UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: MCNEIL CONSUMER HEALTHCARE, ET AL., MARKETING AND SALES PRACTICES LITIGATION	:	MDL NO. 2190
APPLIES TO: ALL ACTIONS	:	

CONSOLIDATED AMENDED CIVIL CONSUMER CLASS ACTION COMPLAINT

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Plaintiffs, individually, and on behalf of other consumers similarly situated, by and through their undersigned counsel, bring this Consolidated Amended Civil Consumer Class Action Complaint against the following Defendants (hereinafter collectively referred to as "Defendants"): McNeil Consumer Healthcare, a Division of McNeil-PPC, Inc. ("McNeil"), Johnson and Johnson ("J&J")(collectively, "the J&J Defendants"), William C. Weldon, Colleen Goggins, Rosemary Crane, Peter Luther, Mary Sue Coleman, Ph.D., Michael M.E. Johns, M.D., Susan L. Lindquist, Ph.D., David Satcher, M.D., Ph.D. (collectively, the "Individual Defendants"), Inmar, Inc., Carolina Supply Chain Services, LLC, Carolina Logistics Services, LLC, WIS International (collectively, the "Associated Defendants"), and hereby allege as follows:

I. NATURE OF THE CASE

1. This civil consumer class action case is brought by Plaintiffs, individually and on behalf of a putative nationwide class of similarly situated individuals located throughout the United States, as well as the following other places: Canada, Dominican Republic, Dubai (UAE), Fiji, Guam, Guatemala, Jamaica, Puerto Rico, Panama, Trinidad & Tobago, and Kuwait[1] ("the Class")(and/or one or more Sub-

[1] The above-listed countries and territories are hereinafter referred to as "Other Places". A complete list of the countries and territories in which products subject to the claims at issue in this case were distributed and sold is not possible at this time, due to the lack of discovery from Defendants at this point in the case. However, Plaintiffs have identified the above "Other Places" based upon information publicly available, and Plaintiffs expect to be able to provide a

Classes the Court may certify in the exercise of its discretion to effectively manage this litigation), for declaratory and other equitable relief, and to recover drug payments and overpayments made from at least December 2008 through the present (hereinafter the "relevant time period"), as a result of Defendants' unlawful scheme and conspiracy involving the manufacture, distribution, marketing, promotion and sale of consumer products used to treat ailments in children and adults, and the suppression and concealment of material information from the Plaintiffs and the Class about such products, including their potentially harmful effects as a result of undisclosed manufacturing defects and deficiencies at the time of sale. Because of Defendants' concealment of material information about their products, including the fact that the products were not of the quality and condition as represented at the time of sale, a complete list of all products covered by the claims in this lawsuit is not possible at this time. Once discovery is completed, however, Plaintiffs expect to create such a complete product list for trial. At a minimum, and based upon the best available information and good faith investigation and belief of Plaintiffs at this time, the consumer products included in this case include, at a minimum, all forms (including all sizes, dosages and flavors) of the products listed in **Exhibit "A"** hereto (hereinafter collectively referred to as the "**Subject Products**").

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complete list of the places included in the claims by the time of the Court's decision on class certification, provided appropriate discovery is produced by Defendants.

2. For years, Defendants have marketed and sold their Subject Products to consumers located throughout the United States and Other Places for their own use and for use by their young children. These sales were at prices higher than those otherwise available for comparable products, based in large part upon the purported reputation of the J&J Defendants for producing safe and effective medications, a reputation that all Defendants worked hard to maintain in order to allow the J&J Defendants to continue to charge premium prices for otherwise unremarkable consumer products insofar as their availability in generic, over-the-counter form at retail outlets.

3. Consumers traditionally have been willing to pay more money for J&J and McNeil brand-name Subject Products based in part upon consumers' trust in such reputation. That is one reason why the failure of Defendants to timely notify consumers about the truth about the serious degradation of the quality and condition of the Subject Products has caused harm to consumers, who continued to pay inflated, premium prices for **all Subject Products** – not just those Defendants chose to recall when government scrutiny became too great to avoid public disclosure any longer.

4. Once a company has spoken about its products, it has a duty to speak the truth about such products. Here, Defendants knew that the Subject Products had serious problems. Yet, the Defendants deliberately chose to not reveal publicly the truth

until late in the evening on Friday, April 30, 2010. Prior to that time, they engaged the Other Defendants to conduct "phantom recalls" and take other steps to conceal from consumers the truth about the Subject Products.

5. On April 30, 2010, it was revealed by the J&J Defendants publicly for the first time that they had had been flagrantly violating the rules and regulations set up by the Food and Drug Administration ("FDA") to protect consumers from harmful drug products being sold in this country. On that day, it was revealed publicly for the first time that McNeil had been cited for twenty (20) major violations in its manufacturing processes, exposing innocent children throughout the country and Other Places to dangerous products which never should have been sold, but which remain in the open market and in the cupboards of consumers throughout the country. As discussed herein, these violations had been ongoing at the company for years, and they continued unabated and undisclosed into 2010.

6. On April 30, 2010, the FDA issued a report (late made public) – discussed more fully herein – detailing its inspection of McNeil facilities in Fort Washington, Pennsylvania. As a result of such inspection, 20 major "observations" were made about deficiencies in McNeil's manufacturing processes respecting certain Subject Products at issue herein.

7. A recall was issued by McNeil for a subset of the Subject Products at issue in this case, and only as to certain National Drug Codes ("NDCs"), production dates and

lot numbers. As discussed more fully herein, J&J and McNeil deliberately delayed announcing such recall until late in the evening so as to avoid substantial media attention – and with it widespread disclosure to consumers -- and to minimize the J&J Defendants' exposure to having to pay full cash refunds to concerned consumers.

8. As a result, only a small portion of the consumers who purchased the Subject Products have ever learned about the recall, and only a smaller portion of those knowledgeable consumers ever attempted to recover as part of a limited refund program set up McNeil (as described more fully herein). This is one reason why a class action is warranted to address this situation: there are millions of consumers in this country and Other Places who may never know that the Subject Products they purchased are subject to recall, that they are worth less than what they paid for them, and, in some cases, they may be harmful.

9. The subset of Subject Products in the J&J recall include the following:

Tylenol Infants' Drops
Concentrated Tylenol Infants' Drops 1 oz Grape Flavor: 50580-144-01
Concentrated Tylenol Infants' Drops 0.5 oz Grape Flavor: 50580-144-15
Concentrated Tylenol Infants' Drops 1 oz Cherry Dye Free: 50580-167-01
Concentrated Tylenol Infants' Drops 0.5 oz Cherry Flavor: 50580-143-15
Concentrated Tylenol Infants' Drops 1 oz Cherry Flavor: 50580-143-30
Concentrated Tylenol Infants' Drops 0.5 oz Grape - Hospital: 50580-144-18
Concentrated Tylenol Infants' Drops 0.25 oz Grape - Sample: 50580-144-40

Children's Tylenol Suspensions
Children's Tylenol Suspension 2 oz Cherry Blast Flavor: 50580-123-02
Children's Tylenol Suspension 4 oz Cherry Blast Flavor: 50580-123-04

Children's Tylenol Dye-Free Suspension 4 oz Cherry Flavor: 50580-166-04
Children's Tylenol Suspension 4 oz Grape Splash: 50580-296-04
Children's Tylenol Suspension 4 oz Bubblegum Flavor: 50580-407-04
Children's Tylenol Suspension 4 oz Very Berry Strawberry Flavor: 50580-493-04
Children's Tylenol Suspension 1 oz Cherry Blast Flavor - Sample: 50580-123-01
Children's Tylenol Suspension 4 oz Cherry Blast Flavor - Hospital: 50580-123-03

Children's Tylenol Plus Suspensions
Children's Tylenol Plus Suspension 4 oz Cough and Sore Throat Cherry Flavor: 50580-247-04
Children's Tylenol Plus Suspension 4 oz Cough and Runny Nose Cherry Flavor: 50580-249-04
Children's Tylenol Plus Dye Free Suspension 4 oz Cold and Stuffy Nose Grape Flavor: 50580-253-04
Children's Tylenol Plus Dye Free Suspension 4 oz Cold and Cough Grape Flavor: 50580-254-04
Children's Tylenol Plus Dye Free Suspension 4 oz Multi-Symptom Cold Grape Flavor: 50580-255-04
Children's Tylenol Plus Suspension 4 oz Flu Bubblegum Flavor: 50580-386-04
Children's Tylenol Plus Suspension 4 oz Cold Grape Flavor: 50580-387-04
Children's Tylenol Plus Suspension 4 oz Cold & Allergy Bubblegum Flavor: 50580-390-04
Children's Tylenol Plus Suspension 4 oz Multi-Symptom Grape Flavor: 50580-391-04

Motrin Infants' Drops
Concentrated Motrin Infants' Drops 1 oz Berry Dye Free: 50580-198-01
Concentrated Motrin Infants' Drops 0.5 oz Berry Dye Free: 50580-198-15
Concentrated Motrin Infants' Drops 0.5 oz Berry Flavor*: 50580-100-15

Children's Motrin Suspensions
Children's Motrin Suspension 4 oz Berry Dye Free: 50580-184-04
Children's Motrin Suspension 2 oz Berry Flavor: 50580-601-02
Children's Motrin Suspension 4 oz Berry Flavor: 50580-601-04
Children's Motrin Suspension 4 oz Tropical Punch Flavor: 50580-215-04
Children's Motrin Suspension 4 oz Grape Flavor: 50580-603-04
Children's Motrin Suspension 4 oz Bubblegum Flavor: 50580-604-04
Children's Motrin Suspension 1 oz Grape Sample: 50580-603-01
Children's Motrin Suspension 1 oz Bubblegum Sample: 50580-604-01
Children's Motrin Suspension 1 oz Berry Sample: 50580-601-01

Children's Motrin Cold Suspensions
Children's Motrin Suspension 4 oz Cold Berry Flavor: 50580-902-04

Children's Zyrtec Liquids in Bottles
Children's Zyrtec Sugar-Free Dye-Free 4 oz Bubblegum Syrup: 50580-721-04
Children's Zyrtec Sugar-Free Dye-Free 4 oz Grape Syrup: 50580-730-04
Children's Zyrtec Sugar-Free Dye-Free 0.5 oz Grape: 50580-730-15
Children's Zyrtec Sugar-Free Dye-Free 0.5 oz Bubblegum: 50580-721-15
Children's Zyrtec Sugar-Free Dye-Free 2 X 4 oz Bubblegum Liquid: 50580-721-08

Children's Benadryl Allergy Liquids in Bottles
Children's Benadryl Allergy 4 oz Sugar-Free Dye-Free Bubblegum Flavored Liquid: 50580-535-04

This subset of Subject Products, as well as other Subject Products on Schedule A that were later recalled, are hereinafter collectively referred to as the "**Recalled Subject Products**".

10. As McNeil stated on its website at the time, the recall of the above Recalled Subject Products was "voluntary" and "**Only Certain Products are being Recalled."** http://www.tylenol.com/page2.jhtml?id=tylenol/news/ndc_finder.inc (emphasis in original.)

11. In other words, the J&J and Individual Defendants **did not recall all of the Subject Products affected by their conduct**, and are not offering all consumers in the consumer Class full cash refunds of their out-of-pocket payments made for all Subject Products – only the select few Recalled Subject Products chosen by Defendants.

12. This case seeks, among other remedies available under the law, full cash refunds of the entire out-of-pocket payments made for Subject Products, plus additional costs incurred. Such payments included at least the retail costs of the Subject Products – which costs vary across the country and Other Places – as well as all applicable sales taxes, the costs of proper disposal of the products, and related incidental damages.

13. In terms of the cost of disposal, the J&J Defendants strongly admonished consumers to take proper steps to dispose of the now-worthless Subject Products. Consumers are not permitted to just dump the unused contents down a sink or drain, or throw unused bottles in the trash. Instead, J&J advises:

"What should I do if I have the product in my home?

… [A]s a precautionary measure, parents and caregivers should not administer these products to their children. For information on disposing of over-the-counter medications, please go to www.smarxtdisposal.net."

The "smarxtdisposal" website further provides:

> "Follow your medication prescriber's instructions and use all medications as instructed. If you do not use all of your prescribed or over-the-counter medication, you can take a few small steps to make a huge impact in safeguarding lives and protecting the environment by disposing of unused medicines properly:
>
> 1. **DO NOT FLUSH unused medications and DO NOT POUR them down a sink or drain.**
> 2. **Be Proactive and Dispose of Unused Medication In Household Trash.** When discarding unused medications, ensure you protect children and pets from potentially negative effects:

a. Pour medication into a sealable plastic bag. If medication is a solid (pill, liquid capsule, etc.), add water to dissolve it.
b. Add kitty litter, sawdust, coffee grounds (or any material that mixes with the medication and makes it less appealing for pets and children to eat) to the plastic bag.
c. Seal the plastic bag and put it in the trash.
d. Remove and destroy ALL identifying personal information (prescription label) from all medication containers before recycling them or throwing them away.

These additional precautions required to properly dispose of the Subject Products were caused by the acts and omissions of Defendants and should be compensated.

14. For those limited Recalled Subject Products, McNeil initially offered select consumers a limited opportunity to request a "high value coupon" for a future McNeil product. The documents produced by the J&J Defendants pursuant to the Court's directive – which documents are attached hereto collectively at **Exhibit "B"** -- reveal that in the early days following the recall, the J&J Defendants encouraged consumers who called for refunds to take "high value coupons" over cash. Of course, with the McNeil Fort Washington plant shut down, such coupons were and remain worthless. However, the J&J Defendants tried to convince consumers otherwise by pushing the worthless coupons over cash.

15. Such coupons have no present cash value and are not transferrable – as would be required under the class action rules which govern this case if Defendants had attempted to resolve Plaintiffs' claims by offering coupons instead of cash. Consequently, Defendants could not get away with offering consumers worthless

coupons under the stringent standards of Federal Rule 23 for providing coupons in settlement of a class action case.

16. Some members of the consumer Class in this case received such worthless coupons, and therefore have not been compensated adequately for their losses described herein.

17. The consumer Class paid cash for the Subject Products at issue here; full cash refunds should be made available to all consumers of Subject Products.

18. At some point after the recall announcement was made, the J&J Defendants began offering select consumers a limited opportunity to request a cash refund of part of their out-of-pocket payments made for Recalled Subject Products. Such refunds were not offered to all consumers in the Class; instead, only select consumers were given the opportunity to receive a partial cash refund if they meet the stringent eligibility criteria established exclusively by J&J and McNeil without any external oversight, judicial or otherwise.

19. Since Defendants can no longer be trusted to do the right thing respecting their Subject Products, having repeatedly and deliberately betrayed the trust of consumers and the government investigating Defendants, it is only by the superior vehicle of this class action lawsuit, the declaratory and other relief it seeks, and the Court's supervisory powers under Federal Rule 23, that Defendants will be forced to properly compensate consumers for their losses.

II. JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. §§ 1332(a) and 1332(d), because there are more than 100 class members nationwide and outside the country, at least one class member is of diverse citizenship from one Defendant, more than two-thirds of the members of the putative Class are citizens of states different from that of these Defendants, and the aggregate amount in controversy exceeds $5,000,000.00 exclusive of interest and costs.

21. The Court also has subject matter jurisdiction pursuant to the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq*.

22. The Court has further subject matter jurisdiction pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq*.

23. Venue is proper in this jurisdiction under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District, because McNeil, other operating companies within J&J, and certain Individual Defendants may be found within this judicial District, two of the major manufacturing facilities which produced certain Subject Products are located in Fort Washington and Lancaster, Pennsylvania, respectively, and the branch of the FDA which has led the investigation of McNeil is located on Chestnut Street in Philadelphia, Pennsylvania – all within this judicial district.

24. This Court has personal jurisdiction over Plaintiffs because certain of them reside within the Commonwealth of Pennsylvania while others located outside the Commonwealth submit to the jurisdiction of this Court.

25. This Court has personal jurisdiction over Defendants because certain of them are located and/or have business operations in the Commonwealth, while others have sufficient minimum contacts with the Commonwealth, and otherwise intentionally avail themselves of markets in Pennsylvania through their manufacture, distribution, promotion, marketing and sale of Subject Products and other products in Pennsylvania so as to render this Court's exercise of jurisdiction permissible under traditional notions of fair play and substantial justice.

26. Moreover, Defendants carried out their unlawful manufacturing, distribution, promotion, marketing and sales scheme, the suppression and concealment of the same, and the conspiracy respecting the same in this District. Accordingly, Defendants have submitted themselves to the jurisdiction of this Court by transacting business here and otherwise committing tortious acts within this State, and this judicial District specifically.

27. Indeed, by voluntarily choosing to locate McNeil and its principle manufacturing facilities in Pennsylvania, the J&J and Individual Defendants have purposefully availed themselves of the benefits and protections of Pennsylvania law for the

entire relevant time period, and they have agreed thereby to be bound by such laws and the burdens of compliance therewith.

III. THE PARTIES

A. Plaintiffs

28. John Thrasher is an individual and resident of 2921 E. La Rocas Drive, Phoenix, **Arizona** 85028 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Mr. Thrasher, like other members of the Class (and/or possible Sub-Class of Arizona consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from his out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Mr. Thrasher has not been reimbursed fully for his out-of-pocket payments for Subject Products.

29. Janelle Bridges is an individual and resident of 10675 Bottle Rock Road, Kelseyville, **California** 95451 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Bridges, like other members of the Class (and/or possible Sub-Class of California consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result

from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Bridges has not been reimbursed fully for her out-of-pocket payments for Subject Products.

30. Dana Rivera is an individual and resident 14142 Martinque Drive, Moreno Valley, **California** who, during the relevant time period, purchased a number of Subject Products including some Recalled Subject Products. As a result, Ms. Rivera, like other members of the Class (and/or possible Sub-Class of California consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Rivera has not been reimbursed fully for her out-of-pocket payments for Subject Products.

31. Wayne Burrell is an individual and resident of 19521 Saturnia Lake Drive, Boca Raton, **Florida** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Mr. Burrell, like other members of the Class (and/or possible Sub-Class of Florida consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from his out of

pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Mr. Burrell has not been reimbursed fully for his out-of-pocket payments for Subject Products.

32. Brittney Spivey is an individual and resident of 273 Mojave Court, Merritt Island, **Florida**, 32952, who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Spivey, like other members of the Class (and/or possible Sub-Class of Florida consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Spivey has not been reimbursed fully for her out-of-pocket payments for Subject Products.

33. John Smith is an individual and resident of 1637 N. 20th Avenue, Melrose Park, **Illinois** who, during the relevant time period, purchased Subject Products, including some Recalled Subject Products. As a result, Mr. Smith, like other members of the Class (and/or possible Sub-Class of Illinois consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from his out of pocket payments

for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Mr. Smith has not been reimbursed fully for his out-of-pocket payments for Subject Products.

34. Landy Nguyen is an individual and resident of 1627 South Cora Street, Des Plaines, **Illinois** who, during the relevant time period, purchased Subject Products including some Recalled Subject Products. As a result, Ms. Nguyen, like other members of the Class (and/or possible Sub-Class of Illinois consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Nguyen has not been reimbursed fully for her out-of-pocket payments for Subject Products.

