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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION	Civil Action No. 10-2033(FLW)

CONSOLIDATED
AMENDED COMPLAINT

TABLE OF CONTENTS

"You will 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!"

- Johnson & Johnson's Instructions to Consultants Hired to Perform a "Phantom Recall" of Motrin

"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."

- Representative Darrell Issa (R – California)

Plaintiffs Minneapolis Firefighters' Relief Association, the Hawaii Laborers Pension Fund and Jeanne M. Calamore ("Lead Plaintiffs"), and Albert L. Feldman, Walter E. Ryan, Jr., and the Trustees comprising the Investment Committee of the NECA-IBEW Welfare Trust Fund ("NECA-IBEW") ("Additional Plaintiffs" and together with Lead Plaintiffs, "Plaintiffs"), by their attorneys, allege the following for their Verified Consolidated and Amended Shareholder Derivative Complaint (the "Complaint"). Plaintiffs make the below allegations upon personal knowledge as to themselves and their own acts, and as to all other matters upon information and belief. The allegations have been informed by an investigation that included, among other things: (a) analysis of the Company's public filings with the U.S. Securities and Exchange Commission ("SEC"); (b) review of news articles and other publicly available information; (c) review and analysis of multiple *qui tam* complaints and complaints filed by the Department of Justice and/or State Attorneys General and (d) investigation of individuals with personal knowledge of the events giving rise to this action. Plaintiffs believe additional evidentiary support will exist for their allegations after a reasonable opportunity for discovery.

I. INTRODUCTION

1. The job of a corporate board of directors, first and foremost, is to act in good faith to ensure that the company's business is conducted lawfully.

2. Johnson & Johnson ("J&J" or the "Company") was founded in 1886 and grew into one of the world's leading health care products and pharmaceutical companies. The Company manufactures, markets, and sells medical products, including familiar over-the-counter ("OTC") medications sold directly to consumers, powerful and potentially dangerous prescription drugs that are promoted to doctors and medical institutions, and manufactures and sells complex surgical devices and diagnostic tests.

3. For over a century, Defendants' predecessors in the boardroom and executive suite developed and enhanced the Company's reputation, making J&J the gold standard for integrity and excellence in its industry. Over the better part of the past decade, Defendants' utter disregard for their fiduciary duties, including permitting and fostering a culture of systemic, calculated and widespread legal violations has destroyed J&J's hard-earned reputation.

4. As described below, the J&J board of directors (the "Board") was warned, specifically and repeatedly over a number of years, that J&J's drug and medical device manufacturing and marketing practices represented systemic and widespread violations of the law. These "red flags" came in many forms and from many sources. The Board learned about dozens of red flags, including at least:

- six FDA warning letters and additional violation notices specifically identifying unlawful marketing practices or public health and safety violations and demanding that J&J cease the identified practices and all similar misconduct;
- six *qui tam* complaints that detailed J&J's unlawful activities;
- twelve subpoenas or informational inquiries from Congress and federal prosecutors regarding marketing and safety issues;
- six inquiries from State Attorneys General on the same topics;
- numerous federal government and State complaints seeking civil and criminal relief; and

- two criminal pleas accepted by J&J subsidiaries for violating regulations that cut to the heart of J&J's business.

5. Faced with this litany of "red flags," Defendants were under a duty to specifically inform themselves of the nature and extent of these problems and to take aggressive action to cure violations and prevent them from recurring. Defendants were also well aware that the consequences of permitting or fostering a culture of legal non-compliance could be catastrophic to J&J's business, and could include corporate criminal indictment or exclusion from participation in federal programs like Medicare and Medicaid. Inexplicably, instead of remedying these drug and medical device manufacturing and marketing violations, the misconduct continued unabated and in many ways it proliferated.

6. Recent events at J&J illustrate the Board's conscious disregard and breach of fiduciary duty in a years-long breakdown in J&J's compliance with these regulations across the Company's operations. These events also show that J&J's senior management cloaked the truth about its misconduct and the J&J Board allowed what the United States Congress has described as a "pattern of concealment." Put simply, the J&J Board only takes action to curtail illicit practices at the Company when facing imminent civil or criminal penalties.

7. First, J&J's lack of control over its drug manufacturing practices has led to unprecedented product recalls that have impaired major revenue-producing drugs for a myriad of reasons, including metal in tablets and capsules, medications that failed to properly dissolve, and drugs plagued with a nausea-inducing musty odor. In the wake of increasing FDA scrutiny, J&J recalled key drugs in 2005 and 2006, so the Defendants have no excuse to claim ignorance about the Company's manufacturing problems. An internal 2007 J&J report detailed manufacturing failures within the very plant that J&J ultimately closed, yet Defendants took no action to clean up the operations, and the Company continued to distribute known contaminated products

manufactured there. Thus, despite these prior warnings, in 2009 and 2010, J&J's material recalls were constant, one more severe and troubling than the last.

8. J&J pulled millions of pills of children's medicine off the shelves, recalled hip replacement parts that had already been surgically implanted in patients, and pulled contact lenses that burned users' eyes. These recalls affected high profile brands like Tylenol, Motrin, Rolaids and Benadryl.

9. Under the Defendants' supervision, J&J even tried to conceal its non-compliance with current Good Manufacturing Practices ("cGMP"), initiating a "phantom" recall of defective Motrin tablets. Specifically, J&J hired a contractor to clandestinely purchase all of the available stock of the flawed product at retail stores across the nation. The contractors were specifically instructed to conceal the fact of any drug recall, as the Company sought to sweep this serious safety issue under the rug. It is far-fetched for the Board to disclaim knowledge of a national and complex effort to conceal wrongdoing. Worse yet, if the Board denies involvement, the question becomes, how did this happen without their involvement?

10. As J&J's drug manufacturing problems accelerated in recent years, the regulators at the U.S. Food and Drug Administration increased its focus on the Company's manufacturing facilities. In April 2010, J&J shut down a major manufacturing facility in Fort Washington, Pennsylvania. The FDA's investigation revealed, among other things, an absence of procedures for production and process controls, a failure of existing controls to assure safety of the pill production process, a failure to review and cure identified discrepancies between practice and safety policies, a failure to establish scientifically sound and appropriate test procedures to assure product safety.

11. On December 9, analysts predicted that the Company would be forced to shut down its facility in Las Piedras, Puerto Rico. Also on December 9, the FDA updated its Fort Washington related investigative findings, which show that even today, as Congress and the public are expressing outrage over J&J's near-total failure to exercise compliance controls, Defendants are still disregarding their duties. The December 9 report observes, among other things, that: (1) procedures regarding how to handle complaints are deficiently written; (2) control procedures to monitor output and validate manufacturing processes are not established; (3) there is a failure to review unexplained product discrepancies; (4) record maintenance does not sufficiently permit evaluation of quality standards; and (4) identified problems with one batch of drugs should have but did not trigger inquiries into other batches of the same drug or other associated drugs. As explained below, Defendants were apprised of the pertinent drug recalls, FDA warning letters, and increased facility reviews yet took no effective good faith actions to correct them.

12. Congressional investigation has revealed that despite years of "repeated instances of alarming problems with Johnson & Johnson's children's medicine from 2008 to 2010," the Company's investigation into these events was "unjustifiably delayed and terminated prematurely." These problems were reported to the Board, and the Company's Chairman and Chief Executive Officer ("CEO") has admitted, "[i]n 2008, there were adverse events reported that we knew."

13. J&J's lack of control over its manufacturing practices also affected its medical device business, including those that are surgically implanted into patients. Again, under Defendants' supervision, J&J looked the other way, allowing the misconduct to continue.

Further, these problems were not reported to the U.S Food and Drug Administration (the "FDA"), and defective products were knowingly sold to the market.

14. J&J's recent (and historic) product recalls are only the latest in a long line of unlawful practices used to market and sell the Company's products. J&J aggressively promoted its most lucrative prescription drugs for uses and purposes that were not approved by the FDA. The Company improperly marketed Risperdal, Topamax and Natrecor for unapproved uses, including dangerous use by children and by the elderly.

15. As part of its improper promotional efforts, the Company also engaged in a kickback scheme, unlawfully paying nursing home pharmacist Omnicare tens of millions of dollars in unlawful kickbacks to induce Omnicare to aggressively promote multiple J&J medications. The DOJ is continuing to investigate J&J's role in connection with this scheme, and has intervened in a *qui tam* action against the Company. The J&J Board acknowledged in multiple public filings the federal investigation of the kickback scheme and the $98 million settlement.

16. In addition, J&J unlawfully marketed Topamax to treat numerous ailments and diseases for which it was not indicated and for which it had never received FDA approval. This unlawful promotion included marketing the drug for eating disorders, drug addiction and anxiety. Another J&J subsidiary has now accepted a criminal plea relating to Topomax.

17. Despite repeatedly receiving letters from the FDA requesting that the Company put an end to its off-label marketing, the J&J Board failed to remedy these unethical and illegal sales tactics. Several of the drugs at the heart of the off-label marketing scheme were such large revenue generators for J&J that it is inconceivable, other than through willful blindness, that the Board was unaware of the illegal practices through which they were sold to the public.

Considering that certain drugs were only approved for uncommon conditions with a limited market, yet the reported sales were in the billions of dollars, it was clear to the Board that a huge percentage of the drug's sales were the consequence of illegal off-label sales. Indeed, the litany of subpoenas, warnings, and governmental investigative demands were specifically disclosed in Forms 10-K signed by the Director Defendants in this action while the wrongdoing was ongoing.

18. This case is about holding Defendants accountable for the damage their bad faith actions and inactions has caused the Company and its shareholders and to ensure that the J&J ship is righted and that it conducts its business in a law-abiding manner in the future.

II. JURISDICTION AND VENUE

19. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332. Plaintiffs are domiciled in Connecticut, Minnesota, Hawaii, California, Illinois, Indiana, Kentucky and Nevada. None of the Defendants is a citizen of Connecticut, Minnesota, Illinois, Hawaii, California, Indiana, Kentucky or Nevada. Nominal defendant J&J is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

20. The amount in controversy exceeds $75,000. This action is not brought collusively to confer jurisdiction on this Court which it would not otherwise have.

21. Venue is proper in this District pursuant to 28 U.S.C. §§1391(a)(2) and (3) and 1401 because some or all of the events, actions, and failures to act giving rise to the claims asserted herein occurred in this District.

III. THE PARTIES

A. Plaintiffs

22. Plaintiff Minneapolis Firefighters' Relief Association ("MFRA") owns and has continuously owned common stock in J&J throughout the period of the wrongdoing. Plaintiff MFRA is a citizen of Minnesota.

23. Plaintiff Hawaii Laborers Pension Fund ("HLPF") owns and has continuously owned common stock in J&J throughout the period of the wrongdoing. Plaintiff HLPF is a citizen of Hawaii.

24. Plaintiff Calamore owns and has continuously owned common stock in J&J throughout the period of the wrongdoing. Plaintiff Calamore is a citizen of Connecticut.

25. Plaintiff Albert L. Feldman ("Feldman") owns and has continuously owned common stock in J&J throughout the period of the wrongdoing. Plaintiff Feldman is a citizen of California.

26. Plaintiff Walter E. Ryan, Jr. ("Ryan") owns and has continuously owned common stock in J&J throughout the period of the wrongdoing. Plaintiff Ryan is a citizen of Nevada.

27. Plaintiffs Jim Bailey ("Bailey"), Jaye Fuller ("Fuller"), Terry Gipson ("Gipson"), Jon Huston ("Huston"), and Ted Uppole ("Uppole") are Trustees comprising the Investment Committee of the NECA-IBEW Welfare Trust Fund. NECA-IBEW owns and has continuously owned common stock in J&J throughout the period of wrongdoing. Plaintiffs Fuller, Huston and Uppole are domiciled in Indiana; Plaintiff Bailey in Illinois; and Plaintiff Gipson in Kentucky. The Investment Committee is authorized to commence litigation, such as this, on behalf of the Welfare Trust Fund.

B. Nominal Defendant

28. Nominal Defendant J&J is a corporation organized under the laws of New Jersey with its principal executive offices and corporate headquarters located in New Brunswick, New Jersey. J&J manufactures and sells pharmaceutical products, medical devices and consumer packaged goods.

C. Individual Defendants

1. Director Defendants

29. Defendant Mary Sue Coleman, Ph.D. ("Coleman") has been a Director since 2003. Coleman has been a member of the Audit Committee and the Science & Technology Advisory Committee since 2003. Coleman is a citizen of Michigan.

30. Defendant James G. Cullen ("Cullen") has been a Director since 1995, and is the Presiding Director of the Board and Chairman of the Audit Committee. Cullen has been a member of the Audit Committee since 1997 and a member of the Nominating & Corporate Governance Committee since 2004. Cullen is a citizen of Virginia or New Jersey.

31. Defendant Michael M.E. Johns, M.D. ("Johns") has been a Director since 2005 and is a member of the Compensation & Benefits Committee and the Science & Technology Advisory Committee since 2006. Johns is a citizen of Georgia.

32. Defendant Arnold G. Langbo ("Langbo") was a Director from 1991 through April 2010. Langbo was member of the Nominating & Corporate Governance Committee and Chairman of the Compensation and Benefits Committee. In addition, Langbo served on the Audit Committee from 1997 through 2003. Langbo was also a member of the Nominating & Corporate Governance Committee from 2004 to April 2010. Langbo is a citizen of Vermont.

33. Defendant Susan L. Lindquist, Ph.D. ("Lindquist") was elected to the Board in 2004 and is a member of the Science & Technology Advisory Committee and the Public Policy Advisory Committee since 2004. Lindquist is a citizen of Massachusetts.

34. Defendant Leo F. Mullin ("Mullin") has been a Director since 1999 and is a member of the Audit Committee since before 2002 and Chairman of the Public Policy Advisory Committee. Mullin has been a member of the Audit Committee since 2000, a member of the

Public Policy Advisory Committee since 2006 and a member of the Nominating & Corporate Governance Committee from 2000 to 2005. Mullin is a citizen of Georgia.

35. Defendant William D. Perez ("Perez") was elected to the Board in 2007 and is a member of both the Compensation & Benefits Committee and the Public Policy Advisory Committee since 2007. Perez is a citizen of Oregon.

36. Defendant Charles O. Prince, III ("Prince") was elected to the Board in 2006 and is a member of the Compensation & Benefits Committee and chairman of the Nominating & Corporate Governance Committee since 2007, and chair since 2008. Prince is a citizen of New York or Florida.

37. Defendant David Satcher, M.D., Ph.D. ("Satcher) was elected to the Board in 2002 and is Chairman of the Science & Technology Advisory Committee since 2003 and a member of the Public Policy Advisory Committee since 2002. Satcher is a citizen of Georgia.

38. Defendant William C. Weldon ("Weldon") was elected to the Board and named Vice Chairman of the Board in 2001 and assumed his current responsibilities as Chairman of the Board and Chief Executive Officer in April 2002. Weldon joined the Company in 1971 as a sales representative at McNeil Pharmaceutical. In 1989, he became Vice President, Sales and Marketing for Janssen. He was appointed to the Executive Committee and named Worldwide Chairman, Pharmaceuticals Group, in 1998, and became Chairman of the Executive Committee in 2002. Weldon is a citizen of Pennsylvania.

2. Officer Defendants

39. In addition to being named as Director Defendants above, defendants Weldon is also named as an Officer Defendant.

40. Defendant Russell C. Deyo ("Deyo") joined the Company in 1985 and became Associate General Counsel in 1991. He became a member of the Executive Committee and Vice

President, Administration in 1996 and Vice President, General Counsel and Chief Compliance Officer in April, 2004. Deyo was given the additional responsibility for Human Resources in November, 2009. Deyo has responsibility for legal compliance activities of Johnson & Johnson and its operating subsidiaries. He is on the Public Policy Advisory Committee of the Board. Deyo is a citizen of New Jersey.

41. Defendant Alex Gorsky ("Gorsky") is Worldwide Chairman, Medical Devices and Diagnostics Group since September 2009, and a member of Johnson & Johnson's Executive Committee since January 2009. He rejoined J&J in 2008 as Company Group Chairman and Worldwide Franchise Chairman for Ethicon, Inc. after working for four years at the head of the North American pharmaceuticals business at Novartis Pharmaceuticals Corporation. Prior to 2004, Gorsky served in various management positions at J&J, beginning as a sales representative with Janssen in 1988. Over the next fifteen years, he advanced through positions of increasing responsibility in sales, marketing and management, and was named President of Janssen in the U.S. in 2001. His responsibilities included the marketing of Risperdal. Gorsky is a citizen of Pennsylvania.

42. Defendant Peter Luther ("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. Luther served as the President of LifeScan, another J&J subsidiary, from March 2000 to March 2006, until he became President of J&J's North American Beauty Care division, a position he held until January 2009. Since January 2009, Luther has been the President of McNeil Consumer Healthcare. Luther is a citizen of New Jersey.

43. Defendant Christine A. Poon ("Poon") was elected to the Board and named a Vice Chairman of the Board in 2005. She left the Board on March 1, 2009. Her career with J&J

began in November, 2000, as Company Group Chairman, Pharmaceuticals. In August, 2001, she was promoted to the Executive Committee and named Worldwide Chairman, Pharmaceuticals. In October, 2003, Poon was appointed Worldwide Chairman, Medicines and Nutritionals. In 2007, Poon assumed responsibility for the J&J Development Corporation, the Corporate Office of Science and Technology, the Corporate Office of Information Management, Worldwide Procurement and Worldwide Operations. Poon is a citizen of Ohio.

44. Defendant Joseph C. Scodari ("Scodari") joined J&J in 1999. In 2001 he was named Company Group Chairman for the Johnson & Johnson North American Pharmaceuticals business, and became a member of the Pharmaceuticals Group Operating Committee. From 2003 to 2005, Scodari was Company Group Chairman of J&J's Biopharmaceutical Business, and was Worldwide Chairman, Pharmaceuticals Group. Scodari was also a member of the Executive Committee from March 2005 until March, 2008. Scodari is domiciled in Pennsylvania.

45. Defendant Nicholas Valeriani ("Valeriani") is Vice President, Strategy & Growthsince February 2007. Valeriani has been with the J&J family of companies since 1978. In January 2001, he was named Company Group Chairman and the following year, he became Worldwide Franchise Chairman for the DePuy franchise. He was promoted to Corporate Vice President, Human Resources, Johnson & Johnson, and became a member of the Executive Committee in September 2003, with responsibility for compensation and benefits and education. Valeriani was a member of the Management Compensation Committee and the Pension Committee. Additionally, in the first quarter of 2004, he was named Worldwide Chairman, Diagnostics. Valeriani is domiciled in New Jersey.

46. The "Director Defendants" and "Officer Defendants" named in paragraphs 29 to 45 are collectively referred to herein as the "Individual Defendants."

IV. SUBSTANTIVE FACTUAL ALLEGATIONS

A. Description of J&J's Business

47. J&J is organized into three business segments: Consumer, Pharmaceutical, and Medical Devices & Diagnostics. J&J's improper and illegal business practices at issue occurred across all three segments of the Company: Consumer, Pharmaceutical and Medical Device and Diagnostics

48. J&J's Consumer segment manufactures, markets and sells premium brand consumer products. The Consumer segment also manufactures numerous OTC pharmaceutical products through, among other franchises, J&J's McNeil Consumer Healthcare franchise. These OTC products include household brands such as Tylenol, Motrin, Benadryl and Zyrtec, many of which have been the subject of the recalls described herein.

