UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION	Civil Action No. 10-2033 (FLW)
IN RE JOHNSON & JOHNSON FCPA SHAREHOLDER DERIVATIVE LITIGATION	Civil Action No. 11-2511 (FLW)
COPELAND v. PRINCE, *et al.*	Civil Action No. 11-4993 (FLW)

DECLARATION OF HARVEY L. PITT IN SUPPORT OF SETTLEMENT

Harvey L. Pitt, an attorney admitted to practice in the State of New York and District of Columbia, declares under penalty of perjury, pursuant to 28 U.S.C. § 1746:

I. Introduction

1. This Declaration is submitted in support of the proposed settlement of various shareholder derivative claims brought for the benefit of nominal defendant Johnson & Johnson ("J&J" or the "Company") against certain of the Company's officers and directors (the "Individual Defendants").[1]

2. I am the founder and Chief Executive Officer of Kalorama Partners, LLC ("Kalorama"), a global strategic business consulting firm, specializing in corporate governance, transparency, regulatory,

[1] As set forth in the Stipulation and Agreement of Settlement, filed July 11, 2012 (the "Settlement Agreement"), the derivative claims include those asserted in demand letters (the "Demand Letters") sent by shareholders to the Company's Board of Directors ("Board"), Court cases in which plaintiffs allege that it would have been futile to demand that the Board investigate and pursue litigation against the Individual Defendants (the "Demand Futile Actions") and Court cases in which plaintiffs allege that the Board wrongfully refused demands made to the Board (the "Demand Refused Actions") (collectively, the Demand Letters, Demand Futile Actions and the Demand Refused Actions are referred to herein as the "Derivative Actions").

accounting, and economic and risk/crisis management issues. I am also the founder and Chief Executive Officer of Kalorama Legal Services, PLLC, Kalorama's law firm affiliate.

3. I was retained in August 2011 by Plaintiffs' Counsel in the Demand Futile Actions, as an expert on corporate governance matters to advise on, and assist in crafting, corporate governance and compliance reforms in connection with their efforts to negotiate a global settlement of the Derivative Actions.

4. Demand Futile Plaintiffs' Counsel have now requested that I review the terms of the Settlement Agreement, in particular, the "Governance Reforms" (Settlement Agreement, Ex. A) and "Governance Enhancements and Changes" (Settlement Agreement, Ex. B), and provide my opinion on whether these governance reforms and enhancements will afford substantial benefits to J&J and its shareholders.

5. The views expressed in this Declaration are solely mine and are based on my experience and background (described below), as well as my review of certain documents that are part of the record in this litigation and other documents, such as minutes of meetings held by J&J's Board of Directors (the "Board") and Audit Committee, from December 2002 through July 18, 2011, and management presentations to the Board and Audit Committee (all of which are identified in Exhibit A to this Report). I have drafted this Declaration, with assistance from Kalorama colleagues working under my supervision. I reserve the right to revise or supplement this Declaration in the event that I later become aware of additional relevant information.

6. I will receive a flat fee plus reimbursement for out-of-pocket expenses for the work I have performed in this matter, including the preparation of this Declaration, and the receipt of my fee is not contingent upon whether the Court approves the Settlement Agreement.

II. Summary of Conclusions

7. In my opinion, based upon my experience with respect to corporate governance matters, the terms of the proposed settlement will provide J&J and its shareholders with substantial benefits, by among other things:

(a) affirming the Board's commitment, through its adoption of the Core Quality and Compliance Objective (the "Core Objective"), that the Company will:

- operate all its businesses in compliance with applicable laws, regulations and internal policies and standards;

- maintain an enhanced system of internal controls designed to detect, correct and prevent violative activities; and

- ensure the ongoing development of a robust compliance culture;

(b) providing the Board, through its newly-formed Regulatory, Compliance & Government Affairs Committee (the "RCGC"), with the information necessary for it to exercise meaningful review and oversight of the implementation and effectiveness of the Company's compliance and quality programs[2] and the activities of management in this regard;

(c) helping ensure that the Board, through the RCGC, is kept fully apprised of the status of the compliance and quality efforts at J&J's operating companies, and made aware—on a *timely* basis—of potential significant problems, so that the Board can respond proactively in directing management to take appropriate corrective measures—before these problems rise to the level of governmental investigations and actions, *qui tam* proceedings, other legal and regulatory proceedings, and Congressional hearings; and

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[2] At J&J, Health Care Compliance ("HCC") and Quality & Control ("Q&C") are separate and distinct areas. HCC relates to the laws, regulations and industry standards pertaining to the research and development and promotion and marketing of drugs, medical devices and health care services. Q&C involves both regulated and non-regulated quality functional areas, such as: quality assurance, including oversight of manufacturing plants and suppliers; quality control, including clinical and laboratory testing; and compliance with FDA regulations. Q&C also encompasses the Company's oversight and quality management of products and services, sites and operating companies. Report of the Special Committee of the Board of Directors of Johnson & Johnson ("Special Committee Report"), filed June 27, 2011, at 27.

I have attempted to recognize this distinction in this Declaration but, in a broad sense, HCC and Q&C each involve "compliance" in that each involves adherence to particular requirements, expectations and/or industry standards by J&J's operating companies. Failures in either area may result in exposing the Company to legal and regulatory risk and reputational damage.

(d) centralizing and enhancing the Company's compliance and quality frameworks and systems of internal control, through mandatory and qualitatively uniform "bottom-up" reporting to the RCGC and "top-down" driven enhancements to the Company's Enterprise Risk Management ("ERM") Framework, including the Product Risk Management ("PRM") Standard.

At the same time, J&J's core business structure, which profits from a decentralized management model and business sector alignment of its subsidiaries, will be preserved.

8. Viewed holistically, I believe that the proposed "Governance Reforms" together with the "Governance Enhancements and Changes" that the Company has already implemented, or is in the process of implementing, should lead to a more effective internal compliance regime and increased accountability by senior management, and strengthen Board oversight of the Company's compliance with applicable drug manufacturing and marketing rules and regulations. As such, I believe that the proposed settlement's reforms and enhancements should go a long way toward helping the Company avoid or mitigate legal and regulatory risk and reputational harm, such as that which resulted from the underlying problems that gave rise to the Derivative Actions, and will thus help promote shareholder (and public) confidence in J&J.

9. I note that my opinions regarding the proposed settlement are not based on a *post hoc* analysis. Rather, as I noted above, I was retained initially to provide advice on corporate governance improvements that might form the basis of a meaningful (from a shareholder point of view) proposed settlement with defendants and to assist in crafting provisions to implement these improvements. And, over the course of several months, I regularly provided advice to Plaintiffs' Counsel in the Demand Futile Actions on various settlement proposals and counter-proposals, advised on the relative importance of various settlement terms and assisted in drafting certain proposals.

10. For example, I expressed my view that the settlement ought to include detailed provisions regarding the scope of the oversight responsibility and functioning of the RCGC; these suggestions ultimately were reflected in the RCGC's Charter and Operating Procedure.

11. My approach throughout the process was to view the settlement of this litigation as an opportunity for J&J to improve the quality and design of its governance system, and to highlight the importance of regulatory and compliance matters as a core focus of that system.

12. I also note that this is not the first time I have served as an expert on corporate governance matters in a shareholder derivative action against a major pharmaceutical company. In 2010, I was retained by the *defendant* independent directors of the Board of Directors of Pfizer, Inc. in connection with a derivative action asserting claims not unlike those asserted in the Derivative Actions, *i.e.*, that the director defendants breached their fiduciary duties to the company, by consciously disregarding red flags of widespread non-compliance in connection with the marketing of certain drugs.[3] In the *Pfizer* matter, I provided two expert declarations: one that explained my view that the independent directors had a reasonable, good faith basis for their actions and decisions, and were justified in believing they properly fulfilled their oversight responsibilities; and the other in support of the proposed settlement of that litigation, which featured the creation of a Regulatory and Compliance Committee.

13. Of course, there are no "silver bullets" that guarantee perfect board responses to crisis situations. And, although the proposed settlement will effect a number of significant improvements to the Company's corporate governance mechanisms and compliance and quality control programs, the effectiveness of these improvements necessarily will depend on the ongoing commitment by the Company's senior management, and the vigilant oversight by the Company's directors, to ensure that the improvements embodied in the Settlement Agreement are appropriately implemented and that short-term commercial considerations do not effectively receive precedence over longer term goals. The settlement, if implemented in good faith, will provide meaningful checks to guard against this. In addition, because good corporate governance is not a static concept, future enhancements to the Company's governance and compliance frameworks should be considered regularly, and may also result in additional benefits to the Company and its shareholders.

III. Experience and Background

14. I am an attorney at law, admitted to practice before the state and federal courts in New York State and the District of Columbia.

15. I received a BA degree in 1965 from the City University of New York (Brooklyn College) and a JD degree from St. John's University School of Law ("SJU") in 1968. In 2002, I received an LL.D. (Hon.) from

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[3] Consolidated, Amended and Verified Shareholder Derivative Complaint, *In re Pfizer Inc. Shareholder Derivative Litigation*, No. 09-CV-7822 (JSR) (S.D.N.Y. filed Nov. 18, 2009), available at http://www.blbglaw.com/cases/00143_data/Pfizer-AmendedComplaint-11.18.09.pdf.

SJU, and in 2003 I was awarded the Brooklyn College President's Medal of Distinction. I am admitted to practice in, and have argued before, all federal appellate courts, as well as the U.S. Supreme Court.

16. Upon graduating from SJU, I served on the Staff of the Securities and Exchange Commission ("SEC") for over ten years, from 1968 until 1978, the last three years of which I served as General Counsel, the Agency's Chief Legal Officer. In my role as General Counsel, I provided advice to the Commission, its senior Staff and to federal and state courts as *amicus curiae*, on a broad scope of securities, corporate and administrative legal and policy issues. A significant part of my responsibilities involved the fiduciary and compliance obligations of public companies, like J&J, and their boards, managers and outside advisors.

17. After leaving the SEC, for nearly a quarter of a century (1978-2001), I served as a senior corporate partner at the international law firm of Fried, Frank, Harris, Shriver & Jacobson LLP ("Fried Frank"). From 1998-2001, I was Co-Chairman of Fried Frank, responsible for all facets of the administration of a global law firm. Prior to 2001, I chaired Fried Frank's Washington, D.C. office, headed the Firm's securities and regulatory practice group, and chaired the Firm's Policy Planning Committee.

18. My practice at Fried Frank covered administrative and corporate law, financial services regulation, federal securities regulation, corporate governance and corporate transactional work. During my tenure at Fried Frank, I represented many corporate clients operating in highly regulated industries, including the financial services industry, the health care and drug industries, the defense industry, the agriculture industry and the insurance industry, among others. As part of my practice, I regularly advised boards, audit committees, corporate management and accountants with respect to their fiduciary, disclosure, regulatory and compliance obligations. I represented boards, management, audit committees, and accounting firms in SEC enforcement proceedings and investigations, and represented special committees and audit committees in internal investigations. I also advised clients as to corporate governance matters and counseled many boards of directors in connection with shareholder and derivative litigation.