35. Candy Angel is an individual and resident of P.O. Box 303, Greenup, **Kentucky** 41144 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Angel, like other members of the Class (and/or possible Sub-Class of Kentucky consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of

pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Angel has not been reimbursed fully for her out-of-pocket payments for Subject Products.

36. Farlesher Murphy is an individual and resident of 2430 13th Street, Lake Charles, **Louisiana**, 70601, who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Murphy, like other members of the Class (and/or possible Sub-Class of Louisiana consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Murphy has not been reimbursed fully for her out-of-pocket payments for Subject Products.

37. Justin Michaud is an individual and resident of 42 Lexington Road, Millbury, **Massachusetts** who, during the relevant time period, purchased Subject Products, including some Recalled Subject Products. As a result, Mr. Michaud, like other members of the Class (and/or possible Sub-Class of Massachusetts consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from his out of

pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Mr. Michaud has not been reimbursed fully for his out-of-pocket payments for Subject Products.

38. Ethel Ingram is an individual and resident of 1122 North 26th Circle, Omaha, **Nebraska** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Ingram, like other members of the Class (and/or possible Sub-Class of Nebraska consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Ingram has not been reimbursed fully for her out-of-pocket payments for Subject Products.

39. Catherine Roselli is an individual and resident of 518 A Butler Avenue, Point Pleasant, **New Jersey** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Roselli, like other members of the Class (and/or possible Sub-Class of New Jersey consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of

pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Roselli has not been reimbursed fully for her out-of-pocket payments for Subject Products.

40. Rhonda Mannara is an individual and resident of 1 Hunt Point, Rochester, **New York,** 14624 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Mannara, like other members of the Class (and/or possible Sub-Class of New York consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Mannara has not been reimbursed fully for her out-of-pocket payments for Subject Products.

41. Brandie Carroll is an individual and resident of 4238 Barber Mill Rd., Lot 33, Clayton, **North Carolina** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Carroll, like other members of the Class (and/or possible Sub-Class of North Carolina consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result

from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Carroll has not been reimbursed fully for her out-of-pocket payments for Subject Products.

42. Amber Coleman is an individual and resident of 2714 Queen City Avenue, Cincinnati, **Ohio** who, during the relevant time period, purchased a number of Subject Products including some Recalled Subject Products. As a result, Ms. Coleman, like other members of the Class (and/or possible Sub-Class of Ohio consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Coleman has not been reimbursed fully for her out-of-pocket payments for Subject Products.

43. Joyce Taylor is an individual and resident of 47 Jackson Street, Lockbourne, **Ohio** 43137 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Taylor, like other members of the Class (and/or possible Sub-Class of Ohio consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments

for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Taylor has not been reimbursed fully for her out-of-pocket payments for Subject Products.

44. Daniel Pack is an individual and resident of 2618 Slabtown Rd., Lima, **Ohio** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Mr. Pack, like other members of the Class (and/or possible Sub-Class of Ohio consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from his out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Mr. Pack has not been reimbursed fully for his out-of-pocket payments for Subject Products.

45. Gene Renz is an individual and resident of 2274 Oakfield Rd., Warrington, **Pennsylvania** 18976 who, during the relevant time period, purchased a number of Subject Products for the treatment of the ailments of his children, including some Recalled Subject Products. As a result, Mr. Renz, like other members of the Class (and/or possible Sub-Class of Pennsylvania consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by

Defendants, which damages result from his out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Mr. Renz has not been reimbursed fully for his out-of-pocket payments for Subject Products.

46. Edna Scott is an individual and resident of 1631 W. Victoria Street, Philadelphia, **Pennsylvania** 19140 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Scott, like other members of the Class (and/or possible Sub-Class of Pennsylvania consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Scott has not been reimbursed fully for her out-of-pocket payments for Subject Products.

47. Donna Varner is an individual and resident of 1119 US HWY 522 North, Lewistown, **Pennsylvania** 17044 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Varner, like other members of the Class (and/or possible Sub-Class of Pennsylvania consumers only), suffered damages from the unlawful scheme and

conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Varner has not been reimbursed fully for her out-of-pocket payments for Subject Products.

48. Maura McDaid is an individual and resident of 257 Fox Run Road, King of Prussia, **Pennsylvania** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. McDaid, like other members of the Class (and/or possible Sub-Class of Pennsylvania consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. McDaid has not been reimbursed fully for her out-of-pocket payments for Subject Products.

49. Emile and Amber Roberson are individuals and residents of 1810 Creegan Park Court, Houston, **Texas** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, the Roberson's, like other members of the Class (and/or possible Sub-Class of Texas consumers only), suffered damages from the unlawful scheme and conspiracy, and

the concealment of the same by Defendants, which damages result from their out of pocket payments for Subject Products which were unsafe at the time of sale, were not worthless as medicines. The Roberson's have not been reimbursed fully for their out-of-pocket payments for Subject Products.

50. Jason and Jody Munn are individuals and residents of 17006 E. Morningside Lane, Greenacres, **Washington**, 99016 who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, the Munns, like other members of the Class (and/or possible Sub-Class of Washington consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. The Munns have not been reimbursed fully for their out-of-pocket payments for Subject Products.

51. Kylie Hess is an individual and resident of 12 Powell Street, Salem, **West Virginia** who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, Ms. Hess, like other members of the Class (and/or possible Sub-Class of West Virginia consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of

pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. Hess has not been reimbursed fully for her out-of-pocket payments for Subject Products.

52. Jennifer DeGroot is an individual and resident of 268 Old Highway 24 RR #3, Waterford, **Ontario, Canada** who, during the relevant time period, purchased Subject Products including some Recalled Subject Products. As a result, Ms. DeGroot, like other members of the Class (and/or possible Sub-Class of consumers in Other Places only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from her out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. Ms. DeGroot has not been reimbursed fully for her out-of-pocket payments for Subject Products.

B. <u>Defendants</u>

53. McNeil Consumer Healthcare is a division of McNeil-PPC, Inc., located in Fort Washington Pennsylvania ("McNeil"). McNeil is the largest consumer company within the Johnson & Johnson Family of Companies. McNeil manufactures, distributes, markets and sells a broad range of well-known brand name, over-the-counter ("OTC") products, including Tylenol®, Motrin®, Zyrtec®, and

Benadryl®. Many of McNeil's products are made specifically for children. Among these products are the Subject Products listed at paragraph 2 above and Exhibit "A" hereto (which are the products at issue in this case).

54. Johnson & Johnson ("J&J") is a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson has more than 250 companies located in 57 countries around the world, including McNeil, and sells consumer products and prescription products throughout Pennsylvania, New Jersey and the United States, including its territories. J&J is responsible for McNeil, as well as the manufacture, distribution, marketing and sale of the Subject Products at issue in this case.

55. William C. Weldon ("Weldon") is an individual and resident of the Commonwealth of Pennsylvania who is the current Chairman and Chief Executive Officer of Johnson & Johnson. Mr. Weldon joined J&J in 1971 and served in several sales, marketing and international management positions. Mr. Weldon was appointed to the Executive Committee and named Worldwide Chairman, Pharmaceuticals Segment in 1998, was elected to the Board of Directors and was named vice Chairman of the Board in 2001. On April 25, 2002, Mr. Weldon became Chairman and CEO of Johnson & Johnson, the position he currently holds. Throughout the relevant time period, Mr. Weldon had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort

Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case. As described more full herein, on September 30, 2010, Mr. Weldon testified before Congress and admitted responsibility for the problems at McNeil which give rise to the claims at issue in this case.

56. Colleen Goggins ("Goggins") is an individual and resident of Princeton, New Jersey who is the current Worldwide Chairman of the Johnson & Johnson Consumer Healthcare Segment. In her position, she is a member of the Group Operating Committee ("GOC") of Johnson & Johnson and reports directly to Mr. Weldon. Throughout the relevant time period, Ms. Goggins had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case. As described more full herein, on September 30, 2010, Ms. Goggins also testified before Congress and admitted responsibility for the problems at McNeil which give rise to the claims at issue in this case.

57. Rosemary Crane ("Crane") is an individual and resident of 33 Teal Drive, Langhorne, Pennsylvania, who, beginning in 2002 and during the relevant time period when the acts and failures to act at issue took place, was the Company Group Chairman and member of the GOC of Johnson & Johnson with

responsibility for McNeil, the McNeil Consumer Healthcare Segment, and the Subject Products at issue in this case. During the relevant time period, Ms. Crane had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

58. Peter Luther ("Luther") is an individual and, upon information and belief, a resident of the State of New Jersey. Mr. Luther has served as the President of McNeil since January 2009. From 1991 through March 2000, Luther was the franchise director of McNeil's Consumer & Specialty Pharmaceuticals. From March 2000 through March 2006, Mr. Luther served as President of LifeScan, another J&J subsidiary. From March 2006 through January 2009, Mr. Luther was President of J&J's North American Beauty Care division. Mr. Luther also has served as a member of the J&J Board of Directors. Throughout the relevant time period, Mr. Luther had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

59. Mary Sue Coleman, Ph.D. ("Coleman") is an individual, and upon information and belief, a resident of the State of Michigan. Dr. Coleman has served as a Board of

Director at J&J since 2002 and is a member of the Science & Technology Advisory Committee. Throughout the relevant time period, Dr. Coleman had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

60. Michael M.E. Johns, M.D. ("Johns") is an individual and, upon information and belief, a resident of the State of Georgia. Dr. Johns has served on the Board of Directors since 2005 and is a member of the Science & Technology Advisory Committee. Throughout the relevant time period, Dr. Johns had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

61. Susan L. Lindquist, Ph.D. ("Lindquest") is an individual and, upon information and belief, a resident of the Commonwealth of Massachusetts. Dr. Linquist has served on the Board of Directors since 2004 and is a member of the Science & Technology Advisory Committee. Throughout the relevant time period, Dr. Lindquist had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was

integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

62. David Satcher, M.D., Ph.D. ("Satcher") is an individual and, upon information and belief, a resident of the State of Georgia. Dr. Satcher has served on the Board of Directors since 2002 and is a member of the Science & Technology Advisory Committee. Throughout the relevant time period, Dr. Satcher had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

63. Inmar, Inc., on information and belief, is a North Carolina corporation with a principal place of business located at 2601 Pilgrim Court, Winston-Salem, North Carolina. Inmar, Inc.'s business operations include the processing and management of returned/recalled pharmaceutical products serving retailers, wholesalers, manufacturers and pharmacies. Inmar, Inc. was hired by, and/or acted on behalf of, Johnson & Johnson and/or McNeil to conduct the 2009 Phantom Recall and other "market assessments", including market assessments related to the April 30, 2010 recall. Inmar, Inc's involvement in these activities is, in part, the subject of a current Congressional investigation.

64. Carolina Supply Chain Services, LLC, ("CSCS"), on information and belief, is a limited liability company organized under the laws of the State of North Carolina with a principal place of business located at 2601 Pilgrim Court, Winston-Salem, North Carolina. CSCS's business operations include reverse logistics and supply chain management. CSCS's sole member is/was Carolina Logistics Services, LLC. CSCS was/is a subsidiary of Inmar, Inc. CSCS was hired by, and/or acted on behalf of, Johnson & Johnson and/or McNeil to conduct the 2009 Phantom Recall and other "market assessments", including market assessments related to the April 30, 2010 recall. CSCS's involvement in these activities is, in part, the subject of a current Congressional investigation.

65. Carolina Logistics Services, LLC, ("CLS") is a limited liability company organized under the laws of the State of North Carolina with a principal place of business located at 2601 Pilgrim Court, Winston-Salem, North Carolina. CLS's business operations include reverse logistics and supply chain management. CLS is the surviving entity of a 2008 merger between CLS and CSCS. CLS's sole member is Inmar, Inc., and is liable for the acts of CSCS pursuant to the terms of the Articles of Merger, and Article I, Section 3 of the Plan of Merger, between CSCS and CLS dated November 24, 2008, filed December 17, 2008 with the Department of the Secretary of the State of North Carolina, effective December 29, 2008, in accordance with the North Carolina Limited Liability Company Act.

66. WIS International is believed to be a Canadian business entity with its U.S. headquarters located at 9265 Sky Park Court, Suite 100, San Diego, California. WIS International's business operations include inventory services, compliance audits, price verifications, shopper surveys, discontinued items and product placement allocation. It is believed and therefore averred that WIS International was recruited/hired by Inmar, Inc./CSCS and acted on behalf of Johnson & Johnson and/or McNeil and assisted Inmar, Inc./CSCS, with the conduct of the 2009 Phantom Recall and other "market assessments", including market assessments related to the April 30, 2010 recall. WIS International's involvement in these activities is, in part, the subject of a current Congressional investigation.

67. The acts alleged in this Complaint to have been done by Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs. As detailed at length below, the conduct was specifically authorized by the relevant officers and executive officers of the Defendants.

IV. FACTUAL ALLEGATIONS

A. Defendants' Unlawful Scheme to Manufacture, Distribute, Market and Sell Products Which Were Unsafe, Ineffective and/or Worth Less than Cheaper Alternatives Due to Defendants' Scheme and Conspiracy, and Their Concealment of the Same

1. The McNeil/Johnson & Johnson Relationship

68. Johnson & Johnson engages in the research and development, manufacture, distribution and sales of various products in the healthcare field worldwide. The Company was founded in 1886 and is based in New Brunswick, New Jersey.

69. Johnson & Johnson is structured as a "partner group" organization consisting of numerous "operating companies" as its partners.

70. Johnson & Johnson is currently comprised of approximately 250 companies worldwide.

71. These operating companies are organized into business segments, *i.e.*, Consumer Health Care, Medical Devices and Diagnostics, Pharmaceuticals (hereinafter "Segments").

72. The Pharmaceutical Segment offers products in various therapeutic areas such as anti-infective, antipsychotic, cardiovascular, contraceptive, dermatology, gastrointestinal, immunology, neurology, oncology, urology, and virology.

73. The Consumer Health Care Segment provides products including over-the-counter pharmaceutical products, including the Subject Products at issue in this action, wellness and prevention platforms, baby care, skin care, oral care, wound care and women's health products.

74. McNeil is an operating company within the Consumer Health Care Segment of Johnson & Johnson, and thus a member the Johnson & Johnson corporate partner group.

75. Individual Defendants Weldon, Goggins, Crane, Luther, Coleman, Johns, Lindquist, and Satcher all had responsibility for the Consumer Health Care Segment.

76. Other Defendants all performed work, either directly or indirectly, for the Consumer Health Care Segment.

77. McNeil is the largest consumer company within the Johnson and Johnson group of companies.

78. In 1959, J&J acquired McNeil Laboratories, a company focused on direct marketing of prescription products to hospitals, pharmacists and doctors. In 1955, McNeil introduced an acetaminophen based Subject Product, Tylenol Elixer.

79. A year after acquiring McNeil Laboratories, J&J's McNeil division was able to sell Tylenol without a prescription.

80. In 1961 McNeil laboratories moved to its Fort Washington, Pennsylvania headquarters.

81. In 1977, McNeil Laboratories created two companies: McNeil Pharmaceutical and McNeil Consumer Healthcare.

82. McNeil Pharmaceutical focused on the marketing of prescription drug products and in 1993 merged with Ortho Pharmaceutical Corporation forming Ortho-McNeil Pharmaceutical ("OMP").

83. McNeil Consumer Healthcare focuses on the manufacture and marketing of a variety of over-the-counter (OTC) products for the U.S. market, including the Subject Products at issue in this action. These products are produced at four separate McNeil manufacturing facilities located in the United States, Puerto Rico and Canada, including McNeil's Fort Washington and Lancaster, Pennsylvania manufacturing plants.

2. Corporate Hierarchy at Johnson & Johnson

84. The current Chairman and Chief Executive Officer of Johnson & Johnson is William C. Weldon. Mr. Weldon assumed control of Johnson & Johnson during a time of tremendous economic pressure on large brand name drug companies, like Johnson & Johnson. With many brand name prescription drugs losing their patent protection and facing stiff competition from generic drugs and even newer brand name, therapeutic competitor drugs, on top of overall slowing growth for the entire healthcare industry, Johnson & Johnson needed to satisfy its shareholders, who demanded higher profits from the company.

3. J&J's "Credo", Principles of Corporate Governance and Policy on Business Conduct

85. In 1943, Robert Wood, a member of Johnson & Johnson's founding family and former Chairman from 1932 to 1963, crafted "Our Credo", a document that provides the values that allegedly guide current decision making at Johnson & Johnson.

86. Indeed, Johnson & Johnson specifically states that "'Our Credo' is more than just a moral compass. We believe it's a recipe for business success."

87. The Credo dictates, in pertinent part, that "our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality." (Emphasis added).

88. The Credo further dictates that "[w]e must provide competent management, and their actions must be just and ethical" and that "[w]e are responsible to the communities in which we live and work and to the world community as well."

89. According to J&J's Principles of Corporate Governance, corporate governance is also governed by the values set forth in "Our Credo," and that "good corporate governance results from sound processes that ensure that our directors are well supported by accurate and timely information, sufficient time and resources and unrestricted access to management."

90. The Principles of Corporate Governance provide that the responsibilities of the Board of Directors include the duties to "select, oversee and monitor the performance of the senior management team," and to "exercise their business judgment on matter of critical and long-term significance to the Company in furtherance of what they reasonably believe to be in the best interest of the Company."

91. Similarly, J&J's Policy on Business Conduct emphasizes the Company's purported dedication to enforcement and compliance with high ethical standards and legal regulations, providing in pertinent part that:

> All managers shall be responsible for the enforcement of and compliance with this Policy on Business Conduct including necessary distribution to ensure employee knowledge and compliance. The board of directors or other governing body of each affiliate company shall formally adopt this Policy as its own corporate policy binding on all directors, officers, and employees of the company.
>
> Consistent with our Credo and business philosophy, it is the policy of Johnson & Johnson to comply with the laws of each country in which our companies do business. It is the responsibility of each company's management and employees to be familiar with the laws and regulations that relate to their business responsibilities and to comply with them.
>
> No aspect of our business is more subject to governmental regulation than the development, manufacture, approval, sales and marketing of our health care products. Because of the complex nature of many of these regulations management must take particular care to ensure appropriate employees are aware of regulatory requirements and take necessary steps to comply with them.

92. J&J has adopted a Code of Business Conduct & Ethics for the members of the Board of Directors and the Executive Offices of the Company. The Code of Business Conduct & Ethics also emphasizes the Board's responsibilities in ensuring that the Company adheres to ethical and legal regulations and J&J's policies, providing in pertinent part that:

> Each Director and Executive Officer shall be responsible for complying with this Code. Executive Officers of the Company must comply with the Johnson & Johnson Policy on Business Conduct also.
>
> If any Director or Executive Officer believes that a prohibited act under this Code has occurred, then he or she shall promptly report such belief to the Chairman of

the Board, the Presiding Director and the General Counsel. While this is the preferred reporting procedure, and Director or Executive Officer should feel free to report any such alleged prohibited act hereunder to the Chairman of the Audit Committee or the Chairman of the Nominating and Corporate Governance Committee.

Consistent with our Credo and business philosophy, it is the policy of Johnson & Johnson to comply with the laws of each country in which our companies do business. Each Director and Executive Officer shall comply with all applicable laws, rules and regulations, and shall use all reasonable efforts to oversee compliance by employees, other Directors and other Executive Officers with all applicable laws, rules and regulations.