49. From 2003 through 2009, J&J generated revenues of $26.5 billion from the sale of its OTC products, constituting over 32% of the Consumer segment's total revenue. J&J's Pharmaceutical segment manufactures, markets and sells prescription drugs to pharmacies, wholesalers and doctors. Risperdal and Topamax, two drugs J&J illegally promoted, are examples of products manufactured and marketed by J&J's Pharmaceutical segment.

50. From 2003 through 2009, J&J generated revenues of $23.6 billion and $12.5 billion from the drugs Risperdal and Topamax, respectively, constituting over 22% of **t**he Pharmaceutical segment's total revenue during this period.

51. Finally, J&J's Medical Devices and Diagnostics segment manufactures, markets, and sells a broad range of medical devices and surgical implants to wholesalers, hospitals, laboratories and doctors. The Medical Devices and Diagnostics segment includes, among other franchises, DePuy Orthopaedics ("Depuy"), Cordis and Vision Care franchises, which has each been plagued by misconduct giving rise to this action.

52. From 2003 through 2009, J&J generated more than $66 billion in revenues from these franchises, constituting almost 50% of the Medical Devices and Diagnostics segment's total revenue.

53. For the period 2003 through 2009, J&J reported spending $15.6 billion on the marketing and promotion of its products.

B. J&J's Business is Subject to Extensive Government Regulation

54. The improper manufacture, promotion, distribution, packaging, labeling or sale of pharmaceuticals or medical devices can cause serious harm to the user of those products, including death. As a result, most of J&J's businesses are subject to governmental regulation, primarily with respect to product safety, efficacy, manufacturing, advertising, labeling and safety reporting.

55. J&J's business practices in the health care industry have come under increased scrutiny, particularly in the U.S., by government agencies and state Attorneys General. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties. Despite knowing this, the Board has allowed the Company to disregard and violate health and safety regulations across the entire spectrum of J&J's business segments.

1. Drug Manufacturing Regulation

56. The U.S. Food and Drug Administration ("FDA") regulates drug manufacturing and marketing in the U.S. Pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA is charged with, among other things, ensuring that drugs marketed in the U.S., are safe, effective, and are manufactured in accordance with cGMP.

57. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, distributing, labeling and packaging of drugs.[1] The FDA enforces cGMP regulations and defines cGMP 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 manufactures of medications adequately control manufacturing operations. ***This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating 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. (Emphasis Added)

58. Under the cGMP regulations, each manufacturer is required to implement a formal system of controls and to put in place a quality control system that ensures its drugs are safe. A violation of cGMP indicates a breakdown in a manufacturer's quality system that can have enormous consequences for a company and patients relying on a company's drugs.

59. The FDA inspects facilities every two to three years to ensure compliance with cGMP. The FDA increases the frequency of inspections when warranted by past problems or by products that are difficult to manufacture or are of an especially high risk. When on site, FDA inspectors identify gaps in manufacturing standards and discuss potential solutions with the offending companies.

60. Firms typically recall products when cGMP violations are identified, especially when those violations have a significant impact on product quality or safety. In addition, patterns of non-compliance that create a public health risk can result in a wide range of

[1] *See* 21 CFR 820 and following

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

2. Drug Marketing Regulation

61. The FDCA requires that the manufacturer or sponsor of a new drug submit a New Drug Application ("NDA") to the FDA, which identifies all of the proposed uses of the drug intended by the manufacturer, together with the proposed label for those uses, as well as data generated in randomized, adequate and well-controlled clinical trials. Approval requires that the data demonstrate to the FDA's satisfaction that the drug will be safe and effective for its intended uses. *See* 21 U.S.C. §331(d) and §355(b).

62. In order for the FDA to approve a drug, the manufacturer must demonstrate that the drug is "safe for use" for all "conditions prescribed, recommended, or suggested" in the drug's label. 21 U.S.C. §355(b). Until the FDA approves the NDA, including the proposed labeling, and makes a determination regarding safety and efficacy for the uses proposed, the FDCA prohibits the manufacturer from introducing the drug into interstate commerce. 21 U.S.C. §355(a).

63. Even once approved, the marketing of the drug must be confined to the approved use and dosage, as described on the drug's label. Drug companies may not engage in marketing or promoting unapproved or "off label" uses or dosages, *i.e.* uses or dosages for which the drug has not been approved by the FDA and that are not on the label, because such off-label uses or dosages have not been proven safe and effective.

64. The FDCA also prohibits the marketing or promotion of any drug that is misbranded. A drug is misbranded if the labeling or the advertising for the drug is false or misleading, or if the labeling or the advertising contains inadequate directions for the drug's intended use. Because the FDA will not approve labels with directions for off-label uses or

dosages, off-label marketing also violates the FDCA's prohibition on the marketing or promotion of drug that are misbranded.

65. Proving that a specific use or dosage is safe and effective for large numbers of patients requires lengthy clinical trials and is very expensive. On the other hand, drug companies derive immediate and substantial profits from off-label prescriptions. As a result, drug companies have a substantial short-term financial incentive to break the law by marketing and promoting their drugs for uses and dosages that are not proven to be medically safe and effective in treating large numbers of patients. For the same reasons, drug companies have a short-term financial incentive to improperly provide gifts, money and other kickbacks to doctors to induce and encourage off-label prescriptions. The resulting improper prescriptions are frequently reimbursed by federal healthcare programs such as Medicaid and Medicare, which in turn subjects the perpetrator to liability under the False Claims Act and Federal anti-kickback statute.

66. The federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) (the "Federal Anti-Kickback Statute"), makes it illegal to offer, receive, or solicit any remuneration, kickback, bribe or rebate, whether directly or indirectly, in cash or in kind, for the purpose of inducing any person to purchase or recommend the purchasing of any goods, service or item for which payment may be made in whole or in part under a government health care program.

67. Drug companies that violate the FDCA prohibition against misbranding or introducing drugs, uses or dosages without FDA approval are also subject to criminal prosecution and, if convicted, face exclusion or "debarment" from Federal healthcare programs. A violation of the Federal Anti-Kickback Statute can subject the perpetrator to exclusion from participation in federal health care programs. Such federal debarment would result in catastrophic damage to the Company and its shareholders because Medicaid and Medicare would

no longer cover the costs of any J&J drug and most patients would therefore find an alternative drug sold by a competitor or would forego treatment altogether.

68. Under the FDCA, drug companies are not allowed to market a drug until the drug has been approved by the FDA. Even once approved, the marketing of the drug must be confined to the approved use and dosage, as described on the drug's label. Drug companies may not engage in marketing or promoting unapproved or "off label" uses or dosages, *i.e.* uses or dosages for which the drug has not been approved by the FDA and that are not on the label, because such off-label uses or dosages have not been proven safe and effective.

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subjects the perpetrator to liability under the False Claims Act and Federal anti-kickback statute.

71. Congress enacted the Medicaid Drug Rebate Statute of the Social Security Act, 42 U.S.C. §1396r-8 (the "Medicaid Drug Rebate Statute"), to ensure that the Medicaid program would receive the benefit of the same discounts and prices on drugs that other large public and private purchasers enjoy. *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.A.A.N. 2017, 2108.

72. Under the Medicaid Drug Rebate Statute, in order for a brand name drug, such as J&J's antipsychotic drug, Risperdal, to be covered and reimbursed by the Medicaid program, its manufacturer has two primary obligations. First, a manufacturer must report on a quarterly basis to the Secretary of DHHS the drug's Average Manufacturer's Price ("AMP"), which is the average price paid by wholesalers for drugs distributed to retailers, and the best price offered for that drug. 42 U.S.C. §1396r-8(b)(3)(A). Second, a manufacturer must pay each state a quarterly rebate equal to the total number of drug units (*e.g.*, tablets) purchased by the state times the greater of (i) 15.1% of the drug's AMP, or (ii) the difference between the AMP and the best price. 42 U.S.C. §1396r-8(c)(1)(A).

3. OIG Compliance Program Guidance

73. The federal government, including the DOJ and the Office of the Inspector General of the DHHS ("OIG"), has taken increasingly aggressive action to enforce pharmaceutical companies' compliance with federal drug marketing and anti-kickback laws.

74. On June 11, 2001, the OIG published a notice in the Federal Register soliciting information and recommendations for developing "compliance program guidance" for the pharmaceutical industry. *See* 66 Fed. Reg. 31246-47 (June 11, 2001). The OIG listed the following "seven elements that we consider necessary for a comprehensive compliance program and which the OIG would consider in any criminal sentencing:

a. The development of written policies and procedures;

b. The designation of a compliance officer and other appropriate bodies;

c. The development and implementation of effective training and education programs;

d. The development and maintenance of effective lines of communication;

e. The enforcement of standards through well-publicized disciplinary guidelines;

f. The use of audits and other evaluation techniques to monitor compliance; and

g. The development of procedures to respond to detected offenses and initiate corrective action. *See* 66 Fed. Reg. 31247.

75. In October 2002, the OIG published a draft OIG Compliance Program Guidance for pharmaceutical manufacturers. 67 Fed. Reg. 62057-67 (October 3, 2002). The OIG explained that "a good faith effort by the company to comply with applicable statutes and regulations, as well as Federal health program requirements, demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior." 67 Fed. Reg. 62059.

76. According to the OIG, "[i]n order for a compliance program to be effective, it must have the support and commitment of senior management and the company's governing body." 67 Fed. Reg. 62058-59. Thus, "every effective compliance program must begin with a formal commitment by the pharmaceutical manufacturer's board of directors or other governing body," and the OIG "strongly encourage[d] the participation and involvement of the pharmaceutical manufacturer's board of directors, CEO, president, members of senior management, and other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the code of conduct." 67 Fed. Reg. 62059; 62060.

77. On May 5, 2003, the OIG published its Compliance Program Guidance in the Federal Register. 68 Fed. Reg. 23731-43 (May 5, 2003) (the "OIG Guidelines"). The OIG Guidelines again discussed the necessary elements for an effective compliance program, encouraging pharmaceutical companies, for example, to implement a "thorough monitoring of its implementation and an ongoing evaluation process." 68 Fed. Reg. 23741. In this regard, the OIG noted that compliance audits should focus on the divisions of the company that have substantive involvement with federal healthcare programs (including the sales and marketing divisions), and "evaluate whether the: (1) Pharmaceutical manufacturer has policies covering the identified risk areas; (2) policies were implemented and communicated; and (3) policies were followed. 68 Fed. Reg. 23741.

78. The OIG Guidelines also noted that management should immediately investigate reasonable indications of suspected noncompliance to "identify the root cause of the problem" and, if a violation occurred, to take "decisive steps to correct the problem." 68 Fed. Reg. 23742. As the OIG explained, "[v]iolations of a pharmaceutical manufacturers' compliance program, failure to comply with applicable federal or state law, and other types of misconduct threaten the company's status as a reliable, honest, and trustworthy participant in the health care industry" and "[d]etected but uncorrected misconduct can endanger the reputation and legal status of the company." 68 Fed. Reg. 23742.

79. Uncorrected misconduct can lead to the exclusion of the company and management from participation in federal healthcare programs, including Medicare and Medicaid. *See* 42 U.S.C. §1320a-7(b)(15). Such exclusion or federal "debarment" is mandatory in case of a conviction for a felony violation of the FDCA or the payment of kickbacks, and can

have devastating financial consequences because the company can no longer contract with the federal government for its drugs.

80. The pharmaceutical industry was keenly aware of the OIG Guidelines and the increased enforcement efforts. In April 2006, senior level executive speakers from seventeen pharmaceutical companies, including J&J, and hundreds of pharmaceutical executives met at the "Pharmaceutical Marketing Summit" in New Brunswick, New Jersey, to participate in a number of marketing forums. *See* "Pharma Compliance With OIG Guidelines for Executive Marketing & Management Forum to be Attended By 400-600 Delegates on April 4-5 in New Brunswick, NJ," redOrbit, January 4, 2006. The keynote address at this compliance forum, "Prosecutions and the Benefits of Compliance," was given by the Chief of the Health Care Fraud Unit in the United States Attorneys' Office for the District of Massachusetts, Michael Loucks. *See* "Pharma Compliance for Marketing & Management Conference to Feature 17 High-Level Pharmaceutical Company Presenters Plus OIG and FDA," redOrbit, January 31, 2006. In addition to Mr. Loucks' address, a number of "presenting companies" (including Johnson and Johnson) discussed various compliance topics, including "Medicare Modernization Act Challenges: Fraud & Abuse Implications in Pharma Marketing & Sales" and "Prepare for Increased OIG Scrutiny on Off-Label Activity." *See id.*

81. The public recall of a pharmaceutical company's product can have wide-ranging, and potentially devastating effects, on the company's business. Public recalls, however, are a critical element of the pharmaceutical company's contract with the consuming public as well as with various government regulatory agencies. If a product is either dangerous or was manufactured in an unsafe manner, the pharmaceutical company has a legal and ethical

obligation to make the facts known to the public and the Government by carrying out as effective and public a recall as possible.

82. A pharmaceutical company's officers and directors have an overriding obligation to insure that robust procedures and standards are implemented within the company to insure that – when necessary – the recall is carried effectively and with candor.

83. These OIG guidance publications were consistent with contemporaneous regulatory and law enforcement action that clearly emphasized director responsibility for oversight of compliance programs. For example, revisions to the Federal Sentencing Guidelines, effective November 1, 2004, addressed the role of the organization's "governing authority" -- in most cases, a board of directors -- in an effective compliance program:

> The organization's governing authority *shall be knowledgeable about* the content and operation of the program to prevent and detect violations of law and *shall exercise reasonable oversight with respect to the implementation and effectiveness* of the program to prevent and detect violations of law.
>
> Specific individual(s) within the high level personnel of the organization shall be assigned direct, overall responsibility to ensure the implementation and effectiveness of the program to prevent and detect violations of law. Such individual(s) shall be given adequate resources and authority to carry out such responsibility and shall report on the implementation and effectiveness of the program to prevent and detect violations of law directly to the governing authority or an appropriate subgroup of the governing authority.

Federal Sentencing Guidelines, Chapter Eight - Part B, § 8B2.1.(b)(2)(A) and(B) (emphasis added). Similarly, in January 2003, the DOJ issued revised Principles of Federal Prosecution of Business Organizations, directing prosecutors to consider, in making corporate charging decisions, whether the "Directors [have] established an information and reporting system in the organization reasonably designed to provide management and the board with timely and accurate information sufficient to allow them to reach an informed decision regarding the organization's compliance with the law."

C. J&J Suffers Fundamental Control Breakdowns Across All of its Business Segments

1. Recalls Based on Manufacturing Failures and Related Regulatory Violations

84. J&J, through its McNeil subsidiary, manufactures some of the world's most widely recognized pharmaceutical products, including varieties of the ubiquitous Tylenol brand.

85. Notwithstanding the critical nature of these products to J&J's business – and reputation – the Defendants have permitted a systemic deterioration of the manufacturing processes and internal controls and standards at McNeil. The result has been devastating. Since 2008, J&J has experienced an extraordinary and unprecedented number of fundamental control breakdowns, including:

a. nine major product recalls, including the recall of hundreds of millions of bottles of various children's Tylenol products;

b. the issuance of a January 15, 2010 FDA warning letter concerning deficient manufacturing processes and protocols at the Las Piedras Facility stating that "that when J&J became aware of FDA's concerns about the thoroughness and timeliness of McNeil's investigation, whether all potentially affected products had been identified, and whether the recall was adequate in scope, J&J did not take appropriate actions to resolve these issues";

c. the issuance of highly critical Form 483 inspection reports by the FDA regarding the Las Piedras Facility and Fort Washington Facility, which outlined a series of violations and deficiencies at these plants including McNeil's failure to timely report contamination, McNeil's failure to follow written procedures, McNeil's failure to implement effective internal investigations and McNeil's failure to follow through with corrective measures after product recalls;

d. the ultimate closing of the Fort Washington Facility

e. the initiation of at least one Congressional investigation into J&J's implementation of a secret "Phantom Recall" of a defective Motrin product.

86. Nor were these recent serious issues the first problems, or warning signs, that something was amiss at J&J. In 2004, the FDA sent a Warning Letter to J&J after a series of late 2003 inspections at various J&J manufacturing facilities found recurring "***systemic violations in***

the quality management system employed to ensure the safety and effectiveness of [J&J's] drug-eluting stents." (Emphasis Added).

87. The letter went on to note that J&J had failed to establish and maintain adequate procedures for corrective and preventive actions. In addition, the letter cautioned the Company that "other Federal agencies are advised of the issuance of all Warning Letters so that they may take this information into account when considering the award of government contracts," and that J&J's "***responses appear to be specific spot fixes and do not take a systematic approach to comprehensively cover the corrections***, the corrective actions and the preventive actions. ***None of the responses adequately deal with true preventive actions***." (Emphasis Added).

88. Subsequently, the number of product recalls to which the Company was subjected grew significantly from 2004 to 2006, and continued throughout 2007. The FDA's website reveals that during this period, the number of recalls of J&J products was significantly greater than the number of recalls for any of the other top ten pharmaceutical companies. These recalls span all three of J&J's business segments, and included, for example: (i) approximately 400,000 Catheters; (ii) approximately 20,000 DePuy spine surgery products (based on compromised sterility of products); (iii) over 1 million Ethicon sutures; and (iv) over 90,000 bottles of Ultram (based on failure to dissolve due to manufacturing defect).

89. In addition, recalls of consumer products manufactured by McNeil, among others, included: (i) Imodium Advanced Caplets (based on a failure to dissolve); (ii) almost 10.4 million units Children's Tylenol Meltaways (based on confusing packaging that could lead to improper dosing); (iii) Children's Tylenol SoftChews Fruit Flavor (same); (iv) Infant Tylenol Concentrated Drops – Cherry Flavor (based on metal shavings in product); (v) Children's Tylenol SoftChews (based on a label error on declared strength of product); (vi) Children's

Tylenol Oral Suspension (based on the presence of pieces of wire ties); and (vii) Tylenol Arthritis Extended Relief (based on the presence of broken metal pieces compressed into caplets).

90. All of the 2004-2007 recalls listed above, which were published on the FDA website, were based on regulatory actions by the FDA.

91. The fact of widespread quality and cGMP problems at J&J's consumer healthcare products manufacturing facilities was well known to management. According to Confidential Witness # 5 ("CW5"), a former Manager of Quality & Engineering at the facility, a report, dated August 2007, was prepared for senior management based on an internal assessment at the Fort Washington, Pennsylvania plant. This report was provided to, among others, Colleen Goggins, Chairman of J&J's Consumer Group and member of the Executive Committee. Despite this report, which detailed widespread manufacturing problems at the plant going back as early as 2005, no action was taken. According to CW 5 and CW 4, cost concerns drove the decision not only to continue manufacturing operations unabated despite the identified risks, but also to continue to distribute known contaminated products.

92. Thus, the pervasive product and manufacturing problems continued. A 2008 FDA report outlines an increasing number of complaints about consumer tablets of Tylenol Arthritis. The report explains J&J's failure to timely report contamination at its facilities or to follow up on corrective commitments related to product recalls. Among other things, the report notes that written procedures were not followed and internal investigations were deficient.