19. In my second tour of duty with the SEC, from 2001 to 2003, I served as its 26th Chairman. During my tenure as Chairman, among other things, I oversaw the SEC's response to market disruptions resulting from the terrorist attacks of 9/11, I created the SEC's "real time enforcement" program, a policy geared towards making the SEC's enforcement initiative more efficient and effective for individual investors, and I also led

the SEC's adoption of dozens of rules in response to the corporate and accounting crises generated by the excesses of the 1990s (for example, scandals involving WorldCom, Enron, Adelphia and Tyco), including implementation of rules required by the Sarbanes-Oxley Act ("S-Ox").[4]

20. I am currently an independent director of Premier Alliance Group, Inc. ("Premier"), a publicly-held professional services company focused on business and technology advisory and consulting services. I am a member of Premier's Audit Committee.

21. I am also an independent director of GWU Medical Faculty Associates, Inc. ("MFA"), a not-for-profit corporation, organized pursuant to §501(c)(3) of the Internal Revenue Code, that provides health care and educational assistance from its headquarters in Washington, DC. I am a member of MFA's Audit, Compensation and Compliance Committees.

22. I am an independent director of the offshore funds of Paulson & Co, Inc., and a member of their Audit Committees.

23. I am a member of the Compliance Advisory Forum of Millennium Management, LLC, a U.S.-based global hedge fund manager, and I am also a member of the Global Advisory Forum for CQS (UK) LLP and CQS Investment Management Ltd., an international group of alternative asset management funds headquartered in London, England.

24. In 2011, I was inducted in the NACD (National Association of Corporate Directors) Directorship 100 Hall of Fame, which acknowledges professionals for their accomplishments in providing a lasting and positive

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[4] Sarbanes-Oxley Act of 2002, Pub. L. 107-204, 116 Stat. 745 (2002). In particular, I oversaw the Commission's adoption of rules relating to:

(1) CEOs and CFOs certifying their financial statements;
(2) acceleration of insider transaction reporting to two days;
(3) pro-forma financial information;
(4) codes of ethics for senior executives;
(5) financial experts on audit committees;
(6) trading during pension fund blackout periods;
(7) disclosure of material off-balance sheet transactions;
(8) retention of audit records;
(9) independence standards for public company auditors;
(10) standards of conduct for corporate attorneys;
(11) application of certain S-Ox certifications and disclosure requirements to registered investment companies;
(12) proxy voting by investment companies and investment advisers;
(13) listing standards related to audit committees;
(14) investment adviser and investment company compliance policies; and
(15) certifications by analysts.

influence on corporate governance. And, earlier this year, I was appointed as a member of the Advisory Council of the Public Company Accounting Oversight Board, for a three-year term.

25. I previously served for three years (2006-2009) on the National Cathedral School's ("NCS") Board of Trustees, and was variously Board Vice-Chair, Co-Chair of the Board's Governance Committee and Chair of the NCS Audit and Compensation Committees.

26. I also previously served for four years (2004-2008) on the Board of Directors of Approva Corporation, a closely-held software manufacturer that assists corporations in improving their internal controls and compliance with the requirements of S-Ox. I was a member of Approva's Audit and Strategic Planning Committees.

27. I have taught—in an adjunct professor capacity—courses on fraud and fiduciary duties under the federal securities laws (Georgetown University Law Center), market structure (George Washington University Law School), fraud and fiduciary duties and takeover practice/law (University of Pennsylvania School of Law) and corporate governance (Yale Law School).

28. I have been a guest lecturer on various topics at (among other places) Harvard Law School, Yale Law School, The Wharton School, MIT Sloan School of Management and Georgetown University's McDonough School of Business.

29. I previously served as a regular contributing columnist to Compliance Week on subjects relating to corporate law, compliance and governance, and I am a frequent contributor to other publications on these subjects, as well as a frequent lecturer on various issues related to corporate law and economics.[5]

30. Since 2006, I have provided expert reports, and related testimony in a number of cases, including in the *Pfizer* matter referenced above.[6]

31. My experiences in government, in the private practice of law advising and representing boards, management and accounting firms, and now, in providing compliance and governance advice to clients of Kalorama, give me a unique knowledge of, and perspective on, the

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[5] Exhibit B contains a list of articles I have written and various lectures of mine that have been published, from 2000 to the present.

[6] Exhibit C contains a list of the cases in which I have prepared expert reports and provided related deposition testimony.

importance of strong compliance structures and internal controls, particularly regarding the roles of directors, CEOs, CFOs, Controllers, internal auditors and external auditors in helping to assure that companies comply with applicable statutes, regulations and internal policies.

IV. Relevant Background

32. In order to put my statements and opinions in context, I summarize briefly below certain background information pertaining to the Company, the alleged violations and the present posture of the Derivative Actions.

A. Johnson & Johnson: The Company, its Operating Structure and Compliance and Quality Frameworks

33. As described in the Company's most recent Form 10-K (for the period ending January 1, 2012), J&J has more than 250 operating companies; through its operating companies, it conducts business in "virtually all countries of the world,"[7] and the Company and its subsidiaries have approximately 117,900 employees worldwide, who are "engaged in the research and development, manufacture and sale of a broad range of products in the health care field."[8]

34. J&J's operating companies are organized into three business sectors: Pharmaceutical, Medical Devices and Diagnostics ("MD&D") and Consumer.[9] The Pharmaceutical sector includes products in the following areas: anti-infective, antipsychotic, contraceptive, dermatology, gastrointestinal, hematology, immunology, infectious diseases, neurology, oncology, pain management, thrombosis and vaccines. The MD&D sector includes a range of products distributed to wholesalers, hospitals and retailers, used by physicians, nurses, therapists, hospitals, diagnostic laboratories and clinics, including electrophysiology and circulatory disease products, orthopaedic joint reconstruction, spinal care, neurological and sports medicine products, and disposable contact lenses. The Consumer sector manufacturers and sells a range of products, including those used in baby care, skin care, oral care, wound

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[7] Johnson & Johnson Form 10-K, Annual Report (for fiscal year ended Jan. 1, 2012, filed Feb. 23, 2012) ("Form 10-K"), at 1, available at http://www.sec.gov/Archives/edgar/data/200406/000119312512075565/0001193125-12-075565-index.htm.

[8] *Id.*

[9] *Id.*

care and women's health care, as well as nutritional and OTC pharmaceutical products.[10]

35. The Company utilizes a decentralized management structure, with its Executive Committee responsible for strategic operations, resource allocation, and oversight and coordination of the activities of the Company's three business sectors.[11] Following the principle of decentralized management, senior management groups at each of J&J's U.S. and international operating companies are responsible for each company's strategic plan and day-to-day operations. Generally, each operating company is managed by citizens of the country where it is located.[12]

36. As noted in the Special Committee Report, consistent with J&J's decentralized operating model the "primary responsibility for Compliance has always resided at the operating company level, with varying degrees of oversight by the Corporate Center over time."[13] The underlying rationale for this approach is that "personnel closest to the ground are most knowledgeable about the business and must take full responsibility for the quality of its operations and products."[14]

37. The "varying degrees of oversight" by J&J's Corporate Center included initiatives to promote a uniform approach toward health compliance and quality, through the communication of enterprise-wide directives and expectations to its operating companies. The Company also restructured certain aspects of its compliance and quality functions.

38. For example, in March 2004, J&J established the Worldwide Office of Health Care Compliance ("HCC") and in July 2004, the Company

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[10] Form 10-K, at 1-2.

[11] Each business sector is headed by a Worldwide Chairman and each has a Group Operating Committee ("GOC") headed by the respective Worldwide Chairman and comprised of senior managers who oversee and coordinate the activities of the U.S. and non-U.S. operating companies within the sector. Each operating company is headed by its own Chairman, President, General Manager or Managing Director, who reports, directly or indirectly, to the sector Worldwide Chairman. Special Committee Report, at 25. (A discussion of the mandate of the Special Committee is set forth in ¶ 53 below.)

[12] Form 10-K, at 1; *see also* Special Committee Report, at 24.

[13] Special Committee Report, at 28.

[14] *Id.*; *see also id.* at 119 ("Consistent with J&J's decentralized corporate structure, the compliance system was similarly decentralized. The Board, and senior management, believed that, with proper training and professional resources available at the Corporate Center, a decentralized compliance system would be more innovative and flexible and, ultimately, more effective.").

issued its "U.S. Health Care Compliance Framework,"[15] which required its major U.S. pharmaceutical companies to implement compliance programs consistent with the guidance in the "Compliance Program Guidance for Pharmaceutical Manufacturers," issued by the Office of the Inspector General of the U.S. Department of Health and Human Services (the "OIG Guidance").[16] The OIG Guidance identified seven elements as fundamental to an effective compliance program:

- "Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action."[17]

39. And, in 2005, the Company issued to its non-U.S. operating companies an International HCC Framework, which included the same requirements as the U.S. framework.[18]

40. However, consistent with J&J's decentralized business model, the operating companies retained full responsibility for developing their own HCC policies and operating procedures.[19] In a September 13, 2004 "Health Care Compliance" presentation by Corporate Compliance to

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[15] Special Committee Report, at 29.

[16] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers,* U.S. Department of Health and Human Services, Office of the Inspector General, 68 Fed. Reg. 23,731 (May 5, 2003), available at http://www.gpo.gov/fdsys/pkg/FR-2003-05-05/pdf/03-10949.pdf.

[17] *Id.* at 23,731.

[18] Special Committee Report, at 30.

[19] *See, e.g.*, *id.* at 29, 31.

the Audit Committee, "Operating Principles" for the Company's Health Care Compliance framework were described as follows:

> "The Operating Companies are accountable for sustained compliance through implementation of a robust program to comply with laws, regulations and standards governing their sales and marketing, research, contracting and educational interactions with Health Care Professionals."[20]

41. In 2006, J&J, with the assistance of McKinsey & Co., Inc., conducted a Corporate Center Review ("CCR") "to clarify the respective roles of the Corporate Center and operating companies with respect to Compliance, reduce unnecessary burdens on the operating companies, eliminate redundancies and inefficiencies, and enhance Compliance and operational efficiency."[21]

42. As a result of the CCR, in 2007 J&J restructured the Corporate Center to "shift accountability for compliance risks to GOC/Franchises" and reduced staff at the Corporate Center level: Worldwide HCC staff was reduced by 25 percent, from a headcount of 16 to 12, and Worldwide Quality & Control ("Q&C") staff was reduced by 35 percent, from a headcount of 43 to 28.[22]

43. With the reductions in staff in the Worldwide HCC function and a transitioning of responsibilities from Worldwide HCC to the GOCs and operating companies, the GOCs and operating companies, while retaining responsibility for developing company-specific HCC policies and standard operating procedures, also became responsible for, among other things: "managing the HCC self-assessment process, performing routine MAP [Management Action Plan] reviews, preparing new general HCC training modules, and overseeing the annual certification process."[23] Similar changes were made in the Worldwide "Q&C" function. Accordingly, with the transition of oversight responsibilities for Q&C to the operating companies and GOCs, the worldwide function became responsible for "identifying emerging regulations and industry practices affecting Q&C;" providing technical and regulatory support to operating companies dealing with global regulatory agencies; "establishing

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[20] *Johnson & Johnson Health Care Compliance Presentation*, Audit Committee Update (Sept. 13, 2004) (J&J0000615).