4. Recent History of Violating Federal and State Laws

93. J&J has been plagued with ethical and legal violations in recent years.

94. These not insubstantial transgressions, detailed in part below, should have caused the Company and the Board to be on "heightened alert" for the problems and conduct alleged herein.

i. The Omnicare Nursing Home "Kickback" Scheme

95. For example, beginning in the late 1990s and into the early 2000s, J&J conducted a widespread kickback scheme in order to bolster the sale of its products.

96. Specifically, Omnicare, the largest nursing home pharmacist in the United States, was used by J&J to market Risperdal® to elderly patients who suffered from dementia. Omnicare provides pharmaceuticals and related pharmacy and ancillary services to long-term health care institutions. Among the services that Omnicare engages in is the delivery of prescription drugs to patients in nursing homes and related facilities.

97. After Omnicare delivers drugs to patients, it submits reimbursement claims on behalf of those patients to their insurers. Omnicare submits approximately 65% of these claims to Medicaid. Omnicare also employs hundreds of "consultant pharmacists." Consultant pharmacists make recommendations to nursing home physicians about the drugs they should prescribe to nursing home residents. Consultant pharmacists became necessary after Congress decided to act to prevent the excessive use of antipsychotic drugs.

98. Under the amendment to the Social Security Act, psychopharmacologic drugs may be administered only on the orders of a physician and only as a part of a plan designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such Products.

99. The Department of Health and Human Services ("DHHS") implemented this amendment to the Social Security Act by mandating that a licensed pharmacist review the drug regimen of each resident and report any irregularities to the attending physician. During this review, the consultant pharmacists make recommendations to remove, change, or add medications.

100. J&J used Omnicare's pharmacist consultants as a branch of their marketing department. J&J and Omnicare both used the term "intervention" to refer to the

means by which Omnicare pharmacists and consultant pharmacists obtained physician authorization to switch nursing home patients from one drug to another.

101. For years, Omnicare's primary purpose in intervention was to drive prescriptions of Risperdal®, which was used at nursing homes as a chemical restraint. The aim was to increase spending by Medicaid and other federal health care programs on J&J Products.

102. Defendants and other J&J employees knew that it was a violation of the anti-kickback statute to offer or pay remuneration, in any form, to induce a customer like Omnicare to purchase or to recommend J&J drugs. Similarly, Defendants and other J&J employees responsible for handling the Omnicare account understood that J&J could violate the law by using payments to customers for data as a substitute for discounts or rebates that, if disclosed, could increase J&J's financial obligations to the Medicaid program. It was understood that it would be a kickback to bribe a customer like Omnicare for the sake of fostering a relationship or for goodwill, where the goal was always to convince Omnicare to purchase and to recommend J&J Products.

103. At one point, J&J and Omnicare signed a multi-year performance contract which provided "incentives to Omnicare to advocate appropriate use of J&J products." These incentives were a valuable tool for J&J to drive sales through Omnicare. For example "a $3MM investment in rebates with Omnicare," allowed J&J to gain

"$9MM in sales." J&J understood that rebates were very important to Omnicare and represented approximately 60% of Omnicare's net income. These payments, however, constituted illegal kickbacks. The value of the kickback scheme was all the Company executives considered in embracing it, disregarding not only the law but also the best interest of the public and the Company.

104. For years, J&J paid Omnicare tens of millions of dollars in market share rebates pursuant to performance agreements between the companies. Often, at Omnicare's request, J&J paid quarterly rebates to Omnicare in advance, thus effectively providing Omnicare with interest-free loans of millions of dollars.

105. The scheme caught the attention of federal authorities after two "whistleblowers" from Omnicare filed *qui tam* actions. The U.S. Department of Justice (the "DOJ") soon intervened in these actions, and Omnicare settled the claims against it for engaging in the kickback scheme for nearly $100 million.

106. In its November 7, 2005 Form 10-Q, J&J first disclosed that on September 26, 2005, the Company had received a subpoena from the United States Attorney's Office, District of Massachusetts, seeking documents related to sales and marketing of eight products to Omnicare.

ii. The DePuy Kickback Scheme

107. On September, 27, 2007, the Department of Health and Human Services Office of the Inspector General filed a criminal complaint in the United States District Court

for the District of New Jersey. Pursuant to the settlement between the government and the company, in September 2007, J&J was forced to pay $84.7 million, and its DePuy Orthopedics subsidiary was charged with conspiracy to violate the federal Anti-Kickback Statute and forced to enter into a deferred prosecution agreement and a Corporate Integrity Agreement in a combined resolution of criminal and civil charges for paying and offering inducements to orthopedic surgeons to use DePuy hip and knee joint reconstruction and replacement products.

iii. Kickbacks and Other Schemes

108. On January 15, 2010, the DOJ filed a complaint against J&J and two of its subsidiaries, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (the successor in interest to Janssen Pharmaceutical Products, L.P. and Ortho-McNeil Pharmaceutical Products, L.P.) and Johnson & Johnson Health Care System, Inc. The complaint revealed the scope and extent of J&J's violations of applicable law.

109. The DOJ's complaint accuses the Company of violating federal false claims and anti-kickback laws among others. The DOJ is seeking treble damages and restitution of J&J's unjust enrichment. In addition, a consumer class action was filed on behalf of nursing home patients harmed by J&J's and Omnicare's conduct. The Company faces significant liability from the DOJ and the consumer actions. In addition, J&J faces liability from litigation commenced by numerous states, including Arkansas, Louisiana, Pennsylvania, South Carolina and Texas, to recoup

losses suffered as a result of violations of the Medicaid Act and various state consumer protections statutes.[2]

110. J&J subsidiary OMP, LLC agreed in late April 2010 to plead guilty to a misdemeanor crime and pay a $6.15 million fine for misbranding its products. Another J&J subsidiary, Ortho-McNeil- Janssen Pharmaceuticals, Inc. also agreed in April 2010 to pay $75 million to resolve claims for its illegal promotion of its products, specifically Topamax. J&J will also enter into a wide-ranging corporate integrity agreement with the Office of Inspector General of DHHS. The agreement requires Ortho-McNeil-Janssen Pharmaceuticals, Inc. to increase transparency and accountability in its operations.

iv. Schemes to Promote Off-Label Use of Prescription Drugs

111. In addition to its widespread kickback schemes, J&J also engaged in multiple off-label marketing schemes as well. Doctors are allowed to prescribe to patients any drug they see fit, but the FDA prohibits pharmaceutical companies from promoting off-label uses to doctors. As such, drug manufacturers cannot legally label or promote drugs without prior FDA approval.

[2] For example, on December 12, 2010, following a non-jury trial between the Commonwealth of Pennsylvania and Johnson & Johnson, Judge Robert Simpson of the Commonwealth Court of Pennsylvania issued judgment against Johnson & Johnson and awarded nearly 52 million dollars in restitution and civil penalties for violating Pennsylvania's Unfair Trade Practices and Consumer Protection Law by willfully engaging in unfair or deceptive practices regarding the Commonwealth's Medical Assistance and PACE programs.

112. Over the last decade, J&J has engaged in multiple off-label marketing schemes, which has drawn the scrutiny of federal investigations. Specifically, J&J's off-label marketing schemes, including the following products: Topamax, Risperdal, Narecor, and biliary stents.

113. From approximately 1996 through 2007, J&J, through its subsidiary Cordis Corporation ("Cordis"), pursued illegal off-label marketing related to medical devices known as biliary stents. In September 2006, a *qui tam* action was filed on behalf of, *inter alia*, the United States in the Northern District of Texas, under the False Claim Act seeking damages, penalties and other remedies related to the off-label marketing concerning the biliary stents pursued by several companies, including J&J and its subsidiary, Cordis.

114. In its 2004 Annual Report, J&J reported that it was under investigation for its off-label marketing of Topamax and Risperdal. The 2003 Form 10-K was signed by Weldon, Coleman, Lindquist and Satcher, among other Board members, which demonstrates that they had notice of J&J's off-label marketing scheme. The J&J Board, however, did nothing in response to this investigation and took no actions to prevent illegal off-label marketing schemes from occurring.

115. J&J's subsidiary, Ortho-McNeil Pharmaceutical, Inc. then continued to market Topamax for off-label uses by staging "Consultant Conferences". Indeed, reports exist that over 75% of prescriptions for Topamax were off-label. J&J's off-label

marketing scheme related to Topamax caused J&J to plead guilty to a misdemeanor and pay a $6.14 million criminal fine. J&J further agreed to pay $75.37 million to resolve civil claims under the False Claims Act.

116. Likewise, the disclosure in its 2003 Annual Report did not stop J&J from continuing to promote Risperdal for off-label uses. As a result, J&J received more subpoenas and/or requests for information related to the marketing and sales of Risperdal after the initial January 2004 subpoena. In this regard, both J&J's 2005 and 2006 Annual Reports detail further subpoenas and investigations related to the off-label marketing of Risperdal.

117. In its August 2005 Form 10-Q, J&J disclosed that the government was investigating its marketing practices related to Natecor, which was a drug developed by Scios Inc. J&J bought Scios Inc. in 3003 for $2.5 billion, and knew about the Scios Inc.'s aggressive off-label marketing schemes at the time that the Board approved this acquisition.

118. In its 2007 Annual Report, J&J reported that the Company had received separate subpoenas from the U.S. Attorney's Offices located in Philadelphia, Boston, and San Francisco relating to the marketing and sales of Topamax, Risperdal, and Nactrecor through three of J&J's subsidiaries.

119. In its 2008 Annual Report, J&J disclosed that in June 2008, the company received a subpoena relating to the marketing of biliary stents by Cordis from the United States Attorney's Office for the District of Massachusetts.

120. The company faces liability exposure in the amount of billions of dollars as a result of its unlawful off-label promotion of these Products.

5. FDA Oversight of Drug Manufacturing

121. The FDA is an agency of the United States Department of Health and Human Services and is responsible for regulating drug manufacturing in the United States. Under the Federal Food, Drug, and Cosmetic Act, the FDA is charged with, among other things, ensuring that Products marketed in the United States are safe and effective, and are manufactured in accordance with current Good Manufacturing Practices ("cGMP").

122. The cGMP regulations for Products contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packaging of a drug product. The regulations are intended to ensure purity, potency, and quality of drug products, and to prevent unsafe products from reaching consumers. The FDA enforces cGMP regulations and defines them as follows:

> cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing, processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operation procedures, detecting and

investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mixups, deviations, failures, and errors. This assures that drug products meet their quality standards.

123. Under the cGMP regulations, each manufacturer sets specifications for its own products for such factors as potency, stability and purity, and puts in place a quality system that ensures those specifications are met. Critical to the cGMP process is that a company must meet its own standards. A violation of cGMP indicates that a breakdown in a manufacturer's quality system has occurred and is an indication that a company needs to take effective steps to fix the problem(s) promptly.

124. The FDA inspects facilities to ensure compliance with cGMP standards. These inspections occur on average for domestic facilities every two to three years. The FDA increases the frequency of inspections for facilities when warranted by past problems or by products that are difficult to manufacture or are especially high risk. When on site, FDA inspectors identify gaps in manufacturing standards and discuss with companies how they can fix them.

125. Firms may choose to recall products when there are cGMP violations, especially when those violations have a significant impact on product quality or safety. For products, patterns of non-compliance that put the public's health at risk leads to

appropriate enforcement action by the FDA, including warning letters, seizures, injunctions and, in the most extreme cases, criminal prosecution.

6. Lack of Quality Control at Johnson & Johnson

126. Prior to 2002, Johnson & Johnson had what was considered to be fairly high quality control standards and a thriving quality control department.

127. Despite those standards, Johnson & Johnson operating companies were still subject to criticism from the FDA from time to time.

128. For example, in 1996 the FDA issued McNeil a warning letter regarding deficiencies in McNeil's manufacturing and testing processes.

129. However, starting in approximately 2002, McNeil's quality control department began to weaken resulting from, *inter alia*, repeated layoffs of experienced quality control staff and replacement with staff that for the most part lacked technical pharmaceutical experience to the point that by 2008, a department that had been previously staffed almost entirely by experienced, full time employees, was now 50% staffed by contract workers.

130. At one point, the quality control team that tested McNeil's production lines was dubbed by McNeil employees as the "EZ Pass system."

131. In 2004, the FDA issued a report to McNeil that criticized McNeil's quality control citing multiple infractions including incomplete investigations, bad sampling practices and poor record keeping.

132. Despite the FDA's report, quality control issues continued at McNeil.

133. For example, in 2005, a batch of more than one million bottles of St. Joseph aspirin was blocked from shipment under company procedures by McNeil quality control employees because a sample was found to have a dissolution problem.

134. McNeil quality control management asked in a threatening manner if the employees liked working at McNeil, and insisted that the batch be passed by ordering that the batch be retested, the scores of the two tests averaged – in clear violation of FDA standards and a wholly improper quality control process -- so that the aspirin batches could be shipped, as is.

135. Unfortunately for consumers, the products were not sold in an "as is" condition, at a reduced price, after full disclosure of the lack of quality assurance that attended these products. Instead, they were sold at the same premium price Johnson & Johnson had always sold its St. Joseph aspirin.

136. In 2007, McNeil issued an internal memo which cited a high percentage of operator errors in every work center, as well as quality control teams who put little effort into its own processes.

137. According to four former J&J employees, prior to 2007, J&J had a corporate compliance group that oversaw all of the different companies, but it was drastically cut down in 2007 by Mr. Weldon and others. The group, helmed by Corporate Compliance Officer Brenda Davis, conducted tough biannual audits of J&J's

operating companies and helped set up "management action plans" for improving quality control. Ms. Davis, who left the company in 2007, has declined requests for comment as to the changes at J&J prior to her departure.

138. According to one former J&J executive, "[t]he whole idea was creating a Hawthorne effect: If people know they're being watched, they'll do better." But after the group was cut, some divisions lost their focus on quality. "The heads of the operating companies let their hair down," according to the former executive.

139. In February of 2008, following an FDA inspection of McNeil's Fort Washington, Pennsylvania plant, the FDA issued another report criticizing McNeil for conducting less than adequate investigations.

140. In June of 2009, the FDA issued yet another report regarding the Fort Washington facility citing mishandling of complaints and investigations.

141. Mr. Weldon has stated publicly that, in the wake of the many product recalls at J&J, he created a new position: an operations chief who was to oversee quality across J&J and report directly to him. Weldon also said the company had been busy inspecting facilities at all of its 250 operating companies at the time of the 2010 recalls, adding, "This is not a systemic problem at J&J."

142. That assertion was quickly undercut. About a week after Weldon proclaimed the situation at McNeil to be an anomaly, Johnson & Johnson issued two more recalls -- both in divisions completely separate from McNeil. One was for contact lenses

made by Vision Care, and the other involved hip implants made by DePuy (described above).

7. Recent McNeil Product Recalls

143. One of the results of Johnson & Johnson's quality control problems has been a significant number of recalls, including a string of recent recalls, including the recall of the Subject Products in this action.

144. This recent string of product recalls is notable given the sheer number of recalls over a compressed timeframe, as well as the comparableness of the underlying causes of the recalls.

i. The "Phantom" and July 2009 Recalls of Motrin

145. In August of 2008, McNeil distributed over 88,000 packages of defective Motrin IB 200.

146. McNeil subsequently discovered three months later that there was a dissolution problem with the drug in which the components of the drug dissolved at different rates rendering the product subpotent and ineffective.

147. Rather than publically recall the defective drug, McNeil hired third-party contractors to perform a clandestine phantom recall enlisting the services of consultants to quietly remove the company's defective products in order to avoid the financial and regulatory ramifications of a formal recall.

148. In a May 27, 2009 email from Defendant Peter Luther to approximately six McNeil employees, Luther endorsed the "market withdraw of Motrin" instructing "Let's make this happen ASAP."

149. McNeil's third-party contractors, including Inmar, Inc., WIS International, and CSCS, provided their employees with lists of retail outlets, and instructed them to visit those outlets, purchase all of the Motrin IB in the store, act like regular customers of the retail outlet, and to not discuss their purchases as being a recall of the product.

150. Indeed, J&J's specific instructions to the contractors hired to perform the phantom recall were to "quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave . . . THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!"

151. McNeil subsequently misrepresented to the FDA that McNeil's third-party contractors were merely performing an audit of retailers to determine whether McNeil should initiate a formal recall.

152. The FDA eventually became aware of the phantom recall when it received a copy of an internal memo containing the above instructions and confronted McNeil regarding those activities.

153. On July 9, 2009, as a result of the above, McNeil publically recalled the Motrin IB, at a delay of approximately 8 months.

154. This phantom recall, in part, spurred the House Committee on Oversight and Government Reform to conduct a Congressional investigation and hold two separate Congressional hearings in 2010 respecting, *inter alia*, this phantom recall.

ii. The September 2009 Recall

155. In May and June of 2009, the FDA discovered that from April through June 2008, McNeil had used microcrystalline cellulose, an ingredient used in liquid adult and children's Tylenol products, that had been potentially contaminated with a gram negative bacteria, *Burkholder cepacia*.

156. *B. cepacia* infections can be potentially severe, particularly in high-risk patients, such as those with underlying pulmonary disease, cystic fibrosis or compromised immune systems.

157. In July of 2009, McNeil once again utilized the services of Inmar to conduct a market assessment to determine how much product remained on store shelves.

158. McNeil's use of partial lots of the contaminated microcrystalline cellulose was determined by the FDA to be a violation of the cGMP regulations.

159. In August/September of 2009, McNeil initiated a formal recall of nearly 8 million finished bottles of product.

iii. The November and December 2009 Recalls

160. Beginning in approximately the Fall of 2008, McNeil began receiving reports regarding musty, moldy odors emanating from McNeil Tylenol pills manufactured at its Las Piedrad, Puerto Rico facility.

161. McNeil did not fully investigate these reports for approximately one year notwithstanding McNeal's obligation to notify the FDA of such reports within three days.

162. Only after the FDA insisted that McNeil conduct a thorough investigation was it discovered that the odor was the result of contamination by a product called 2,4,6-Tribromoanisole ("TBA"), a pesticide used on the wooden pallets that stored and transported packaging materials for the medications.

163. According to McNeil's own press release, the health effects of TBA have not been well studied.

164. McNeil's initial recall identified only 5 lots of product for recall.

165. However, in December 2009, McNeil expanded this recall to include all lots of the Tylenol pills.

166. These recalls were eventually expanded in January, June and July of 2010.

iv. The January 2010 Recall

167. On January 15, 2010, McNeil expanded its November and December 2009 recalls to encompass additional McNeil products, including Benadryl, Motrin, Rolaids,

Simply Sleep, St. Joseph Aspirin, and Tylenol, because of the same musty, moldy smell identified in the November and December recall.

168. The company determined that the odor was again caused by the presence of 2,4,6-tribromoanisole (TBA), the same chemical contamination that precipitated the November and December recalls.

v. The April 2010 Recall Of Infant Products

169. In April of 2010, McNeil recalled approximately 40 types of children's and infants' products manufactured at its Fort Washington, Pennsylvania plant because of filth and contamination, including acetaminophen, cellulose, nickel and chromium particulate contamination, involving McNeil's liquid infant and children's products including Tylenol, Motrin, Benadryl, Zyrtec and Tylenol Infants' Drops.