93. The damage caused by these repeated and habitual violations has been severe. J&J has already lost hundreds of millions of dollars and will, in all likelihood, suffer significant future losses as a result of lost sales and regulatory and legal penalties.

94. The damage to J&J's reputation is no less significant. J&J was, at one time, regarded as the model pharmaceutical company – trusted throughout the industry and by the consuming public. J&J's reputation was built on the hard work of J&J for over a century. Yet, as a consequence of the Defendants' bad faith conduct and abandonment of oversight, that reputation has been seriously tarnished, perhaps irreparably.

2. The "Phantom Recall" of Motrin

95. In or about June 2008, J&J learned that there were health and safety risks with certain batches of Motrin, a popular pain reliever. Instead of proceeding – as it should have done – with a product recall, J&J implemented a scheme designed to recall the product without informing the public or the FDA (hereinafter the "Phantom Recall"). The Phantom Recall was designed and implemented by J&J to hide Defendants' conduct.

96. To carry out the Phantom Recall, J&J designed – and initiated – a comprehensive program whereby hired contractors would travel to retail locations where the tainted Motrin had been shipped, and then purchase all remaining lots of the effected merchandise from the particular vendor. J&J instructed the contractors to mislead the merchants as to the reasons for the abnormally large purchases of Motrin. In particular, internal J&J documents indicate that the outside contractor CSCS was given explicit and detailed instructions on how to carry-out this clandestine recall. By way of example, a June 12, 2010 memorandum concerning the "CSCS Motrin Purchase Project" sets forth as follows:

> WIS has been asked by CSCS (our client) on behalf of Johnson & Johnson to purchase all Motrin IB Caplet 8ct Vial in the stores you have been scheduled for. You will quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave.
>
> You should simply "act" like a regular customer while making these purchases. **THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!** If asked, simply state that your employer is checking the

> distribution chain of this product and needs to have some it purchased for the project. (Emphasis in original)

97. This memorandum underscores the degree and scope of the breakdown of good corporate management and practices at J&J. Not only was the Phantom Recall initiated in direct disregard of J&J's obligations to the public and the FDA, but the Phantom Recall was designed like a clandestine spy mission - with specific instructions for the contractors to conceal their true purposes.

98. The Phantom Recall violated the public's trust. As facts regarding the Phantom Recall have become known, there has been predictable outrage by the public and by the Government. As a result, in May 2010, Edolpus Towns, the Chairman of the House's Committee on Oversight and Government Reform ("HCOGR"), initiated an investigation into the Phantom Recall. In connection with this investigation, Chairman Towns' committee issued various subpoenas to J&J, requesting voluminous documentation concerning the facts of the Phantom Recall.

99. At the hearings conducted by Chairman Towns, J&J continued to hide the truth about the recalls, contending that it was actually a "soft market withdrawal" approved by the FDA pursuant to a heretofore undisclosed agreement. The FDA itself has denied that any such agreement existed and, stated that J&J had mislead it concerning both the scope of the Motrin problem and the true nature of the plan J&J implemented to allegedly rectify the problem.

100. At a subsequent September 30, 2010 hearing, Chairman Towns stated that "documents subsequently obtained by the [HOCGR] show that J&J dictated how the Phantom Recall would be carried out. Internal emails and other documents indicate that J&J clearly knew what it was doing and why."

101. At the September 30 hearing Towns also disclosed a number of damning internal J&J communications. Referring to the problems with Motrin that resulted in the Phantom Recall, one J&J executive stated, "***we are just trying to prevent a recall and a lot of expended $***." In another internal email, a J&J executive refers to the phantom recall and says, "this was a major win for us as it limits the press that will be seen." Most notably, the president of a J&J division apparently gave the green light to the Phantom Recall, stating: "***Let's make this happen asap***."

102. According to the HCOGR, the Phantom Recall was part of a "pattern of concealment" by the Company of its manufacturing deficiencies.

3. 2009 Tylenol Recalls

103. In November 2009, J&J recalled five lots of Tylenol Arthritis Pain Caplet 100 count bottles because of an unusual smell or taste. Consumers had reported nausea and related symptoms.

104. In December 2009, J&J expanded the November 2009 recall to include all lots of Tylenol Arthritis Pain 100 count because of the unusual, moldy odor.

4. The January 15, 2010 Las Piedras Warning Letter

105. On January 8, 2010, the FDA conducted an inspection of J&J 's Las Piedras Facility. Just two days later, the FDA issued a scathing warning letter (the "Las Piedras Warning Letter") to Chairman and CEO Weldon.

106. The Warning Letter noted that as early as 2008, J&J had received a host of "uncharacteristic odor" complaints concerning OTC products – some of which caused adverse events, such as gastrointestinal distress. The odor – a musty mildew smell – was due to contamination of the product with 2,4,6 Tribromoanisole ("TBA"), a pesticide and flame

retardant. The complaints continued into 2009 and eventually led to the recall of multiple lots of OTC products.

107. The Las Piedras Warning Letter explained in detail that J&J's investigation into the problem was "unjustifiably delayed" and "terminated prematurely," and concluded that the company "did not conduct a timely, comprehensive investigation." In particular, the FDA wrote that:

> Numerous complaints were received over a four month period in 2008 before they were considered a trend and before actions were initiated to determine the root cause. When microbiological testing in August 2008 did not support an initial speculation that microbial contamination was the root cause of the odor, the investigation was closed. No other possible root causes were pursued. ***Your firm lacked adequate justification for this decision.*** (Emphasis added).

108. The Las Piedras Warning Letter was also highly critical of J&J's compliance with cGMP at the Las Piedras Facility. It states:

> [T]he timing and depth of your investigative efforts regarding uncharacteristic odor complaints were insufficient to meet good manufacturing practice. Your firm's management, including the Quality Control Unit was not proactive in response to consumer complaints. In addition, during 2008 examination of complaint samples, your firm's analysts noted that the tablets, once removed from the bottle, did not have an unusual odor but the bottle retained a strong odor. Nonetheless, you did not pursue chemical testing at that time.
>
> Your firm's quality management should have ensured the start of chemical testing far earlier. Failure to do so prolonged identification and resolution of the problem, resulting in continued consumer exposure. Quality problems must be thoroughly investigated, root causes determined, and appropriate corrective and preventive actions implemented as quickly as possible to limit exposure of the public to substandard drugs.

109. The Las Piedras Warning Letter further states:

> The Agency is concerned about the response of Johnson & Johnson (J&J) to this matter. It appears that when J&J became aware of FDA's concerns about the thoroughness and timeliness of McNeil's investigation, whether all potentially affected products had been identified, and whether the recall was adequate in scope, ***J&J did not take appropriate actions to resolve these issues. Corporate management has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management at J&J nor***

> ***at McNeil Consumer Healthcare assured timely investigation and resolution of the issues.*** (Emphasis added).

110. On February 19, 2010, senior representatives met with J&J's senior management. The FDA again expressed its significant concern that there was a pattern of misconduct at J&J including failure to report material information to the FDA in a timely manner, miscalculating and/or misstating risks and benefits of J&J products, and a reactive approach to product quality problems. The FDA told the Company's leadership that significant, immediate steps were needed to address issues of compliance and quality, especially in investigating product quality issues so that the Company could take preventive action to avoid problems.

111. From September 20, 2010 through November 2, 2010, the FDA conducted additional inspections at the Las Piedras Facility. On November 2, 2010, the FDA issued a Form 483 Inspection Report identifying eight additional significant manufacturing and process failures at the plant, including:

a. Drug products failing to meet established quality control are not rejected.

b. The responsibilities and procedures applicable to the quality control unit are not fully followed;

c. Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

d. Written production and process control procedures are not followed in the execution of production and process control functions.

e. Established laboratory control mechanisms are not followed.

112. Despite the FDA's repeated efforts, J&J took no effective action to correct these endemic and dangerous patterns of operation which were known to the highest levels of J&J management. Indeed, the systematic manufacturing and process failures identified at the Las

Piedras Facility were also prevalent at other J&J manufacturing facilities, including the Fort Washington Facility.

5. The FDA Form 483 Inspection Reports of the Fort Washington Facility

113. During inspections of the Fort Washington Facility from April 19 through April 30, 2010, the FDA determined that J&J did not conduct proper quality control procedures or maintain adequate lab facilities. The Fort Washington Facility manufactures various medications, including children's and infants' versions of Tylenol, Motrin, Zyrtec, and Benadryl. These products represent a vital portion of the revenues of J&J's Consumer segment.

114. The FDA Form 483 Inspection Report for Fort Washington is damning. It identifies a host of severe safety and process concerns which mirror the violations found at the Las Piedras Facilit. The 483 lists 20 significant observations that document the systemic breakdown in the plant including, among others, the following:

a. Written production and process control procedures are not followed in the execution of production and process control functions;

b. The responsibilities and procedures applicable to the quality control unit are not fully followed;

c. 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;

d. Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity;

e. There are no control procedures to monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and drug product;

f. There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed;

g. GMP training is not conducted with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them;

h. Procedures describing the handling of all written and oral complaints regarding a drug product are not followed;

i. There is no written testing program designed to assess the stability characteristics of drug products;

j. Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure the components and drug products conform to appropriate standards of identity, strength, quality and purity.

115. These critical and damning observations related to every aspect of the drug manufacturing process at the Fort Washington Facility. The FDA returned to the Fort Washington Facility between October 27, 2010 and December 9, 2010. Following these inspections, the FDA issued another damning Form 483 Report on December 10, 2010.

116. The December 10, 2010 Form 483 Inspection Report details the historical pattern of manufacturing abuses and violations J&J allowed at the Fort Washington Facility. Like the earlier Form 483 Inspection Report, this report is a catalogue of violations and deviations from cGMP – including the knowing distribution of non-conforming products into the marketplace.

117. By way of example, the report noted that there were multiple instances between May 2008 and March 2010 where Benadryl Allergy Fast Melt tablets were manufactured out of specification, but were nonetheless released to the market.

118. Most striking, the report documented the complete inadequacy of the response of the Company to the persistent presence of a foul odor in certain products which had been traced to the chemical TBA. The report noted that there was simply no comprehensive action plan initiated regarding TBA – no identification of trends associated with TBA, no site specific plan, and no evaluation of consumer complaints.

119. The December 10 Form 483 Inspection Report also contained a laundry list of additional failures and breakdowns including the failure to: (1) maintain procedures for the

handling of written and oral complaints; (2) monitor the output and validate the performance of the manufacturing processes; (3) maintain sufficient records to evaluate quality standards; and (4) fully investigate batch failures or discrepancies.

120. Finally, the report identified a large volume of defective merchandise – tainted by the chemical TBA – which were distributed into the marketplace and still had not been recalled as of December 9, 2010.

121. Put simply, this latest report clearly documents the systemic breakdown at the Fort Washington Facility, and the systemic failure of J&J to monitor, control and remedy these persistent manufacturing and quality control problems.

6. J&J's Massive Recall of Children's and Infants' Medications

122. The endemic manufacturing deficiencies and deviations from cGMP identified by the FDA negatively affected J&J, the efficacy of its products and the safety of consumers, including children. On April 30, 2010, in the wake of the devastating Fort Washington Form 483 Inspection Report, J&J recalled infant and children's liquid products due to manufacturing deficiencies that could affect the quality, purity or potency of the medications. The recall involved all unexpired lots of seven products in 43 different flavors and sizes, including Tylenol Infants' Drops, Children's Tylenol Suspensions, Infants' Motrin Drops, Children's Zyrtec liquids in bottles and Children's Benadryl Allergy liquids.

123. In a press release issued the day after the recall notification on May 1, 2010, entitled "FDA Provides Consumer Advice Following Recall of Products for Infants and Children," the FDA provided additional guidance and information regarding the recall, stating "[s]ome of the products included in the recall may contain a higher concentration of active ingredient than specified; others contain inactive ingredients that may not meet internal testing requirements; and others may contain tiny particles."

124. The recall was one of the largest ever, affecting hundreds of millions of doses of Tylenol and approximately 70% of all products that J&J marketed for children and infants. Operations at the Fort Washington Facility – employing over 400 people - were suspended indefinitely. The problems that led to this devastating recall were not the result of a rogue employee or a statistical anomaly. To the contrary – it was the inevitable result of Defendants wilfull disregard for compliance and cGMP in the management of J&J's core business. J&J admitted as much in testimony to Congress. Specifically, at a hearing before the HCOGR on May 27, 2010, J&J executive Colleen Goggins stated that the recall came down to "people and leadership and process." As a result of this judgment, she testified that "We've made significant changes to leadership."

125. On September 30, 2010, before the same Congressional committee, Chairman and CEO Weldon echoed Goggins' sentiments. Regarding the recalls – including the Phantom Recall and the Children's Tylenol recall – Weldon stated that "[w]e recognized then, and we recognize now, that we need to do better, and we will work hard to restore the public's trust and faith in Johnson & Johnson, and strive to ensure that something like this never happens again."

7. J&J Recalls Defective Contact Lenses

126. On August 18, 2010, J&J subsidiary Vision Care Inc. began a voluntary recall of about 100,000 boxes of Acuvue brand contact lenses, with each box containing either 30 or 90 lenses (the "Acuvue Recall"). In addition to the product recall, J&J suspended shipments of affected lots still in its control.

127. The Acuvue Recall took place in twenty-four countries following reports of irritation and pain among users. The recalled contact lenses were manufactured in Ireland, and J&J admitted that it identified higher-than-expected levels of a type of acid used in

manufacturing the lenses that had not been fully removed during the lens rinsing process. This leftover acid caused the defective lenses to burn and sting users.

128. While J&J described the incident as "***an isolated issue . . . affecting a limited number of lots***," the Acuvue Recall was not an isolated event. It was the Company's ***tenth distinct product recall in the past year*** (and not its last) and reflected the same attitude toward monitoring and correcting manufacturing failures evident with the recalls in 2005, 2006 and 2007, as well as in the 2007 Fort Washington internal report. Compliance was put to the side. Cost control to drive profit margins was at the heart of J&J's business model

129. The Acuvue Recall was far more damaging than the costs associated with replacing the defective product; the recall further undermined consumer confidence in the healthcare giant, an admission the Chairman and CEO made in response to the Company's damaged goodwill. On August 27, 2010 Chairman and CEO Weldon admitted the Company and the Board's misconduct, lamenting "We've learned a lot of lessons. They've been very painful."

130. In a September 5, 2010 *Financial Times* interview, Weldon stressed the need for remedial measures while conceding that "there is potential" ahead for criminal action against J&J that would be spawned by recent government investigations, including a review by Congress. Weldon admitted that the problems had been "most disheartening . . . we've let the people who use our products down. This is a very difficult situation."

131. Roughly three months after Weldon's *Financial Times* interview and the Acuvue Recall, Weldon's admission regarding the possibility of additional recalls proved prescient. On December 1, 2010, the Company confirmed that it was forced to expand the Acuvue Recall exponentially to a total of about 492,000 boxes—nearly *five times* as many contact lenses as the 100,000 boxes announced in August 2010.

132. The expanded Acuvue Recall came to light only after details were posted on a U.K. healthcare regulatory agency website. In fact, J&J confirmed that the recall expansion actually took place in late October 2010. Despite the Company's claims regarding an increased dedication to transparency and responsibility, J&J announced the expanded recall by press release only in Japan.

133. In fact, Gary Esterow, a spokesman for J&J's Vistakon vision care unit, confirmed that only regulatory authorities in all countries with affected lots were notified of the expanded recall in late October, leaving it up to the respective government agencies to notify customers. Approximately 25 nations in Europe were involved in the expanded recall, including the U.K., Sweden, Italy, Spain, Ireland, Switzerland and Germany. In addition, Acuvue lenses were recalled in Canada, Australia, South Korea, Hong Kong, Malaysia, New Zealand and Singapore.

134. The serious facts regarding the initial Acuvue Recall in August 2010 were well known to the Board, yet, as set forth above, the Board took no real action to effectively manage the circumstances of the expanded recall in October. To the contrary, the expanded recall was designed much like the Phantom Recall – to take place in the dark.

8. J&J Recalls Orthopedic Devices

135. On August 24, 2010, J&J disclosed that the FDA ordered J&J to stop sales of its Corail Hip System because the Company was marketing it for an unapproved use.

136. The FDA explained the device was strictly to be used without cement, but that the Company's website prominently promoted cement use, which was not approved by the FDA. The FDA stated in an August 19 letter to the Company that these types of modified uses "represent a major change or modification in the intended use of your device that require a new premarket notification."

137. The same letter warned J&J that its TruMatch Personalized Solutions System artificial knees lacked FDA approval. The FDA asked the Company to submit information to decide whether the product could be legally marketed in the US. J&J was selling the TruMatch artificial knees before the Company sought approval.

138. On August 26, 2010, just two days after news of the FDA's August 19 letter, J&J announced the recall of 93,000 orthopedic hip replacements (the "Orthopedic Recall") following a report that one out of every eight patients (12%-13%) who had received one of the recalled devices had to undergo revision surgery within five years of receiving it. Of the 93,000 total recalled orthopedic hip replacements, 37,000 were implanted in the United States.

139. The Company received widespread notice of medical problems beginning as early as 2007 in connection with its artificial hip device. However, further evidence of the Company's practice to hide and minimize manufacturing problems, *The New York Times* reported on December 16, 2010 that when J&J pulled the product from the market in late 2009, it said the decision reflected lagging sales, with no mention of safety issues. Demonstrating the adverse reputational impact such conduct has in the medical community, the article quoted Dr. Stephen Graves, the Director of Australia's orthopedic database as stating: "When it is clear to the orthopedic community that a company has not been honest, that is a problem. I think J.&J. has a major issue."

140. J&J has been sued in both Federal and State courts by patients who have been treated with one of the defective devices. On December 4, 2010, the Judicial Panel on Multidistrict Litigation ordered that U.S. District Judge David A. Katz of the Northern District of Ohio will oversee all pretrial proceedings in lawsuits against J&J arising from the Orthopedic Recall, paving the way for the consolidated adjudication of the various actions pending against

the Company. As J&J continues to struggle with its failing reputation, the damage to the Company from the Orthopedic Recall is significant, both in terms of exposure in tort actions and harm to the Company's increasingly damaged goodwill.

141. Further costs associated with the Orthopedic Recall will come in the form of medical visits by relevant patients that the Company has pledged to pay for. David Floyd, president of J&J's Orthopedics division said the company is committed to paying for the cost of doctor visits, tests and procedures associated with the recall, and "is advising patients with an ASR device to visit their surgeons for evaluation of their implant performance." The Company went on to say yearly monitoring was advised, casting the costs of the Orthopedic Recall long into the future.

9. Ongoing 2010 Recalls

142. Multiple subsequent recalls, including another relating to one of J&J's most prominent products – Tylenol, provided additional blows to J&J's reputation.

143. On October 18, 2010, the Company's plagued McNeil unit announced another recall of a Tylenol product, its 8 Hour Caplet in 50 Count (the "October 2010 Recall"). An official J&J press release detailed the October 2010 Recall, which addressed about 128,000 bottles. The October 2010 Recall again stemmed from numerous consumer complaints of a musty or moldy smell emanating from the medication. The October 2010 Recall is particularly indicative of the Company's systemic disregard for its manufacturing practices because of an FDA Warning Letter received by J&J in January 2010 complaining that J&J violated Good Manufacturing Practices by failing to fully investigate consumer complaints of a musty odor in its products. The FDA said the Company began receiving complaints in June of 2008, and the October 2010 Recall underscores the Company's sheer unresponsiveness and non-compliance with best practices and general disregard for the safety and quality of its products.