[21] Special Committee Report, at 30-31.

[22] *Id.* at 31-32 (quoting J&J documents without attribution to specific documents).

[23] *Id.* at 31.

compliance policies; developing talent;" and providing oversight through risk assessments.[24]

44. In other words, the same staff responsible for establishing sector business strategy and goals were also responsible for managing quality and compliance risk.

45. As part of the 2007 restructuring effort, the Company formed a Compliance Committee, chaired by the Chief Compliance Officer (the "CCO") and comprised of senior management from a number of corporate functions (including Corporate Internal Audit, Human Resources, the Legal Department, Worldwide Operations, Q&C Worldwide, Worldwide HCC, Environment, Health and Safety, and Privacy) and the three sector CCOs, with responsibility for (a) overseeing "HCC, Q&C, environment, health and safety, privacy, anti-corruption laws and regulations," and compliance with health authorities' regulatory requirements, and (b) "approving business sector-specific and corporate policies, procedures and programs."[25]

46. Also in 2007, the Company formed a Triage Committee, comprised of J&J's CCO and certain members of the Compliance Committee, to: (a) address potential "serious issues" (*i.e.*, violations by management or by multiple employees or that might involve a loss greater than $500,000) involving HCC and FCPA/anti-corruption; and (b) determine whether issues brought to its attention should be investigated and, if so, by what office.[26] The types of issues that may affect J&J products throughout their life cycle, which the new Product Risk Management Standard (the "PRM Standard") is designed to address under the proposed settlement, however, are not within the purview of the Triage Committee, since this Committee does not focus on product quality issues.[27]

47. Since 2010, a number of significant governance enhancements and changes have been made for both internal and external reasons, including the institution of the Derivative Actions and

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[24] Special Committee Report, at 32.

[25] *Id.* at 32.

[26] *Id.* at 32-33; *see also Johnson & Johnson 2011 Responsibility Report,* at 25 (the Triage Committee addresses "questionable activities," identified during process reviews for compliance with HCC and FCPA legal requirements), available at http://www.jnj.com/2011responsibilityreport.

[27] As noted above, at J&J HCC and Q&C are distinct functional areas, *see supra,* n.2.

underlying conduct, and government investigations and actions referenced in the Derivative Actions.[28]

48. At the Board level, before the recent creation of the RCGC, the Company's Audit Committee was responsible for monitoring and overseeing the Company's compliance efforts. Of course, the Audit Committee's primary responsibility pertains to financial matters, *i.e.*, assisting the Board in overseeing preparation of the Company's financial statements, the audits conducted by the Company's independent auditors, and the integrity of the Company's financial statements.[29] As for the Audit Committee's compliance oversight responsibilities, its mandate was general: the Audit Committee's charter required that it "review and monitor, as appropriate"—

> "i. Results of the Company's compliance programs, including the Company's Policy on Business Conduct.
>
> ii. Litigation or other legal matters that could have a significant impact on the Company's financial results.
>
> iii. Significant findings of any examination by regulatory authorities or agencies, in the areas of securities, accounting or tax, such as the Securities and Exchange Commission or the Internal Revenue Service.
>
> iv. The Company's disclosure controls and procedures."[30]

B. Summary of Allegations

49. The Consolidated Amended Complaint filed in the Demand Futile Actions[31] (the "Amended Complaint") generally alleges that the Individual Defendants breached their fiduciary duties to the Company and its shareholders by allowing various improper activities to occur in connection with the Company's manufacture, production, distribution and

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[28] Those reforms and enhancements are set forth in "Governance Enhancements and Changes") (Settlement Agreement Ex. B) and are discussed, *infra*, ¶¶ 114-126.

[29] *See generally* J&J, *Audit Committee Charter* (a copy of which is attached as Exhibit A-1).

[30] *Id.* at 3 (*Assist the Board in Oversight of the Company's Compliance with Policies and Procedures Addressing Legal and Ethical Concerns*).

[31] The Demand Futile Actions were consolidated under the caption, *In re Johnson & Johnson Derivative Litigation,* Civil Action No. 10-2033 (FLW) (D.N.J.) (filed Dec. 7, 2010).

marketing of various medical and consumer products and by ignoring "red flags" that such activity was occurring.[32]

50. More specifically, the Amended Complaint alleges that there was "pervasive" wrongful conduct at the Company and that the director defendants ignored years of red flags, from 2003 through the end of 2010, warning of systemic noncompliance with drug manufacturing and marketing laws involving each of the Company's business sectors, including:

Pharmaceutical

(a) Numerous federal and/or state criminal and civil investigations over the course of four years, from 2003 to 2007, relating to off-labeling marketing, improper marketing practices and/or payment of kickbacks involving Topamax, Risperdal, Natrecor and/or other J&J drugs;[33]

(b) FDA warning letters relating to the Company's false and misleading marketing of Topamax and Ultram ER, issued in 2004 and 2009, respectively;[34]

(c) Various governmental (federal and state) actions instituted during the period from 2006 to 2008, alleging off-label promotion of Risperdal;[35]

(d) Inquiries in 2007 from the U.S. Senate Finance Committee concerning the marketing and promotion of Risperdal for use by elderly patients;[36]

(e) Institution in 2009 of a DOJ action alleging that J&J engaged in a fraudulent scheme to market and promote Natrecor for off-label use;[37]

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32 *See generally* Amended Complaint.

33 *Id.* ¶¶ 280-283.

34 *Id.* ¶ 280 (Topamax), ¶ 282 (Ultram ER).

35 *Id.* ¶¶ 281-82.

36 *Id.* ¶ 282.

37 *Id.* ¶ 282.

(f) Federal government intervention in 2010 in two Omnicare *qui tam* actions, asserting claims under the federal False Claims Act in connection with the marketing of several drugs to Omnicare and the institution of an action by the U.S. Department of Justice ("DOJ") alleging, among other things, violations of the federal anti-kickback statute arising out of J&J's payment of illegal kickbacks to Omnicare to induce it to purchase or recommend J&J drugs;[38]

(g) Settlement of two *qui tam* actions and the entry of an expansive Corporate Integrity Agreement ("CIA") involving J&J subsidiaries Ortho-McNeil Pharmaceutical LLC ("Ortho-McNeil") and Ortho-McNeil-Janssen Pharmaceuticals Inc. ("Janssen") in 2010, arising out of the off-label promotion of Topamax, pursuant to which Ortho-McNeil and Janssen paid $81.5 million to resolve criminal claims alleging misbranding and civil allegations under the False Claims Act, and Ortho-McNeil agreed to plead guilty to a misdemeanor for the misbranding of Topamax.[39]

Medical Devices and Diagnostics

(a) Criminal proceedings brought by the Department of Health and Human Services ("DHHS"), alleging that J&J subsidiary DePuy Orthopaedics, Inc. ("DePuy") paid illegal kickbacks to orthopaedic surgeons to induce them to cause providers to use DePuy hip and knee joint replacements in order to maintain or increase market share, and ultimately resulting in a settlement in 2007 whereby DePuy paid $84.7 million, pled guilty to conspiracy to violate the federal Anti-Kickback Statute, and entered into a Deferred Prosecution Agreement ("DPA") and comprehensive CIA requiring, among other things, the appointment of a monitor to oversee compliance with the DPA.[40]

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[38] Amended Complaint, ¶¶ 283-84.

[39] *Id.* ¶ 285.

[40] *Id.* ¶ 282.

(b) FDA warning letters in 2010 pertaining to the improper marketing of various medical devices manufactured by J&J's DePuy subsidiary;[41] and

(c) Recalls of two DePuy hip replacement products (the ASR Hip Resurfacing System and ASR XL Acetubular System) in 2010.[42]

Consumer

(a) Numerous product recalls in 2009 and 2010, including the recall of hundreds of millions of bottles of various children's Tylenol products and other over-the-counter ("OTC") products, due to quality and/or safety issues, including possible bacterial contamination, unusual smell or taste, or unusual odors;[43]

(b) An FDA warning letter in 2010 concerning failures to comply with FDA current Good Manufacturing Practice ("cGMP"), citing deficient manufacturing processes and protocols at the McNeil-PPC ("McNeil") facility in Las Piedras, Puerto Rico and musty and mildew odors in certain OTC products manufactured at that facility;[44]

(c) Closure of McNeil's Fort Washington, Pennsylvania facility in 2010; [45] and

(d) A Congressional hearing regarding the Company's "phantom recall" of defective OTC product.[46]

51. All told, the Amended Complaint alleges that defendants overlooked approximately 54 red flags warning of off-label promotion,

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41 Amended Complaint, ¶ 283.

42 *Id.*

43 *Id.* ¶¶ 282-85.

44 *Id.* ¶ 283

45 *Id.* ¶ 285.

46 *Id.*

misbranding and/or marketing of J&J drugs; 13 red flags warning of off-label promotion, payment of kickbacks and/or product design problems of J&J orthopedic and other medical devices; and 25 red flags warning of quality and compliance problems in the manufacture of OTC products.

52. The Amended Complaint seeks, among other things, a judgment directing the Company "*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*."[47]

C. Procedural History

(1) The Special Committee

53. After the first three Demand Letters were received, the Board adopted a resolution establishing a special committee (the "Special Committee") "to review, analyze and investigate the allegations"[48] in the Demand Letters and "to recommend to the Board what actions, if any, should be taken in the best interests of the Company."[49] Thereafter, the Board expanded the authority of the Special Committee to include an investigation, review and analysis of any new allegations asserted in subsequent Demand Letters, the Demand Futile Actions and the Demand Made Actions.[50]

54. The efforts of the Special Committee resulted in a report to the Board recommending that the Company: (a) decline to pursue any pending derivative litigation or initiate litigation based on the Demand Letters; (b) reject the shareholder demands; and (c) pursue dismissal of the pending derivative claims.[51]

55. In its Report, the Special Committee acknowledged that certain of the underlying manufacturing and marketing problems the Company encountered may have resulted from the decentralized nature of J&J's quality program and its over-reliance on the operating

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47 Amended Complaint, *Prayer for Relief*, ¶ iv (emphasis added).