170. In addition to the particulate contamination, some of the products were found to have higher than expected dosage concentrations of the active ingredient, in effect, super-doses of the Tylenol based children's product, and in some cases substandard amounts of active ingredient.

171. McNeil recalled over 136 million bottles of product, the largest recall of children and infant medicine in history, and shut down manufacturing operations at its Fort Washington plant.

172. Just days after McNeil's decision to shut down the Fort Washington facility, FDA inspectors, performing an expedited inspection of the facility because of McNeil's past problems, identified some 20 major cGMP violations.

173. This recall directly spurred the House Committee on Oversight and Government Reform to conduct a Congressional investigation and to hold two separate Congressional hearings in 2010 regarding this specific recall, as well as the above discussed phantom recall of 2009.

vi. The June 2010 Recall

174. On June 15, 2010, McNeil expanded its January 15, 2010 recall regarding TBA contamination to include five more lots of Benadryl and Tylenol that were allegedly "inadvertently" omitted from the initial recall action.

175. These additional lots were recalled for the same moldy, musty odor that caused the January 2010 recall, contamination by TBA.

vii. The July 2010 Recall

176. On July 8, 2010, McNeil issued yet another recall related to the moldy, musty odor of the January 15, 2010 recall. This time, twenty-one lots of certain Benadryl, Tylenol Meltaways, Motrin, and Tylenol were recalled.

177. These additional lots were recalled for the same moldy, musty odor that caused the January 2010 recall, contamination by TBA.

viii. The August 2010 Recall

178. Between June 22 and July 9, 2010, the FDA conducted an inspection of Johnson & Johnson's Lancaster, Pennsylvania manufacturing plant.

179. The plant is owned by Johnson & Johnson-Merck Consumer Pharmaceuticals (a joint venture between J&J and Merck) but is operated by J&J's McNeil division.

180. On July 9, 2010, the FDA issued a "Form 483" citing problems and deficiencies regarding manufacturing practices at the plant including, but not limited to, unexplained manufacturing discrepancies, improper documentation regarding equipment malfunctions, failure to test medicine batches for quality following an equipment failure, inadequate maintenance records, unlabeled test tubes filled with product sitting on open counters, improper cleansing of utensils used in the drug making process, failure to follow up on consumer complaints, including instances of improper packaging, product type and strength packaging mix-ups, as well as complaints of product "lack of effect".

181. The FDA report cites multiple violations of cGMP regulations at the Lancaster plant, at least five of which were also observed by the FDA at McNeil's Fort Washington facility.

182. On approximately August 10, 2010, Johnson & Johnson-Merck Consumer Pharmaceuticals initiated a recall of one lot of Pepcid Complete Acid Reducer and one lot of Original Strength Pepcid AC because of potential punctures to the bottles during the packaging process.

183. However, these Pepcid products have disappeared altogether from store shelves.

ix. The October 2010 Recall

184. On October 18, 2010, McNeil recalled Tylenol 8 Hour caplets related to moldy, musty odors.

185. This recall included Tylenol products manufactured at McNeil's Fort Washington, Pennsylvania plant in March of 2010 (prior to the plant's closing).

186. The odors were again traced to contamination respecting TBA.

187. One hundred twenty eight thousand bottles of Tylenol were recalled.

x. The November 2010 Recall

188. On November 15, 2010, McNeil recalled all Benadryl tablets and junior strength Motrin caplets because of "insufficiencies in the development in the manufacturing process," as well as Rolaids Extra Strength Softchews for "uncharacteristic consistence or texture" related to crystallized sugar.

189. On November 24, 2010, McNeil recalled Tylenol multi-symptom liquid products because the packaging did not disclose alcohol as an active ingredient as well as 71,000 packages of Rolaids because of an "uncharacteristic consistency or texture" linked to improper sugar crystallization.

xi. The December 2010 Recall

190. On December 2, 2010, McNeil recalled 12 million bottles of Mylanta and 85,000 bottles of AlternaGel liquid antacid because the presence of alcohol as an active ingredient in the product that was not disclosed on the packaging.

191. On December 9, 2010, McNeil recalled 13 million packages of Rolaids Extra Strength Plus Gas Softchews and Rolaids Multi-Symptom Plus Anti-Gas Softchews because of the presence of metal and wood particles in the products.

8. FDA Meetings and Warnings

192. Over the last several years, there has been growing concern within FDA regarding the quality of McNeil's manufacturing processes.

193. Between January 2008 and April 2010, the FDA received 775 reports of adverse events, including 30 deaths, that involved J&J products. After April 30, 2010, the FDA received several hundred more complaints, including seven complaints involving deaths.

194. These concerns manifested themselves in a number of unsatisfactory FDA inspections of McNeil facilities, including its Fort Washington and Lancaster, Pennsylvania facilities, and the above-described string of consumer recalls of McNeil and Johnson & Johnson products.

195. These problems included, *inter alia*, laboratory controls, equipment cleaning processes, and a failure to investigate identified problems.

196. For example, in January of 2010, the FDA issued McNeil a warning letter expressing the FDA's serious concerns regarding McNeil's control over the quality of its products and the company's failure to aggressively investigate and correct quality problems.

197. The FDA, in prepared testimony presented at a Congressional hearing on May 27, 2010, noted that "neither upper management at Johnson & Johnson nor at McNeil assured timely investigation and resolution of the issues."

198. On February 19, 2010, the FDA took the extraordinary step of convening a meeting with senior officials from McNeil as well as McNeil's parent company Johnson & Johnson, including Defendant Peter Luther, to express the FDA's concern regarding McNeil's pattern of non-compliance.

199. The meeting was held in part to put senior officials from Johnson & Johnson on notice regarding the FDA's rising concerns about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency and safety of its products.

200. In addition, the FDA raised with Johnson & Johnson its concerns about Johnson & Johnson's oversight of McNeil considering the string of recalls of McNeil products, as well as its concern that there was a pattern of conduct including failure to report material information to the FDA in a timely manner, miscalculating

and/or misstating risks and benefits of their products, and reactive as opposed to proactive approaches to product quality problems.

201. However, and as discussed above, problems at McNeil continued including the massive 126 million bottle recall of McNeil's liquid infant and children's products in April 2010, which directly spurred the 2010 Congressional investigation and hearings.

9. FDA Reports

i. The April 30, 2010 Report

202. On or about April 30, 2010, the FDA issued a "Form 483" report (released in early May) pertaining to an inspection of the facilities of McNeil in Fort Washington, Pennsylvania (hereinafter, "the April 30, 2010 Report"). The April 30, 2010 Report was issued by the local branch of the FDA, located at the United States Customs House, Room 900, 2nd and Chestnut Streets, Philadelphia, Pennsylvania. The April 30, 2010 Report was issued by four local investigators from the FDA, and was issued to the Vice President of Operations of McNeil. The April 30, 2010 Report concerned inspections of McNeil which took place between April 19, and April 30, 2010. *See* April 30, 2010 Report at Exhibit "C" hereto.

203. As detailed in the April 30, 2010 Report, there were 20 separate "observations" made by the FDA investigators respecting deficiencies in the manufacturing operations at McNeil. These observations included the following:

a. **Observation 1**: The responsibilities and procedures applicable to the Quality Control Unit are not fully followed. The Quality Control Unit ("QA") Authorities most responsible for overseeing daily operations at McNeil did not insure that responsibilities for quality assurance were enforced. Such laps in oversight, led to raw materials with "known contaminations" to be included in the manufacture of Subject and Infant's Tylenol drug products which are still on the market today.

b. **Observation 2**: There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, problems were found with the manufacture of Infant's Dye-Free Tylenol Suspension Drops, Cherry formula.

c. **Observation 3**: Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity.

d. **Observation 4**: Control procedures are not established which monitor the output and value the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Specifically, the FDA Report observed that "control procedures used did not validate the manufacturing processes that cause variability in the characteristics of the drug product." The FDA Report cites the processing of "super potent batches" including batches for Infant's Dye-Free Tylenol Suspension Drops.

e. **Observation 5**: Written production and process control procedures are not followed in the execution of production and process control functions. Specifically, no Corrective Action Preventative Action ("CAPA") process was initiated for batches of Subject Products from May 2009 through April 2010 where "foreign material, particulate matter and/or contamination were observed." In addition, no CAPA was initiated for 46 consumer complaints that were made regarding "foreign materials, black or dark specks from June 2009 to April 2010."

f. **Observation 6**: There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, a thorough investigation or additional analytical testing was not conducted for Infant's Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8mL. Further, "vendor lots" from December 4, 2008 and December 23, 2008 were "contaminated with gram-negative organisms." These lots were used to

manufacture the following Tylenol Infant and Subject products which were marketed/distributed and remained within expiration dating as follows:

(1) Tylenol Infant's Drops, 80 mg/0.8mL, expiration date 11/10

(2) Tylenol Oral Suspension, expiration date 11/10

(3) Tylenol Oral Suspension, expiration date 11/10

(4) Tylenol Oral Suspension, expiration date 11/10

(5) Subject Tylenol Plus Cold, expiration date 11/10

(6) Subject Tylenol Plus Multi-Symptom Cold, expiration date 11/10

(7) Subject Tylenol Plus Cold, expiration date 11/10

(8) Subject Tylenol Plus Multi-Symptom Cold, expiration date 12/10

(9) Subject Tylenol Oral Suspension, expiration date 11/10

(10) Subject Tylenol Oral Suspension, expiration 11/10

(11) Subject Tylenol Plus Multi-Symptom Cold, expiration date 11/10

(12) Subject Tylenol Plus Cold & Cough, expiration date 12/10

(13) Infant's Tylenol Drops, expiration date 12/10

(14) Subject Tylenol Oral Suspension, expiration date 12/10

(15) Infant's Tylenol Drops, expiration date 12/10

(16) Infant's Tylenol Drops, expiration date 12/10

(17) Subject Tylenol Oral Suspension, expiration date 11/10

(18) Subject Tylenol Plus Cold & Cough, expiration date 12/10

(19) Subject Tylenol Oral Suspension, expiration date 12/10

(20) Subject Tylenol Oral Suspension, expiration date 12/10

(21) Subject Tylenol Plus Cold and Cough, expiration date 12/10

(22) Subject Tylenol Oral Suspension, expiration date 12/10

(23) Subject Tylenol Oral Suspension, expiration date 12/10

(24) Subject Tylenol Oral Suspension, expiration date 12/10

(25) Tylenol Infant's Drops, expiration date 12/10

(26) Subject Tylenol Plus Cold & Cough, expiration date 12/10.

g. **Observation 7**: Training is not conducted with sufficient frequency to assure that employees remain familiar with current, good manufacturing practices requirements applicable to them.

h. **Observation 8**: Procedures describing the handling of all written and all complaints regarding a drug product are not followed. Specifically, a problem in this regard was noted with respect to Infant's Dye-Free Tylenol Suspension Drops, Cherry.

i. **Observation 9**: Each container dispensed to manufacturing is not examined by a second person to assure weight and measures are correct as stated in the batch records. Specifically, a problem in this regard was noted with respect to Infant's Dye-Free Tylenol Suspension Drops, Cherry.

j. **Observation 10**: Strict control is not exercised over labeling. Specifically, labeling was accessible to all warehouse operators and personnel and was not kept in a locked environment with limited access.

k. **Observation 11**: No written testing program designed to assess the stability of drug products. Specifically, there is a lack of stability data to support the expiration date assigned to lots produced following the manufacturing change for Infant's Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8mL.

l. **Observation 12**: Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products confirm to appropriate standards of identity, strength, quality and purity. Specifically, it is unknown why the firm does not test TSA, a non-selective general microbial growth medium, during growth promotion tests.

m. **Observation 13**: The quality control unit does not have access to adequate lab facilities for testing and approval or rejection of components and drug products. Specifically, the calibration, airflow and leakage were Other. Also, during the walkthrough of the Microbiological Laboratory, many deviations were observed regarding dust, debris and lack of cleanliness. Specific deviations were observed during microbiological testing of Subject Zyrtec Sugar Free Syrup.

n. **Observation 14**: Laboratory records do not include complete records of the periodic calibration of laboratory instruments, gauges, and recording devices. Specifically, laboratory refrigerators were not calibrated adequately.

o. **Observation 15**: Written specifications for laboratory controls do not include a description of the sampling procedures used. Specifically, it does not identify the dilution to use or the microbiological swab used for swabbing equipment after cleaning for Bioburden samples.

p. **Observation 16**: Samples taken of in-process materials for determination of conformance to specifications are not representative. Specifically, the raw material sample pulled by the manufacturer is not a representative sample.

q. **Observation 17**: Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected. Specifically, there were not separate or defined areas to prevent contamination or mix-ups.

r. **Observation 18**: Components are not microscopically examined when appropriate. Specifically, there are no monthly trend reports.

s. **Observation 19**: Records are no kept for the maintenance and inspection of equipment.

t. **Observation 20**: The persons double-checking the cleaning and maintenance are not dating and signing or initialing the equipment cleaning and use log

ii. The December 9, 2010 Report

204. On or about December 9, 2010, the FDA issued another "Form 483" report pertaining to an inspection of the McNeil's Fort Washington, Pennsylvania facility (hereinafter, "the December 9, 2010 Report"). The December 9, 2010 Report was issued by the local branch of the FDA, located at the United States Customs House, Room 900, 2nd and Chestnut Streets, Philadelphia, Pennsylvania. The December 9, 2010 Report also was issued by four local investigators from the FDA, and was issued to Hakan Erdemir, McNeil Consumer Health Care's Vice

President of Operations. The December 9, 2010 Report concerned inspections of McNeil which took place between October 27, and December 9, 2010. *See* December 9, 2010 Report at Exhibit "D" hereto.

205. As detailed in the December 9, 2010 Report, there were seven (7) separate "observations" made by the FDA investigators respecting deficiencies in the manufacturing operations at McNeil. These observations included the following:

a. **Observation 1**: Procedures describing the handling of written and oral complaints related to drug products are deficiently written.

b. **Observation 2**: Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and the drug product.

c. **Observation 3**: There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

d. **Observation 4**: Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

e. **Observation 5**: Investigations of an unexplained discrepancy and a failure of a batch to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

f. **Observation 6**: Written records are not always made of investigations into unexplained discrepancies.

g. **Observation 7: The responsibilities and procedures applicable to the quality control unit are not fully followed.** (Emphasis added)

10. Prior FDA Reports

206. The 2010 FDA Reports and the slew of recalls of McNeil products are not the first time that McNeil has been cited by the FDA. In fact, according to the FDA's January 11, 2006, Enforcement Report ("Enforcement Report"), many of the same Recalled Subject Products involved in the subject recall were cited by the FDA over four (4) years ago for the same reasons that they were cited in the April 30, 2010 FDA Report.

207. Specifically, the January 11, 2006 Enforcement Report details that NDC # 50590-604-04, Children's Motrin Bubblegum Suspension 4 oz bottle, one of the Recalled Subject Products, was the subject of FDA Recall # D-081-6. The Enforcement Report states further that McNeil was notified about the recall by letter dated September 19, 2005, and that the recall was necessary because of "presence of particulate matter" in the product. As detailed above, the presence of particulate matter in this Recalled Subject Product is the subject of Observation No. 5 in the April 30, 2010 FDA Report. Indeed, as detailed in the April 30, 2010 FDA Report, there were 46 consumer complaints about particulate matter after the Enforcement Report issued in September 2005, and still Defendants did not fix the problem at McNeil. Indeed, the manufacture and sale of Subject Products with particulate matter in them after 2005 was reckless.

208. Likewise, the January 11, 2006 Enforcement Report details two other Recalled Subject Products that were the subject of citations and recalls for the "presence of foreign substance": NDC # 50580-407-04, Bubblegum Yum Flavor Subject Tylenol Oral Suspension 4 oz bottles (which was the subject of Recall # D-090-6) and NDC # 50580-123-04, Cherry Blast Flavor Subject Tylenol Oral Suspension 4 oz bottles (which was the subject of Recall # D-091-6).

209. Lastly, the January 11, 2006 Enforcement Report states that NDC #50580-601-04, referring to Original Berry Flavor Children's Motrin Oral Suspension 4 oz bottles, was the subject of Recall # D-088-6. That Recalled Subject Product was recalled previously in 2005 for being "subpotent". In contrast, many of the Subject Products in this case are currently being recalled for being "super-potent", meaning that they contain too much of the active ingredient as opposed to too little. *See* April 30, 2010 FDA Report Observation No. 4.

11. Congressional Investigations & Hearings

210. On May 5, 2010, as a direct result of the April 30, 2010 recall of McNeil's Subject Products, as well as the 2009 phantom recall, the House Committee on Oversight and Government Reform opened an investigation and subsequently held two separate hearings in which Johnson & Johnson's highest level executives were asked to appear and testify.

211. With respect to the investigation, Chairman Edolphus Towns (D. New York) stated that he was "deeply concerned about the recall of popular pediatric medications widely used by infants and children across the country."

212. Representative Darrell Issa (R-California) has been quoted and saying, "It is a moral outrage for a company specifically marketing its products for children to allow a culture of neglect and irresponsibility to taint the medicines that parents and physicians trust to help children get well."

i. The May 27, 2010 House Committee on Oversight and Government Reform Hearing

213. On May 27, 2010, the House Committee held its initial hearing to determine what went wrong respecting, *inter alia*, McNeil's pediatric products.

214. Among those providing testimony was Joshua M. Sharfstein, MD, Principal Deputy Commissioner, U.S. Food and Drug Administration ("FDA"), Department of Health and Human Services, who confirmed that the FDA had had for some time growing concerns about the quality of McNeil's manufacturing processes, and that the FDA had in fact scheduled expedited inspections, particularly with respect to McNeil's Fort Washington facility, issued formal warning letters, and took the extraordinary step of holding meetings with senior officials of both McNeil and J&J regarding those concerns.

215. Notwithstanding the FDA's comments, Defendant Colleen A. Goggins, Worldwide Chairman of the Johnson & Johnson Consumer Group stated that "[a]cross our

organization, we believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers, and all others who use our products and services", a reference to the J&J Credo.

216. Ms. Goggins further admitted that with respect to the April 30, 2010 recalled products, that J&J and McNeil had "not lived up to that responsibility."

217. However, Ms Goggins attempted to minimize the problems by claiming that there were no health risks related to use of the recalled products and thereafter attempted to downplay the particulate contamination by characterizing it as "minute".

218. Chairman of the Committee, Edolphus Towns, noted that J&J was not forthcoming in their testimony, and that what the Committee had heard from J&J was troubling in that there was not just one recall but rolling recalls, a phantom recall, a plant shut down and management firings, among other things at McNeil, and that the Committee intended to pursue the issue further.

ii. The September 30, 2010 House Committee on Oversight and Government Reform Hearing

219. On September 30, 2010, the House Committee held a second hearing, this time regarding both the children's product recall and the phantom recall.

220. Chairman Towns noted that the second hearing was necessary because the Committee had obtained documents that raised "troubling" questions regarding the accuracy of J&J 's May 27, 2010 testimony and the extent of the phantom recall,

including documents showing the company president giving the go-ahead for the phantom recall.