144. A J&J spokeswoman stated that while the October 2010 Recall is different than previous recalls, it was related to the same issue as the recall in December 2009, revealing the Company's continued failure to address high-profile and systemic manufacturing problems at J&J.

145. On November 15, 2010, J&J announced another massive product recall. Because of manufacturing "insufficiencies" J&J recalled four million packages of Benadryl Fastmelt tablets, 800,000 Motrin caplets and 71,000 caplets of Extra Strength Rolaids and Mylanta products.

146. On November 24, 2010 the Company announced the recall of nearly nine million bottles of Tylenol Cold Multi-Symptom liquid medication (together with the November 22, 2010 recall, the "November 2010 Recalls"). An internal review revealed that "information about the presence of alcohol from flavoring agents was noted as an inactive ingredient listed on the package, but not on the front panel of the product."

147. On November 29, 2010, J&J was forced to recall twelve million bottles of the heartburn medication Mylanta and almost 85,000 bottles of AlternaGel liquid antacid (the "December 2010 Recall").

148. The extent of the recall only came to light after details were posted on a U.K. healthcare regulatory agency website.

149. On December 1, 2010 the Company stated that its October recall of 1 Day Acuvue TruEye contact lenses was expanded to a total of about 492,000 boxes, nearly five times as many contact lenses as J&J recalled by Johnson & Johnson in August.

150. On December 9, J&J recalled more than thirteen million packages of Rolaids, the Company's popular antacid drug because of consumers discovering metal and wood particles in

the products. The recall involves all lots of Rolaids Extra Strength Softchews, all lots of Rolaids Extra Strength Plus Gas Softchews and Rolaids Multi-Symptom Plus Anti-Gas Softchews sold in the United States. The Company suspended production of the recalled products and won't restart production until corrective actions have been implemented.

151. *The New York Times* reported on December 9, 2010 that:

> The Rolaids recall "reinforces the committee's ongoing investigation surrounding the safety protocols in place at J.&J.'s facilities and how the F.D.A. is managing food and drug safety." Kurt Bardella, a spokesman for the committee chairman-designate, Representative Darrell Issa, Republican of California, said. "The committee is in the process of and will continue to seek answers from J.&J. and the F.D.A."

152. The article noted that J&J executives estimated earlier that recalls and closure of the Pennsylvania plant would reduce sales by about $600 million this year. On December 9, 2010, Wells Fargo downgraded shares of J&J to market perform, citing risks associated with J&J's problems. *The New York Times'* article stated that:

> In a note to investors on Thursday, Larry Biegelsen, an analyst at Wells Fargo, estimated that there was a 25 to 50 percent chance that McNeil would close the plant in Puerto Rico because of the latest F.D.A. report.
>
> "We believe there is risk to J&J's McNeil" over–the-counter business in 2011, he wrote, "and see few potential offsets and prefer to stay on the sidelines until there is some clarity."

153. One confidential witness employed by J&J during the Relevant Period ("CW4") at the Fort Washington Facility attributed manufacturing problems to the Company's dangerous cost-saving.

154. CW4 worked in the Validations department. CW4 stated that he had learned that upper management refused to invest in new equipment at the facility. CW4 explained that the Validations department had identified that certain equipment needed to be replaced. CW4 stated that the effort to convince upper management to purchase new equipment started before he

worked at McNeil and continued throughout his tenure. CW4 stated that due to the age of the machines, there were times when the machines would not work at all, or the machines would completely ruin a batch or take three to four times longer than they should.

155. Sacrifice at the expense of safety is consistent with the Company's cost-cutting at the facility, which cut 478 jobs at a factory outside Philadelphia between 2005 and 2009.

156. All told***, more than 200 million bottles of J&J products have been recalled in the past year***, including painkillers Tylenol and Motrin, allergy treatment Benadryl and Rolaid antacid.

157. The damage to the Company's bottom line from recalls over the last two years began to come into focus in the fiscal third quarter of 2010 ("Q3 Results"). On October 19, 2010, J&J announced the Q3 Results which revealed a staggering ***19.4 percent drop in sales of its over-the-counter business***. U.S. ***sales of nonprescription medicines, such as Tylenol and Benadryl, plunged 40 percent*** as the company worked to provide stores with new supplies and to address quality control issues that closed the Pennsylvania manufacturing plant.

158. J&J is losing millions of dollars every month in, *inter alia*, lost sales and legal settlements as a result of product recalls. J&J's ***subsidiary, McNeil, is also under a federal criminal investigation and faces substa***ntial additional liability.

10. Congressional Testimony Relating to Record-Setting Recalls

159. In the wake of the recalls described above, J&J executives have been called in front of Congress to testify regarding the Company's unlawful conduct.

160. In a closing statement issued by HCOGR, Representative Towns lamented J&J's lack of candor in its communications with Congress. "I was hoping that J&J would be completely forthcoming today, but I think there are still unanswered questions" the statement

reads after opening with the troublesome conclusion "Frankly, what we have heard today is not reassuring."

161. In particular, Towns was troubled by apparent discrepancies in J&J's accounts of its activities. For example, the Company told members of Towns' staff that the recall involved ***six million*** bottles of children's medicine while it informed the FDA that the recall involved more than ***136 million bottles***. Similarly, during an interview in late May 2010, Defendant Luther told House investigators that the Fort Washington Facility did not make products for other companies; however, four days later Blacksmith Brands, which markets PediaCare children's medicines announced its own voluntary recall "as a precautionary step" because certain of its cough and cold products were manufactured at the Fort Washington Facility. Representative Eleanor Holmes Norton, who sits on the House Oversight Committee, said the Company's conduct seemed to her to demonstrate a continuing lack of transparency.

162. On September 30, 2010, Chairman and CEO Weldon testified before the HOCGR concerning the Company's numerous product recalls and conduct in response thereto. Among other things, Weldon conceded that the Phantom Recall was improper and a mistake.

163. Weldon also admitted that the Company "did not maintain [its] high quality standards." With respect to the Company's delayed response to consumer complaints about illness from defective products, Weldon admitted that the Company began to investigate the problem upon initial complaints, ***but decided to stop when complaints became less frequent.***

D. J&J's Systemic and Widespread Unlawful Marketing Practices

164. The extensive pattern of cGMP violations detailed above occurred in the midst of a pervasive and long-standing off-label marketing scheme at the Company involving at least three of J&J's largest blockbuster drugs – Risperdal, Topamax and Natrecor.

165. Over the course of multiple years, the Individual Defendants have been confronted with an array of red flags, including multiple subpoenas and investigatory requests for documents and FDA Warning Letters regarding alleged off-label marketing of these drugs. During the Relevant Period, Risperdal and Topomax together generated more than $10 billion in annual sales revenue.

166. Drug and device sales information was closely tracked by J&J in-house, with the Company having an entire market research unit whose principle function is to closely track IMS figures daily. IMS, a third party information provider that has been in existence throughout the Relevant Period, tracks prescriptions *by indication*, at a minimum.

167. IMS is able to track prescriptions in this manner because of the longstanding requirement in the U.S. that every prescription must include an ICD9 code, which identifies the reason, or indication, for which the drug is being prescribed. Thus, for example, there is a separate ICD9 code for each of the various indications – both on and off label – for which Risperdal might have been prescribed, including for example, schizophrenia, Bipolar disorder, anxiety, depression and dementia. As a result, J&J was able to track its drug sales data on a detailed, granular level, including by drug, by region, and by indication. Tracking this IMS data has been and is important to the Company in many ways, including, *inter alia*, making resource allocation decisions and setting in-house sales targets. For these reasons, this information has always been closely followed at the highest levels of the Company, including at the Board level.

1. Illegal Marketing and Promotion of Risperdal

168. On December 29, 1993, J&J obtained FDA approval to sell Risperdal oral tablets for a single purpose – to treat psychotic disorders in adults. From the outset, J&J recognized the commercial potential of promoting Risperdal for off-label uses, such as ADHD, depression, anxiety, mood disorder, bipolar disorder, and aggression associated with late-onset dementia.

169. To this end, J&J commenced a deliberate and multi-faceted off-label promotion campaign (the "Risperdal Off-Label Promotion Scheme") for the drug. This illegal conduct has been the subject of multiple complaints filed by State Attorneys General around the country (collectively, the "State AG Complaints"). As described in the State AG Complaints, this pervasive off-label promotion scheme included, *inter alia*:

a. inducements to "key opinion leaders" to publicly disseminate information concerning off-label uses of Risperdal;

b. control over the content of Continuing Medical Education ("CME") programs in which presenters would disseminate information concerning off-label uses of Risperdal;

c. initiating, controlling, and producing scientifically-insignificant studies (small-scale clinical trials, investigator-initiated research, and pilot studies), not for the purpose of legitimate scientific research, but instead to spread information concerning off-label uses of Risperdal;

d. causing the publication of "ghost written" articles – written by J&J-paid personnel but signed by ostensibly independent doctors and researchers – promoting off-label uses of Risperdal; and

e. promoting the development of medication algorithms utilized by states to prioritize medications to be used for specific conditions, which algorithms specifically included the use of Risperdal in unapproved indications.

See, e.g., ¶¶ 9.2 – 9.4, Texas AG Complaint.

170. In addition, State AG Complaints set forth the Company's illegal direct solicitation of physicians to prescribe Risperdal for off-label uses (*see, e.g.*, Arkansas Complaint, ¶ 51; Louisiana Complaint, ¶ 19; South Carolina Complaint, ¶ 69; Pennsylvania Complaint, ¶ 65), and the Louisiana Complaint sets forth that the Company "actively train[ed] employees in methods of avoiding detection of their activities by the FDA." *Id.*, ¶ 19.

171. As a result of the Risperdal Off-Label Promotion Scheme, sales of the drug skyrocketed. As reported by Bloomberg.com on March 10, 2010, while in 1993, J&J predicted it

would take seven years for Risperdal to reach $295 million in annual sales, Risperdal sales hit $343 million in less than two years. By 1997, Risperdal sales had increased to $589 million, making it the top selling antipsychotic drug on the market.

172. Supporting these remarkable sales increases, the *Bloomberg.com* article quoted a 1994 internal J&J report that "Schizophrenia represents only 35 percent of antipsychotic prescriptions, ... Aggressive expansion of Risperdal use in other indications is therefore mandatory."

173. By 1999, the Risperdal Off-Label Promotion Scheme drew the attention of the FDA. In a letter sent to the Company (the "FDA 1999 Risperdal Warning Letter"), dated January 5, 1999, the agency warned the Company it was unlawfully promoting Risperdal to elderly patients for the treatment of dementia, an unapproved use of the drug. The FDA 1999 Risperdal Warning Letter explained that J&J promotional materials for Risperdal were false and misleading, claiming for example that Risperdal:

a. was safe and effective for elderly patients, despite little or no data to support such claims;

b. is safer or more effective than other antipsychotics;

c. "enhances daily living" or that it offers "quality control of symptoms for daily living";

d. can "control health-related quality of life";

e. is a safe and effective treatment for hostility in the elderly; and

f. is a safe and effective treatment for "psychotic symptoms associated with a broad range of disorders," including schizophrenia, schizophrenia form disorder, schizoaffective disorder, bipolar disorder and elderly psychosis.

174. Because it had provided such a financial windfall for J&J's bottom line, the Company continued ramping up the Risperdal Off-Label Promotion Scheme in the face of the

FDA 1999 Risperdal Warning Letter. Indeed, the Company's Year 2000 Business Plan called for a doubling of J&J's geriatric sales force in an effort to increase Risperdal's market share for elderly dementia sales to $302 million. The Year 2000 Business Plan further stated that "[t]he geriatric market represents Risperdal's second wave of growth" and "[t]he aging population will continue to drive market growth well into the next century." Margaret Cronin Fisk, et al, "J&J Pushed Risperdal for Elderly After U.S. Warnings, Files Show, Bloomberg.com, March 10, 2010.

175. On March 3, 2002, the FDA notified the Company that the agency was further limiting the approved use of Risperdal from the treatment of psychotic disorders to the treatment of schizophrenia in adults, the only segment of the population on which the drug had actually been tested.

176. Despite the FDA's clear directive with respect to the sole approved use of Risperdal, J&J continued its unlawful and highly lucrative promotional scheme.

177. For example, J&J developed a business relationship with Joseph Biederman, a doctor who, according to a New York Times article, dated November 24, 2008, helped "fuel a fortyfold increase … in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children." According to a February 2002 e-mail from Georges Gharabawi, a J&J executive, Dr. Biederman had approached the Company "multiple times to propose the creation" of a research center for child psychopathology at Massachusetts General Hospital. "The rationale of this center," the message stated, was to generate and disseminate data supporting the use of Risperdal in children and adolescents. Even though Risperdal was not approved by the FDA for use by children or adolescents, the Company elected to fund the center "to move forward the commercial goals of J&J." *Id.*

178. J&J's support for Dr. Biederman's work was not limited to funding the research center. The Company also ghostwrote a study for Dr. Biederman on the effect of Risperdal in children with disruptive behavior disorder. This study was to be presented at the 2002 annual meeting of the American Academy of Child and Adolescent Psychiatry.

179. The article concluded that only the condition of children given Risperdal improved, while that of those given placebos did not. This was false. Dr. Gahan Pandina, the J&J executive who forwarded the study to Biederman, noted in his cover email that the children given placebos as well as those given Risperdal both improved significantly. Confidential Witness # 1 ("CW1"), a former Region Business Director for Ortho-McNeil, Janssen, and J&J, provided an insider's perspective on the Risperdal Off-Label Promotion Scheme. CW1 stated that there was a clear direction to sell Risperdal to elderly patients for treatment of dementia and Alzheimer's disease, both unapproved uses of the drug. CW1 noted that much of this direction came from senior management during National Sales and Marketing Meetings presenting slides explaining how to market Risperdal for both the FDA-approved indication of schizophrenia and for the non-indicated (unapproved) treatment of elderly patients with dementia, Alzheimer's, or PTSD. The slides and discussions centered on conveying to physicians the proper dosage for treating schizophrenia, and the lower dosage considered "best practice" for using Risperdal to treat elderly patients.

180. CW1, based on his personal experiences and knowledge of J&J's business, contends that J&J's Chairman and CEO Weldon saw the dementia sales figures as a break-out from total Risperdal sales figures because that source of sales revenue was a very significant contributor to total Risperdal sales. CW1 further explained that any expansion of Risperdal sales into a new target market (such as the long-term care market) required approval from J&J's

Executive Committee, on which all of the division presidents sat and which Defendant Weldon chaired, and on which Officer Defendants Poon, Valeriani, Scodari and Deyo sat. Because Risperdal was a flagship brand, CW1 stated that all eyes were on it throughout the tenure of CW1's employment.

181. On April 19, 2004, the FDA sent a Warning Letter to J&J (the FDA 2004 Warning Letter), and copied CEO and Chairman Weldon. In the FDA 2004 Warning Letter, the FDA warned that the Company was sending information to healthcare providers that was "false" and "misleading," by, (i) omitting material information about Risperdal; (ii) minimizing potentially fatal risks associated with the drug; (iii) failing to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible; and (iv) claiming that Risperdal was safer than other atypical antipsychotics without adequate substantiation, in violation of §§502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§352(a) and 321(n).

182. In April 2005, the FDA determined that treating behavioral disorders in elderly patients with dementia with atypical antipsychotic drugs like Risperdal was associated with increased mortality. As a result of these findings, the FDA required J&J to include a "black box warning" in their labeling describing this risk and emphasizing that Risperdal was not approved for these conditions. Notably, a similar black box warning was not required on older antipsychotics.

183. The State AG Complaints allege that J&J nonetheless continued its aggressive off-label promotion of Risperdal to elderly patients. For example, the complaint by the Louisiana AG, filed on August 28, 2008, alleged: "Upon information and belief, despite the foregoing [the requirement by the FDA for the Black Box warning], Defendants continue to promote Risperdal as safe and effective for dementia in elderly patients."

184. In his capacity as a senior Janssen executive, including as President beginning in 2001, defendant Gorsky knew or and/or facilitated or allowed to continue the Risperdal Off-Label Promotion Scheme alleged herein.

185. In light of the Company's decade long off-label marketing scheme with respect to Risperdal and refusal to comply with the FDA's requests, regulatory scrutiny increased. As reported in the Company's public filings, beginning in early 2004, the Company began to receive multiple subpoenas and document requests from federal and state regulators.

186. On January 20, 2004, OIG issued a subpoena to the Company, demanding documents related to sales, marketing and all payments to doctors in connection with sales and marketing of, and clinical trials for Risperdal from 1997 to 2002. Thereafter, the Company disclosed that documents subsequent to 2002 have also been requested.

187. On July 27, 2004, the Company received an additional investigatory demand for documentation, this time from the New York Attorney General, pertaining to marketing off-label sales and clinical trials for Risperdal, as well as for five other drugs, including Topamax, Procrit, Reminyl, Remicade and Aciphex.

188. In November 2005, the U. S. Attorney's Office in Philadelphia served on the Company another subpoena related to alleged off-label promotion and marketing, as well as adverse side effects, of Risperdal. Only months later, in January 2006, the Texas State Attorney General sent a civil investigative demand to the Company seeking documents related to the sales and marketing of Risperdal.

189. By the end of 2006, the Company had received two additional government subpoenas related to off-label sales of Risperdal. In September 2006, Janssen received a subpoena from the California State Attorney General seeking the production of documents

related to the sales, marketing and side effects of Risperdal, and in October 2006, the Texas State Attorney General joined a *qui tam* action filed against Janssen in Texas state court alleging off-label marketing of Risperdal and seeking compensation for alleged adverse reactions due to Risperdal.

190. Defendants' refusal to stop off-label promotion of the drug was directly related to the Company's bottom line. ***J&J's Risperdal sales for 2006 topped $4.2 billion, an increase of over 17.8% over the prior year.*** In 2007, the antipsychotics franchise (primarily Risperdal) achieved ***sales of $4.7 billion, an increase of 12.3% over the prior year***.

191. According to a complaint by the Louisiana Attorney General, the off-label promotion and sale of Risperdal continued up until at least August 28, 2008. This action resulted in a jury award on October 15, 2010 in the amount of $257.7 million against the Company. The jury found, *inter alia*, that based on sales calls and letters to Louisiana healthcare providers, J&J had committed more than 35,500 violations of the State's Medical Assistance Programs Integrity Law in that one state, alone.

192. The Company continues to face substantial liability from both the still open and ongoing federal investigation by the U.S. Attorneys' Office in Philadelphia, as well as by multiple, unresolved State AG Complaints.

2. Illegal Marketing and Promotion of Topamax

193. Topamax is an anti-epileptic drug, designed to reduce the frequency of a patient's seizures. Topamax was discovered and developed by J&J subsidiary R. W. Johnson Pharmaceutical Research Institute. Significantly, when the FDA approved the drug in 1996, Topamax was only approved as an "add-on" treatment for patient's already taking another anti-seizure medication. In 1999, the FDA approved Topamax for pediatric add-on treatment. In August 2004, Topamax received approval for the prevention of migraine headaches in adults.