48 Special Committee Report, at 2; *see also* Settlement Agreement, ¶ D.

49 Special Committee Report, at 2; *see also* Settlement Agreement, ¶ D.

50 Special Committee Report, at 12-13.

51 *Id.* at 120-21.

companies. For example, regarding the OTC product quality issues and recalls of Consumer sector products, the Special Committee notes:

> "A potential contributing factor to the apparent failure of the checks and balances built into the J&J Q&C Worldwide organization and operation may also trace back to the restructuring of the J&J Corporate Center in early 2007, pursuant to the Corporate Center Review conducted in 2006. As previously noted, that restructuring reduced the headcount at the corporate Q&C Worldwide organization by 35%, took away the authority to conduct unannounced Q&C audits at operating companies, and assigned responsibility for reviewing management's compliance with MAPs [Management Action Plans] to the GOCs. With the benefit of hindsight, it appears that the restructuring may have been imperfectly executed by the Consumer GOC. Among other things, the Consumer GOC should have paid more attention to Q&C, and exercised more management oversight of McNeil. With reduced central oversight and tasked with implementing the Pfizer Healthcare acquisition, some McNeil employees may have lost focus and commitment to maintain quality standards. And the change in the corporate Q&C audit function meant that cGMP issues at McNeil had more of a chance to develop until they reached a critical point."[52]

56. The Special Committee recommended—whether for the purpose of assisting in avoiding a recurrence of quality problems or for some other reason[53]—that the Board create a new Regulatory and Compliance Committee "charged with responsibility for monitoring and oversight of HCC and Q&C systems and issues, including compliance with the Topamax CIA, the McNeil Consent Decree and Action Plan, and the FCPA DPA."[54]

57. At its July 18, 2011 meeting, the independent members of the Board unanimously approved the recommendations of the Special Committee.[55]

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[52] Special Committee Report, at 63.

[53] The Special Committee did not explain its reasons for this recommendation.

[54] Special Committee Report, at 121.

[55] *Johnson & Johnson Meeting of the Board of Directors* (July 18, 2011) (J&J0001462-65).

(2) The Motion to Dismiss

58. On February 21, 2011, J&J filed a motion to dismiss the Demand Futile Actions on the grounds that the plaintiffs had failed to satisfy the particularity pleading requirements for demand futility, as required under Rule 23.1 of the Federal Rules of Civil Procedure. Following briefing and oral argument, by Opinion and Order dated September 29, 2011, the Court granted defendant's motion without prejudice to file an amended pleading. Plaintiffs' time to re-plead was extended while the parties pursued settlement discussions.[56]

59. In granting defendant's motion, the Court found that plaintiffs had not sufficiently pled facts to show demand futility, because they had failed to allege facts from which the Court could conclude that the Board was aware of the "red flags" described in the Amended Complaint and that the Board acted in bad faith, by failing to address any systemic misconduct.

60. I offer no opinion with respect to any effort by plaintiffs to file an amended pleading, since that is not within the scope of this Declaration. Nor do I express any view on the merits of the allegations against the Individual Defendants; that also is not within the scope of this Declaration. However, in assessing the proposed settlement and whether it will confer a benefit on the Company and its shareholders, I considered whether the proposed settlement is meaningful in light of the allegations that the Individual Defendants breached their fiduciary duties, as well as in the context of the underlying allegations pertaining to the manufacture and marketing of J&J products.

IV. The Settlement Agreement Terms: Overarching Considerations for Evaluation

61. Any evaluation of the proposed governance reforms and enhancements must focus, in my opinion, on whether they will create a more robust governance framework than that which previously existed, and whether the reforms and enhancements have been designed to prevent or mitigate a recurrence of the types of underlying problems alleged in the Amended Complaint. More broadly, the assessment must consider whether the terms of the Settlement Agreement are likely to provide a benefit to the Company and its shareholders. In my opinion, based on my experience both with allegations of the nature alleged here, and the form of relief being proposed, it is my strong view that the proposed governance reforms and enhancements will accomplish these goals.

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[56] Settlement Agreement, ¶ I.

62. From a legal perspective, the proposed settlement terms implicitly acknowledge the difference between the core responsibilities and roles that management and the Board each have to the Company and its shareholders in connection with the design, implementation and oversight of J&J's compliance and quality frameworks—*i.e.*, that management is responsible for design and implementation, and taking appropriate corrective action when problems arise, while the Board is responsible for providing effective oversight of management to satisfy itself that management is fulfilling its fiduciary responsibilities to the Company's shareholders in the performance of these activities.

63. Viewed from a substantive perspective, as I discuss in more detail below, I believe that the governance reforms and enhancements will, among other things:

(a) empower and incentivize management to design and implement appropriate policies, procedures and controls;

(b) affirm the Board's commitment to compliance and quality;

(c) provide the Board meaningful tools to accomplish its oversight responsibilities, which will allow the Board to become aware early on of any potential compliance and quality issues and, if necessary, direct management to take appropriate remedial action;

(d) impose a rigorous risk management framework for the development and manufacture of product; and

(e) help promote a robust culture of compliance at J&J.

V. Governance Reforms (Exhibit A)

A. The Quality and Compliance Core Objective

64. In my view, the Quality and Compliance Core Objective ("Core Objective") is the overarching governance reform in the proposed settlement, serving as the basis for other of the proposed reforms and to "inform" the work of the RCGC. The Core Objective is designed to be a Board-level pronouncement that would be disseminated enterprise-wide, affirming the Company's resolve to operate its businesses, sectors, entities and franchises:

- **"in compliance with applicable laws, regulations and J&J's policies and standards;**

- **to deliver high quality products that patients and providers can trust;**

- **to conduct its activities and have policies and procedures in place so as to minimize adverse regulatory enforcement action; and**

- **to maintain enhance and support effective quality and health care compliance systems designed to timely detect, correct and prevent activities violative of applicable laws, regulations and/or Company policies and standards."**[57]

65. Reflective of earnest efforts to improve governance in a meaningful manner, this Governance Reform requires J&J to

> **"adopt and/or maintain policies, procedures and standards to ensure the effective implementation of the Q&C Core Objective . . . design and/or maintain robust quality control and quality assurance systems to prevent, detect and correct noncompliance with the Quality Policy and standards within Johnson & Johnson, including tracking remediation against established timelines."**[58]

66. The Core Objective further states that the Company's

> **"quality systems will be subject to benchmarking and metrics that will evolve to reflect successful implementation of the Core Objective. The Company will design and/or maintain robust systems to actively monitor for, and prevent or remedy breaches of internal J&J policies and standards and regulatory or legal compliance in the areas of quality and health care compliance. The Company's compliance systems will provide the resources and information necessary to review, escalate and resolve issues arising from the development or marketing of Johnson & Johnson products. Compliance with applicable laws, regulations, and internal policies, procedures and standards will be reviewed regularly**

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[57] **Settlement Agreement, Ex. A ¶ I.**

[58] ***Id.***

throughout the life-cycle of products, including those related to the marketing and promotion of drugs and devices."[59]

67. It also explicitly authorizes the Company's senior officers—the CEO, CCO, and CQO—to "take all appropriate and reasonable actions necessary to achieve" the Core Objective.[60]

68. Based on my experience, I believe that the Core Objective will achieve several significant goals—each of which will inure to the benefit of the Company and its shareholders:

(a) It reflects the Board's full understanding of the importance of imposing rigorous health care compliance and quality systems in connection with all the Company's commercial endeavors;

(b) It confirms the Board's commitment that J&J's operating companies must conduct their business activities in conformity with applicable laws, regulations and internal policies; and

(c) In furtherance of the second goal, it includes a Board-level *direction* to the Company to adopt and maintain appropriate policies, procedures and standards and systems to *prevent and detect* instances of noncompliance; develop tools to measure the efficacy of its systems; monitor for possible breaches of law, regulations and the Company's internal standards; develop escalation processes and remediation tracking; and to conduct regular review for compliance with applicable laws, regulations and internal standards throughout development of product.

69. In addition, as a Board-level communication, which will be disseminated to all J&J employees immediately following its adoption, and on annual basis thereafter (and to new employees upon hire), the Core Objective establishes a critical and appropriate "tone at the top," and demonstrates the importance that J&J—as an enterprise—places on compliance and quality in all its business activities, including in the development, marketing and promotion of product.

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[59] Settlement Agreement, Ex. A ¶ I.

[60] *Id.*

70. To further the Company's efforts to establish a robust compliance culture, the Board's enterprise-wide communication of the Core Objective will "instruct that adherence to and furtherance of the Core Objective will be considered in the evaluation and compensation of all J&J employees."[61]

71. In my opinion, the Core Objective, along with the RCGC, will be critical in reaffirming J&J's commitment to compliance and quality, and as such, would provide a substantial benefit to the Company and its shareholders.

B. Adoption of Charter and Operating Procedure for New Regulatory, Compliance & Government Affairs Committee

72. A key component of the Settlement Agreement is the proposed Charter and Operating Procedure for the newly formed RCGC. For the first time in the history of J&J, there is now a standing committee of the Board dedicated to providing oversight of J&J's compliance with regulatory requirements and internal policies.[62] Under the terms of the Settlement Agreement, the RCGC will operate under a comprehensive set of guidelines, in the form of a detailed Charter and separate Operating Procedure, designed to ensure and support the continuous and thorough oversight of J&J's compliance and quality programs—and to do so with the benefit of mandatory and timely reporting up.

73. I have long advocated, as a regulator, in my professional practice matters, and in lectures and articles, that corporate boards should establish committees, separate and apart from their audit committees, dedicated to the oversight of legal and regulatory issues. This is not to say that audit committees are unable to bear responsibility for compliance oversight. Rather, in light of the increasingly demanding responsibilities placed on audit committees, especially since the adoption of S-Ox and the Dodd-Frank Act, I believe it is optimal to have a separate committed devoted exclusively to regulatory and compliance matters.[63]

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[61] Settlement Agreement, Ex. A ¶ II. In furtherance of this mandate, the RCGC also is required to consult with the Board's Compensation and Benefits Committee regarding the Company's adherence to this provision, *see id*. at Ex. A, ¶ III.A., *Duties and Responsibilities of the Committee ("Duties")*, 12.

[62] *Id.* at Ex. A. ¶ III, *Introduction*. Matters pertaining to financial compliance (*i.e.*, accounting, auditing and financial reporting) would remain under the auspices of the Audit Committee, *id*. at Ex. A ¶ III.A., *Duties*, 1.

[63] The creation of a Regulatory Committee was a key element of the settlement agreement in the Pfizer matter, and one that I strongly supported.

74. For large companies operating in highly regulated industries and especially those with decentralized business models such as J&J, a specialized board-level regulatory committee, with the detailed roles, responsibilities and reporting obligations set forth in the Charter and Operating Procedure, is particularly critical.

75. The importance of the settlement regarding this Board-level committee devoted exclusively to legal, regulatory and compliance matters for J&J is also borne out by a comparison of the Company's Audit Committee Charter (before compliance oversight responsibilities were transitioned to the RCGC), which not surprisingly focused on the Committee's financial-related responsibilities, with the Charter and Operating Procedure provided for the RCGC under the settlement. The former was limited to a high-level framework for its compliance oversight responsibilities, while the proposed settlement includes a detailed framework and extensive guidelines for the Committee to execute its mandate.

76. In my opinion, the structural framework and extensive guidelines the proposed settlement terms provide for the RCGC will confer a significant benefit on J&J and its shareholders, by among other things, helping to ensure that the Board is: (a) fully aware, on a timely basis, of the status of the operating companies' compliance and quality efforts; and (b) advised of potentially significant problems so that the Board can assess the efficacy of management's responses, and if it is not satisfied, direct management to take additional or different corrective action.