221. Indeed, Joshua M. Sharfstein, MD, Principal Deputy Commissioner for the FDA reiterated his earlier concerns with McNeil by that "[a]ll facilities associated with McNeil [had] been inspected at least once within the last year" and that the FDA had found "inspectional deficiencies of varying degrees of seriousness at all of these facilities", and that one common problem found across all McNeil facilities was a "failure to investigate and correct product problems in a prompt and thorough manner." (emphasis added)

222. With respect to the phantom recall, Defendant William C. Weldon, Chairman and CEO of J&J admitted that McNeil had secretly bought up defective products without informing regulators and consumers of its actions and that it was clear to him that "McNeil should have handled things differently."

223. In addition, Mr. Weldon apologized for not maintaining "high quality standards" with respect to the recalled Subject and infants' products, admitted that McNeil and J&J had "let the public down" by not meeting those standards, and accepted "full accountability for the problems at McNeil."

12. Johnson & Johnson Partial "Refund" Offer

224. Johnson & Johnson purports to offer refunds or product coupons to consumers who purchased the recalled Subject Products[3].

225. To receive a refund or coupon, consumers are instructed to complete and submit a web based "form in full with the required information." *Id.*

226. The purported refund offer is completely silent as to how J&J will calculate refund amounts, if any, or the specific amounts to be paid.

227. Consumers are thereafter required to provide specific information related to their purchases of the Subject Products including the product name, National Drug Code ("NDC") number, lot number and expiration date. *Id*.

228. The form notes that the "NDC numbers can be located on the label of the bottle above the brand name" and that the "[l]ot numbers and Expiration dates can be found on back/side label of the bottle." *Id.* These numbers cannot be located if consumers have discarded the Subject Products, as the J&J Defendants specifically advise consumers to do.

229. There do not appear to be any provisions for consumers who did not retain the product bottle, notwithstanding the J&J Defendant's specific directive to consumers to dispose of the product.

[3] See www.mcneilproductrecall.com/page.jhtml?id=/include/replacement_coupon.inc, last visited January 4, 2011.

230. Moreover, it appears that the J&J Defendants stopped reporting the NDC's for the Subject Products, thereby depriving Plaintiffs and the Class of one key piece of information required to obtain a coupon or partial class refund.

231. As described more fully herein, and based on limited documents produced by J&J [at Exhibit "B" hereto], the partial recall program established by the J&J and Individual Defendants was deficient in many respects and failed to meet the demands of Plaintiffs and the Class in this case under their claims asserted.

232. For instance, the recall was made only as to select products of Defendants' choosing, and did not include all Subject Products covered by this lawsuit.

233. Of the narrow subset of Subject Products subject to the recall and eligible for the worthless coupons or partial cash refunds being offered, consumers could only recover if they were able to provide the NDC for the product, along with the specific lot numbers and expiration dates only available through the product packaging. That means that, if consumers used up the products prior to the announcement of the recall, or followed the advice given by the J&J Defendants on the J&J website and discarded the unused products, or were otherwise unable to provide all the information required by Defendants (because of the unavailability of NDC's on the internet), consumers would have no means of satisfying Defendants' stringent eligibility criteria for receipt of a worthless coupon or partial cash refund.

234. In response to this Court's directive, the J&J Defendants produced 98 pages of documents relating to their product recall. *See* documents labeled McNeil-MDL-0000001-98 at Exhibit "B" hereto. As the Court can see by a quick perusal of the documents, they consist largely of printouts from the J&J Defendants' website, at various times between May and December 2010. *Compare* McNeil MDL-0000001 *with* McNeil-MDL-0000003. Very few documents have been produced from Defendants' internal files relating to the voluntary product recall.

235. J&J produced 9 pages from what appears to be a blog maintained by J&J respecting the recall. *See* McNeil-MDL-0000003-9. Approximately 18 comments were submitted by consumers beginning May 1st and ending May 19, 2010. The comments reveal several important facts for purposes of this case.

236. First, one of the earliest commenters, a man named Evan D. Owen, complained that "your recall announcement at 9:15 p.m. on a Friday night was deliberate to minimize media exposure. You know very well consumers watch very little news during the weekend compared to a weekday. Your hopes that this will be "played out" come Monday morning is completely irresponsible. Your press release was very vague, not dealing what products have which issues nor how extensive these issues have become. There are a lot of angry parents whom need additional information and I hope you'll come clean. Until that time, I will do whatever I can to b[ring] the REAL story to light." McNeil-MDL0000006. To bring this "real

story to light", Mr. Owen started a group on Facebook "so that parents could voice their concerns in regard to [J&J's] recall."

237. In response to Mr. Owen's comment, Marc Monseau, a J&J executive, responded that "the reason the press release was issued late on Friday was because we always work in alignment with the US [FDA] before issuing any statements." Remarkably, Mr. Owen wrote back asking Mr. Monseau to "provide him with the contact person at the FDA" so that he could "confirm [that J&J's] press release coming out at 9:15 p.m. Friday night was the result of being in alignment with them." Mr. Monseau never responded to this request.

238. Mr. Monseau, on behalf of the J&J Defendants, also acknowledges that many consumers "had trouble getting in touch with someone to speak with at our customer information line" and acknowledges "the frustration, inconvenience and concern that this caused" people searching for information about the recall. In other words, the recall wasn't working in getting consumers answers to important questions they had, let alone fully compensating them for their losses.

239. Importantly, Mr. Owen's response to Mr. Monseau complained that the folks handling the customer service lines for the recall were "data collectors and coupon issuers," bolstering Plaintiffs' claims that the initial focus of the recall and refund effort encouraged coupons, not cash (McNeil-MDL0000007).

240. Several "bloggers" complained about a lack of transparency and honest information from J&J in the wake of the recall.

241. And, as to the refund program, the bloggers all report that J&J was encouraging a coupon first. One individual named "Aaron L" is reported as saying "has anyone else had issues with the amount of their refund? I had to destroy 6 various McNeil products and received a check for $10.00." This complaint proves Plaintiffs' point in this lawsuit that the J&J refund program has inadequately compensated Plaintiffs and the Class for their actual out of pocket losses.

242. A document dated May 13, 2010, and signed by individual Defendant, Peter Luther, attaches a Q&A "addressing some common questions" J&J received. One question states, "Can patients get a refund or coupon?" The response is that "McNeil is offering two options" one of which was a "refund for the average retail price of the product". McNeil-MDL-0000012-13. No further explanation is provided as to how Defendants determined the "average retail price", but it is clear from other documents that such price did not include applicable taxes. This fact is revealed by two documents produced by the J&J Defendants, McNeil-MDL-0000016 (reporting the retail prices for children's products at even increments), and McNeil-MDL-0000018 (same). A later document produced by the J&J Defendants (McNeil-MDL-0000040-41) reveals a discrepancy between what the J&J Defendants calculated to be the average retail price at various points in time.

243. The earlier-referenced documents reveal a date of May 2, 2010. However, McNeil-MDL-0000040-41, entitled "U.S. Peds Recall Product List 05/11/10" was prepared 9 days later. Discrepancies exist in a number of Recalled Subject Products, including Children's Tylenol 2 oz. (listed at $4.00 on May 2nd and $4.50 on May 11th), Children's Benadryl 4 oz. (listed as $6.00 on May 2nd and $6.50 on May 11th), and Infant Motrin 1 oz. (listed as $9.20 on May 2nd and $10. 39 on May 11th). These variations show that Defendants did not properly value the retail prices paid by Plaintiffs and the Class and did not properly compensate them for their out of pocket payments.

244. Furthermore, in support of Plaintiffs' claim that Defendants first pushed worthless coupons on consumers as part of their recall/refund, McNeil-MDL-0000063 entitled "Recall Update: Change to Compensation Policy" points out that "Effective immediately, we want to ensure consumers looking for compensation are offered a **check first** and then a coupon." Such a change as part of a "training alert" would only have been necessary if Defendants were insisting that their customer service representatives offer a coupon first, as alleged by Plaintiffs.

245. In sum, the documents produced by the J&J Defendants support Plaintiffs' claim that the partial refund offered by the J&J and Individual Defendants did not fully and fairly compensate Plaintiffs and all members of the Class for their losses, which losses this lawsuit seeks to recover.

V. CLASS ACTION ALLEGATIONS

246. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this action on behalf of themselves and a Class, defined as follows:

> All individuals in the United States and Other Places, who, for purposes other than resale, purchased/or paid for Subject Products from at least December 2008 through the present. For purposes of the Class definition, individuals "purchased" Subject Products if they paid all or part of the purchase price, including taxes.

247. Excluded from the Class are Defendants and any entities in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors. Also excluded from the Class are any judges or justices to whom this action is assigned, together with any relative of such judge(s) or justice(s) within the third degree of relationship, and the spouse of any such person.

248. Plaintiffs contend that this suit is properly maintainable as a class action pursuant to Rules 23(b)(1), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure.

A. NUMEROSITY

249. The Class consists of consumers throughout the United States, including its territories, and Other Places, making individual joinder impractical, in satisfaction of Rule 23(a)(1). Plaintiffs are unable to provide an approximation of the number of potential consumer Class members, but note that the dollar sales amount of the Defendants' Subject Products was in the hundreds of millions of dollars throughout

the relevant time period. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court.

B. TYPICALITY

250. The claims of the representative Plaintiffs are typical of the claims of the Class, as required by Rule 23(a)(3), in that Plaintiffs, like all consumer Class members, purchased Subject Products. Like all Class members, Plaintiffs have been damaged by Defendants' misconduct, in that, among other things, they paid for Subject Products to treat their ailments and those of their young children, while Defendants were actively engaged in their unlawful manufacturing marketing, sales and concealment scheme.

C. COMMON QUESTIONS OF LAW AND FACT

251. The factual and legal bases of Defendants' unlawful manufacturing, distribution, marketing and sales scheme and conspiracy, and the concealment of the same, are common to all members of the Class and represent a common thread of misconduct resulting in injury to Plaintiffs and all members of the Class.

252. Questions of law and fact common to Plaintiffs and the Class abound in this case, and those questions predominate over any questions affecting individual Class members, within the meaning of Rule 23(a)(2) and (b)(3). These common questions of law and fact include, but are not limited to, the following:

(a) Whether Defendants engaged in the manufacturing, distribution, marketing, and sales scheme and conspiracy, and the concealment of the same, alleged herein;

(b) Whether Defendants engaged in an unfair and deceptive scheme of improperly manufacturing, distribution, marketing, and selling any of the Subject Products that were not medically safe, efficacious, effective, useful or worth what consumers paid;

(c) Whether Defendants engaged in a pattern and practice with the intent of misleading and deceiving Plaintiffs and the Class and with the intent of suppressing the unlawful conduct;

(d) Whether Defendants violated the consumer fraud laws;

(e) Whether Defendants violated RICO;

(f) Whether Defendants violated the Magnuson-Moss Warrant Act;

(g) Whether Defendants Subject Products were defective as a result of a manufacturing defect, failure to warn and/or as a result of a breach of the implied warranty of merchantability and fitness for a particular purpose;

(h) Whether Defendants were negligent in the performance of their duties;

(i) Whether Defendants committed fraud;

(j) Whether Defendants engaged in a conspiracy, concert of action and/or aiding and abetting;

(k) Whether Defendants unjustly enriched themselves at the expense of Plaintiffs and members of the Class;

(l) Whether Plaintiffs and the Class are entitled to compensatory damages, and, if so, the nature of such damages;

(m) Whether Plaintiffs and the Class are entitled to statutory damages;

(n) Whether Plaintiffs and the Class are entitled to punitive damages, treble damages or exemplary damages and, if so, the nature of such damages;

(o) Whether Plaintiffs and the Class are entitled equitable relief pursuant to their claim for unjust enrichment or otherwise; and

(p) Whether Plaintiffs and the Class are entitled to an award of reasonable attorneys' fees, prejudgment interest, post-judgment interest and costs of suit.

D. ADEQUACY

253. Plaintiffs will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience and expertise in the prosecution of both statewide and nationwide class actions. Plaintiffs and their counsel are committed to the vigorous prosecution of this action on behalf of the Class and have the financial resources to do so. Neither Plaintiffs nor counsel have any interests adverse to those of the Class.

E. SUPERIORITY

254. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.

255. A class action procedural device is superior to an out-of-court, voluntary private settlement program, or other forms of administrative relief, joinder, intervention, consolidation, or individual actions. None of these potential alternatives offer a superior mechanism for the fair and efficient adjudication of the instant case to the existing class action device, which offers streamlined adjudication of the rights of all similarly situated consumers by experienced counsel advocating on their behalf before an experienced jurist.

256. A defendant-sponsored voluntary private settlement program is inferior to this class action as it avoids objective and unbiased judicial supervision of the claims adjudication process. Moreover, Defendants' private settlement program does not offer the layer of accountability inherent in class actions of this nature, including court-appointed counsel in leadership positions, court-approved settlement evaluation and approval, court-approved notice, and a court-approved claims administrator, among other things.

257. The Defendants' voluntary private settlement program offering worthless coupons on future products that may never be available avoids the heightened judicial scrutiny of the fair, reasonable and adequate standards required by the Class Action Fairness Act and the revised Rule 23.

258. The prosecution of separate actions by or against individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with

respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for the Defendants which would, as a practical matter, be dispositive of the interests of the other class members not parties to the adjudications or would substantially impair or impede their ability to protect their interests.

259. Defendants also have acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate declaratory and other relief with respect to the Class as a whole.

VI. CLAIMS FOR RELIEF

A. Count I: Violations of Consumer Fraud Laws

260. This Count is asserted by each named class representative and the members of the Class.

261. Defendants are incorporated, maintain their principal places of business, reside, and/or maintain business operations in either California, Georgia, Massachusetts, Michigan, North Carolina, New Jersey or Pennsylvania. In addition, named class Plaintiffs reside in Arizona, California, Florida, Illinois, Kentucky, Louisiana, Massachusetts, Nebraska, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Texas, Washington and West Virginia. Each of these states has enacted statutes to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. The statutes of these

states, legally and substantively common, provide consumers with a private right of action, as follows:

Arizona:	A.R.S. § 44-1522(A), *et seq.*
California:	Cal. Civ. Code §§ 1750, Bus. & Prof. Code § 17200, *et seq.* and 17500, *et seq.*
Florida:	Fla. Stat. Stat. §§ 501.201-501.213
Illinois:	815 ILCS § 505/1, *et seq.*
Kentucky:	K.R.S. 367.170, *et seq.*
Louisiana:	La. Rev. Stat. Ann. § 51:1405
Massachusetts:	M.G.L.A. § 93A *et seq.*
Nebraska:	Neb. Rev. Stat. § 59-1601, *et seq.*
New Jersey:	N.J. Stat. Ann. §§ 56:8-1 - 56:8-24
New York:	N.Y. Gen. Bus. L. §§ 349-350
North Carolina:	N.C.G.S.A. § 75-1.1 *et seq.*
Ohio:	Ohio Rev. Code § 1345.01 *et seq.*
Pennsylvania:	73 Pa. Stat. § 201-1 *et seq.*
Texas:	Tex. Bus. & Com. Code §§ 17.41 – 17.63
Washington:	RCW 19.86.010, *et seq.*
West Virginia:	W.VA. Code § 46A-6-101, *et seq.*

262. Defendants' conduct, as alleged in this Consolidated Amended Complaint, constitutes unfair and deceptive acts or practices, unconscionable practices, fraud, false pretense, false promise, misrepresentation, concealment, suppression or omission of material fact in violation of these statutes. Defendants' continuing violations include, among others:

(a) Failing to disclose material facts in the conduct of trade or commerce in that they have not disclosed the truth about their Subject Products, the deficiencies in their manufacturing processes, citations by the FDA and other acts and omissions;

(b) Making false or misleading statements of fact concerning the Subject Products in that they have not disclosed the truth about their Subject Products, the deficiencies in their manufacturing processes, citations by the FDA and other acts and omissions;

(c) Knowingly making false representations in a transaction by representing that the Subject Products were of a quality and condition that they did not possess at the time of sale.

263. Defendants willfully engaged in such practices knowing them to be deceptive and with the intent that Plaintiffs and the Class would rely thereon.

264. The wrongful conduct alleged in this Consolidated Amended Complaint occurs, and continues to occur, in the ordinary course of Defendants' business or occupation and has caused great harm to Plaintiffs and the Class, who were foreseeable and direct victims.

265. Defendants have injured the public interest, and Defendants' actions continue to pose a threat to the public.

266. As a direct and legal result of Defendants' misleading, deceptive, unfair, false and fraudulent trade practices, Plaintiffs and the Class have sustained damages.

1. **Violations of Arizona Consumer Fraud Act (A.R.S. § 44-1522(A))**

267. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

268. Plaintiffs and the Class are consumers who purchased the Subject Products for personal use. Arizona has enacted statutes to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. Arizona allows consumers a private right of action under these statutes.

269. A.R.S. § 44-1522(A), provides in part:

> The act, use, or employment by any person of any deception, deceptive act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice.

270. Defendants, by engaging in the conduct described above, perpetrated in connection with the sale of the Subject Products, violated and continue to violate A.R.S. § 44-1522(A).

271. The deceptive, false, and/or fraudulent conduct included misrepresentations, concealment and other non-disclosures of material facts by the Defendants which caused the Plaintiffs and the Class to suffer losses within the meaning of the aforementioned Arizona statute.

272. In addition, the Defendants' use of media to promote the sale of their Subject Products through false and deceptive representations, and other conduct as alleged above, constitutes unfair competition and unfair, deceptive, untrue, or misleading advertising within the meaning of the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*

273. Defendants' untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit Plaintiffs (and their children) and the Class; (b) unsafe, likely causing Plaintiffs and their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

274. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

275. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without the disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under Arizona's consumer protection laws.

276. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Arizona, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

2. **Violations of California Business & Professions Code § 17200 *et seq.* ("The Unfair Competition Act")**

277. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

278. Section 17200 of the California Business & Professions Code prohibits unfair competition by prohibiting any "unlawful, unfair or fraudulent business acts or practice..."

279. Plaintiff and the Class have been injured as a direct and proximate result of Defendant's unfair, unlawful, and/or fraudulent business practices as alleged above, and these proceedings are instituted pursuant to section 17203 and 17204 of the California Business and Professions Code individually, to obtain relief from Defendants' business acts and practices that violate the Unfair Competition Act.

280. The Defendants' conduct as alleged herein violates the Unfair Competition Act. The business acts and practices of Defendants constituted and constitute a common continuous and continuing course of conduct of unfair competition by means of unfair, unlawful and/or fraudulent business acts or practices within the meaning of

the Unfair Competition Act including, but in no way limited to, representing to Plaintiffs, the Class and the general public that said Subject Products were safe, fit, effective and cost effective for use, knowing that said representations were false, and concealing from the Plaintiffs, the Class and the general public that said products had a serious propensity to cause injuries to users by virtue of, *inter alia*, manufacturing quality control problems at the Fort Washington Plant and other facilities in violation of FDA rules and regulations.

281. Defendants' business acts and practices are unfair, unlawful, and/or fraudulent to consumers in the State of California within the meaning of Business and Professions Code section 17200.

282. Defendants' acts and practices are fraudulent within the meaning of Business and Professions Code section 17200.

283. Defendants' business acts and practices, as described above, whether or not in violation of Business and Professions Code section 17200 *et seq*. and whether or not the product of concerted action are otherwise unfair, unconscionable, unlawful and/or fraudulent.