194. In clinical trials, Topamax had a number of serious side effects, including psychomotor slowing, loss of appetite and weight loss, severe psychosis, affective disorder, cognitive problems, kidney stones, myopic and secondary glaucoma, and anorexia.

195. Despite knowledge of Topamax's side effects, J&J developed an extensive program to promote the drug for a laundry list of ailments and diseases for which it was not indicated and for which it had not received FDA approval. These illegal off-label uses included: (1) pediatric bipolar disorder; (2) juvenile myoconic epilepsy; (3) binge eating; (4) Tourette's syndrome; (5) bullimia nervosa; (6) infantile spasms; (7) headache pain in pediatric patients; (8) obesity; (9) anxiety disorders; (10) aggression disorders; (11) adult bipolar disorder; (12) mood stabilization; (13) absence seizures; (14) essential tremor; (15) headaches; (16) neuropathic pain; (17) sleep apnea; (18) Parkinson's syndrome (19) stroke; (20) ALS; (21) psudotumor cerebri; (22) monotherapy; (23) alcohol, drug and tobacco addiction; and (24) diabetes.

196. According to *qui tam* complaints filed against J&J, the Company did not have any valid scientific evidence that supported the safe use of Topamax for the treatment of these conditions, yet J&J aggressively marketed the drug as a potential treatment for each of these conditions. J&J trained its sales force to mislead physicians into believing that such evidence existed by referring to –non-existent "scientific evidence".

197. Further, in the limited instances where any evidence existed, it had no scientific value because the studies suffered from numerous scientific flaws including that: (1) they were negligible in size; (2) they were not blind; (3) conducted by paid physicians working for J&J; and (4) consisted of retrospective chart review.

198. In some instances, the Company would mail copies of studies to doctors. These marketing reports were specifically designed to conceal the lack of scientific validity of the studies.

199. In addition to affirmatively promoting the use of Topamax for various unapproved uses, the Company also instructed its sales force to intentionally mislead physicians about the serious side effects of Topamax, including serious risks to children.

200. According to the U.S. Government, the Topamax scheme also utilized a program known as "Doctor-for-a-Day" whereby the Company paid outside physicians to join sales representatives who were promoting Topomax for unapproved usesin their visits to doctors. Such "Doctors for a Day" also spoke at meetings and dinners about prescribing Topamax for unapproved uses and doses. These speakers were frequently the recipients of large grants and speaker "honoraria" from J&J. Disturbingly, the Company utilized the "Doctor-for-a-Day" program to promote the use of Topamax to treat various psychiatric disorders. J&J, however, had no legitimate clinical data to demonstrate that Topamax was safe or effective to treat any psychiatric condition.

201. As with Risperdal, the Company aggressively used key opinion leaders and medical conferences to market Topamax for off-label uses. In addition to psychiatric conditions, J&J aggressively promoted Topamax for migraines. Confidential Witness #2 ("CW 2"), a J&J sales representative in the Central Nervous System Division, has confirmed many of these disturbing practices. For example, CW2 helped to engage key opinion leaders ("KOL") who were heavy prescribers of Topamax for migraines. CW2 noted that the use of Topamax for preventing migraines normally came up at speaker programs used to promote the off-label use of drugs. CW2 stated that she attended the speaker presentations that she helped arranged – that

was the normal practice – and was instructed that the speaker could not initiate a discussion of off-label uses for Topamax. As instructed, CW2 would ask a question to initiate the discussionCW2 said the main reason for her to attend the presentations was to make sure the subject of prescribing Topamax for migraines was brought up so that the speaker could disseminate information about this off-label use of the drug. CW2 stated the sales management encouraged providing physicians with information about its use to treat migraines.

202. The Company's efforts were so widespread, and successful, that by 2003, *Knight Ridder* concluded in a December 2003 report that nearly 80% of Topamax prescriptions (as well as 65% of all Risperdal prescriptions) were for off-label uses. As a result of this off-label marketing scheme, Topamax sales grew explosively from $687 million in 2002 to more than $2.7 billion in 2008, the year before its patent expired. Given the narrow indication for which Topamax did have FDA approval, the vast majority of these sales were for off-label uses. An informed board – aware of the limited nature of Topamax's approved indication – should have been aware that the only way for a drug like Topamax to achieve billions of dollars would be through extensive off-label promotion by the Company. As detailed below, the Board had knowledge throughout J&J's implementation of the off-label drug promotion schemes of the subpoenas, investigative demands and *qui tam* suits in connection with Topamax, as well as with other blockbuster drugs, Risperdal and Natrecor, much of which was specifically identified in Forms 10-K the Director Defendants personally executed.

203. On September 15, 2004, the FDA sent a warning letter (the "Topamax Warning Letter') to J&J concerning marketing activities with respect to Topamax. The Topamax Warning Letter warned that J&J's promotional materials were false and misleading because they omitted material risk information about the drug's side effects, including oligohidrosis in pediatric

patients (decreased sweating and elevation of normal body temperature), hyperthermia and metabolic acidosis (excess acid in bodily fluids). The Topamax Warning Letter stated:

> Oligohidrosis and hyperthermia are very serious risks whose negative impact may be mitigated with appropriate monitoring. It is also noteworthy that the majority of reports of these adverse reactions have been in children. Metabolic acidosis is a very serious risk whose manifestations may include hyperventilation, cardiac arrhythmias or stupor. Monitoring in this case, measurement of serum bicarbonate, is quite important. Therefore, we view these adverse reactions of Topamax to be material when promoting the drug. Because the materials omit material risk information, they are false and misleading.

204. The FDA demanded that J&J withdraw the false and misleading promotional materials from circulation and respond with a plan of action to disseminate complete Topamax risk information to the audiences exposed to the misleading materials.

205. Despite the Topamax Warning Letter, J&J continued to aggressively promote Topamax for numerous unapproved and potentially dangerous uses. During this time, Defendants took no effective action to stop the systemic unlawful promotion of Topamax because of the drug's remarkable profitablility.

206. In December 2003, the Company received a multitude of subpoenas and requests for documents in connection with federal and state regulatory investigations of the off-label marketing of Topamax. Then, in March 2007, the Company received subpoenas from three separate U.S. Attorneys' Offices related to three separate investigations of the Company's off-label marketing of Topamax, Risperdal, and Natrecor.

207. In April 2010, J&J's McNeil subsidiary pled guilty to violating the FDCA and paid a $6.14 million criminal fine for its illegal promotion of Topamax for psychiatric uses. At the same time, J&J's McNeil subsidiary resolved two whistleblower claims by agreeing to pay $75.37 million for its illegal promotion of Topamax for off label uses.

208. As in the case of the other illegal off-label marketing schemes and the Phantom Recall of Motrin, the multi-year Topamax off-label marketing scheme was so extensive and systemic that, at a minimum, there was a complete breakdown of oversight that remained uncorrected during multiple years while the drug was generating billions of dollars in revenues.

3. Illegal Marketing and Promotion of Natrecor

209. Natrecor was discovered and developed by Scios, Inc. ("Scios"). Scios's initial new drug application for Natrecor was rejected due to safety concerns.Natrecor has the propensity to cause symptomatic hypotension (unusually low blood pressure that can leave to a life-threatening condition called "shock"). Thereafter, Scios sponsored the VMAC (Vasodilatation in the Management of Acute Congestive Heart Failure) study to determine dosages of Natrecor that that could be used to treat acute compensated heart failure without undue risk of hypotension.

210. Based on VMAC study and results , the FDA approved Natrecor for the following limited use in August 2001:

> Natrecor (nesiritide) is indicated for the intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea[2] at rest or with minimal activity. In this population, the use of Natrecor reduced pulmonary capillary wedge pressure and improved dyspnea.

211. By definition, an "acute" episode of decompensated congestive heart failure (CHF) with dyspnea at rest or with minimal activity is an emergency situation that does not occur on a scheduled basis. Moreover, the VMAC study involved hospitalized patients who received Natrecor infusions over a period of 24 to 48 hours under doctor supervision, while outpatient infusions and doctor supervision typically lasted only six hours or less.

[2] Dyspnea means difficult or labored breathing.

212. Scios developed an unlawful marketing plan around promoting Natrecor for regularly scheduled outpatient infusions. An important component of this plan was encouraging health care providers to open and operate such outpatient Natrecor infusion clinics. Scios implemented this plan, constituting a direct, off-label marketing of the drug, despite the known risks to patients and the absence of scientific evidence that regularly scheduled outpatient infusions was safe or would offer patient benefits.

213. J&J acquired Scios in April 2003 for approximately $2.5 billion with Board approval, following comprehensive due diligence. During this due diligence, J&J learned about Scios's unlawful marketing scheme. For example, a complaint the U.S. government filed in June 2009 as part of a criminal investigation, following its intervention in a *qui tam* action (the "Federal Natrecor Complaint"), the scheme to illegally promote Natrecor for off-label use was approved and encouraged at the highest levels of J&J, including by J&J Chairman and CEO Weldon. In addition, the only drug that Scios was marketing at the time was Natrecor.

214. J&J officers learned during the due diligence process that:

a. J&J was directly involved in Scios's marketing of Natrecor for serial, outpatient use. J&J knew and approved of Scios's marketing goals and strategies that included marketing Natrecor for serial, outpatient use. For example, even before the acquisition, J&J officers learned during the due diligence process that:

b. The FDA had only approved Natrecor for treatment of acute congestive heart failure, not treatment of chronic congestive heart failure;

c. Despite Natrecor's approved use, Scios was marketing Natrecor for serial outpatient use;

d. There would be significant upside potential if Scios were able to achieve an indication for chronic outpatient use – *i.e.*, the sales forecast would increase by $330 million (from $600 million to $930 million);

e. Scios's Business Plan included continuing to market Natrecor for outpatient use;

f. Success in the outpatient setting would depend on Medicare continuing to reimburse for "treatment on a chronic basis," and that until Medicare's view was clear, "it is a risk that is difficult to assess"; and

215. Immediately following the acquisition, J&J prepared a marketing plan to grow the outpatient congestive heart failure market to $100 million in 2004, $200 million in 2005, over $300 million in 2006, and over $400 million in 2007. This plan was a key component of J&J's objective to grow Scios's total revenue to over $1 billion by 2007. On June 27, 2003, Chairman and CEO Weldon, visited Scios and approved the Natrecor business plan, which set out the strategy to aggressively expand marketing Natrecor for outpatient use, and set separate sales goals for "Outpatient" sales.

216. Also, in March 2004, J&J Company Group Chairman Defendant Scodari reviewed and approved a 2004 business and strategic plan for Natrecor that : (i) discussed the plan to continue marketing Natrecor for outpatient use by "[e]stablish[ing] a growing prescriber and advocate base that will drive Natrecor as the preferred management strategy in the outpatient setting (increase monthly infusion revenue from $3M to $9.5M);" (ii) provided separate sales goals for off-label "Outpatient" sales,; and (iii) estimated that there were 129,000 potential outpatients patients who could be targeted.

217. In line with the objectives of this plan, in late 2003, Director of Sales, Kim Hillis, directed the sales force to help develop new Natrecor outpatient infusion clinics.

218. During a sales representative training session in February 2004, J&J discussed sales goals for "Outpatient" sales, and the objective of continuing to the marketing of Natrecor for outpatient use by "establish[ing] a growing prescriber and advocate base that will drive Natrecor as the preferred management strategy in the outpatient setting."

219. The 2004 strategic plan approved by Scodini likewise discussedthe "Development Strategy for Natrecor for the Chronic Intermittent Outpatient Market;" and "Leveraging the Natrecor Platform" for Outpatient chronic heart failure.

220. This strategic plan also discussed J&J's objective of rewarding healthcare providers who would open outpatient infusion clinics to prescribe Natrecor. It dicussed "Improv[ing] infusion procedure payment rate in hospital outpatient department," and "Increas[ing] business acumen of treating physicians."

221. One of the strategies detailed in the 2004 Business Plan for Natrecor was the "Centers for Excellence" program, under which J&J sent health care practitioners who were interested in starting outpatient infusion clinics to existing outpatient clinics that used Natrecor, in order to observe and learn.

222. As alleged in the Federal Natrecor Complaint, the 2004 Business Plan for Natrecor relied on the Centers of Excellence program as the primary tactic for achieving the goal of "doubling the number of outpatient clinics delivering more than 20 infusions of Natrecor per month." One of these Centers of Excellence was the South Bay Cardiovascular Associates ("South Bay"), located in West Islip, New York. From 2003 to 2005, J&J paid over $100,000 to a nurse at South Bay for making promotional speeches relating to the outpatient use of Natrecor, and training other health care providers on the outpatient use of Natrecor. The nurse was also listed as an author on various publications relating to the outpatient use of Natrecor, including, "Nesiritide in an Outpatient Infusion Clinic Setting – Case Studies of 17 patients," which was published in *The Journal of Cardiac Failure* in August 2002.

223. The 2004 business plan, under the description: "Outpatient Management Market - Business Driver – Number of Treaters," also discussed the ADHERE LM program, a registry of

heart failure treatment and outcomes data maintained by J&J, as a vehicle to attract prescribers and promote the outpatient use of Natrecor. J&J also maintained an Outpatient Infusion Center database to, evaluate the market opportunities represented by outpatient infusion centers, measure the amount of Natrecor revenue being generated by outpatient infusion centers, and accelerate adoption of Natrecor in the outpatient infusion market.

224. Other aspects of the Company's off-label promotion scheme for Natrecor included payment to health care professionals who authored articles, made promotional speeches, and/or taught continuing medical education courses about outpatient use of Natrecor. For example, from 2003 to 2005, J&J paid a cardiologist at Hackensack University Medical Center over $250,000 for speaking abouthe outpatient use of Natrecor, and appearing as an author of articles on Natrecor, including at least two articles that were ghost-written at J&J's expense.

225. On or about May 2004, J&J paid a $500,000 grant to the University of Texas Southwestern Medical Center for a cardiology fellowship. A cardiologist at this Center was a key proponent of Natrecor outpatient infusions, authoring articles and giving speeches that promoted the outpatient use of Natrecor. Likewise, from 2003 to 2005, a cardiologist and former Medical Director at the Midwest Heart Specialists received over $160,000 for promoting Natrecor. In addition, the Midwest Heart Foundation, which is affiliated with Midwest Heart Specialists, received over $250,000 in grant funds from Scios.

226. Not only were members of J&J's senior executive management, including defendants Weldon, Scodari and Poon, fully aware of the Natrecor Off-Label Promotion Scheme, but so was J&J's Board, which approved the approximately $2.5 billion cash offer after conducting comprehensive due diligence to acquire Scios on February 9, 2003.

227. According to the Federal Natrecor Complaint, since the April 2003 acquisition of Scios, J&J has exercised strict supervision, control, and dominion over Scios's activities, decisions, policies, and practices related to sales goals, sales tactics, compliance, regulatory affairs, medical affairs, research and development, human resources, legal issues, budget, accounting, employee compensation, employee benefits, employee expenses, manufacturing, and public relations.

228. In addition, J&J has set Scios's business objectives and sales goals and regularly reviewed and approved Scios's sales numbers and projections. For example, in February 2004, J&J replaced Scios's President and CEO, Richard Brewer, with a J&J executive, Jim Mitchell, who confirmed to J&J that Scios's strategies included achieving the 2004 Business Plan, growing Natrecor's revenue to $1 billion by 2007.

229. J&J's off-label promotion strategies detailed above were wildly successful. In January 2005, J&J estimated that Natrecor outpatient sales had increased by 173% for 2004 and would continue to increase by another 81% for 2005. In February 2005, *Forbes.com* reported that "in 2004, sales of [Natrecor] more than doubled to $300 million according to Raymond James, an investment bank." *The New York Times*, on July 21, 2005, reported an even higher number – $400 million in Natrecor sales for 2004.

230. The Company's aggressive and improper *promotion* tactics continued to drive accelerating growth in 2005 as well. For example, *Newsinferno.com* reported in August 2005 that: "Na*trecor has been aggr*essively marketed with sales of the drug now reaching almost $700 million this year."

231. During this period concerns in the *medical co*mmunity about Natrecor's safety intensified. In early 2005, two articles were p*ublished in promi*nent medical journals discussing

concerns about the renal and mortality effects of Natrecor. In response, in June 2005, J&J convened a panel of tencardiologists, led by Dr. Eugene Braunwald of Harvard Medical School, to review Natrecor's safety and efficacy, and to make recommendations concerning the use and further clinical studies of the drug (the "Special Advisory Panel"). The Special Advisory Panel concluded that Natrecor should be strictly limited to treating ill patients in hospitals.

232. The Special Advisory Panel's findings however were directly contrary to the Company's active promotional efforts to increase Natrecor drug sales through scheduled, off-label outpatient treatments. As reported by *The New York Times* on August 9, 2005:

> Rather than the milquetoast findings often returned by such advisory panels, Dr. Braunwald's committee of 10 medical experts determined that use of Natrecor, an expensive intravenous therapy, should be strictly limited to acutely ill patients in hospitals. The committee asked [J&J] to begin warning doctors against the drug's use in outpatients, a treatment that had not been approved by the Food and Drug Administration but that had helped turn Natrecor into a big money maker.

233. On June 13, 2005, the Special Advisory Panel recommended that the Company conduct a trial to assess the long-term safety and efficacy of Natrecor.

234. Consistent with the Company's overall policy to avoid or delay taking action that could adversely affect pharmaceutical sales, the Company resisted the Special Advisory Panel's recommendation that outpatient use of Natrecor be discontinued. As the August 9, 2005 *New York Times* article reported:

> Some committee members said that their concerns about [J&J's] handling of their recommendations began soon after the panel reported its findings to the company on June 13. The report's crucial finding was unambiguo*us. Natrecor shou*ld not be used in outpatients.
>
> But rather than simply disseminate the report, [J&J] created its own prefacing news release. The committee's conclusion that Natrecor should not be used in outpatient settings was not clearly stated until the final page of the five-page company document. Instead, the news release played up the panel's recommendation that [J&J] gather further data by continuing with a clinical trial, called Fusion II, to determine the drug's usefulness in outpatients.

> "The press release emphasized a small aspect of our recommendations – that clinical trials should continue; it de-emphasized or made little mention of the more important take-home points of our recommendations," said Dr. Milton Packer, a cardiologist at the University of Texas Southwestern Medical Center in Dallas who served on the committee.
>
> Dr. Packer also said that the committee members were shocked several weeks later when they received invitations as part of a mass mailing to enroll in a continuing medical education program, financed by [J&J], that seemed to promote the outpatient use of Natrecor, whose chemical name is nesiritide.
>
> "We were flabbergasted," Dr. Packer said. "Scios was sponsoring meetings to discuss nesiritide and its potential use in outpatients."

235. On July 14, 2005, Dr. Eric Topol of the Cleveland Clinic charged in *The New England Journal of Medicine* that J&J's subsidiary was aggressively marketing Natrecor for repeated administrations in outpatient settings for a "tune-up." Dr. Topol said that J&J was showing doctors how to bill Medicare for the off-label treatments, and that the regimen used nearly ten times the amount of the drug administered to acute outpatient patients in hospitals, resulting in fees of as much as $700 per dose to the doctors.

236. On July 20, 2005, Dr. Braunwald of the Special Advisory Panel sent a letter to Dr. Randall Kaye, the Vice President of Medical Affairs at J&J subsidiary, stating that "members of the Natrecor Advisory Panel have been disturbed by what we consider to be significant omissions and lack of clarity in Scios' efforts to comply with the Panel's recommendations."