77. Not only does the RCGC have the stature of an independent Board-level committee, but under the terms of its proposed Charter and Operating Procedure, which I discuss in further detail below, the RCGC will have compliance and quality oversight for J&J on an enterprise-wide basis, while J&J continues to operate using a decentralized management structure.

78. The presence and operation of a Board-level committee that is devoted to compliance and quality issues also will reinforce the importance of compliance and quality, both within J&J's internal culture and externally to the Company's shareholders and the public, especially consumers of J&J products.

As Chairman of the SEC, charged with implementing the objectives of S-Ox through Agency rulemaking, I personally led the Commission's adoption of rules giving special recognition to corporations that adopted quality legal and compliance committees. *See* 17 C.F.R. § 205.3(c) (relieving in-house and outside counsel of any obligation to assess the responses of a public company suspected of possible misconduct if the board as formed a "qualified legal compliance committee.").

(1) Membership and Meetings

79. Under the terms of the Settlement Agreement, the RCGC will consist of at least three members of Board, all of whom are to be independent directors[64], who will "report to and assist the Board . . . by providing oversight of regulatory, compliance, quality and governmental affairs matters that may impact the Company."[65] All members of the RCGC must be or become sufficiently informed within a reasonable time "with respect to matters of legal and regulatory compliance" under the Committee's oversight responsibilities, including the Company's Health Care Compliance and Privacy ("HCC&P") and Q&C programs and polices,[66] and at least one member must also be a member of the Audit Committee.[67] Appointment and removal of RCGC members is subject to majority resolution of the non-employee Board directors.[68]

80. The RCGC will be required to meet at least four times annually, report to the full Board after each Committee meeting, and hold at least two executive sessions each year.[69] Further, the RCGC will be required to hold private semi-annual meetings with each of the General Counsel, the CCO, the CQO, and the Vice President of Corporate Internal Audit ("VP CIA") and, notably, the CCO, CQO, VP CIA, and VP Supply Chain will have "direct access to the Committee and its Chairman."[70]

81. The Settlement Agreement also will require that the RCGC and Audit Committee have one joint meeting to discuss significant non-financial compliance matters at J&J. Both this and the requirement for a common member will promote coordination between the two committees and help ensure that matters do not "fall through the cracks." Regulatory, compliance and quality matters can have an impact on the Company's financial statements, and it is therefore important that the RCGC not operate in a vacuum.

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64 Settlement Agreement, Ex. A,¶ III.A., *Membership*, 1-2.

65 Id. at Ex. A, ¶ III.A., *Purpose.*

66 *Id.* at Ex. A, ¶ III.A., *Membership*, 5.

67 *Id.* at Ex. A, ¶ III.A., *Membership*, 3.

68 *Id.* at Ex. A, ¶ III.A., *Membership*, 4.

69 *Id.* at Ex. A, ¶ III.A., *Meetings*, 1.

70 *Id.* at Ex. A, ¶ III.A., *Meetings*, 2; Ex. A, ¶ III.B.6.

(2) Duties and Responsibilities

82. Under the terms of the proposed RCGC Charter, the RCGC will have broad responsibility for overseeing all "major compliance programs with respect to regulatory requirements," including the Company's policies and procedures for monitoring:

- health care compliance, including HCC&P programs and policies;
- product quality and compliance, including Q&C programs and policies;
- product safety; and
- compliance with the FCPA.[71]

The RCGC also will oversee the Company's exposure to risks relating to regulatory compliance, HCC&P and Q&C matters.[72] As such, the RCGC will have oversight responsibility over all compliance programs that govern the manufacture, promotion and marketing of products—*i.e.*, the activities that plaintiffs allege were problematic—as well as risks in these areas.

83. Consistent with the RCGC's oversight of major compliance systems, it also will be responsible for conducting an annual review with each of the CCO and CQO regarding the implementation and effectiveness of J&J's compliance and quality programs, including the quality and compliance programs of newly acquired companies, and the adequacy of resources for those programs.[73]

84. The specific reference to newly acquired companies is particularly important: not only does J&J have a history of acquiring smaller companies but, based on my experience, new acquisitions often present compliance and quality challenges, if for no other reason than that their compliance and quality programs and risk assessment tools are different from those of the acquiring company.

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[71] Settlement Agreement, Ex. A, ¶ III.A., *Duties*, 1.

[72] *Id.* at Ex. A, ¶ III.A., *Duties*, 10.

[73] *Id.* at Ex. A, ¶ III.A., *Duties*, 3-4. Under the terms of the Settlement Agreement, J&J will be required to provide sufficient resources to fund all the terms of the Settlement, *see infra,* ¶¶ 107-110.

85. Under the terms of the Settlement Agreement, the RCGC also will be required to review the metrics used by management to evaluate J&J's compliance and quality systems and will be responsible for annually reviewing and approving the Company's internal audit plans related to quality and compliance.[74]

86. The RCGC also will have oversight responsibility regarding any existing CIAs or similar obligations the Company enters into with government agencies[75] and "significant complaints and other matters" that are raised through the Company's reporting structure.[76]

(3) "Reporting Up"

87. In order for the RCGC to carry out its oversight functions effectively, it is critical that it receive appropriate information, and do so in a timely fashion. In this regard, the proposed Operating Procedure for the RCGC provides for regular, mandatory reporting from J&J's senior management responsible for compliance and quality. Specifically, the Operating Procedure contemplates that the RCGC will receive in-person reporting regarding the most critical aspects of compliance programs—*global* implementation, monitoring, and effectiveness—on at least a quarterly basis from J&J's CCO, CQO, and VP CIA, and on an annual basis from J&J's VP Supply Chain.[77] Viewed from senior management's perspective, through these reporting provisions, they will now have regular direct access to the Board to raise any and all compliance and quality issues.

88. Furthermore, the Operating Procedure provides that the Committee, at least annually, will receive reports from other J&J officers, as the Committee determines appropriate, regarding J&J's ERM program for quality and compliance issues[78] and requires the RCGC to consider, at least biennially, the effectiveness of J&J's ERM program for areas under its purview, and to communicate recommended changes to the full Board.[79]

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74 Settlement Agreement, Ex. A, ¶ III.A., *Duties*, 11.

75 *Id.* at Ex. A, ¶ III.A., *Duties*, 2.

76 *Id.* at Ex. A, ¶ III.A., *Duties*, 7.

77 *Id.* at Ex. A, ¶ III.B.3.

78 *Id.* at Ex. A, ¶ III.B.3e

79 *Id.* at Ex. A, ¶ III.B.4.

(4) Proactive Mandate

89. One of the main components of the RCGC's proposed Charter and Operating Procedure—and critical to any effective system of compliance or quality oversight framework—are provisions that require and enable the RCGC to respond in a proactive manner, *before* civil and criminal proceedings are instituted, FDA warning letters are received and massive product recalls occur.

90. For example, under the proposed RCGC Charter, the RCGC is required to consider and evaluate recent developments and "current and emerging trends" regarding regulatory compliance and quality issues that could potentially affect J&J.[80] To assist the RCGC in satisfying this duty, the Operating Procedure requires annual reports from the J&J CCO and CQO on "strategic goals and objectives" and "a review of trends" affecting their respective organizations, as well as "plans of action to respond to such trends from a preventative standpoint."[81] Similarly, the annual report by the VP Supply Chain to the RCGC must include a "review of trends affecting the Company's supply chain" and "plans of action to respond to such trends from a preventative standpoint."[82]

(5) Ownership Through Self-Assessment

91. The terms of the Settlement Agreement also require the RCGC to "take ownership" of its responsibilities through mandatory annual self-assessments of its own performance in fulfilling those responsibilities.

92. The RCGC also is tasked with assessing the "adequacy of the reporting and information provided by management to support the Committee's oversight responsibilities,"[83] as well as reviewing the adequacy of the Charter itself.[84]

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93. In my opinion, the robust framework for the RCGC provides it with the mandate and tools to exercise effective and timely oversight of

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80 Settlement Agreement, Ex. A, ¶ III. A., *Duties*, 13.

81 *Id.* at Ex. A, ¶ III.B.3a-b.

82 *Id.* at Ex. A, ¶ III.B.3d.

83 *Id.* at Ex. A, ¶ III.A., *Oversight*, 3.

84 *Id.* at Ex. A, ¶ III.A., *Oversight*, 4.

the Company's legal, regulatory, compliance and quality matters. As a Board-level committee, not only will its authority be unassailable, but it also will unify and centralize high-level oversight of legal, regulatory, compliance and quality matters across the myriad operating companies. And, as an independent committee, it will be able to exercise it best judgment unimpaired by potential commercial pressures.

94. With the RCGC thus empowered, the Board should be able to exercise more effective oversight of the Company's compliance and quality control processes and take appropriate and timely action if product marketing or manufacturing problems, such as those alleged in the Amended Complaint, occur. Indeed, in my opinion, faithful implementation of the settlement should substantially reduce the opportunity for widespread or systemic problems and financial harm occasioned by adverse governmental and other actions.

C. New PRM Standard

95. As alleged in the Amended Complaint and in governmental actions, and as discussed above, over the course of a number of years, J&J was faced with a host of marketing and/or manufacturing problems involving each of its three business sectors. These alleged problems included, among other things: (a) off-label promotion of Risperdal at Janssen, off-label promotion of Topamax at Ortho-McNeil, and off-label promotion of Natrecor at Scios; (b) the payment of kickbacks by DePuy to induce purchases of product; (d) violations of FDA cGMPs in connection with the manufacture of OTC product at McNeil's Fort Washington, Pennsylvania and Las Piedras, Puerto Rico facilities; and (e) massive recalls of OTC product.

96. The Settlement Agreement provides for a new, mandatory enterprise-wide PRM Standard, which I believe will help prevent the future recurrence of problems similar to those alleged in the Amended Compliant.[85] The PRM Standard, which would be adopted as a component of J&J's developing ERM framework and as a Quality Standard under J&J's Quality and Policy and Quality Framework, will address overall quality processes and involve the development of actions plans, resolution timelines, documentation requirements, escalation reporting lines, metrics for evaluating issue resolution, and tracking remediation against established timelines. The CQO will be responsible for ensuring the design and adoption of appropriate sector standards and standard

[85] I reviewed a presentation prepared by Plaintiffs' pharmaceutical expert, Dr. Mitchell Glass, which was provided to me by Demand Futile Plaintiffs' Counsel, for background information regarding the PRM Standard. I understand that Dr. Glass' presentation was shared with the Company, including J&J's CQO.

operating procedures ("SOPs"), as necessary, to implement the PRM Standard.

97. In my opinion, the PRM Standard achieves a number of benefits: first, it implements the directives in the Core Objective;[86] second, it provides an enterprise-wide quality structure imposing accountability and resolution expectations at the product team level; third, it requires tracking of problems and their timely remediation within the independent Quality organization; and fourth, it requires identification of problems, resolution against established timelines and escalation of unresolved issues.

98. In other words, J&J employees at the product team level within the business units, who are in closest proximity to the issue, would have the responsibility to identify issues as they arise and develop remediation plans with a clear sense of expectations and standards. Parallel tracking through the Quality Organization will help ensure that no quality issues linger without resolution, and simultaneously, that all issues are escalated up the independent quality reporting structure towards the RCGC and senior management, where appropriate.