284. The illegal conduct alleged herein is continuing and there is no indication that Defendants will not continue such activity into the future.

285. The business acts and practices of Defendants, as alleged herein, constituted and constitute a common continuous and continuing plan and scheme to deceive the

public by means of unfair, unlawful and/or fraudulent business practices affecting the trade or commerce in insurance products in violation of California Business & Professions Code, Section 17200, *et seq*., and federal and California law.

286. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures, as alleged herein, constituted and constitute unfair, unlawful and/or fraudulent business practices within the meaning of California Business & Professions Code, Section 17200 *et seq*.

287. Plaintiff and the members of the Class are entitled to relief, including full restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits which may have been obtained by Defendants as a result of such business acts or practices and enjoining defendants to ease an desist from engaging in the practices described herein.

288. To prevent unjust enrichment pursuant to the California Business and Professions Code, Defendants should be required to place all disgorged illegal gains and profits in a constructive trust to be established by the court for the purpose of making full restitution to all injured parties.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

3. Violations of the Florida Deceptive and Unfair Trade Practices Act

289. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

290. Plaintiffs and the Class are consumers who purchased Subject Products for personal use. The State of Florida has enacted laws to protect consumers against unfair methods of competition, unconscionable acts or practices, and/or unfair or deceptive acts or practices in the conduct of any trade or commerce pursuant to the Florida Deceptive and Unfair Trade Practices Act. Fla. Stat. § 501.201 (2006), *et seq.*, Florida allows consumers a private right of action under such law.

291. By the misrepresentations as to, non-disclosure, and concealment of material facts as alleged above, the Defendants have engaged in unfair methods of commerce, unconscionable acts and practices, and/or unfair or deceptive acts or practices, and deceived and continue to deceive consumers like the Plaintiffs and the Class.

292. The unfair methods of commerce, unconscionable acts and practices, and/or unfair or deceptive acts or practices committed by the Defendants occurred with respect to the marketing and sales of the Subject Products, and therefore occurred in trade or commerce and thus constitute a violation of the Florida Deceptive and Unfair Practices Act. § 501.204, *et seq.*

293. The conduct alleged herein and as set forth above was "willful" within the meaning of the Florida Statute and constitutes a violation thereof. See §501.2075 and § 501.203(3).

294. Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the children of Plaintiffs and the Class; (b) unsafe, likely causing children of Plaintiffs and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

295. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

296. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under the Florida Deceptive and Unfair Trade Practices Act.

297. Plaintiffs and the Class further seek any available statutory damages, fees and costs as prescribed by Florida Statutes §501.211(2) and §501.2075.

298. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Florida, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

4. Violations of the Illinois Consumer Fraud and Deceptive Business Practices Act

299. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

300. Plaintiff and the Class are consumers who purchased Subject Products for personal use. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, prohibits unfair methods of competition and unfair and deceptive acts or practices, including, *inter alia*, "the use or employment of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression or omission of any material fact, whether any person has in fact been misled, deceived, or damaged thereby." The Illinois Consumer and Deceptive Business Practices Act is to be liberally construed.

301. In distributing, promoting, marketing, and selling Subject Products to Plaintiffs and the Class, and in otherwise engaging in the conduct more fully described herein

with respect to Subject Products, the Defendants are engaging in trade or commerce directly or indirectly affecting Plaintiffs and the Class within the meaning of the Illinois Consumer Fraud and Deceptive Business Practices Act.

302. By the untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products alleged above, the Defendants deceived and continue to deceive consumers, such as Plaintiffs and the Class. This conduct constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of the Illinois Consumer Fraud and Deceptive Business Practices Act and warrants the application of the laws of Illinois to Defendants in this Court.

303. The unfair methods of competition, unfair and deceptive misleading misrepresentations, and non-disclosure of material facts by the Defendants caused the Plaintiffs and the Class to suffer losses within the meaning of the Illinois Consumer Fraud and Deceptive Business Practices Act. Specifically, Defendants' untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products caused Plaintiffs and the Class to purchase Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit Plaintiffs, their children and the Class; (b) unsafe, likely causing children of Plaintiff and the Class to suffer side effects or longer durations of illness due to the

ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

304. But for the misrepresentation and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased Subject Products.

305. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without the disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful products and alternative courses of treatment. Such conduct is actionable under the Illinois Consumer Fraud and Deceptive Business Practices Act.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

5. Violations of Kentucky Consumer Protection Act, KRS 367.170

306. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

307. Plaintiffs and the Class are consumers who purchased Subject Products for personal use. The State of Kentucky has enacted laws to protect consumers against

unfair, deceptive or fraudulent business practices, unfair competition and false advertising. KRS 367.170 (1) provides: "Unfair, false, misleading or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

308. By the misrepresentations as to, non-disclosure, and concealment of material facts as alleged above, the Defendants have engaged in "unfair, false, misleading or deceptive acts or practices, in violation of KRS 367.170.

309. The misrepresentations, non-disclosure and concealment occurred with respect to the marketing and sales of Subject Products, and therefore occurred in trade or commerce.

310. Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

311. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

312. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under Kentucky's Consumer Protection Law.

313. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Kentucky, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

6. Violations of Louisiana Unfair Trade Practices Law (LUTPA) and Consumer Protection Law

314. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

315. Plaintiffs and the Class are consumers who purchased the Subject Products for personal use. The State of Louisiana has enacted Statutes to protect consumers against unfair, deceptive or fraudulent trade or business practices, unfair competition and false advertising.

316. LSA-R.S. § 51:1405 provides in part: "A. Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

317. By the acts and omissions set forth herein, the Defendants' conduct violates the Statute referenced in the previous paragraph.

318. Defendants, by engaging in the conduct described above, perpetrated unfair, deceptive or fraudulent trade or business acts or practices, unfair competition, and false advertising in connection with the sale of the Subject Products, and have violated and continue to violate LSA-R.S. § 51:1401, *et seq*., including LSA-R.S. § 51:1405(A).

319. Defendants, by engaging in the conduct described above, perpetrated unfair, deceptive or fraudulent trade or business acts or practices, unfair competition, and false advertising in connection with the sale of the Subject Products, and deceived and continue to deceive Consumers like the Plaintiff and the Class in violation of LSA-R.S. § 51:1401, *et seq*., including LSA-R.S. § 51:1405(A).

320. The unfair, deceptive, false and/or fraudulent conduct of the Defendants, including misrepresentations, concealment and other non-disclosures of material facts, caused the Plaintiffs and the Class to suffer losses within the meaning of the aforementioned Louisiana Statute. LSA-R.S. § 51:1401, *et seq.*

321. The misrepresentations, non-disclosure and concealment occurred with respect to the marketing and sales of Subject Products, and therefore occurred in trade or commerce.

322. Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

323. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

324. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under Louisiana's Unfair Trade Practices Law (LUTPA) and consumer protection laws.

325. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Louisiana, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

326. Plaintiffs and the Class Members seek damages as permitted by law for their injuries caused by Defendants' intentional and/or flagrant violations pursuant to these statutes.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

7. **Violations of Massachusetts Consumer Fraud Law**

327. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

328. Plaintiffs and the Class are consumers who purchased Subject Products for personal use. The State of Massachusetts has enacted laws to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising.

329. M.G.L.A 93A, §2 provides: "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

330. By the misrepresentations as to, non-disclosure, and concealment of material facts as alleged above, the Defendants have engaged in unfair or deceptive acts or practices, and deceived and continue to deceive consumers like the Plaintiffs and the Class. This conduct constitutes unfair competition and/or unfair, deceptive acts or fraudulent acts or practices in violation of M.G.L.A 93A, *et seq.*, including § 2.

331. The misrepresentations, non-disclosure and concealment occurred with respect to the marketing and sales of Subject Products, and therefore occurred in trade or commerce.

332. Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment

for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

333. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

334. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under Massachusetts Consumer Protection Law.

335. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Massachusetts, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

8. Violations of Nebraska's Consumer Protection Act Neb. Rev. St. § 59-1601 *et seq.*

336. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

337. Nebraska has enacted statutes to protect consumers against unfair, deceptive and fraudulent acts or practices. *See* Neb. Rev. St. § 59-1601 *et seq*.

338. Plaintiffs and the Class are persons under the Act. *See* Neb. Rev. St. § 59-1601(1).

339. The Act protects Plaintiffs and the class because Defendants engaged in the sale of assets, services or commerce directly or indirectly affecting the people of the State of Nebraska. Neb. Rev. St. § 59-1601(2).

340. Nebraska's Consumer Protection Act provides in pertinent part that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce shall be unlawful." Neb. Rev. St. § 59-1602.

341. By the misrepresentations as to, non-disclosure, and concealment of material facts as alleged above, the Defendants have engaged in "[u]nfair methods of competition and unfair or deceptive acts or practices" in violation of the Act.

342. Defendants, by engaging in the conduct described above, perpetrated in connection with the sale of the Subject Products, violated and continue to violate Nebraska's Consumer Protection Act.

343. The unfair and/or deceptive acts or practices include misrepresentations, concealment and other non-disclosures of material facts by the Defendants which caused the Plaintiffs and the Class to suffer losses within the meaning of the aforementioned Code.

344. In addition, the Defendants' use of media to promote the sale of their drugs through false and deceptive representations, and other conduct as alleged above, constitutes unfair competition and unfair, deceptive, untrue, or misleading advertising within the meaning of the Act, 46A-6-101.

345. Defendants' untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase Subjects Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

346. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

347. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful products and alternative courses of treatment. Such conduct is actionable under Nebraska's Consumer Protection Act.

348. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Nebraska, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

9. **Violations of the New Jersey Consumer Fraud Act**

349. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Amended Complaint, as if fully set forth herein.

350. Plaintiffs and members of the patients Class are consumers who purchased Subject Products for personal use. New Jersey has enacted laws to protect consumers against unfair, deceptive or unconscionable business practices, unfair competition

and false advertising. New Jersey allows consumers a private right of action under such laws.

351. By the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products alleged herein, Defendants deceived and continue to deceive consumers, such as Plaintiffs and the Class. This conduct constitutes unlawful, unfair, deceptive acts and/or unconscionable business practices within the meaning of the New Jersey Consumer Fraud Act, 56:8-1, *et seq.,* and warrants the application of the laws of New Jersey to all Defendants in this Court.

352. The misrepresentation, non-disclosure of material facts and unconscionable business practices by the Defendants caused the Plaintiffs and the Class to suffer losses within the meaning of the New Jersey Consumer Fraud Act. Specifically, Defendants' misrepresentations, non-disclosure of material facts and unconscionable business practices relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase Subject Products that were (a) ineffective for the treatment they were indicated for and therefore did not benefit Plaintiffs and the Class; (b) unsafe; and (c) more expensive than other reasonable alternatives for the condition treated.

353. But for the misrepresentations and non-disclosure of material facts, relating to the safety, efficacy and cost effectiveness of Subject Products Plaintiffs and the Class

would not have purchased Subject Products to treat the conditions for which these medications were purchased to treat.

354. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, their purchases of Subject Products as a result of false and misleading statements and omissions relating to the safety, efficacy and cost effectiveness of the Subject Products. Such conduct is actionable under the New Jersey Consumer Fraud Act.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

10. **Violations of New York General Business Law § 349**

355. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

356. Plaintiffs and the Class are consumers who purchased Subject Products for personal use.

357. Defendants' conduct as alleged in this Amended Complaint constitutes deceptive acts or practices in violation of General Business Law §349.

358. By the untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products alleged above, the Defendants deceived and continue to deceive consumers, such as Plaintiffs and the Class, and the general public. This conduct

constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of the GBL § 349, and warrants the application of the laws of New York to defendants in this Court.

359. The unfair methods of competition, unfair and deceptive misleading misrepresentations, and non-disclosure of material facts by the Defendants caused the Plaintiffs and the Class to suffer losses within the meaning of statute prohibiting deceptive acts and practices, GBL § 349. Specifically, Defendants' untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products caused Plaintiffs and the Class to purchase Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing children of Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

360. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products, Plaintiffs and the Class would not have purchased Subject Products.

361. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for Subject Products without disclosure of

information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for treatment for Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under the statute prohibiting deceptive acts and practices, GBL § 349.

WHEREFORE, Plaintiffs, on behalf of themselves and the member of the Class, respectfully seek the relief set forth below.

11. **Violations of North Carolina Consumer Fraud Act**

362. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

363. Plaintiffs and the Class are consumers who purchased the Subject Products for personal use. The State of North Carolina has enacted Statutes to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising.

364. The State of North Carolina provides consumers a private right of action under these Statutes.

365. N.C.G.S.A § 75-1.1 provides in part: (a) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful.

366. By the acts and omissions set forth herein, the Defendants' conduct violates the Statute referenced in the previous paragraph.

367. Defendants, by engaging in the conduct described above, perpetrated unfair, deceptive or fraudulent business acts or practices, unfair competition, and false advertising in connection with the sale of the Subject Products, and have violated and continue to violate N.C.G.S.A § 75-1.1, *et seq.*, including N.C.G.S.A § 75-1.1(a).

368. Defendants, by engaging in the conduct described above, perpetrated unfair, deceptive or fraudulent business acts or practices, unfair competition, and false advertising in connection with the sale of the Subject Products, and deceived and continue to deceive Consumers like the Plaintiff and the Class in violation of N.C.G.S.A § 75-1.1, *et seq.*, including N.C.G.S.A § 75-1.1(a).

369. The unfair, deceptive, false and/or fraudulent conduct of the Defendants, including misrepresentations, concealment and other non-disclosures of material facts, caused the Plaintiffs and the Class to suffer losses within the meaning of the aforementioned North Carolina Statute. N.C.G.S.A § 75-1.1, *et seq*.

370. The misrepresentations, non-disclosure and concealment occurred with respect to the marketing and sales of Subject Products, and therefore occurred in trade or commerce.

371. Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

372. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

373. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under North Carolina's consumer protection law.

374. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including North Carolina, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

375. Plaintiffs and the Class Members seek damages as permitted by law for their injuries caused by Defendants' intentional and/or flagrant violations pursuant to these statutes.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

12. **Violations of Ohio's Consumer Sales Practices Act**

376. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

377. Plaintiffs and the Class are consumers who purchased the Subject Products for personal use. The Ohio Consumer Sales Practices Act, Ohio Revised Code §1345.01 *et seq.,* prohibits unfair methods of competition and unfair and deceptive acts or practices, including, *inter alia,* "the use or employment of any deceptions, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression or omission of any material fact, whether any person has in fact been misled, deceived, or damaged thereby." The Ohio Consumer Sales Practices Act is to be liberally construed.

378. In distributing, promoting, marketing, and selling the Subject Products to Plaintiffs and the Class, and in otherwise engaging in the conduct more fully described herein with respect to the Subject Products, the Defendants are engaging in trade or commerce directly or indirectly affecting Plaintiffs and the Class within the meaning of the Ohio Consumer Sales Practices Act.

379. By the untrue, deceptive, and misleading misrepresentation and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products alleged above, the Defendants deceived and continue to deceive consumers, such as Plaintiffs and the Class. This conduct constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of the Ohio consumer Sales Practices Act and warrants the application of the laws of Ohio to Defendants in this Court.

380. The unfair methods of competition, unfair and deceptive misleading misrepresentations, and non-disclosure of material facts by the Defendants caused the Plaintiffs and the Class to suffer losses within the meaning of the Ohio Consumer Sales Practices Act. Specifically, Defendants' untrue, deceptive, and misleading misrepresentations and nondisclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase Subject Products that were (a)ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children

and the Class; (b)unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

381. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and costs effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

382. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for treatment for Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under the Ohio Consumer Sales Practices Act.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

13. Violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL")

383. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

384. Plaintiffs and the Class are consumers who purchased Subject Products for personal use. Pennsylvania has enacted laws to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. Pennsylvania allows any "person" who suffers a loss a private right of action under such laws. Plaintiffs and the Class for which they bring the instant action, are "persons" within the meaning of 73 P.S. §201-2(3).

385. In distributing, promoting, marketing, and selling Subject Products to Plaintiffs and the Class, and in otherwise engaging in the conduct more fully described herein with respect to the Subject Products, the Defendants are engaging in trade or commerce directly or indirectly affecting Plaintiffs and the Class within the meaning of 73 P.S. §201-2(3).

386. By the untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products alleged above, the Defendants deceived and continue to deceive consumers, such as Plaintiffs and the Class. This conduct constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of the Pennsylvania UTPCPL 73 P.S. § 201-2(4), *et seq.* and warrants the application of the laws of Pennsylvania to defendant in this Court.

387. Defendants' conduct more fully described herein is proscribed and declared unlawful by 73 PA. STAT. § 201-8.

388. The unfair methods of competition, unfair and deceptive misleading misrepresentations, and non-disclosure of material facts by the Defendants caused the Plaintiffs and the Class to suffer losses within the meaning of the Pennsylvania UTPCPL. Specifically, Defendants' untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products caused Plaintiffs and the Class to purchase Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

389. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of Subject Products, Plaintiffs and the Class would not have purchased Subject Products.

390. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for treatment for Subject Products over cheaper,

more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under the Pennsylvania UTPCPL.

WHEREFORE, Plaintiff, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

14. Violations of Texas Deceptive Trade Practices-Consumer Protection Act

391. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

392. Plaintiffs and the Class are consumers who purchased the Subject Products for personal use. The State of Texas has enacted Statutes to protect consumers against unfair, deceptive or fraudulent trade or business practices, unfair competition and false advertising.

393. The State of Texas provides consumers a private right of action under these Statutes.

394. V.T.C.A., Bus. & C. § 17.46 provides in part: (a) False, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful and are subject to action by the consumer protection division under Sections 17.47, 17.58, 17.60, and 17.61 of this code.

395. By the acts and omissions set forth herein, the Defendants' conduct violates the Statute referenced in the previous paragraph.

396. Defendants, by engaging in the conduct described above, perpetrated unfair, deceptive or fraudulent trade or business acts or practices, unfair competition, and false advertising in connection with the sale of the Subject Products, and have violated and continue to violate V.T.C.A., Bus. & C. § 17.41, *et seq*., including V.T.C.A., Bus. & C. § 17.46(a), (b)(5) & (7).

397. Defendants, by engaging in the conduct described above, perpetrated unfair, deceptive or fraudulent trade or business acts or practices, unfair competition, and false advertising in connection with the sale of the Subject Products, and deceived and continue to deceive Consumers like the Plaintiff and the Class in violation of V.T.C.A., Bus. & C. § 17.41, *et seq*., including V.T.C.A., Bus. & C. § 17.46(a), (b)(5) & (7).

398. The unfair, deceptive, false and/or fraudulent conduct of the Defendants, including misrepresentations, concealment and other non-disclosures of material facts, caused the Plaintiffs and the Class to suffer losses within the meaning of the aforementioned Texas Statute. V.T.C.A., Bus. & C. § 17.41, *et seq*.

399. The misrepresentations, non-disclosure and concealment occurred with respect to the marketing and sales of Subject Products, and therefore occurred in trade or commerce.

400. Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety,

efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

401. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

402. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under Texas' Deceptive Trade Practices-Consumer Protection Act.

403. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Texas, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

404. Plaintiffs and the Class Members seek damages as permitted by law for their injuries caused by Defendants' intentional and/or flagrant violations pursuant to these statutes.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

15. Violations of Washington Consumer Protection Act ("CPA"), Wash. Rev. Code § 19.86.010, *et seq.*

405. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

406. Plaintiffs and the Class are consumers who purchased Subject Products for personal use. The State of Washington has enacted laws to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. Pursuant to the Washington Consumer Protection Act ("CPA"), Wash. Rev. Code § 19.86.010, *et seq.,* Washington allows consumers a private right of action under such laws.

407. By the misrepresentations as to, non-disclosure, and concealment of material facts as alleged above, the Defendants have engaged in unfair or deceptive acts or practices, and deceived and continue to deceive consumers like the Plaintiffs and

the Class. This conduct constitutes unfair competition and/or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*, including § 19.86.020.

408. The misrepresentations, non-disclosure and concealment occurred with respect to the marketing and sales of Subject Products, and therefore occurred in trade or commerce.

409. Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

410. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

411. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without

disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medication and alternative courses of treatment. Such conduct is actionable under Washington's consumer protection law.

412. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Washington, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

16. Violations of West Virginia's Consumer Credit and Protection Act

413. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

414. West Virginia has enacted statutes to protect consumers against unfair, deceptive and fraudulent acts or practices. *See* 46A-6-101(1).

415. West Virginia allows consumers a private right of action under these statutes. See 46A-6-106(a).

416. Plaintiffs and the Class are consumers under the Act because they engaged in a consumer transaction and purchased the Subject Products for personal, family, or household use.

417. West Virginia's Consumer Protection Act provides in pertinent part that:

> The Legislature hereby declares that the purpose of this article is to complement the body of federal law governing unfair competition and unfair, deceptive and fraudulent acts or practices in order to protect the public and foster fair and honest competition. It is the intent of the Legislature that, in construing this article, the courts be guided by the interpretation given by the federal courts to the various federal statutes dealing with the same or similar matters. To this end, this article shall be liberally construed so that its beneficial purposes may be served.

46A-6-101(1).

418. The Act provides that unfair methods of competition and unfair or deceptive acts or practices means and includes, but is not limited to, any one or more of some sixteen specified acts or practices. *See* 46A-6-102(7).

419. By the misrepresentations as to, non-disclosure, and concealment of material facts as alleged above, the Defendants have engaged in "unfair, deceptive and fraudulent acts or practices" in violation of 46A-6-101(1).

420. Defendants, by engaging in the conduct described above, perpetrated in connection with the sale of the Subject Products, violated and continue to violate The West Virginia Consumer Credit and Protection Act.

421. The unfair, deceptive and fraudulent acts or practices include misrepresentations, concealment and other non-disclosures of material facts by the Defendants which

caused the Plaintiffs and the Class to suffer losses within the meaning of the aforementioned Code.

422. In addition, the Defendants' use of media to promote the sale of their drugs through false and deceptive representations, and other conduct as alleged above, constitutes unfair competition and unfair, deceptive, untrue, or misleading advertising within the meaning of West Virginia's Consumer Credit and Protection Act, 46A-6-101 *et seq.*

423. Defendants' untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products caused Plaintiffs and the Class to purchase Subjects Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, their children and the Class; (b) unsafe, likely causing Plaintiffs, their children and the Class to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

424. But for the misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products, Plaintiffs and the Class would not have purchased the Subject Products.

425. Defendants directly and proximately caused Plaintiffs and the Class to suffer damages by, as described above, paying for the Subject Products without

disclosure of information regarding the safety, efficacy and cost effectiveness of the Subject Products. Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful products and alternative courses of treatment. Such conduct is actionable under West Virginia's consumer protection laws.

426. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including West Virginia, Plaintiffs and the Class have and will continue to suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

17. Violations of Consumer Protection Statutes of Other States, District of Columbia and Puerto Rico

427. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

428. Plaintiffs and the Class are individual consumers who purchased Subject Products for their own personal use or for the personal use of those on whose behalf they have purchased the Subject Products. All 34 of the remaining states, and the District of Columbia and Puerto Rico have enacted statutes to protect consumers against unfair, unconscionable, deceptive or fraudulent business practices, unfair

competition and false advertising. Most states allow consumers a private right of action under these statutes.

429. By the actions and failures to act of Defendants as described herein, Defendants deceived, and continue to conceal their deception of consumers like Plaintiffs and members of the Class. This conduct constitutes unlawful, unfair, unconscionable, deceptive and fraudulent business practices within the meaning of consumer protection statutes of the remaining 34 states, the District of Columbia and Puerto Rico.

430. Defendants directly and proximate caused Plaintiffs and the Class to suffer damages by, as described above, paying for Subject Products without knowing about the lack of safety, efficacy and cost effectiveness of Subject Products due to Defendants' scheme involving false and misleading statements and omissions relating thereto. Plaintiffs and the Class paid exorbitant prices for treating their children with Subject Products over cheaper, more effective and less harmful medications and alternative courses of treatment. Such conduct is actionable under the laws of the remaining 34 states, the District of Columbia and Puerto Rico.

431. As a direct and proximate cause of Defendants' unfair and deceptive trade practices throughout the 50 states, the District of Columbia and Puerto Rico, Plaintiffs and the Class have suffered losses and damages in an amount to be determined at trial, and are entitled to compensatory damages, treble damages,

attorneys' fees and costs of suit and any other damages provided under these statutes.

432. The Class groups its claims as follows:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-5(5), *et seq.;*

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-393, *et seq*.;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.16.2(a), *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207(1), *et seq.*;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code § 75-24-5(1), *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-103, *et seq.;*

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Puerto Rico's consumer protection laws;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-200(A), *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.18, *et seq.*; and

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

B. Count II: Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C.A § 1341 (Mail Fraud), 18 U.S.C.A § 1343 (Wire Fraud), 18 U.S.C.A § 1503 (Obstruction of Justice)

433. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

434. Plaintiffs and the Class are private individuals who have been injured in their business or property by reason of Defendant's violations of the Racketeer Influenced and Corrupt Organizations Act (hereinafter "RICO"). 18 U.S.C.A § 1962 (c) provides that "[i]t shall be unlawful for any person employed by or associated with any enterprise engaged in, or in the activities of which affect, interstate or foreign commerce, to conduct or participate directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C.A § 1962 (d) provides that "[i]t shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section.

435. This cause of action asserts claims against Defendants McNeil, J&J, Weldon, Goggins, Crane, Luther, Coleman, Johns, Lindquist, Satcher, Inmar, Inc., CSCS, CLS, and WIS, for violations of 18 U.S.C.A § 1962 (c) and (d) for conducting the

affairs of various "enterprises," as described herein, through a "pattern of racketeering activity."

436. During the relevant time period, Defendants McNeil, J&J, Weldon, Goggins, Crane, Luther, Coleman, Johns, Lindquist, Satcher, Inmar, Inc., CSCS, CLS, and WIS, Named Plaintiffs and the members of the Nationwide Class and/or Sub-Classes were and are each a "person," as that term is defined in 18 U.S.C. § 1961(3).

437. At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendants conducted the affairs of certain association-in-fact enterprises identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

438. During the relevant time period, as alleged above, pursuant to their contractual agreements and course of dealing, there existed separate "associations-in-fact" between J&J and McNeil separately (the "Corporate Family Enterprise"), as well as between J&J, McNeil and each of the firms retained to conduct the Phantom Recall, other recalls, "market assessments", and other acts, namely (a) J&J, McNeil and Inmar, (b) J&J, McNeil and CSCS, (c) J&J, McNeil and CLS, and (d) J&J, McNeil and WIS (collectively the "Contractor Enterprises"). Each one of these "associations-in-fact" between J&J, McNeil and each of the contractor firms

retained to carry out the above conduct constituted a separate "enterprise," as that term is defined in 18 U.S.C. § 1961(4).

439. The J&J Corporate Family Enterprise has an ascertainable structure separate and apart from the pattern of racketeering activity in which Defendants have engaged since at least 2008.

440. Each of the Contractor Enterprises have an ascertainable structure separate and apart from the pattern of racketeering activity in which Defendants have engaged since at least 2008.

441. J&J, McNeil and the contractors, Inmar, CSCS, CLS and WIS are each ongoing organizations which engage in, and the activities of which effect, interstate and foreign commerce.

442. At all relevant times, both J&J and McNeil were aware of each company's marketing and sales scheme and conspiracy described herein (“Misleading Marketing Scheme”), was a knowing and willing participant in that scheme, and reaped profits from that scheme.

443. At all relevant times, each one of the Contractors was aware of J&J and McNeil's Misleading Marketing Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme.

444. Each Defendant associated with the Corporate Family Enterprise.

445. Each Defendant associated with the Contractor Enterprises.

446. Further, during the relevant time period, as alleged above, there existed separate "associations-in-fact" between (a) J&J and its executives, Weldon and Goggins (the "J&J Executive Enterprise"); (b) J&J and the members of its Board of Directors, Luther, Coleman, Johns, Lindquist, and Satcher (the "J&J Board of Directors Enterprise"); and (c) McNeil and its executives, Goggins and Crane (the "McNeil Executive Enterprise"), collectively the "Misleading Marketing Enterprises." Each one of these "associations-in-fact" between J&J and its executives, J&J and the members of its Board of Directors, and McNeil and its executives constituted a separate "enterprise," as that term is defined in 18 U.S.C. § 1961(4).

447. The J&J Executive Enterprise, the J&J Board of Directors Enterprise, and the McNeil Executive Enterprise, each have an ascertainable structure separate and apart from the pattern of racketeering activity in which Defendants have engaged since at least 2008.

448. At all relevant times, the J&J Executive Enterprise, the J&J Board of Directors Enterprise, and the McNeil Executive Enterprise were aware of each company's Misleading Marketing Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme.

449. Each Defendant associated with the Misleading Marketing Enterprises.

450. Each Defendant intended that the various enterprises discussed herein transmit false and misleading information as set forth herein to Plaintiffs, members of the proposed class, government investigators, and consumers throughout the country and Other Places through means of domestic and international mail and wire carriers.

451. During the relevant time period, Defendants J&J and McNeil violated 18 U.S.C. § 1962(c) by conducting the affairs of the Corporate Family Enterprise, a RICO "enterprise," through a "pattern of racketeering activity," as that term is defined in 18 U.S.C. § 1961(1)(A)-(B) & (5). Defendants J&J, McNeil and the Contractor Defendants, violated 18 U.S.C. § 1962(c) by conducting the affairs of the various Contractor Enterprises, each a separate RICO "enterprise," through a "pattern of racketeering activity," as that term is defined in 18 U.S.C. § 1961(1)(A)-(B) & (5). Defendants Weldon and Goggins violated 18 U.S.C. § 1962(c) by conducting the affairs of the J&J Executive Enterprise, a RICO "enterprise," through a "pattern of racketeering activity," as that term is defined in 18 U.S.C. § 1961(1)(A)-(B) & (5). Defendants Coleman, Johns, Lindquist, and Satcher violated 18 U.S.C. § 1962(c) by knowingly directing the affairs of the J&J Board of Directors Enterprise, a RICO "enterprise," through a "pattern of racketeering activity," as that term is defined in 18 U.S.C. § 1961(1)(A)-(B) & (5). Lastly, Defendants Crane and Luther violated 18 U.S.C. § 1962(c) by conducting the affairs of the McNeil

Executive Enterprise, a RICO "enterprise," through a "pattern of racketeering activity," as that term is defined in 18 U.S.C. § 1961(1)(A)-(B) & (5).

452. Defendants Inmar, CSCS, CLS, and WIS each knowingly agreed to facilitate the Misleading Marketing Scheme through their involvement in the conduct described above, like the Phantom Recall, and did so through their participation and role in the operation of the Enterprises, as alleged above. In doing so, those Defendants agreed with J&J and McNeil to commit the predicate acts described herein pertaining to the Phantom Recall and other acts and admissions concerning product recalls with the knowledge that those acts were part of a pattern of racketeering activity in violation of in 18 U.S.C. §1962(b). Those Defendants agreed to conceal the nature of their conduct - buying "ALL of the Motrin product described [ ] [with] NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!" *See* Exhibit “E” hereto.

453. As discussed throughout this Amended Complaint, J&J and McNeil made false statements and/or misrepresentations about the safety of the Subject Products and suppressed and concealed material information from the Plaintiffs and the Class about such products, including their potentially harmful effects as a result of undisclosed manufacturing defects and deficiencies at the time of sale. Further, J&J and McNeil, and the individual "persons" referenced above, directed that Inmar, CSCS, CLS and WIS make similar misrepresentations and omissions, by

deliberately directing them to specifically conceal the nature of the Phantom Recall and other recalls as follows: "quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave . . . THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!" *Id.*

454. Defendants carried out a scheme to defraud Plaintiffs and misrepresent the deficiencies in the manufacturing process of the Subject Products which caused those products to contain, *inter alia*, "particulate matter" and/or "foreign substances." To show a violation of Section 1962(c) of RICO, plaintiff must allege "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Sedima, S.P.R.L. V. Imex Co.*, 473 U.S. 479, 496 (1985).

455. In this case, Defendants violated sections of the RICO statute when they participated in mail fraud, in violation of 18 U.S.C. § 1341, wire fraud, in violation of 18 U.S. C § 1343 and obstruction of justice, in violation of 18 U.S.C. § 1503. The use of the mails (or the wires) need not be essential to the scheme to defraud, or even done by a defendant, so long as the mailing is closely related and reasonably foreseeable incident of the scheme. *Schmuck v. United States*, 489 U.S. 705, 710-711 (1989).

456. Specifically, the mail and wire fraud statutes prohibit the use of the mail or telephone lines "for the purpose of executing" "any scheme or artifice to

defraud…or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises…" 18 U.S.C.A § 1341, 1343 Thus, to demonstrate a violation of the mail or wire fraud statutes, Plaintiffs must show two elements: (1) a scheme to defraud, and (2) a mailing or wire in furtherance of that scheme. *Greenberg v. Brewster*, 816 F. Supp. 1039, 1049 (E.D. Pa. 1993).

457. The *locus classicus* of fraud is Defendants' affirmative false statement or half truth, *i.e*. a statement that is literally true but is made misleading by a significant omission. *Emery v. American Gen. Fin., Inc.*,71 F. 3d 1343, 1348 (7th Cir. 1995). Thus, the failure to disclose information may constitute a fraudulent representation under the mail and wire fraud statutes if the defendant was under a legal, professional or contractual duty to make such a disclosure. Here, the Defendants had a conscious knowing intent to defraud Plaintiffs in order to sell inferior products. Defendants' actions include intentional concealment of the documents related to the Subject Products, the test results identifying contamination and degradation of the raw materials used in manufacturing the Subject Products, and misleading and deceptive responses to consumers regarding the affected Subject Products.

458. Specifically, several predicate acts form the basis of the racketeering activity. First, Defendants intentionally engaged in separate acts of unlawful schemes to manufacture, distribute, market and sell Subject Products that were "subpotent" or

"superpotent," contained foreign particulate matter or otherwise were contaminated. Problems with the manufacturing and inspection processes, and the quality, condition and efficacy of the Subject Products was first discovered in at least 2008 by Johnson & Johnson. This information was brought to the attention of Sean P. Davoren, President and Chief Executive Officer, WIS, William C. Weldon, chief executive of Johnson & Johnson, and Colleen Goggins, head of Johnson & Johnson's Consumer Health Care Segment.

459. Importantly, in April 2009, in an executive summary report, Johnson & Johnson learned that *Burkholderia cepacia* bacteria tainted some raw materials that were to be used to make children's and infant Tylenol. Defendants failed to thoroughly review any unexplained discrepancies in the batches of products and failed to properly keep records regarding the batches of products.

460. Although Defendants learned of the discovered contamination in the Subject Products, they continued to manufacture, produce, market and sell the products, which contained tainted raw materials, to its consumers, including Plaintiffs in May 2009. The companies' website promoted the children's and infant Tylenol, dispelled any rumors of contamination, and encouraged parents, consumers and Plaintiffs to continue to purchase Defendants' products at premium prices over other less expensive and safer generic products.

461. Defendants continued to ship, *via* United States Postal Service, more than eight million bottles of the Subject Products across the country to various retailers. In fact, according to emails sent between McNeil staff members, including Colleen Goggins, Defendants continued to ship the Subject Products to retailers and consumers until June 4, 2009 – the same day the FDA investigators cited the company for violating good and standard manufacturing practices.

462. Defendants, by and through their chief executive officers and presidents, hired contractors to allegedly determine how many bottles remained on store shelves. This contract was effectuated, documented and recorded in communications between Johnson & Johnson staff and the contractor staff on or about June – August 2009. This act was done with deliberate disregard to the ongoing investigation of the FDA into the tainted Subject Products.

463. Defendants violated both mail fraud and wire fraud statutes when, prior to recalling the tainted Subject Products, they contracted with WIS, CLS, CSCS and Inmar, Inc., to purchase its suspect Motrin products from retail stores. As discussed above, Defendants J&J and McNeil directed the Contractor Enterprises to "quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave . . . THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!" At such direction, the Contractor Enterprises proceeded to conduct the Phantom Recall, as discussed

above, concealing the nature and the impetus for such action –*i.e.*, Defendants' knowledge that the Subject Products were unsafe - from the public and the Class. This action shows Defendants' ongoing "criminal enterprise" solely for the purpose of defrauding not only millions of consumers, but the United States Government as well. The actions are systematic, deliberate and designed to defraud consumers in order to sell inferior and potentially dangerous products and to conceal the nature of Defendants' misrepresentations.

464. Moreover, many of the same recalled Subject Products, including Children's Tylenol Infant Drops, Concentrated Motrin Suspension and Children's Tylenol Cold Suspensions, involved in the FDA Report described above were cited for the same reasons as in the Enforcement Report. This fact establishes a pattern of "racketeering activity" on the part of Defendants to defraud customers into purchasing Subject Products that were worth less than Defendants represented, were unsafe and were potentially dangerous to the consumers who used them.

465. More importantly, Defendants' interstate correspondences with WIS and CSCS of Inmar, Inc. regarding contracting the latter's services in the phantom recall of Motrin products as referred to in the Congressional Committee's letter, clearly illustrates Defendants' attempts to cover up the deficiencies using the mail or interstate wires to further their unlawful scheme of making millions of consumers believe that Defendants' products were safe and effective. Tellingly, Defendants

instructed WIS and CSCS, "…there must be no mention of this being a recall of the product" – a clear act of misrepresentation and fraud intended to deceive its customers (*See* Exhibit "E").

466. Defendants also engaged in various activities to obstruct and hinder legitimate investigations of their criminal conduct in violation of 18 U.S.C. § 1503. Specifically, Defendants ignored the warnings and findings of the FDA, carelessly recorded results in the official records, and intentionally deceived investigators regarding its manufacturing problems. All the while, Defendants continued to manufacture, distribute, market and sell the Subject Products, and attempted to conceal their activities through a phantom recall and other secretive steps. Such activities were done with the purpose and intent to obstruct and hinder legitimate investigations by the United States House Committee on Oversight and Government Reforms which is investigating and conducting hearings regarding the recalls.