237. On July 28, 2005, J&J Worldwide Chairman, Pharmaceuticals Group and Executive Committee Member, defendant Scodari, instituted a communications team comprised mostly of J&J employees to oversee the response to the Special Advisory Panel's recommendations and all communications about Natrecor. Scodari participated in the team's weekly conference calls, and instructed Scios's President and CEO to "ensure a review on the

return to promoting the on-label outpatient use (acute) is conducted" in Scios's 2006 Strategic Plan (emphasis in Federal Natrecor Complaint, ¶104).

238. In March 2006, responding in part to concerns raised by the medical community, the federal Centers for Medicare & Medicaid Services issued a national coverage determination denying coverage for outpatient use of Natrecor. On November 29, 2007, J&J announced that it would record a $440 million write-down due to declining Natrecor sales. *The New York Times* reported that the Company explained that sales had declined significantly after outside medical researchers raised questions in 2005 about possible increased risk of kidney problems and death associated with the drug.

239. In September 2009, defendants moved to dismiss the Federal Natrecor Complaint. By decision dated December 23, 2009 (*see* 2009 WL 5062323 (N.D. Cal.), the court denied defendants' motion to dismiss. The court found that "Defendants had no evidence supporting the efficacy of Natrecor in the outpatient context. Plaintiff effectively alleges that they acted in reckless disregard of the truth when they encouraged submission of such claims to Medicare."

240. As the result of the decision of the Board and J&J's most senior executive officers to complete the Scios acquisition and to expand the off-label promotion of Natrecor for outpatient treatment, the Company is potentially liable for hundreds of millions of dollars.

4. Illegal Marketing and Promotion of Biliary Stents

241. Biliary stents are medical devices implanted in the bile duct to aid drainage for patients suffering from biliary cancer.

242. From 1996 through at least 2007, J&J pursued an unlawful off-label marketing strategy to drive sales of biliary stents (the "Biliary Stent Off-Label Promotion Scheme"). Pursuant to this scheme, J&J unlawfully marketed biliary stents to doctors for use in the human

vascular system, and induced physicians to seek coverage and reimbursement for such unapproved use.

243. The size of the vascular stent market dwarfs that of the biliary stent market. Each year only a few thousand patients are diagnosed with cancer in the biliary tree. By contrast, hundreds of thousands of patients are diagnosed annually with vascular disease and many of these patients live for decades. Thus, tapping into the vascular stent market represented an extremely lucrative opportunity for J&J.

244. However, unlike biliary stents, vascular stents are Class III medical devices and device manufacturers must clinically establish the safety and efficacy of the devices before they can market them.

245. Biliary stents are Class II medical devices and, their safety and efficacy does not need to be established before they can be marketed.

246. As described in a *qui tam* action filed in the Northern District of Texas on September 26, 2006 on behalf of the United States under the False Claims Act (the "Biliary Stent Complaint"), J&J filed no less than thirty-seven fraudulent pre-market clearance notifications with the FDA falsely certifying that the device "is intended for use in the palliation of malignant neoplasms in the biliary tree." The §510(k) premarket clearance notifications concealed and failed to disclose that J&J marketed these devices to be used off-label as vascular stents in the vascular system as well. Based on these false certifications and statements, the FDA issued a premarket clearance letter for each of the above-listed devices, limited to the stated intended use and imposing restrictions on J&J, prohibiting it from marketing or promoting the device as an FDA approved vascular stent. Indeed, the FDA required J&J to prominently disclose in labeling,

marketing and promotional materials that "[t]he safety and effectiveness of this device for use in the vascular system have not been established."

247. According to the Biliary Stent Complaint, J&J then aggressively promoted and marketed the devices off-label as vascular stents intended to treat peripheral vascular disease. The Company utilized the following measures, among others, to perpetrate the Biliary Stent Off-Label Promotion Scheme:

a. instructing sales representatives to target physicians specializing in peripheral vascular disease to induce the use of the Class II biliary stents as unapproved Class III vascular stent intended for vascular disease;

b. directly or indirectly sponsoring or ***funding studies of the off-label use of the biliary stents*** to treat peripheral vascular disease and providing the study information to sales representatives for use in marketing and promoting the devices to vascular physicians;

c. extensively marketing and promoting the devices in print and electronic advertisements targeting physicians with vascular specialization in an effort to solicit the use of the devices for the vascular system, with simultaneously avoiding any print and electronic marketing of the biliary stents targeted to gastroenterologists and hepatologists (physicians specializing in biliary tree disorders);

d. ***providing unsolicited marketing and promotional literature to physicians concerning the off-label use of the unapproved biliary stents*** to treat vascular disease, including information advising physicians how to develop and expand a peripheral vascular practice, thereby encouraging the unapproved use of the biliary stents;

e. ***giving sales representatives mandatory quotas requiring them to sell the biliary stents off-label*** simply to satisfy the quota;

f. ***establishing compensation schemes for sales representatives which included bonuses for off-label sales***;

g. ***providing reimbursement guidelines and manuals to physicians that instructed physicians to falsely code reimbursement claims*** using procedural codes for approved vascular stents, even though an unapproved biliary stent was utilized;

See Biliary Stent Complaint, ¶¶ 9 and 123 (emphasis added)

248. J&J's unethical and dangerous practices with respect to biliary stents did not go unnoticed by the authorities. According to a March 10, 2007 *The Wall Street Journal* article, in 2004, the FDA forced J&J's Cordis unit to recall an instruction sheet, which wasn't approved by the FDA, for its Precise biliary stent after nine off-label patients were injured."

249. Despite the FDA warning, the Company pushed forward with the Biliary Stent Off-Label Promotion Scheme. In fact, the scheme was so widespread that a study in the American Journal of Therapeutics, estimated that one million biliary stents were used off-label from 2003 to 2006 to open clogged blood vessels in other parts of the body.

250. In addition to uncovering the pervasiveness of the Biliary Stent Off-Label Promotion Scheme, the report in the American Journal of Therapeutics also noted that deaths and serious injuries including aneurisms and amputations had occurred as a result of device malfunctions when the stents were used off-label.

251. Then, in June 2008, the Company received a subpoena from the U.S. Attorneys' Office for the District of Massachusetts relating to its Biliary Stent Off-Label Promotion Scheme.

252. In his capacity as Worldwide Chairman, Cardiovascular Devices and Diagnostics since 2004, Defendant Valeriani knew of and/or facilitated or allowed to continue the Biliary Stent Off-Label Scheme alleged herein.

253. The claims raised in the Biliary Stent Complaint have not been resolved, and the Company continues to face substantial liability for this pervasive misconduct.

E. J&J Engaged in Multiple Violations of the Federal Anti-Kickback Statutes

254. J&J's legal violations were not limited to the manufacturing failures, the recalls of its consumer and pharmaceutical products, and its illegal off-label marketing schemes. J&J also engaged in wide-ranging violations of federal Anti-Kickback Statutes as to numerous drugs and

medical devices, misconduct that was part and parcel with its unlawful strategy to drive the revenues of its pharmaceutical products, including Risperdal.

1. The Omnicare Kickback Scheme

255. As discussed above, J&J aggressively pursued an unlawful strategy to promote Risperdal off-label for elderly patients suffering from dementia. To implement this strategy, the Company also entered into agreements with Omnicare, the largest nursing home pharmacist in the United States. Omnicare provides pharmaceuticals and related pharmacy and ancillary services to patients in nursing homes, and submits reimbursement claims on behalf of those patients to the patients' insurers. Approximately 65% of these claims are submitted to Medicaid.

256. Omnicare's "consultant pharmacists" make recommendations to nursing home physicians about the drugs they should prescribe to nursing home residents. Omnicare uses the term "intervention" to refer to the process by which Omnicare pharmacists and consultant pharmacists obtain physician authorization to switch nursing home patients from one drug to another. From1999 through 2004, Omnicare's "primary intervention" was to drive prescriptions of Risperdal, which was used at nursing homes for off-label use as a chemical restraint. J&J paid Omnicare for this intervention and the goal was to increase spending by Medicaid and other federal health care programs on Risperdal and other J&J drugs.

257. Defendants understood that it was a violation of the Federal Anti-Kickback Statute to pay remuneration, by whatever means, to induce a customer like Omnicare to purchase or to recommend J&J drugs. Defendants also understood that paying Omnicare rebates to switch patients to J&J drugs, making payments to Omnicare for data (that J&J was not actually receiving) as a substitute for rebates or discounts, and/or paying Omnicare various grants and sponsorship fees the purpose of which was to induce Omnicare to purchase and to recommend J&J drugs were illegal form of illegal remuneration.

258. Nonetheless, J&J and Omnicare entered into a drug supply agreement on April 8, 1997 (hereinafter, the "Drug Supply Agreement"). The Drug Supply Agreement provided for J&J to sell Omnicare certain drugs, including Risperdal, Propulsid, Levaquin, Procrit, Duragesic, and Ultram, and for J&J then to pay Omnicare quarterly market share rebates, based on each drug's market share. The Drug Supply Agreement provided that market share would be determined based on Omnicare's purchases of each J&J drug in comparison to Omnicare's purchases of competing products. If Omnicare purchased more J&J products and the increased J&J's relative market share, Omnicare would receive payment of a larger rebate.

259. In May 1999, J&J and Omnicare signed a 5-year performance contract which provided "incentives to Omnicare to advocate appropriate use of J&J products." J&J used these incentives as a valuable tool 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 important to Omnicare, representing approximately 60% of Omnicare's net income.

260. In March 2000, J&J and Omnicare signed a new drug supply agreement (hereinafter, the "Second Drug Supply Agreement"). The agreement provided for J&J to sell certain drugs to Omnicare, and for J&J to pay Omnicare market share rebates and an additional 2% "Annual Product Performance Incentive." The 2000 Agreement included a "Schedule of Qualifying Active Intervention Programs" for specific drugs, including Risperdal.

261. During the period from 1999 through 2004, J&J paid Omnicare tens of millions of dollars in market share rebates pursuant to both drug supply agreements. In many instances, J&J paid quarterly rebates to Omnicare in advance, thus effectively providing Omnicare with interest-free loans of millions of dollars.

262. Under the "set price rule" of the Medicaid Drug Rebate Statute, Medicaid was entitled to receive the same rebates as Omnicare.

263. During the late 1990s and early 2000s, J&J rarely, if ever, reported the Omnicare rebates to state Medicaid programs. In or about October 1999, J&J began discussing with Omnicare the concept of J&J paying Omnicare for data identifying physician prescribers of antipsychotics in lieu of paying it the hundreds of thousands of dollars in rebates Omnicare believed it was owed. As the process evolved, J&J began to consider having the total amount of data fee payments increased in order to serve as a substitute, for the rebate payments, including the 2% Annual Product Performance Incentive contained within the Second Drug Supply Agreement (also referred to as "strategic overlay").

264. J&J and Omnicare signed a Consulting & Services Agreement in October 2000. The agreement had a term of July 1, 2000 to April 1, 2004, and called for J&J to pay Omnicare $450,000 for the first three-month period of the term, and then $300,000 per quarter thereafter, for a total of $4,650,000. At the same time J&J and Omnicare signed the Consulting & Services Agreement, they also signed an amendment to the Second Drug Supply Agreement removing Risperdal from the 2% strategic overlay.

265. The Consulting & Services Agreement was a cover for J&J to pay Omnicare for promoting J&J's products. Omnicare never supplied much of the data J&J had agreed to purchase, and J&J never demanded it. Neither Omnicare's national clinical director nor any other Omnicare employee ever supplied J&J with any quarterly lists of "200 competitive prescribing physicians for each J&J Strategic Brand . . . and the preferred product of such physicians," as part A of the Consulting & Services Agreement required. Instead, as had been the case prior to the signing of the Consulting & Services Agreement, local Omnicare pharmacy

sites occasionally supplied local J&J sales representatives with names of prescribing physicians. As a J&J National Account Director later observed, the Omnicare pharmacies did so "randomly" and "generally not . . . willingly."

266. J&J paid Omnicare as specified under the Agreement. Each payment was referred to as a "marketing fee," and J&J cautioned Omnicare that "some or all of this amount may be considered a Discount which Omnicare may have an obligation to reflect in any cost report or claim for reimbursement with Medicare/Medicaid." J&J itself, however, did not treat the payments as discounts and did not disclose them to Medicaid.

267. J&J also paid Omnicare various other kickbacks in the form of "grants," "educational funding," and meeting sponsorship fees. For example, in mid-October 1999, J&J and Omnicare formally entered into an "Initiative Partnership Agreement" pursuant to which J&J paid Omnicare $300,000 in "educational funding" "to partially defray the cost to Omnicare in developing and marketing mutually acceptable broad-based formulary intervention initiatives, and to assist Omnicare consultant pharmacists overcome obstacles and objections they encounter in implementing intervention programs." In plain English, J&J paid Omnicare $300,000 to promote Risperdal off-label to their nursing home patients. Both Omnicare and J&J referred to this as Omnicare's "Risperdal Initiative." The goal of the Risperdal Initiative was to generate as many Risperdal prescriptions as possible.

268. The Risperdal Initiative began in 1997, after J&J and Omnicare entered into the Drug Supply Agreement. In a summer 2000 memorandum, a J&J employee observed that the Risperdal Initiative "has generated an all time market share high of 55.5% throughout the 1st quarter of 2000. This market share represents Omnicare[']s ability in persuading physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia." By the

following spring, Omnicare had driven Risperdal's share of Omnicare's antipsychotic utilization to 58.5%.

269. Another way Omnicare drove Risperdal prescriptions was through Physician Authorization Letters, encouraging the substitution of medication to occur at the pharmacy level. The Risperdal initiative included requesting a substitution to Risperdal from any new prescription of Zyprexa or Seroquel. Reflecting the success of J&J's off-label promotional efforts under the Omnicare Kickback Scheme, during the 1999 to 2004 period, Omnicare's annual purchases of J&J drugs nearly tripled to almost $300 million.

2. The Scheme Is Revealed and DOJ Files a Complaint Against J&J

270. On November 3, 2009, the DOJ announced that Omnicare agreed to pay $98 million to resolve allegations that it solicited and received kickbacks from J&J in exchange for recommending Risperdal. From January 1999 through December 2004. According to the settlement agreement between Omnicare and the DOJ, the payments included:

a. quarterly rebate payments on Omnicare's purchases of Risperdal under the rebate agreements executed in April 1997 and March 2000 where the rebate agreements conditioned payment of the rebates upon Omnicare engaging in an "active intervention program" to convince physicians to prescribe Risperdal and requiring that all competitive antipsychotic products be "Prior Authorized for Risperdal failure," and where Omnicare failed to disclose to physicians that such intervention activities were a condition of it receiving such rebate payments; and

b. payments ostensibly for the purpose of purchasing prescribing data from Omnicare, making educational grants, and sponsoring and attending Omnicare meetings, when in fact one purpose of the payments was to induce Omnicare to recommend that physicians prescribe Risperdal to their nursing home patients, including patients covered by Medicaid.

See Settlement Agreement dated November 2, 2009 between the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, Omnicare, Inc., and the Relators, at §II.I.4.

271. On January 15, 2010, the DOJ intervened in a *qui tam* suit against J&J and filed its own complaint in the District of Massachusetts alleging that the Company engaged in a 5-year scheme to illegally cause Omnicare to promote Risperdal and Levaquin.

272. The DOJ Omnicare complaint alleges – (i) that J&J paid illegal kickbacks to Omnicare; (ii) J&J's kickbacks induced Omnicare to purchase, order, or recommend J&J drugs in violation of the federal anti-kickback statute; (iii) J&J knowingly caused Omnicare to make or use false records material to false or fraudulent claims paid or approved by the government in violation of the federal False Claims Act; and (iv) J&J violated the federal FCA by conspiring with Omnicare to pay Omnicare kickbacks in violation of the federal anti-kickback statute. The DOJ is seeking to recover all amounts J&J was unjustly enriched by as a result of the illegal kickback scheme.

3. J&J's Orthopedics Kickback Scheme

273. On September 27, 2007, the OIG filed a criminal complaint in the United States District Court for the District of New Jersey (the "DePuy Criminal Complaint").

274. 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 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.

275. According to the DePuy Criminal Complaint, the Company operated this kickback scheme from January 2002 to December 2006. The Company, however, had received a subpoena in March 2005 from the U.S. Attorney's Office, District of New Jersey, seeking records concerning contractual relationships between DePuy and surgeons or surgeons in

training involved in hip and knee replacement and reconstructive surgery. As reflected in the Criminal Complaint, despite this red flag warning, the illegal conduct was permitted to continue at the Company until December 2006.

276. In his capacity as Worldwide Franchise Chairman for DePuy from 2002 through September 2003, Defendant Valeriani knew of and/or facilitated or allowed to continue the DePuy Kickback Scheme alleged herein.

277. The Company settled with the government in September 2007. J&J (1) paid $84.7 million; and (2) its DePuy subsidiary was charged with conspiracy to violate the federal Anti-Kickback Statute and to enter into both a Deferred Prosecution Agreement and a Corporate Integrity Agreement.

F. The Board Received Years of Red Flag Warnings of Systemic Misconduct

278. As detailed below, Defendants received many years of red flags reflecting systemic noncompliance with drug manufacturing and marketing laws. These red flags came in the form of federal and state regulatory investigations, subpoenas and requests for documents, FDA Warning Letters, news articles and the recall of products accounting for hundreds of millions of dollars of corporate losses. Defendants chose to ignore that these red flags indicated to-down and systemic problems. In doing so, Defendants breached their fiduciary duties to J&J and its shareholders.

279. Each of the following red flags was reported to the Board, either by management through existing and necessary internal board reporting processes, or through the Company's annual reports on Form 10-K, which disclosed many of the red flags and which the Director Defendants on the Board at the time of each Form 10-K reviewed and executed.

280. Director Defendants Coleman, Cullen, Langbo, Lindquist, Mullin, Satcher, and Weldon were members of the Board throughout 2003 and 2004. During this time period,

Defendants received many red flags indicating pervasive and ongoing wrongful conduct at the Company. These red flags included:

- **July 2003**: J&J receives a request for documents from the criminal division of the U.S. Attorney's Office in connection with its investigation into various improper drug marketing practices.

- **December 2003**: J&J receives a subpoena from the U.S. Attorney's Office in Boston seeking documents related to the off-label marketing of Topamax.

- **January 2004**: J&J receives subpoena from OIG seeking documents regarding off-label marketing and kickbacks related to Risperdal.

- **April 2004:** FDA sends Warning Letter to CEO and Chairman of the Board Weldon, related to the Company's false and misleading Risperdal warnings.

- **July 2004**: J&J receives document request from the NYAG's Office for documents pertaining to off-label marketing of Topamax, Risperdal, and four other J&J drugs.

- **September 2004**: FDA sends Warning Letter to CEO and Chairman of the Board Weldon, related to the Company's false and misleading marketing of Topomax. The Warning Letter concluded that J&J's marketing materials raised "serious public health concerns because they encourage the unsafe use of Topamax, including, particularly, in pediatric patients".

- **September 2004**: DHHS sends letter to J&J relating to misleading claims about the abuse potential and other risks of the drug Duragesic. DHHS criticizes the Company for suggested that the drug is less abused that other opioid drugs without substantial evidence to support claim and orders Company to stop disseminating promotional materials that "could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventiliation."