99. In my opinion, the comprehensive framework under the PRM Standard would help ensure early awareness and timely resolution of problems—before they rise to the level of disrupting J&J's business activities or cause reputational harm and, as such, I believe that the PRM Standard furthers the goal of the settlement of the Derivative Actions and confers a substantial benefit to the Company and its shareholders, by providing a core tool for improving quality controls across the Company and ensuring escalation, where necessary.

D. Website Disclosure

100. To provide shareholders with transparency regarding the activities of the RCGC in its oversight of J&J's compliance and quality functions, and to add public accountability to its responsibilities, the "Website Disclosure" provisions of the proposed settlement would require J&J to post, for a period of five years, an annual report on its Internet site confirming, among other things, that the RCGC received reporting from management related to:

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[86] In particular, the Core Objective's directive that the Company "adopt and/or maintain policies, procedures and standards to ensure the effective implementation of the Core Objective . . . design and/or maintain robust quality control and quality assurance systems to prevent, detect and correct noncompliance with the Quality Policy and standards within Johnson & Johnson, including tracking remediation against established timelines." Settlement Agreement, Ex. A, ¶ I.

- the "organization, implementation and effectiveness of the Company's compliance and quality programs";

- "compliance and quality trends affecting the Company's regulatory compliance and compliance and quality issues at J&J";

- "implementation and material findings of the annual audit plans";

- "trends affecting the Company's supply chain, medical and quality issues"; and

- "Enterprise Risk Management . . . for ERM areas under the Committee's purview."[87]

101. This provision also would require J&J to confirm the number of meetings the RCGC held with management and to identify the meeting participants;[88] it also requires the Company to affirm that the RCGC reviewed significant compliance and quality matters with management and reported on these matters to the full Board.[89]

102. In essence, the Website Disclosure provides a "window" into the RCGC's oversight role, and is designed to demonstrate that the RCGC is fully satisfying its important responsibilities.

103. I believe, based on my experience, that the Website Disclosure will confer substantial benefit on J&J and its shareholders. It will afford the Company an opportunity to enhance its reputation and reassure shareholders (and the public) of its commitment to Q&C, which is critical for the Company's bottom line, and therefore for shareholder value. Indeed, a number of the plaintiffs' allegations relate to the reputational harm J&J has suffered as a result of Q&C lapses, and the Website Disclosure provides a potentially effective mechanism for rectifying the harm that has resulted from these lapses.

104. In addition, the RCGC's explicit recognition of its oversight responsibilities, posted on the Company's website, would complement and reinforce the Core Objective, by affirming to all J&J constituencies the Company's commitment to high standards of corporate governance.

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87 Settlement Agreement, Ex. A, ¶ V.c-d.

88 *Id.* at Ex. A, ¶ V.b.

89 *Id.* at Ex. A, ¶ V.e-f.

105. The inspiration for this provision comes from regulatory requirements that govern an audit committee's disclosure,[90] and from prior settlements of shareholder derivative actions. In particular, in the *Pfizer* matter, defendants agreed to "prepare a yearly overview of its activities generally for inclusion in Pfizer's Annual Report (or Proxy Statement)," which would be signed by the Regulatory Committee chairperson and all Regulatory Committee members."[91] The proposed Website Disclosure, which requires a statement detailing the number of meetings and participants, contemplates a level of detail beyond that required of an audit committee or in the *Pfizer* settlement.

106. In my view, the confirmations J&J would be required to make regarding the RCGC's oversight of the organization and implementation of the Company's compliance and quality programs, would provide shareholders and the public with the explicit assurance, and greater trust, that the RCGC is performing its duties. Posting these confirmations on the Company's public website also would further accountability by the RCGC, the Board and management to the Company's shareholders.

E. Funding Provision & Settlement Commitment Term

107. Of course, just as the RCGC would not be effective absent a meaningful Charter and robust Operating Procedure, the effectiveness of the Settlement Agreement as a whole depends on the Company's willingness to allocate funding sufficient to achieve the governance reforms and enhancements, as well as a reasonable commitment term.

(1) Funding Provision

108. The Settlement Agreement requires J&J to provide funds "as are necessary to implement and maintain the provisions set forth in

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[90] Under Item 407 (d)(3) of Regulation S-K, pursuant to the Sarbanes-Oxley Act, the SEC requires that public company audit committees disclose specific information in the company's annual report on Form 10-K. *See Item 407 (d)(3) of SEC Regulation S-K*, available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=17:2.0.1.1.11&idno=17#17:2.0.1.1.11.5.31.7. For example, Item 407 requires an audit committee to disclose that it "reviewed and discussed the audited financial statements with management"; similarly, the Website Disclosure provision would require the RCGC to make the confirmatory disclosure "that the Committee reviewed with management significant compliance and quality matters" Settlement Agreement, Ex. A, ¶ V.d.

[91] *Pfizer*, "Stipulation and Agreement of Settlement," Exhibit A, Corporate Governance Regarding Pfizer Compliance, at Charter for Pfizer Board Committee on Regulatory and Compliance, at section C (filed Dec. 2, 2010), available at http://www.pfizer.com/files/about/stipulation_agreement_settlement.pdf.

Exhibits A and B" for a period of five years.[92] This is not insignificant: the Company will be required to commit considerable financial resources to satisfy this term. It is also an explicit recognition and assurance by the Company that funding demands will not stand in the way of its implementation and maintenance of the governance reforms and enhancements.

109. Further, the Funding provision would afford the CQO and CCO authority "to make funding recommendations directly to the Board or an appropriate committee of the Board."[93] This is beneficial, and follows other terms of the proposed settlement, in empowering the leadership of the Company's compliance and quality functions through direct access to the Board to address their funding needs and concerns.

110. Aside from strengthening the roles of the CQO and CCO, this provision also will help ensure that the Board would become informed of any funding challenges the CCO or CQO may face, thereby providing a safeguard against any possible reluctance by management to allocate the necessary financial resources to the envisioned corporate governance and compliance and quality reforms and enhancements.

(2) Settlement Commitment Term

111. As mentioned above, the Company would also undertake to maintain all provisions of the Settlement Agreement "for a period of not less than five years from the Effective Date of the Settlement."[94]

112. I believe that the five-year commitment period term provides a reasonable time to allow the proposed "Governance Reforms" and "Governance Enhancements and Changes" to be fully integrated in the

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[92] Settlement Agreement, ¶¶ 2.2-2.3. Other provisions of the Settlement Agreement also address the Company's commitment to allocate the resources necessary to implement the governance reforms. For example, the Charter for the RCGC explicitly acknowledges that "adequate funding" will be allocated to the RCGC to satisfy its responsibilities, including funding to allow it to retain outside counsel and advisors. *Id.* at Ex. A, ¶ III.A., *Oversight*, 2.

[93] *Id.* ¶ 2.2. As noted above, the RCGC has oversight responsibility for the adequacy of funding for compliance and quality functions, and will receive annual reporting from CCO and CQO on the adequacy of financial resources for J&J and newly acquired companies. *Id.* at Ex. A, ¶ III.A., *Duties*, 3-4. The RCGC also will receive annual reports from VP CIA on the adequacy of resources for the annual audit plan in the relevant areas. *Id.* at Ex. A, ¶ III.B., 3.c.

[94] Settlement Agreement, ¶ 2.3; *see also, id.* at Ex. A. ¶ III.B., 1 (requiring that J&J maintain the RCGC for a period of at least five years); Ex. A, ¶ V. (requiring that the mandated Website Disclosure be in effect for a period of at least five years).

Company's existing compliance and quality frameworks and culture,[95] especially since the term begins with the "Effective Date of the Settlement"—not from 2010 when J&J began improving its corporate governance structure and regime in response to the Derivative Actions.[96]

113. The five-year minimum commitment period also is consistent with the typical duration of a comprehensive CIA.[97] Viewed together with the Company's agreement to provide the funding "necessary" to satisfy the terms of the proposed settlement, I believe the five-year period reflects J&J's overall commitment to improving its compliance and quality frameworks.

VI. Governance Enhancements and Changes (Exhibit B)

114. Since 2010, in response to both internal and external considerations, including the Derivative Actions and underlying conduct and government actions investigations and actions cited in the Derivative Actions, J&J has:

(a) adopted a working ERM framework, which is designed to strengthen centralized corporate oversight and management of risk management;

(b) implemented initiatives to strengthen the roles of the CCO and CQO;

(c) created a global Supply Chain function and established an enterprise-wide Supply Chain Quality & Compliance framework;

(d) amended the J&J Quality Policy, which defines Quality & Compliance requirements throughout the enterprise;

(e) implemented new enterprise-wide quality Standards;

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[95] The Special Committee also recommended that the RCGC should have an initial term of five years, commensurate with the McNeil Consent Decree. Special Committee Report, at 121.

[96] In addition, since J&J is committed to implementing the PRM Standard during 2013, there will be several years post-implementation before the commitment period ends for the PRM Standard to be fully integrated. Settlement Agreement, Ex. A, ¶ IV.A.

[97] See Corporate Integrity Agreements, U.S. Department of Health and Human Services, Office of the Inspector General, available at http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp.

(f) implemented a mandatory two-tier audit program to assess compliance from a top-down and a bottom-up approach; and

(g) created an enterprise-wide HCC&P organization, which is responsible for providing infrastructure and guidance to prevent and detect violations of law, regulations, policies and codes of conduct, and with the creation of the HCC&P, J&J has realigned reporting lines of sector HCC Officers to help ensure their independence and has adopted HCC&P risk management tools.

115. In my opinion, an effective ERM framework is critical to ensure a uniform and consistent approach for managing risk across an enterprise. It is particularly important for a company like J&J, with hundreds of operating companies throughout the world, that there be common understanding of risk and common tools to assess, manage, mitigate and monitor risk.

116. J&J modeled its ERM on the COSO (the Committee of Sponsoring Organizations of the Treadway Commission) ERM Framework, a widely-recognized ERM framework model.[98] J&J's ERM framework includes as components "objective setting, risk identification and assessment, risk response and control activities, and communication and monitoring," with individual business units and risk function areas (*e.g.*, Strategic Planning, Financial Reporting, Legal, HCC&P, Quality and Supply Chain) responsible for performing risk assessments to identify and assess trends and emerging risks; developing action plans when needed; communicating identified risks and strategies for managing those risks to their respective leadership teams; and escalating issues as appropriate to its respective Executive Committee member, the Audit Committee or the RCGC.[99]

117. Oversight responsibility for the ERM framework has been delegated to the Board, which will be assisted in carrying out this responsibility under the terms of the proposed settlement by senior management's regular reports to the RCGC (including the GC, CCO, CQO, VP CIA and VP Supply Chain) on risk management issues as required by the new Charter and Operating Procedure. I believe this is optimal for

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[98] *See* Johnson & Johnson, "Enterprise Governance, Risk, Compliance and Quality Management Framework" (J&J0000044).

[99] *Id.*

ensuring that the Board is kept apprised of management's efforts to fully implement ERM processes.

