUS only

Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, Washington, Maryland, Colorado, Connecticut, and Iowa, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the Cities of Chicago and New York be awarded three times the amount of any payments provided under their Medicaid programs as a result of Defendants' unlawful acts, pursuant to the respective provision of each State FCA under Counts Four (4) through Thirty Three (33);

(b) That Defendants each be held liable for civil penalties of up to $10,000.00, but not less than $5,000.00 (as adjusted pursuant to §3729 of the FCA), to the U.S. for each and every act in violation of the FCA; that the Defendants each be held liable for civil penalties applicable for each and every unlawful act in violation of each respective State FCA;

(c) That this Court award such interest as is available pursuant to the FCA and/or each State FCA;

(d) That in the event the United States intervenes in this action and takes over its prosecution, the Relators be awarded an amount for bringing this action on behalf of the United States of at least 15% but not more than 25% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(1) of the FCA; that in the event any State intervenes in this action and takes over its prosecution, the Relators be awarded an amount for bringing this action for that respective State equal to a percentage of the proceeds paid to that State resulting from the trial or settlement of the claim, pursuant to the applicable provision of that State FCA;

(e) That in the event the United States does not intervene in this action, the Relators be awarded an amount for bringing this action for the United States of at least 25% but not more than 30% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(2) of the FCA; that in the event a State does not intervene in this action, the Relators be awarded an amount for bringing

this action for each respective State equal to a percentage of the proceeds paid to that State resulting from the trial or settlement of the claim, pursuant to the applicable provision of that State's FCA;

(f) That this Court award reasonable attorneys' fees, costs and expenses to the Relators, which were necessarily incurred in bringing and prosecuting this case, pursuant to §3730(d)(1) or (2) of the FCA and each respective State FCA; and

(g) That this Court award such other relief as it deems just, necessary and fair.

JURY DEMAND

Relators requests a trial by jury of all issues so triable.

Respectfully submitted,

Counsel for Plaintiff/Relator

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DATED: August 24, 2015

REDACTED

EXHIBIT A

REDACTED

EXHIBIT B

REDACTED

EXHIBIT C

REDACTED

EXHIBIT D