- The U.S. Senate Finance Committee requested information from J&J on its use of the "nominal pricing exception" in calculating Best Price under Medicaid Rebate Program.

- OIG sent a subpoena seeking documents regarding marketing of J&J drug Procrit from 1997 forward.

- U.S. Attorney's Office asks J&J for assistance in obtaining subpoenaed testimony of several present and former Ortho-McNeil witnesses before a grand jury in Boston.

281. Director defendants Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Satcher and Weldon were members of the Board throughout the course of 2005 and 2006. During this time period, Defendants received many additional red flags indicating the pervasive wrongful

conduct ongoing at the Company. In 2005 and 2006, officer defendant Deyo, the Company's Chief Compliance Officer, sat on the Public Policy Committee of the Board, providing a critical additional source of reporting and information to this committee and, through it, the entire Board. The red flags the Board learned about in 2005 and 2006 include:

- **March 2005**: J&J's DePuy subsidiary receives subpoena from U.S. Attorney for New Jersey seeking documents regarding contractual relationships with surgeons or surgeons-in-training involved in hip and knee replacement and reconstructive surgery. Numerous DePuy employees were subpoenaed in 2006 to testify before the grand jury investigation.

- **July 2005**: J&J's Scios subsidiary receives subpoena from the U.S. Attorney's Office in Boston, seeking documents relating to potential unlawful sale and marketing of Natrecor.

- **August 2005:** J&J's Scios subsidiary is advised that the above investigation will be handled by the United States Attorney's Office for the Northern District of California in San Francisco.

- **August 2005:** A *New York Times* article entitled "Expert Panel Gives Advice that Surprises a Drug Maker" describes J&J's off-label use of Natrecor and the Company's Special Advisory Committee's unfavorable findings. Among other things, the article stated that the "committee of 10 medical experts determined that use of Natrecor, an expensive intravenous therapy, should be strictly limited to acutely ill patients in hospitals. The committee asked Scios to begin warning doctors against the drug's use in outpatients, a treatment that was not approved by the Food and Drug Administration but that had helped turn Natrecor into a big money maker.

- **September 2005**: J&J receives subpoena from the U.S. Attorney's Office, District of Massachusetts regarding the sales and marketing of eight drugs to Omnicare, Inc., including Risperdal. Employees of the Company's pharmaceutical subsidiaries were subpoenaed to testify before the grand jury.

- **November 2005**: J&J's Janssen subsidiary receives additional subpoena from U.S. Attorney in Philadelphia regarding potential illegal marketing and adverse side effects of Risperdal.

- J&J also received a series of requests from the U.S. Senate Finance Committee during 2005, regarding J&J's use of the "nominal pricing exception" in calculating Best Price under the Medicaid Rebate Program and J&J's use of supposed educational grants as a tool to promote the prescriptions of J&J drugs, which could include off-label marketing and unlawful kickbacks.

- The total number of drug, medical device and product recalls at the Company increased significantly during 2005.

- **January 2006:** J&J's Janssen subsidiary receives investigative demand from Texas Attorney General regarding potential illegal marketing of Risperdal. Disclosed in the 2005 and 2006 10-Ks.

- **January 2006:** the U.S. Senate Finance Committee requested additional information regarding J&J's use of educational grants for drug promotional purposes.

- **June 2006:** J&J receives additional subpoena from the Boston U.S. Attorney's Office regarding off-label marketing of Topomax. Disclosed in the 2006 10-K.

- **June 2006:** J&J's DePuy subsidiary receives subpoena from U.S. DOJ, Antitrust Division, regarding the manufacture, marketing and sale of orthopedic devices. The DOJ had search warrants executed in connection with the investigation. In the wake of publicity about the subpoena, DePuy was served with five civil antitrust class actions. Disclosed in the 2006 10-K.

- **September 2006:** J&J's Janssen subsidiary receives subpoena from the California AG regarding potential illegal marketing, kickbacks and sales of Risperdal, as well as interactions with State officials regarding Medicaid-reimbursed drugs. Disclosed in the 2006 -2008 10-Ks.

- **October 2006:** Texas AG joined a *qui tam* action filed against Janssen in Texas state court alleging off-label marketing of Risperdal and seeking compensation for alleged adverse patient reactions from Risperdal. Disclosed in the 2006 10-K.

- The total number of drug, medical device and product recalls at the Company continued to increase significantly during 2006.

282. Throughout the course of 2007, 2008 and 2009 members of the Board, including director defendants Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez (starting in 2008), Poon (starting in 2008), Prince, Satcher and Weldon, received additional multiple red flags indicating the ongoing pervasive wrongful conduct at the Company. These red flags included:

- **February 2007:** Pennsylvania AG files a complaint regarding the off-label promotion and sale of Risperdal, seeking damages, including for the costs to treat state citizens injured from the use of the drug. Attorneys General from eight states and the Office of General Counsel of PA filed actions seeking reimbursement of Medicaid or other public funds for Risperdal prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to Risperdal, civil fines or penalties, punitive damages, or other relief. The number of State AGs that obtained tolling agreements in connection with ongoing investigations exceeded 40.

- **March 2007**: J&J receives subpoena from Philadelphia U.S. Attorney's Office regarding unlawful marketing of Risperdal.

- **March 2007**: J&J also receives subpoena from Boston U.S. Attorney's Office relating to potential illegal marketing of Topamax and for the appearance of Company employees to testify.

- **March 2007:** J&J receives a subpoena from the San Francisco U.S. Attorney regarding unlawful marketing of Natrecor.

- **April 2007**: South Carolina AG files complaint seeking damages and other relief regarding off-label promotion of Risperdal. The State accuses J&J of engaging in a protracted and willful course of misconduct and misrepresentation by, *inter alia*, engaging in a direct, illegal nationwide program of promoting Risperdal for non-medically necessary uses and falsely representing that it is safer and more effective than generic equivalents.

- **May 2007**: U.S. Senate Finance Committee sends the Company a letter regarding the marketing of Procrit. U.S. House of Representatives sent a similar request in March. Also, in May, the New York AG issues a subpoena regarding Procrit. Like the House and Senate requests, the subpoena sought materials relating to the drug's safety, marketing and pricing.

- **September 2007:** Department of Health and Human Services files a criminal complaint in New Jersey alleging systematic illegal kickbacks. The Company announces a settlement pursuant to which: (i) J&J paid $84.7 million to settle charges regarding kickbacks to orthopedic surgeons, (ii) pled guilty to conspiracy to violate the federal Anti-Kickback Statute and entered into a deferred prosecution agreement ("DPA") and a corporate integrity agreement; and (iii) DePuy accepted a monitor to oversee compliance with the deferred prosecution agreement. Disclosed in the 2007 10-K.

- **November 2007**: Arkansas AG files complaint seeking damages and other relief arising from off-label promotion of Risperdal. The State accuses J&J of: (i) engaging in a direct, illegal nationwide program promoting off-label uses of Risperdal; (ii) falsely representing since beginning marketing the drug that it is safer and more effective than less expensive, first generation antipsychotics; and (iii) compromising the general health and welfare of the State's citizens through its failure to adequately warn of the risks of using Risperdal.

- **November 2007:** Massachusetts AG sends investigative demand regarding financial relationships between orthopedic surgeons and providers and J&J subsidiary DePuy.

- **November 2007:** FDA Warning Letter to J&J subsidiary Scios identifying failure to disclose appropriate indication and patient risk information in connection with Natrecor.

- **December 2007:** J&J receives request from U.S. Senate Finance Committee concerning the marketing and promotion of Risperdal for use by nursing home patients. Disclosed in the 2007 10-K.

- **December 2007:** A *Qui Tam* complaint filed by Dr. Gary R. Spivack was unsealed, alleging that J&J engaged in a widespread fraudulent scheme of aggressively promoting

the illegal and off-label use of Topamax. The alleged fraud also included the payment of kickbacks. The Complaint alleged that McNeil "illegally and aggressively promotes …Topamax – for numerous off-label treatments not approved by FDA" through a variety of fraudulent means including "the illegal remuneration of providers to influence their prescribing practices and to induce them to prescribe Topamax." The Complaint specifically alleged the payment of "kickbacks" to physicians to encourage the off-label use of Topamax despite "the serious risks to patients' health."

- The Company again experienced a number of drug, medical device and product recalls at the Company substantially greater than at any other top pharmaceutical company.

- U.S. House Committee on Oversight and Government Reform ("HCOGR") sends a letter to J&J's Cordis subsidiary regarding the marketing and safety of drug-eluting stents.

- Two subpoenas to J&J from the Delaware AG regarding nominal pricing agreements.

- A subpoena to J&J from the USSCF seeking documents relating to kickbacks in the form of continuing medical education payments to specific physicians.

- A letter from the USSCF requesting information concerning payments to a list of physicians, and specification as to whether any such payments were for continuing medical education, honoraria and research support.

- **February 2008:** J&J's DePuy subsidiary receives request for information from the U.S. Senate Special Committee on Aging concerning a number of aspects of the DPA.

- **February 2008:** Fifth Amended Complaint for violation of False Claims Act unsealed in District of Massachusetts, alleging among other things that J&J had engaged in widespread fraudulent scheme regarding off-label marketing of Topamax. The Complaint details how Topamax was fraudulently marketed, including through the use of fictitious and scientifically baseless "studies" The Qui Tam complaint also alleges, in detail and through specific witnesses, how J&J actively sought to minimize and mislead practicing physicians about the serious and life threatening side-effects of Topamax.

- **March 2008:** J&J receives letter from Michigan AG seeking information regarding potential health care reimbursement fraud. Disclosed in the 2008 10-K.

- **June 2008**: J&J receives subpoena from the Boston U.S. Attorney regarding J&J's marketing of biliary stents. Disclosed in the 2008 10-K.

- **August 2008:** Louisiana AG files complaint seeking damages and other relief arising from off-label promotion and sale of Risperdal. The complaint states that J&J engaged in a protracted and willful course of corporate misconduct and misrepresentation, including aggressively marketing of Risperdal by overstating its efficacy while minimizing or concealing its dangerous side effects. The State accuses the Company of deceptively claiming that Risperdal is safe and effective for non-medically accepted uses and is safer and more effective than first generation antipsychotics.

- **September 2008:** J&J received a letter from the FDA concerning violation of the FFDCA and identifying misrepresentations made in promotion its attention of J&J drug Concerta. Marketing materials used for Concerta were false or misleading because they overstated the efficacy of Concerta and omitted material facts regarding use of the drug.

- **December 2008:** Texas AG files complaint seeking damages and other relief arising from off-label promotion of Risperdal. The State claims that J&J developed and executed a marketing plan based on misrepresentations and concealment of material facts to tout the purported superiority, cost-effectiveness, safety and efficacy of Risperdal and to aggressively promote its use beyond the limited FDA approved indications. The Complaint accuses the Company of using sophisticated strategies and tactics to disseminate misrepresentations about the drug's safety and superiority for off-label uses.

- The Phantom Recall, in which J&J hired contractors to pose as customers and buy adult Motrin off the shelves in order to clandestinely remove the product from store shelves, took place in the second half of 2008.

- **April 2009:** J&J received a HIPPA subpoena from the Boston U.S. Attorney regarding the Company's financial relationship with several psychiatrists.

- **April 2009:** J&J was served with complaints in two *civil qui* tam cases regarding the marketing of prescription drugs to Omnicare, Inc. Disclosed in the 2009 10-K.

- **May 2009**: J&J subsidiary DePuy receives a subpoena from New Jersey AG regarding the financial interest of clinical investigators who performed clinical studies for DePuy. Disclosed in the 2009 10-K.

- **May 2009:** the FDA sent a Warning Letter to the Company addressed directly to Weldon describing the illegal marketing the Company had employed to promote its Ultram ER painkiller and stating that J&J promotions were "false or misleading because they omitted and minimized the serious risks of the drug and overstated the efficacy of Ultram ER."

- **June 2009:** The DOJ filed the Federal Natrecor Complaint following its intervention in a *qui tam* action. Complaint details how "J&J engaged in a fraudulent scheme to market and promote Natercor for serial, scheduled outpatient infusions – a use not approved by the FDA." According to the Complaint, J&J trained its "sales force to market for outpatient use because `that's where the money is.'" Simultaneously, J&J was actively and affirmatively misleading the FDA about its activities by representing that it did not market Natrecor for outpatient uses.

- **August 10, 2009:** J&J received a Warning Letter from the FDA concerning failure to adhere to FDA regulations and outlining the deficiencies in the Company's relevant clinical investigations protocol stating that "It is [J&J's] responsibility to ensure adherence to each requirement of the law and relevant FDA regulations. You should address these deficiencies and establish procedures to ensure that any ongoing or future studies will be in compliance with FDA regulations.

- **August 21, 2009:** J&J received a letter from the FDA concerning its violation of the FFDCA in illegally marketing a J&J product. The product advertisement broadened the approved indication of use for the product, contained unsubstantiated efficacy claims about the product, and omitted important risk information.

- **September 2009:** J&J publically recalled 21 different infant and children's products after an FDA inspection of McNeil's Fort Washington plant found that the unused portion of an ingredient contained *B. capacia* bacteria.

- **November 2009**: J&J publicly recalled five lots of Tylenol Arthritis Pain Caplet 100 count bottles because of an unusual smell or taste. Nausea and related symptoms were reported by consumers**.**

- **December 2009**: The Company expanded the November recall to include all lots of Tylenol Arthritis Pain 100 count because of the unusual, moldy odor.

283. Throughout the course of 2010 members of the Board, including director defendants Coleman, Cullen, Johns, Lindquist, Mullin, Perez, Prince, Satcher and Weldon, received many additional red flags indicating ongoing pervasive wrongful conduct at the Company. These red flags included:

- **January 2010:** *New York Times* article detailed widespread off-label marketing of biliary stents.

- **January 2010**: Federal Government filed a complaint, intervening in the two Omnicare *qui tam* cases. The complaint asserts claims under the federal False Claims Act and a related state law claim in connection with the marketing of several drugs to Omnicare.

- **January 2010:** J&J receives Warning Letter relating to Las Piedras Facility. FDA concluded that in relation to complaints about a musty, mildew odor in certain OTC products. The Warning Letter says that "when J&J became aware of FDA's concerns about the thoroughness and timeliness of McNeil's investigation, whether all potentially affected products had been identified, and whether the recall was adequate in scope, J&J did not take appropriate actions to resolve these issues. ***Corporate management has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management at J&J nor at McNeil Consumer Healthcare assured timely investigation and resolution of the issues***."

- **January 2010:** J&J recalled large quantities of Benadryl, Motrin, Rolaids, Simply Sleep, St. Joseph Aspirin, and Tylenol, because of the same musty, moldy smell identified in the November and December 2008 recalls.

- **February 2010**: J&J receives Civil Investigative Demands seeking additional information relating to sales and possible illegal marketing of Risperdal and another J&J drug.

- **April 2010:** J&J agrees to pay $81.5 million and enter a Corporate Integrity Agreement to resolve criminal and civil liability arising from illegal promotion of Topamax.

- **April 2010:** Company recalls more than 40 types and 135 million bottles of children's and infants' products because of quality and safety issues.

- **May 2010:** HCOGR announced an investigation into McNeil's April 30 recall. J&J closed its Fort Washington, Pennsylvania facility.

- **June 2010:** J&J expanded January recall to include five more lots of Benadryl and Tylenol because of unusual odor emanating from products.

- **July 2010**: J&J institutes another recall related to moldy, musty odor emanating from products. Twenty-one lots of certain Benadryl, Children's Tylenol Meltaways, Motrin, and Tylenol were recalled.

- **August 2010**: J&J received a warning letter from the FDA relating to improper marketing of DePuy's TruMatch Personalized Solutions System and the Corail Hip System without the required marketing clearance or approval.

- **August 2010**: J&J recalls two hip replacement products, the ASR Hip Resurfacing System and ASR XL Acetabular System.

- **October 15, 2010**: Louisiana jury returns $257.7 million verdict against J&J relating to 35,000 violations of state's Medical Assistance Programs Integrity Law.

284. Also in 2009, and J&J publically recalled 21 different infant and children's products in September 2009 after an FDA inspection of McNeil's Fort Washington plant found that the unused portion of an ingredient contained *B. capacia* bacteria.

285. Throughout the course of 2010 members of the Board at the time, who included director defendants Coleman, Cullen, Johns, Lindquist, Mullin, Perez, Prince, Satcher and Weldon, received multiple additional red flags relevant to the ongoing existence, scope and nature of pervasive wrongful conduct ongoing at the Company, including but not limited to:

- **January 14, 2010:** *New York Times* article detailed widespread off-label marketing of biliary stents.

- **January 15, 2010**: Federal Government filed a complaint on January 15, 2010 intervening in the two Omnicare *qui tam* cases. The complaint asserts claims under the federal False Claims Act and a related state law claim in connection with the marketing of several drugs to Omnicare. Disclosed in the Company's 2009 10-K.

- **January 15, 2010:** J&J receives Warning Letter relating to Las Piedras Facility. FDA concluded that in relation to complaints about a musty, mildew odor in certain OTC products, "Neither upper management at J&J nor at McNeil Consumer Healthcare assured timely investigation and resolution of the issues."

- **January 15, 2010:** J&J recalled large quantities of Benadryl, Motrin, Rolaids, Simply Sleep, St. Joseph Aspirin, and Tylenol, because of the same musty, moldy smell identified in the November and December 2009 recalls.

- **February 2010**: Government served Civil Investigative Demands to the Company seeking additional information relating to sales and possible illegal marketing of Risperdal and another J&J drug.

- **April 28, 2010:** J&J's Ortho-McNeil-Janssen Pharmaceuticals, Inc. subsidiary and the OIG enter into Corporate Integrity Agreement.

- **April 29, 2010:** J&J agreed to pay $81.5 million to resolve criminal and civil liability arising from illegal promotion of Topamax.

- **April 30, 2010:** Company announced recall of more than 40 types of children's and infants' products because the products did not meet quality standards, including the possibility of the medication containing too much of the active ingredient, containing substandard inactive ingredients, or containing tiny particles. The recall included more than 135 million bottles of children's medication.

- **May 5, 2010:** HCOGR announced an investigation into McNeil's April 30 recall.

- **May 6, 2010**: J&J closed its Fort Washington, Pennsylvania, facility in connection with the April 30 recall.

- **May 25, 2010**: J&J's web blog outlined an action plan designed to improve quality and manufacturing conditions in its facilities.

- **May 27, 2010**: HCOGR held hearing concerning J&J's April 30 recall. Colleen Goggins, worldwide chairman of Company's Consumer Group testified.

- **June 2, 2010:** HCOGR requests information from J&J concerning the Phantom Recall.

- **June 15, 2010:** J&J expanded January recall to include five more lots of Benadryl and Tylenol because of unusual odor emanating from products.

- **July 8, 2010**: J&J institutes another recall related to moldy, musty odor emanating from products. Twenty-one lots of certain Benadryl, Children's Tylenol Meltaways, Motrin, and Tylenol were recalled.

- **August 26, 2010**: J&J recalls two hip replacement products, the ASR Hip Resurfacing System and ASR XL Acetabular System.

- **September 30, 2010**: Chairman and CEO Weldon testified before Congress concerning J&J's myriad of product recalls.