118. During the pendency of the Derivative Actions, J&J also streamlined escalation procedures under the ERM framework to require prompt reporting (within three business days) of certain potential violations of law or internal J&J policies directly to the VP CIA, who in turn, will bring the matter to the Triage Committee for its review and where appropriate, will further escalate these matters to the RCGC.[100]

119. The Company's changes to Supply Chain, which include a *global* function responsible for procurement, manufacturing and supply chain quality assurance and distribution across all J&J's businesses, as well as the use of metrics and risk assessments, are in my opinion also reflective of J&J's enterprise-wide commitment to quality assurance and designed to avoid the massive recalls of OTC product and plant closure the Company faced in 2008-2010. Once the PRM Standard has been implemented enterprise-wide during 2013, product risk management at J&J will encompass all aspects of product development and marketing at the Company.

120. Similarly, other aspects of the new J&J Supply Chain operating model, including the creation of a single framework for Quality & Compliance across all of J&J's operating companies, reflect the Company's commitment to mitigate risk through the use of standardized processes, with oversight by the CQO for each business sector and ultimate oversight by the J&J CQO to whom each sector CQO reports.[101]

121. J&J has also made improvements to its quality and compliance framework in recognition of the importance of centralized oversight, uniformity and consistency in quality requirements and the need for its staff to be able to exercise their best judgment and make decisions unaffected by business line pressures—all features of an effective system of controls. Under its new framework, the J&J CQO provides independent oversight of quality throughout the enterprise,[102] including the implementation of enterprise quality policies and standards, with responsibility for reporting quality and regulatory compliance metrics and issues to Executive Management and, as noted above, to the RCGC. And, all staff in Quality and Regulatory Compliance functions throughout the enterprise have a reporting relationship to the CQO.

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[100] **Settlement Agreement, Ex. B, ¶ II.A.3.a.**

[101] ***Id.* at Ex. B, ¶ II.B.**

[102] **The CQO reports to the VP Supply Chain. *See id* at Ex. B, ¶ C.2.**

122. Further recognizing the importance of "independent" compliance and quality functions, the RCGC Operating Procedure provided for under the proposed settlement expressly requires that the RCGC be promptly notified of decisions and actions related to the appointment and/or termination of, or material compensation changes for, the VP Supply Chain, the CCO or the CQO.[103] I have long advocated compliance frameworks that foster independent decision-making by CCOs and persons in equivalent functions, precisely by requiring that an advisory council or other independent body be notified (or consulted) about matters affecting the employment relationship of CCOs. Through this mechanism, CCOs can take positions that might not necessarily be "popular" with business lines or their priorities, but which are in the best interests of their company and its shareholders.

123. I believe that with centralization, uniformity and consistency, and independence, J&J's quality and compliance framework will be greatly enhanced and, as a result, the potential for manufacturing and marketing problems, such as those alleged in the Amended Complaint, will be substantially reduced. Indeed, the Special Committee also observed that the lack of centralization and independence may have caused or contributed to the product quality problems the Consumer sector experienced.[104]

124. Also, on March 31, 2011, J&J issued a revised version of its Quality Policy (POL-001), the enterprise-level policy defining Quality & Compliance requirements, requiring, among other things, that "*every* J&J company establish an independent quality function with the necessary resources, establish an internal audit program for its quality system, establish a comprehensive system for handling product complaints and reporting adverse events, document the process for investigating and controlling nonconformities, establish procedures for the conduct of field action activities, and establish processes for corrective actions and preventive actions."[105] A number of enterprise-wide quality Standards were also implemented in 2011, including Standards for management review processes at operating company, sector and enterprise levels, escalation of quality and regulatory compliance issues, and field actions.

125. Recent enhancements have also been made to the HCC&P function, including the appointment of senior HCC Officers for each sector

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[103] Settlement Agreement, Ex. A, ¶ III.B.5. This provision would also ensure that the RCGC would become promptly aware of any gap in fulfilling a primary compliance or quality function.

[104] *See supra*, ¶ 55.

[105] Settlement Agreement, Ex. B, ¶ II.C.5 (emphasis added).

as well as for geographic regions,[106] who report through the HCC&P organization, and not through the business units—again helping to ensure independence in the HCC Officer function. With the reorganization of HCC, the management Compliance Committee also expanded and clarified its mission to include: (a) exchanging expertise among its members; (b) reviewing and providing input into reports to sector management, Executive Committee, the RCGC and the Board; (c) escalating Compliance issues to the appropriate management or governing body; (d) reviewing and discussing emerging Compliance concerns and recommending actions; and (e) providing input into J&J's ERM.

126. I believe that, viewed as a whole, these reforms and changes reflect the Company's commitment to implement an effective system of internal controls, which places a premium on independence, centralized oversight, and uniformity and consistency in quality requirements, and as such, will benefit the Company and its shareholders.

VII. Conclusion

127. In my experience, both as a regulator and as a corporate advisor, shareholders fare best when boards exercise independent judgment, insist on being informed of all significant facts and developments on issues of importance—including those involving legal, regulatory, compliance and reputational matters—act proactively, and exercise good faith business judgment in responding to the matters of which they become aware. In my opinion, for the reasons discussed throughout this Declaration, J&J's shareholders will receive these benefits under the terms of the proposed settlement.

128. In my opinion, the terms of the proposed settlement provide the building blocks for substantial improvements to J&J's compliance and quality programs. I also believe that, with the Company's ongoing commitment to implement first-rate compliance and quality programs, the institution of the proposed corporate governance reforms should:

(a) help ensure that J&J does not encounter future problems with product manufacture and marketing, such as those alleged in the Amended Complaint; and

(b) substantially reduce the likelihood of future legal and regulatory violations and thereby mitigate the risk of significant adverse outcomes from governmental and other actions and the attendant adverse financial

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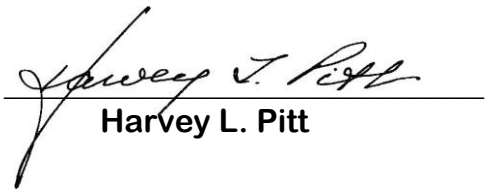
[106] Settlement Agreement, Ex. B, ¶ II.D.3.

consequences that these actions might have on the Company and its shareholders.

129. Obtaining the relief provided in the proposed settlement, without enduring the vicissitudes of litigation, also permits quicker implementation of carefully tailored governance reforms, which, in my opinion, also redound to the benefit of the Company and its shareholders. Of course, more can always be accomplished, and further benefits may be achieved by additional enhancements to J&J's compliance and quality programs.

August 28, 2012



Harvey L. Pitt

Exhibit A

1. Consolidated Amended Complaint, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed Dec. 7, 2010).

2. Johnson & Johnson's Notice of Motion to Dismiss or, in the Alternative, Motion to Stay and Brief in Support of Motion, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed Feb. 21, 2011)

3. Letter from Erik Haas, Esq. to Judge Wolfson, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed Feb. 21, 2011).

4. Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Consolidated Amended Complaint, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed Mar. 21, 2011).

5. Report of the Special Committee of the Board of Directors of Johnson & Johnson, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed July 18, 2011).

6. Opinion and Order, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed Sept. 29, 2011) (granting Defendant's Motion to Dismiss without prejudice).

7. Memorandum of Law in Support of Plaintiffs' Motion for Preliminary Approval of Derivative Action Settlement, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed July 11, 2012).

8. Stipulation and Agreement of Settlement and Exhibits A ("Governance Reforms") and B ("Governance Enhancements and Changes") thereto, *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) (D.N.J.) (filed July 11, 2012).

9. *Johnson & Johnson Form 10-K, Annual Report* (for fiscal year ended Jan. 1, 2012, filed Feb. 23, 2012), available at http://www.sec.gov/Archives/edgar/data/200406/000119312512075565/0001193125-12-075565-index.htm.

10. *Johnson & Johnson 2011 Responsibility Report,* available at http://www.jnj.com/2011responsibilityreport.

11. ***Johnson & Johnson Audit Committee Charter***, prior to formation of RCGC (undated) (copy attached).

12. ***Johnson & Johnson Board of Directors and Audit Committee Meeting Minutes and accompanying presentations*** (Dec. 5, 2002 through July 18, 2011) (J&J0000537-1467).

13. ***Johnson & Johnson Enterprise Governance, Risk, Compliance and Quality Management Framework*** (undated) (J&J0000044).

14. ***Johnson & Johnson Quality & Compliance***, presentation by Kathryn E. Wengel, Chief Quality Officer (Feb. 16, 2012) (J&J0000491-536).

15. ***The Proposed Role of PRMS in ERM***, presentation by Dr. Mitchell Glass (undated).

16. ***Compliance Program Guidance for Pharmaceutical Manufacturers***, U.S. Department of Health and Human Services, Office of the Inspector General, 68 Fed. Reg. 23,731 (May 5, 2003), available at http://www.gpo.gov/fdsys/pkg/FR-2003-05-05/pdf/03-10949.pdf.

17. Consolidated, Amended and Verified Shareholder Derivative Complaint, ***In re Pfizer Inc. Shareholder Derivative Litigation***, No. 09-CV-7822 (JSR) (S.D.N.Y.) (filed Nov. 18, 2009), available at http://www.blbglaw.com/cases/00143_data/Pfizer-AmendedComplaint-11.18.09.pdf.

18. Stipulation and Agreement of Settlement, ***In re Pfizer Inc. Shareholder Derivative Litigation***, No. 09-CV-7822 (JSR) (S.D.N.Y.) (filed Dec. 2, 2010), available at http://www.pfizer.com/files/about/stipulation_agreement_settlement.pdf.

19. ***Corporate Integrity Agreements,*** U.S. Department of Health and Human Services, Office of the Inspector General, available at http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp (last visited Aug. 28, 2012).

Exhibit A-1 ***Johnson & Johnson Audit Committee Charter*, prior to formation of RCGC (undated)**

Audit Committee Charter

The Audit Committee (the "Committee") shall report to and assist the Board of Directors (the "Board") of Johnson & Johnson (the "Company") by providing oversight of the financial management, independent auditors and financial reporting procedures of the Company, as well as such other matters as directed by the Board or this Charter.

Membership of the Committee

1. The Committee shall be comprised of not less than three members of the Board.

2. The composition of the Committee shall meet all the requirements of the Audit Committee Policy of the New York Stock Exchange, which, among other things, prohibits any officer or employee of the Company from serving on the Committee.

3. Each Committee member shall have no other relationship to the Company that may interfere with the exercise of his or her independence from management and the Company, including the receipt from the Company of any compensation other than directors' fees and other compensation related to their service as a director.

4. Each Committee member shall be financially literate or shall become financially literate within a reasonable period of time after appointment to the Committee.

Meetings of the Committee

1. The Committee will meet formally at least four times each fiscal year.

2. The Committee will hold separate private meetings at least twice each fiscal year with each of the Vice President of Internal Audit, a representative of the independent auditors, the General Counsel, the Chief Compliance Officer and the Chief Financial officer.