467. Thus, as a direct and proximate result of Defendants' conduct Plaintiffs were defrauded, mislead and injured. Pursuant to 18 U.S.C. §1964(c), "(a)ny person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefore in any appropriate United States District Court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee…."

468. Plaintiffs and the members of the Class have standing to sue Defendants McNeil, J&J, Weldon, Goggins, Crane, Luther, Coleman, Johns, Lindquist, Satcher, Inmar, Inc., CSCS, CLS, and WIS under 18 U.S.C. §1964(c) and to recover compensatory damages, treble damages, and the costs of suit, including reasonable attorneys' fees. In addition, Plaintiffs and Class members are entitled to declaratory and injunctive relief, pursuant to 18 U.S.C. §1964(a), to remedy and prevent Defendants from engaging in further violations of state and federal law.

469. WHEREFORE, Plaintiffs, on behalf of themselves and the Class, respectfully seek the relief set forth below. Plaintiffs and the Class are entitled to an award of treble and compensatory damages arising out of Defendants' pattern of racketeering activities which proximately caused economic injury to the Plaintiff and members of the Class.

C. Count III: Violations of Magnuson-Moss Act (15 U.S.C. § 2301, *et. seq*.)

470. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

471. Plaintiffs are "consumer[s]" within the meaning of the Magnuson-Moss Warranty Act. *See* 15 U.S.C. § 2301(3).

472. The J&J Defendants are "suppliers" and "warrantors" within the meaning of the Act. *See* 15 U.S.C. § 2301(4), (5).

473. The Subject Products are "consumer products" within the meaning of the Act. *See* 15 U.S.C. 2301(1).

474. The Act provides a cause of action for any consumer who is damaged by the failure of a warrantor to comply with a written or implied warranty. *See* 15 U.S.C. § 2310(d)(1).

475. The J&J Defendants' implied warranties are warranties covered under the Act. *See* 15 U.S.C. § 2301(7).

476. The J&J Defendants breached their warranties to Plaintiffs and the Class as described in detail herein.

477. Plaintiffs and the Class have been damaged because of Defendants' failure to honor their obligations under their implied warranties respecting the defective Subject Products.

478. The amount in controversy is, in the aggregate, more than the sum or value of $50,000 computed on all claims to be determined in this action.

479. This action is brought as a class action and the number of representative plaintiffs is exceeds one hundred.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

D. Count IV: Strict Product Liability-Manufacturing Defect

480. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

481. During the relevant time period, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling to its distributors and otherwise putting the Subject Products into the stream of commerce.

482. During the relevant time period, Defendants did manufacture, distribute and sell the Subject Products. Those products were expected to reach, and did reach, consumers, including Plaintiffs and members of the Class throughout the United States, without significant change in the condition in which they were manufactured and sold.

483. During the relevant time period, the Subject Products were manufactured, sold or otherwise left Defendants' possession in a defective, contaminated, adulterated, and in some cases, unreasonably dangerous condition, and thereafter were placed in the stream of commerce. The varying conditions of the Subject Products included, but were not limited to, one or more of the following particulars:

a. when placed in the stream of commerce, the product contained manufacturing and composition defects, including *inter alia*, far too much or far too little active ingredient, contaminants, particulates and other adulterants, which rendered the product, *inter alia*, super or sub-potent, contaminated, unusable and unreasonably dangerous;

b. when placed in the stream of commerce, the products contained manufacturing defects which resulted in lot to lot variability which rendered the products unusable and unreasonably dangerous;

c. the products' manufacturing defects occurred while the products were in the possession and control of the Defendants;

d. the products were not made in accordance with the Defendants' specifications or performance standards;

e. the products manufacturing defects existed before it left the control of the Defendants.

484. The Subject Products were used by consumers, including the Plaintiffs, in a way that was reasonably foreseeable to Defendants.

485. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain harm including economic losses and other damages and losses for which they are entitled to compensatory, punitive, and equitable damages and declaratory relief in an amount to be proven at trial.

486. Defendants are liable jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law. The plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

E. Count V: Strict Product Liability-Failure to Warn

487. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

488. The Subject Products were defective, contaminated, adulterated and/or otherwise unusable for the purpose intended when those products left the control of Johnson & Johnson/McNeil.

489. At the time of the Subject Products manufacture, testing, packaging, labeling, distribution, and sale, and continuing up to the time of Plaintiffs injury, Defendants knew or should have known of the substantial defects and dangers involved in the reasonably foreseeable purchase, administration and ingestion of the defective Subject Products. The lack of sufficient warnings concerning the Subject Products' defective design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or selling caused Plaintiffs to purchase the Subject Products that were, *inter alia,* ineffective, super or sub-potent, and/or otherwise contaminated or adulterated, thereby causing injury to the Plaintiffs.

490. Defendants knew that the defectiveness of the Subject Products would not be readily recognizable to an ordinary consumer and that consumers would purchase and use these products without inspection or analysis of the product components. Defendants further knew that Plaintiffs and the Class would administer the defective Subject Products to sick and ill infants, children, and others.

491. At all relevant times, Defendants failed to provide adequate warnings, instructions, guidelines, or admonitions to Plaintiffs, the Class, and members of the consuming public of the defects, contaminations or other adulterations, which Defendants knew, or in the exercise of reasonable care should have known, to have existed in the makeup of the Subject Products.

492. At all relevant times, Plaintiffs and members of the Class used the Subject Products in the manner intended by Defendants, including without limitation, administering the Subject Products to sick and ill infants, children, and others. The use of the Subject Products by Plaintiffs and members of the Class was in a manner that was reasonably foreseeable by the Defendants as involving substantial dangers that were not readily apparent to Plaintiffs, and the members of the Class.

493. Plaintiffs' damages were the direct and proximate result of Defendants' failure to provide adequate warnings.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below

F. Count VI: Breach of Implied Warranty of Merchantability and Fitness for a Particular Purpose

494. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

495. Prior to the time of the subject incidents, the Defendants impliedly warranted to members of the general public, including the Plaintiffs, that the Subject Products

were of merchantable quality, and were safe and effective for the use for which they were intended by Defendants, mainly the care, treatment, and/or relief of a variety of common ills, pain and other afflictions.

496. Plaintiffs' relied on the reputation, experience, technical and scientific expertise, ability, and judgment of the Defendants in their selection, purchase and use of the Subject Products as safe, effective and reliable means for treating these various common ills, pain and other afflictions.

497. The Subject Products are/were defective, contaminated, and/or otherwise adulterated and were not safe and/or effective for their intended use. Nor were the Subject Products of merchantable quality as warranted by Defendants in that they were defectively manufactured, labeled, merchandized, promoted, distributed and sold exposing Plaintiffs and members of the Class to damage and potential injury.

498. After Plaintiffs suffered the damage and injury complained of herein, notice was given by Plaintiffs to Defendants by filing this lawsuit in the time, manner, and form prescribed by law of the breach of said implied warranty.

499. As a direct, legal and proximate breach of said implied warranties, Plaintiffs sustained the damages complained of herein. Plaintiffs are, therefore, entitled to damages in an amount to be proven at the time of trial.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

G. Count VII: Negligence

500. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

501. At all times relevant**,** Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling to its distributors, retailers and the public, the Subject Products.

502. Defendants owed Plaintiffs a duty to exercise reasonable care in the designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling to its distributors, retailers and the public, the Subject Products, including a duty to ensure that the Subject Products contained only those ingredients and components, active or otherwise, in the specified amounts, listed or otherwise provided on the labeling and packaging, and that the purchase and/or use of the Subject Products did not cause Plaintiffs any unreasonable harm or injury.

503. Defendants knew or should have known that the Subject Products were defectively manufactured, knew or should have known that the Subject Products contained ingredients, components, impurities, contaminants and/or particulates, not identified on the label and/or packaging, or in some cases ingredients in other than specified amounts and were therefore worthless, ineffective, contaminated, and

otherwise defective, causing damages and potential injury to those purchasing and ingesting the Subject Products.

504. Defendants failed to exercise ordinary and reasonable care and breached their duty by, among other things:

a. Failure to use due care in the designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling to its distributors, retailers and the public, the Subject Products in order to avoid the aforementioned risks to individuals;

b. Failure to provide adequate warning of the super and sub-potency of the Subject Products, and/or the inclusion of contaminates, particulates and/or other adulterations not identified on the label and/or the packaging;

c. Failure to incorporate within the manufacturing and design of the Subject Products reasonable safeguards and protections against components, impurities, contaminants and/or particulates, not identified on the label and/or packaging, or in some cases ingredients in other than specified amounts.

d. Failure to timely and thoroughly investigate complaints and institute effective processes to protect individuals from the aforementioned risks.

e. Being otherwise careless or negligent.

505. Defendants were negligent and breached the duty owed to the Plaintiffs and the Class.

506. As a direct and proximate cause of Defendants' breach, Plaintiffs and the Class have been damaged including, but not limited to, financial loss of purchasing defective, ineffective, adulterated and/or contaminated products at a premium price, as well as being subjected to potential risk of injury.

507. Plaintiffs are entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

H. Count VIII: Negligent Misrepresentation/Fraud

508. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

509. At all times relevant**,** Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling to their distributors, retailers and the public, the Subject Products.

510. By engaging in the acts and omissions alleged in this Complaint, Defendants have committed fraud on the Plaintiffs and the Class.

511. The Defendants acts violate common law proscriptions against negligent and fraudulent misrepresentation.

512. In distributing, marketing, promoting and selling the Subject Products to Plaintiffs and the Class, the Defendants made representations that the Subject Products contained the ingredients, concentrations, components, quality and condition as is identified on the label and/or packaging that accompanied the Subject Products. Defendants also marketed their products to consumers in a similar fashion.

513. These representations were material to the transactions at hand and the Plaintiffs and the Class relied upon these representations when purchasing the Subject Products and administering them to Plaintiffs, members of the Class and their children.

514. As set forth fully herein, the Subject Products were defectively manufactured and the Subject Products contained ingredients, concentrations, components, impurities, contaminants and/or particulates, not identified on the label and/or packaging, or in some cases ingredients in other than specified amounts and were therefore worthless, ineffective, contaminated, and otherwise defective, causing damages and potential injury to those purchasing and ingesting the Subject Products.

515. The Defendants intended that Plaintiffs and the Class would rely on their representations and omissions to their detriment. Plaintiffs and the Class did in fact reasonably rely on the representations and statements of the Defendants and to their detriment, suffered injury and damages thereby, as more fully set forth herein.

516. In addition, the Defendants concealed and suppressed material facts about the defectively manufactured Subject Products and they concealed and suppressed their unlawful acts and omissions as set forth more fully herein. Among other things, once the Defendants became aware that the Subject Products were defectively manufactured, they did not inform the public. Instead, the Defendants continued to allow the Plaintiffs and the Class to purchase and administer these defective and harmful Subject Products to themselves and their children.

517. As an alternative to informing the public and appropriate authorities of the defectively manufactured Subject Products, the Defendants created a scheme and conspiracy to purchase the remaining defective Subject Products off the shelves of retailers. Plaintiffs and the Class were unaware of the above-referenced facts, and would not have purchased the Subject Products or continued to administer the Subject Products to themselves and their children had they known of the facts Defendants concealed and suppressed.

518. The Defendants' untrue, deceptive and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost-effectiveness of Subject Products caused Plaintiffs and the Class to purchase the Subject Products that were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, the Class or their children; (b) unsafe, likely causing the Plaintiffs, the Class and their children to suffer side effects or longer

durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

519. As a direct and proximate result of Defendants' fraudulent conduct, and the concealment and suppression of material facts by Defendants, Plaintiffs and the Class have suffered and will continue to suffer damages.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

I. Count IX: Conspiracy, Concert of Action and Aiding and Abetting

520. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

521. Beginning at least as early as December 2008, the exact date being unknown to Plaintiffs and the Class, and continuing thereafter through the present, Defendants agreed to and did act in concert with one another and with other co-conspirators as described above, in a continuing conspiracy and/or concerted action to violate the aforementioned federal and state laws and to defraud Plaintiffs and the Class by causing Plaintiffs and the Class to purchase the Subject Products based on misrepresentations and omissions relating to the safety and efficacy of the Subject Products. In the absence of Defendants' conspiracy and concerted action, Plaintiffs and the Class would not have purchased the Subject Products and/or

would have paid less for them or for other Products or alternative treatments which would have been more safe and beneficial in treating their conditions.

522. Additionally, over the same relevant time period, Defendants and their co-conspirators, engaged in this conspiracy and/or concerted action to cause Plaintiffs and the Class to purchase these Subject Products despite knowing that they were defective and not safe. Defendants did so by explicitly making and/or disseminating unsubstantiated and/or false representations or statements or material omissions about the safety and efficacy of the Subject Products. In the absence of Defendants' conspiracy and/or concerted action, Plaintiffs and members of the Class would not have purchased the Subject Products and/or would have paid less for them or for other Products or alternative treatments which would have been more safe and beneficial in treating their conditions.

523. Defendants acted with knowledge of their wrongdoing as set forth in this Amended Complaint, and provided substantial assistance or encouragement to each other and other unnamed co-conspirators in the commission of the acts and omissions alleged with respect to Plaintiffs and the Class.

524. Defendants' conduct was a substantial factor in causing the resulting injury and harm alleged herein.

525. Defendants had actual knowledge of their acts and omissions and their impact on Plaintiffs and the Class, and of their respective roles in furthering such conduct.

526. Pursuant to their conspiracy and/or concerted action and/or aiding and abetting alleged herein, Defendants and their co-conspirators engaged in a wide range of activities the purpose and effect of which was to cause harm to the Plaintiffs and the Class. These activities have been set forth in great detail above and throughout this Amended Complaint, and have been incorporated by reference herein, including, but not limited to, Defendants' unlawful scheme and conspiracy involving the manufacture, distribution, marketing, promotion and sale of consumer products used to treat ailments in children and adults, and the suppression and concealment of material information from the Plaintiffs and the Class about such products, including their potentially harmful effects as a result of undisclosed manufacturing defects and deficiencies at the time of sale.

527. As discussed throughout this Amended Complaint, Defendants acted in concert with one another and unnamed co-conspirators and aided and abetted, to commit the conduct and scheme described herein to cause Plaintiffs and the Class to purchase the defective Subject Products, and acted pursuant to a common design or plan with respect to the scheme and conspiracy. As described in this Amended Complaint, Defendants gave substantial assistance or encouragement to each other and to other co-conspirators throughout the country in furtherance and as part of the scheme and conspiracy in order to cause Plaintiffs and the Class to purchase the Subject Products.

528. Defendants' conspiracy, concerted actions and aiding and abetting have directly and proximately caused the Plaintiffs' and the Class members' damages. As a direct and proximate result of Defendants' conspiracies and/or concerted actions and/or aiding and abetting perpetrated upon Plaintiffs and the Class, Defendants are jointly and severally liable to Plaintiff and the Class for all damages Plaintiffs and the Class have sustained, plus exemplary damages and, punitive damages, as well as the cost of suit and reasonable attorneys' fees.

WHEREFORE, Plaintiffs on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

J. Count X: Unjust Enrichment

529. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

530. By engaging in the conduct described in this Complaint, Defendants have knowingly obtained benefits from Plaintiffs and the Class under circumstances such that it would be inequitable and unjust for these Defendants to retain them.

531. Defendants have collected payments for these Subject Products from Plaintiffs and the members of the Class that vastly exceeded the payments to which Defendants were entitled as a matter of law. In exchange for these payments, and at the time they made these payments, Plaintiffs and the Class expected that Subject Products were safe, medically efficacious, cost effective and useful for the particular

conditions or symptoms for which they were administered to children. They were not. Plaintiffs and the Class would not have paid what they did for these Subject Products in the absence of Defendants' wrongful conduct.

532. Thus, Defendants will be unjustly enriched if they are permitted to retain the full amounts paid to them by Plaintiffs and the members of the Class.

533. Plaintiffs and the Class are therefore entitled to an award of compensatory and punitive damages in an amount to be determined at trial or to the imposition of a constructive trust upon the wrongful profits obtained by, revenues obtained by, and benefits conferred upon Defendants as a result of their wrongdoing and the payments made by Plaintiffs and members of the Class.

534. Plaintiffs and the Class have no remedy at law to prevent Defendants from continuing the inequitable conduct alleged herein and the continued unjust retention of the payments made to Defendants by Plaintiffs and members of the Class.

WHEREFORE, Plaintiffs on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

K. Count XI: Declaratory and Other Relief Pursuant to 28 U.S.C. §§ 2201, 2202

535. Plaintiffs incorporate by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

536. An actual case and substantial controversy exists between the Plaintiffs and the Defendants with respect to the Defendants' unfair or deceptive acts or practices and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost effectiveness of the Subject Products. The Plaintiffs contend that the Defendants' acts or practices caused Plaintiffs and the Class to purchase the Subject Products. Plaintiffs further contend that the Subject Products they purchased were (a) ineffective for the treatment for which they were indicated and therefore did not benefit the Plaintiffs, other members of the Class or their children; (b) unsafe, likely causing the Plaintiffs, members of the Class and/or their children to suffer side effects or longer durations of illness due to the ineffectiveness of the Subject Products; and (c) more expensive than other reasonable alternatives for the conditions treated.

537. The Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medications and alternative courses of treatment. The Defendants contend to the contrary. Therefore, the parties herein have adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory relief.

538. The Plaintiffs, on behalf of themselves and all others similarly situated, are entitled to a judgment declaring that the Defendants' practice of perpetrating unfair or deceptive acts and misleading misrepresentations and non-disclosure of material

facts relating to the safety, efficacy and cost effectiveness of the Subject Products is unlawful, and are entitled to further relief pursuant to 28 U.S.C. § 2202.

WHEREFORE, Plaintiffs on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs and the Class demand judgment against Defendants in each claim for relief, jointly and severally, and as follows:

(a) On the claims under the consumer protection fraud laws, compensatory damages, treble damages, punitive damages, and any other damages permitted under such statutes, such amounts to be determined at trial, plus Plaintiff's costs in this suit and reasonable attorneys' fees.

(b) On the claims for violations of RICO and the Magnuson-Moss Act, damages and other relief permitted under such statutes.

(c) On the claims for product liability, compensatory, punitive and other damages in such amounts to be determined at trial.

(d) On the claims for negligence, fraud and conspiracy, compensatory, punitive and other damages in such amounts to be determined at trial.

(e) On the claim for unjust enrichment, recovery in the amount of Plaintiffs' and the Class' payments for these Subject Products.

(f) Awarding Plaintiffs and the Class other appropriate equitable relief, including, but not limited to, disgorgement of all profits obtained from Defendants' wrongful conduct and declaratory and injunctive relief;

(g) Awarding Plaintiffs and the Class pre-judgment and post-judgment interest at the maximum rate allowed by law;

(h) Awarding Plaintiffs and the Class their costs and expenses in this litigation, including expert fees, and reasonable attorneys' fees; and

(i) Awarding Plaintiffs and the Class such other and further this relief as may be just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs and the Class demand a trial by jury on all issues so triable.

Dated: January 12, 2011

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I, Donald E. Haviland, Jr., hereby certify that on January 12, 2011 a true and correct copy of the foregoing Consolidated Amended Civil Consumer Class Action Complaint was served on all counsel of record via CM/ECF.

/s/_____
Donald E. Haviland, Jr.