- **October 15, 2010**: Louisiana jury returns $257.7 million verdict against J&J relating to 35,000 violations of state's Medical Assistance Programs Integrity Law.

- **October 18, 2010:** J&J issued a recall of one product lot of Tylenol 8 Hour caplets in 50-count bottles sold in the United States and Puerto Rico.

- **November 2010:** J&J recalls 71,000 packages of a cherry flavored, extra-strength Rolaids following consumer complaints of "an uncharacteristic consistency or texture."

- **December 2010**: J&J recalled 12 million bottles of Mylanta because the Company omitted material information from the product's label.

- **December 2010:** J&J recalled all lots of three varieties of Rolaids.

G. Demand on the Johnson & Johnson Board of Directors is Futile and Excused

1. The Company's Legal Violations Were Systemic, Widespread and Sustained, Undermining Any Inference of Legitimate Board Ignorance

286. The Director Defendants' challenged misconduct constitutes a conscious and repeated disregard of the Company's systemic violations of the drug marketing laws and regulations.

287. A board that manages and oversees a business that strategically violates the law is not entitled to the protections of the business judgment rule.Breaking the law or permitting a

company to systemically break the law is not a valid exercise of business judgment In such instances, demand on the Board is excused.

288. The particularized allegations herein demonstrate both an actual and implied knowledge of long-term legal violations that were not corrected by the Board for years, despite extensive "red flags" indicating that these violations were taking place and continuing. These Defendants were required to protect the Company from continued legal violations being committed in its name. Instead, Defendantsconsciously ignored the information presented to them and about which they were otherwise made aware concerning the Company's extensive legal violations. As a result, a majority of the current Board engaged in conduct evidencing an absence of good faithand demand is, therefore, excused. These board members are not disinterested or independent and cannot, therefore, properly consider any demand.

289. The misconduct giving rise to this case as detailed above is not the result of a "few bad apples" or rogue employees. Here, the J&J Board was informed, over a period of approximately seven years, of systemic violations of drug safety and involving hundreds if not thousands of employees, and resulting naturally from the Company's top-down strategic plans.

290. Similarly, the Company's current problems arise from multiple schemes.

291. Pursuant to J&J's Principles of Corporate Governance, all of the Company's directors were "well supported by accurate and timely information" and were provided with "sufficient time and resources" to fully attend to all of their crucial oversight responsibilities. Directors have "unrestricted . . . full and free access to officers and employees of the Company." Furthermore, the "Board and each Committee has the authority to engage independent legal, financial or other advisors as it may deem necessary, without consulting or obtaining the approval of any officer of the Company in advance." The Company maintains a "comprehensive

orientation program for all new non-employee directors," which includes "extensive written materials and . . . one-on-one sessions with members of senior management" regarding key oversight topics, including "legal issues, compliance programs and business conduct" matters.

292. As detailed above, six years of red flags reflecting widespread noncompliance with drug marketing laws, federal and state regulatory investigations, subpoenas and requests for documents, FDA Warning Letters, notice in the press and the recall of products which accounted for hundreds of millions in corporate assets, indicate that the directors' decision not to act was not made in good faith and was contrary to the best interests of the Company. This misconduct has been so prevalent over an extended period of time and the red flags to the Board have been so expansive and specific that the likelihood that the Director Defendants would now take action on behalf of the Company to seek redress for this misconduct is virtually non-existent.

293. Encouraging, permitting and failing to stop extensive violations of federal regulations over a period of more than six years indicates that the Board has proven unwilling or unable to seek redress on behalf of the Company. Therefore, demand on the Board is futile and excused.

2. A Majority of The Current Board Members Are Conflicted From Investigating The Company's Misconduct On Their Watch

294. Even if knowingly presiding over criminal misconduct could somehow fall within the ambit of the business judgment rule (which it does not), demand is also futile and excused because a majority of the members of the current Board face a substantial likelihood of liability for failing to take action to stop or prevent misconduct.

295. Seven (7) members of the current Board - Weldon, Coleman, Cullen, Langbo, Lindquist, Mullin, and Satcher - face a substantial threat of personal liability with respect to the off-label promotion of Risperdal, Topamax, Biliary Stents, and Natrecor, the kickback violations

including Omnicare and Depuy, and the persistent manufacturing plant failures that led to massive product recalls.

296. The Director Defendants are likewise conflicted from and unable to pursue the Company's claims against the Officer Defendants. Any effort to directly prosecute such claims against the Officer Defendants for their direct roles in the off-label marketing, kickback schemes or cGMP violations would necessarily expose the Board's own culpability for the very same conduct. In other words, given that the Board was regularly informed concerning the Company's compliance or non-compliance with the drug marketing laws and manufacturing processes, any effort by the Director Defendants to hold the Officer Defendants liable would surely lead the Officer Defendants to defend on the ground that their own conduct was consistent with corporate policy and practice, as established and by and known to the Board.

297. In addition, a majority of the Board's current members acted in bad faith by disregarding their specific duties on committees of the Board:

a. Defendant/Current Board Member Coleman has served on the Board, the Audit Committee and the Science and Technology Advisory Committee since September 2003.

b. Defendant/Current Board Member Cullen has served on the Board since 1995, on the Audit Committee since 1997, and on the Nominating and Corporate Governance Committee since 2004.

c. Defendant/Current Board Member Johns has served on the Board since 2005, and on the Science and Technology Advisory Committee since 2006.

d. Defendant/Current Board Member Langbo has served on the Board since 1991, served on the Audit Committee from at least 1997 to 2003, and has served on the Nominating and Corporate Governance Committee since 2004.

e. Defendant/Current Board Member Lindquist has served on the Board the Public Policy Advisory Committee, and the Science and Technology Advisory Committee since February 2004.

f. Defendant/Current Board Member Mullin has served on the Board since 1999, on the Audit Committee since 2000, on the Public Policy Advisory Committee since 2006, and on the Nominating and Corporate Governance Committee from 2000 to 2005.

g. Defendant/Current Board Member Perez has served on the Board since June 2007 and on the Public Policy Advisory Committee since 2008.

h. Defendant/Current Board Member Prince has served on the Board since 2006 and on the Nominating and Corporate Governance Committee since 2007.

i. Defendant/Current Board Member Satcher has served on the Board since 2002 and on the Public Policy Advisory Committee and the Science and Technology Advisory Committee since 2003.

298. The Company's Audit Committee was responsible at all relevant times for being the Board's front line in the oversight of "Policies and Procedures Addressing Legal and Ethical Concerns," including the "monitoring" of all compliance programs, and reports from the Company's internal audit function concerning "management improprieties." The Audit Committee was required to report regularly to the full board concerning its meetings and discussions and to review with the full Board all "significant issues and concerns" arising at its meetings.

299. The Company's Public Policy Advisory Committee consists both of directors and senior executive officers of the Company, including the General Counsel and senior executives in charge of government and regulatory affairs. The Committee's purpose includes reviewing and advising the Board on governmental and regulatory affairs involving public health issues. The members of the Public Policy Advisory Committee were regularly apprised by the General Counsel and other senior executives of the Company of regulatory affairs and compliance matters affecting the Company regularly reported to the full Board concerning significant issues and concerns arising at the committee's meetings.

300. The Company's Science and Technology Advisory Committee consists of both directors and one or more senior scientific or medical officers of the Company. Historically, all directors serving on this committee have had a background of expertise in medical and biological science issues, and due to their background, have expertise in matters of science, medicine, clinical trial development and conduct, and scientific and medical ethics. The members of the Science and Technology Advisory Committee had special expertise and experience relevant to the various schemes detailed herein.

301. Accordingly, all of the Director Defendants listed above had substantial knowledge relating to the allegations above and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty. Demand is excused with respect to these Defendants for this additional reason.

COUNT I

(Against the Director Defendants for Breach of Fiduciary Duty)

302. Plaintiffs repeat and re-allege each of the allegations set forth above as if fully set forth herein.

303. As directors of a New Jersey corporation, each of the Director Defendants owed and owes fiduciary duties to J&J and its shareholders. Moreover, as members of the Board, these defendants had specific fiduciary duties as defined by the Company's key corporate governance documents and principles. Pursuant to these duties, the Director Defendants specifically owed and owe J&J the highest obligation of good faith and loyalty in the administration of the affairs of the Company, including the duty not to cause or allow J&J to

violate laws and regulations governing the marketing and manufacturing of the Company's products and the obligation to take timely and good faith remedial actions when such violations occurred. Consistent with these duties, the Director Defendants were obligated to educate themselves about relevant laws and regulations concerning pharmaceutical and medical device marketing and manufacturing (including but not limited to FDA requirements, cGMP requirements, federal healthcare program requirements, and/or the Federal anti-kickback statute), and take good faith steps to address J&J's violations of those laws and regulations.

304. Each of the Director Defendants consciously violated these duties. As members of the Board and by virtue of their membership on the aforementioned committees, they were each warned, specifically and repeatedly, over a number of years, about the systemic and widespread legal violations alleged herein. Moreover, these Director Defendants served on committees that gave them direct responsibility for, and detailed information concerning, the systemic compliance issues alleged herein.

305. Faced with the repeated red flags, the Director Defendants had a duty to act in good faith and not knowingly violate the law by, among other things, investigating the issues raised, ensuring that the Officer Defendants were taking appropriate remedial action, and overseeing those remedial measures to ensure that they were effective.

306. The Director Defendants consciously violated their corporate responsibilities and fiduciary duties in at least the following ways:

a. Affirmatively and repeatedly declining to stop and prevent J&J's illegal marketing and promotion of off-label uses of Risperdal, Topamax, Natrecor and the Company's biliary stents after receiving red flag warnings about such illegal activity;

b. Affirmatively and repeatedly declining to stop and prevent J&J's illegal kickbacks to health care professionals and organizations for prescribing, recommending or using multiple J&J drugs and medical devices, in violation of the Federal Anti-

Kickback Statute, 42 U.S.C. §1320a-7b(b), and/or consciously disregarding such reports and activity; and

c. Affirmatively and repeatedly approving and/or consciously disregarding J&J's business plan of marketing its drugs through the widespread illegal promotion of off-label uses and dosages, illegal kickbacks to healthcare professionals and pervasive violations of cGMP in order to, inter alia, maximize J&J's short-term profit but at the expense of shareholder's long-term interests and J&J's reputation and goodwill.

307. As a direct and proximate result of the Director Defendants' conscious failure to perform their fiduciary obligations, the Company has sustained and will sustain significant damages, not only monetarily, but also to its corporate image and goodwill.

308. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

COUNT II

(Against the Officer Defendants for Breach of Fiduciary Duty)

309. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

310. As officers of a New Jersey corporation, each of the Officer Defendants owed the Company and its shareholders a fiduciary duty to act loyally and with good faith, as well as the duty to exercise that degree of care that an ordinarily prudent officer would use under the circumstances. Each Officer Defendant was duty-bound to bring to bear all of his or her knowledge, skill, experience and expertise in the fulfillment of his or her appointed official duties. Moreover, each Office Defendants was required to faithfully pursue the lawful best interests and advantages of the corporation.

311. Defendant Weldon has served as Chief Executive Officer of J&J and Chairman of the Executive Committee from April 2002 until the present. As Worldwide Chairman of the Company's Pharmaceuticals Group and as a member of the Executive Committee from 1998 to

April 2002, and later as CEO and Chairman of the Executive Committee, Weldon had knowledge of, and responsibility for, and approved and directed the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor. Furthermore, as a member of the Executive Committee and as CEO and Chairman of the Executive Committee, Weldon had knowledge of, and responsibility for, and approved and ultimately as CEO directed the use of the Company's off-label promotion strategy relating to biliary stents as well as the kickback strategy employed with DePuy and with Omnicare. Finally, as CEO and Chairman of the Executive Committee, Weldon had knowledge of the Company's receipt of OTC product odor complaints and approved and directed the Company's improper failure to complete a timely and adequate investigation of plant and manufacturiong problems resulting in recalls and regulatory actions, as discussed herein.

312. Defendant Poon joined the Company in 2000 as a Company Group Chairman in the Pharmaceuticals Group, was named a Member of the Executive Committee and Worldwide Chairman, Pharmaceuticals Group in 2001, and was named Worldwide Chairman, Medicines & Nutritionals in 2003. In 2007, Poon assumed responsibility for the J&J Development Corporation, the Corporate Office of Science and Technology, the Corporate Office of Information Management, Worldwide Procurement and Worldwide Operations, and was again named Worldwide Chairman, Pharmaceuticals Group in January 2008. Throughout her executive tenure at J&J, Poon had knowledge of, and responsibility for, and approved and directed, the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor. Furthermore, as a member of the Executive Committee, Poon had knowledge of, and responsibility for, and

approved and directed the use of the Company's off-label promotion strategy relating to biliary stents as well as the kickback strategy employed with DePuy and with Omnicare.

313. Defendant Valeriani served as Worldwide Franchise Chairman for the DePuy franchise beginning in 2002, became a member of the Executive Committee in September 2003, assumed responsibility for the company's diagnostics businesses and was named Worldwide Chairman, Diagnostics in the first quarter of 2004, and later in 2004, was named Worldwide Chairman, Cardiovascular Devices and Diagnostics. In 2006, he assumed responsibility for a newly-created Cardiovascular Devices & Diagnostics Group Operating Committee, which included LifeScan, Inc., Cordis Corporation and Ortho-Clinical Diagnostics, Inc. From 2003 forward as a result of his membership of the Executive Committee, Valeriani had knowledge of, and responsibility for, and approved and directed, the promotional and marketing strategies for the Company's medical device products, including, without limitation, DePuy products and the Company's biliary stent products.

314. Defendant Scodari joined J&J in 1999 and in 2001 was named Company Group Chairman for the Johnson & Johnson North American Pharmaceuticals business, and became a member of the Pharmaceuticals Group Operating Committee. From 2003 to 2005, Mr. Scodari was Company Group Chairman of J&J's Biopharmaceutical Business, and was Worldwide Chairman, Pharmaceuticals Group, and a member of the Executive Committee from March 2005 until March, 2008. Throughout the period from 2000 to his retirement in 2008, Scodari acted as leading deputy to Defendant Poon in the Company's pharmaceutical segment. Throughout his executive tenure at J&J, Scodari had knowledge of, and responsibility for, and approved and directed, the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor. Furthermore, as a

member of the Executive Committee, Scodari had knowledge of, and approved the use of the Company's off-label promotion relating to biliary stents as well as the kickback strategy employed with DePuy and with Omnicare.

315. Defendant Gorsky has been J&J's Worldwide Chairman, Medical Devices and Diagnostics Group since September 2009, and a member of Johnson & Johnson's Executive Committee since January 2009. He came to Johnson & Johnson in 2008 after serving as head of Novartis Pharmaceuticals Corporation's North American pharmaceuticals business. Prior to joining Novartis in 2004, Gorsky had served in various management positions at Johnson & Johnson, beginning as a sales representative with Janssen Pharmaceutica Inc in 1988. Over the next 15 years, he advanced through positions of increasing responsibility in sales, marketing and management, and was ultimately named President of Janssen Pharmaceutica Inc. in the U.S. As leader of Janssen's management board, Mr. Gorsky had responsibility for all of its functional areas, including, *inter alia*, marketing, sales and medical affairs. While at J&J's Janssen subsidiary, Gorsky had principal responsibility for the commercialization of Risperdal, including the conceptualization and execution of the Risperdal Off-Label Promotion Scheme. Gorsky thus had knowledge of, and responsibility for, and approved and directed, the Risperdal Off-Label Promotion Scheme.

316. Defendant Russell Deyo became a member of the Executive Committee and Vice President, Administration in 1996 and Vice President, General Counsel and Chief Compliance Officer in April, 2004. From at least 2002 to 2009, Deyo was a management member of the Board's Public Policy Advisory Committee, thus serving as a key advisor to the Board on matters of governmental and regulatory affairs and compliance. As a member of the Executive Committee since 1996 and as General Counsel and Chief Compliance Officer from 2004

forward, Deyo had knowledge of, and responsibility for, and approved, the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor, including the Risperdal Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, and the Natrecor Off-Label Promotion Scheme, and also had knowledge and approved of the use of the Company's off-label promotion strategy in the Biliary Stent Off-Label Promotion Scheme, as well as the kickback strategy employed in the DePuy Kickback Scheme. Finally, as Executive Committee member, General Counsel, and Chief Compliance Officer, Deyo had knowledge of the Company's receipt of OTC product odor complaints and approved and directed the Company's improper failure to complete a timely and adequate investigation of the matters addressed in the January 2010 Warning Letter, as well as of the other cGMP problems, and resulting recalls and regulatory actions, as discussed herein.

317. Defendant Peter Luther has served as the President of McNeil Consumer Healthcare from January 2009. In that capacity, Luther had knowledge of, and responsibility for the quality of healthcare products manufactured by McNeil Consumer Healthcare, to include ensuring full compliance with relevant cGMP. As alleged herein, and reflected in, *inter alia*, emails and other materials detailed above, Luther was aware of the broad ranging cGMP defects and problems and resulting recalls and regulatory actions, and nonetheless allowed defective products to be shipped and/or delayed and sought to disguise Company efforts to recall defective products.

318. Each of the Officer Defendants was aware of and educated concerning the relevant laws and regulations concerning pharmaceutical and medical device marketing (including but not limited to FDA requirements, federal healthcare program requirements, and/or

the Federal Anti-Kickback Statute), and were duty-bound to abide by the laws and regulations and to enforce compliance therewith.

319. The Officer Defendants consciously violated and breached these duties. They caused J&J to employ a deliberate and systematic business plan pursuant to which J&J improperly increased sales by engaging, for a prolonged period of time, in widespread unlawful sales and promotional practices, including illegal marketing and promotion of off-label uses of J&J drugs and medical devices and the payment of illegal kickbacks to healthcare professionals and organizations to induce the prescription, recommendation and use of J&J drugs and devices. Additionally, they knowingly ignored J&J's widespread violation of cGMP regulations.

320. In addition, each of the Officer Defendants was warned, specifically and repeatedly, over a number of years, about these systemic and widespread legal violations. Faced with a litany of red flags that the Company's legal compliance controls, even where they exist, were rampantly violated and undermined, the Officer Defendants were under a duty to specifically inform themselves of these problems and to take aggressive action to cure violations and prevent them from recurring. Instead of remedying these manufacturing and marketing violations, however, the Officer Defendants allowed the misconduct to continue unabated and, in many ways, proliferate.

321. As a direct and proximate result of the Officer Defendants' breaches of fiduciary duty, the Company has sustained, and will continue to sustain, substantial harm, including the damages set forth herein.

322. The Officer Defendants are liable as a result of the acts alleged herein.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for judgment as follows:

i. Determining that this action is a proper derivative action maintainable under law and demand is excused.

ii. Declaring that the current and former directors and officers named as defendants herein have breached their fiduciary duties as alleged herein;

iii. Requiring the defendants to pay to the Company the amounts by which it has been damaged or will be damaged by reason of the conduct complained of herein;

iv. Directing J&J to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its shareholders from a recurrence of the damaging events described herein.

v. Awarding plaintiffs and their counsel reasonable attorneys' fees, expert fees and other reasonable costs and expenses; and

vi. Granting such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all issues to triable.

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO
Co-Lead Counsel for Plaintiffs

By: /s/ James E. Cecchi
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Dated: December 17, 2010

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