Key Responsibilities

The Company's management is responsible for preparing the Company's financial statements and the independent auditors are responsible for auditing these financial statements. The Committee is responsible for assisting the Board in overseeing the conduct of these activities by the Company's management and the independent auditors, and the integrity of the Company's financial statements. The financial management and the independent auditors of the Company have more time, knowledge and more detailed information on the Company than do Committee members. Consequently, in carrying out its oversight responsibilities, the Committee is not providing any expert or special assurance as to the Company's financial statements or any professional certification as to the independent auditors' work. The Committee is also responsible for preparing the Report of the Audit Committee that SEC rules require be included in the Company's annual proxy statement.

In carrying out its oversight responsibilities, the Committee shall perform the following functions:

Oversight of Independent Auditors.

In the course of its oversight of the independent auditors as provided under this Charter, the Committee will be guided by the premise that the independent auditors are ultimately accountable to the Board and the Committee.

1. The Committee, subject to any action that may be taken by the full Board, shall have the ultimate authority and responsibility to appoint, retain, compensate, evaluate and, when appropriate, terminate the independent auditors. This responsibility includes resolving disagreements between management and the independent auditors regarding financial reporting. The Committee shall assist the Board in its oversight of the qualifications, independence and performance of the independent auditors.

2. The Committee shall:

i. receive from the independent auditors annually, a formal written statement delineating the relationships between the auditors and the Company consistent with Public Company Accounting Oversight Board Rule 3526, *Communication with Audit Committees Concerning Independence* ;

ii. discuss with the independent auditors the scope of any such disclosed relationships and their impact or potential impact on the independent auditors' independence and objectivity; and

iii. recommend that the Board take appropriate action in response to the independent auditors' report to satisfy itself of the auditor's independence.

3. The Committee shall review and approve the original proposed scope of the annual independent audit of the Company's financial statements and the associated engagement fees, as well as any significant variations in the actual scope of the independent audit and the associated engagement fees.

4. The Committee shall set hiring policies for employees or former employees of the independent auditors.

5. At least annually, the Committee shall obtain and review a report by the independent auditors describing: the firm's internal quality-control procedures; any material issues raised by the most recent internal quality-control review, or peer review, of the firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the firm, and any steps taken to deal with any such issues; and (to assess the auditor's independence) all relationships between the independent auditors and the Company.

6. The Committee shall review with the independent auditors any difficulties the auditors encountered in the course of the audit work, including restrictions on the scope of work or access to requested information, and any significant disagreements with management.

Oversight of Internal Auditors.

The Committee shall review and discuss with management and the independent auditors:

1. The quality and adequacy of the Company's internal accounting controls.

2. The organization of the internal audit department, the adequacy of its resources and the competence and performance of the internal audit staff.

3. The audit risk assessment process and the proposed scope of the internal audit department for the upcoming year and the coordination of that scope with independent auditors.

4. Results of the internal auditors' examination of internal controls including summaries of inadequate reports issued and/or management improprieties together with management's response thereto.

Oversight of Management's Conduct of the Company's Financial Reporting Process.

1. *Audited Financial Statements*. The Committee shall discuss with management and the independent auditors the audited financial statements to be included in the Company's Annual Report on Form 10-K (or the Annual Report to Shareholders if distributed prior to the filing of Form 10-K) and review and consider with the independent auditors the matters required to be discussed by the applicable Statement of Auditing Standards ("SAS"). Based on these discussions, the Committee will advise the Board of Directors whether it recommends that the audited financial statements be included in the Annual Report on Form 10-K (or the Annual Report to Shareholders).

2. *Interim Financial Statements*. The Committee will review with management and the independent auditors, prior to the filing thereof, the Company's interim financial results to be included in the Company's quarterly reports on Form 10-Q and the matters required to be discussed by the applicable SAS. The Committee will also discuss the Company's quarterly financial statements with management and the independent auditors, including the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

3. *Financial Reporting Practices*. The Committee shall review:

   i. Changes in the Company's accounting policies and practices and significant judgments that may affect the financial results.

   ii. The nature of any unusual or significant commitments or contingent liabilities together with the underlying assumptions and estimates of management.

   iii. The effect of changes on accounting standards that may materially affect the Company's financial reporting practices.

4. *Financial Information Disclosure*. The Committee shall in a general manner discuss earnings press releases, as well as the types of financial information and earnings guidance that are given to analysts and rating agencies.

5. *Risk Assessment*. The Committee shall discuss with management the guidelines, policies and processes relied upon and used by management to assess and manage the Company's exposure to risk.

Assist the Board in Oversight of the Company's Compliance with Policies and Procedures Addressing Legal and Ethical Concerns.

1. The Committee shall review and monitor, as appropriate:

   i. Results of the Company's compliance programs, including the Company's Policy on Business Conduct.

   ii. Litigation or other legal matters that could have a significant impact on the Company's financial results.

   iii. Significant findings of any examination by regulatory authorities or agencies, in the areas of securities, accounting or tax, such as the Securities and Exchange Commission or the Internal Revenue Service.

   iv. The Company's disclosure controls and procedures.

2. By approving and adopting recommendations of management, the Committee shall ensure that procedures have been established for the receipt, retention and treatment of complaints from Company employees on accounting, internal accounting controls or auditing matters, as well as for the confidential, anonymous submissions by Company employees of concerns regarding questionable accounting or auditing matters.

3. At least annually, the Committee shall meet with the Chief Compliance Officer to review the implementation and effectiveness of the Company's compliance programs.

Oversight of Committee Matters.

1. The Committee shall report regularly to the Board on its meetings and discussions and review with the Board significant issues or concerns that arise at Committee meetings, including its evaluation of the independent auditors.

2. The Committee shall conduct an annual evaluation of its performance in fulfilling its duties and responsibilities under this Charter.

3. The chairman or any one or more members of the Committee, as designated by the Committee, may act on behalf of the Committee.

4. The Committee shall have authority and appropriate funds to retain and consult with outside legal, accounting or other advisors as the Committee may deem appropriate.

5. The adequacy of this Charter shall be reviewed by the Committee on an annual basis. The Committee will recommend to the Board any modifications to this Charter, which the Committee deems appropriate, for approval by the Board.

Exhibit B
List of Published Materials
2000 Current

Published Speeches/Lectures (in ascending date order)[1]

1. *Speech by SEC Chairman: Remarks Before the AICPA Governing Council*, U.S. Securities & Exchange Commission, Miami Beach, FL, (Oct. 22, 2001) (SEC's relationship with the accounting profession on a going forward basis), available at http://www.sec.gov/news/speech/spch516.htm.

2. *Speech by SEC Chairman: Remarks at the PLI 33rd Annual Institute on Securities Regulation*, , U.S. Securities & Exchange Commission, New York, NY (Nov. 8, 2001) (aspects of the SEC's agenda to occupy the Commission over the coming months and years, with a focus on ways the SEC could be improved), available at http://www.sec.gov/news/speech/spch520.htm.

3. *Speech by SEC Chairman: Remarks at the Securities Industry Association Annual Meeting,* U.S. Securities & Exchange Commission, Boca Raton, FL (Nov. 9, 2001) (state of the securities market in the aftermath of 9/11 and other challenges facing the securities markets), available at http://www.sec.gov/news/speech/spch521.htm.

4. *Speech by SEC Chairman: Remarks at the SEC Historical Society Major Issues Conference*, U.S. Securities & Exchange Commission, Washington, DC (Nov. 14, 2001) (highlighting marketplace developments, at home and abroad, that require us to rethink our approach to regulation), available at http://www.sec.gov/news/speech/spch523.htm.

5. *Speech by SEC Chairman*: *Fall Meeting of the ABA's Committee on Federal Regulation of Securities,* U.S. Securities & Exchange Commission, Washington, DC (Nov. 16, 2001) (personal journey from private bar back into government, and major initiatives that SEC is or will be undertaking), available at http://www.sec.gov/news/speech/spch524.htm.

6. *Speech by SEC Chairman: Consumer Federation of America Financial Services Conference,* U.S. Securities & Exchange Commission, Washington, DC (Nov. 29, 2001) (challenges and opportunities SEC must meet to ensure that U.S. markets are transparent and can facilitate capital raising, with a focus on improving financial disclosure and the SEC's

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[1] All of Former Chairman Pitt's speeches during his tenure as the 26th Chairman of the U.S. Securities and Exchange Commission are publicly available on the Commission's website, and those website addresses have been provided.

program of real time enforcement), available at http://www.sec.gov/news/speech/spch525.htm.

7. *Public Statement by SEC Chairman: Regulation of the Accounting Profession*, U.S. Securities & Exchange Commission, Washington, DC (Jan. 17, 2002) (Enron and lessons we can learn about how to prevent failures like this from recurring), available at http://www.sec.gov/news/speech/spch535.htm.
8. *Speech by SEC Chairman: Remarks at the 29th Annual Securities Regulation Institute*, U.S. Securities & Exchange Commission, Coronado, CA (Jan. 23, 2002) (in the aftermath of Enron, how we must improve our existing disclosure and financial reporting system, and what the SEC is proposing), available at http://www.sec.gov/news/speech/spch536.htm.

9. *Speech by SEC Chairman: Remarks at the Winter Bench and Bar Conference of the Federal Bar Council*, U.S. Securities & Exchange Commission, Puerto Rico (Feb. 19, 2002) (perspectives on lessons to be learned from the Enron debacle), available at http://www.sec.gov/news/speech/spch539.htm.

10. *Speech by SEC Chairman: Remarks at the SEC Speaks Conference*, U.S. Securities & Exchange Commission, Washington, DC (Feb. 22, 2002) (crises of Enron and 9/11 require us to reassess how our system functions and likewise how we function within our system; for lawyers and accountants there are professional and ethical issues to consider), available at http://www.sec.gov/news/speech/spch540.htm.

11. *Speech by SEC Chairman: Remarks at SIA Compliance and Legal Division Seminar*, U.S. Securities & Exchange Commission, Palm Desert, CA (Mar. 11, 2002) (what we can learn from the disasters of 9/11 and Enron), available at http://www.sec.gov/news/speech/spch544.htm.

12. *Speech by SEC Chairman: Remarks at the Inaugural Lecture of the JD/MBA Lecture Series*, U.S. Securities & Exchange Commission, Kellogg Graduate School of Management, Northwestern Law School, Chicago, Illinois (Apr. 4, 2002) (the need for people of integrity in accounting, law and business is stronger than ever; in the aftermath of Enron need to assess our corporate governance system), available at http://www.sec.gov/news/speech/spch547.htm.

13. *Speech by SEC Chairman: Remarks Before the Annual Meeting of the Bond Market Association*, U.S. Securities & Exchange Commission, New York, NY (Apr. 25, 2002) (transparency, T+1 initiative, special purpose entities and Securities Act Reform initiatives), available at http://www.sec.gov/news/speech/spch553.htm.

14. *Speech by SEC Chairman: Investor Summit Opening*, U.S. Securities & Exchange Commission, Washington, DC (May 10, 2002) (SEC mandates, introduction of panelists, Summit rules), available at http://www.sec.gov/news/speech/spch560.htm.

15. *Speech by SEC Chairman: Remarks before the Investment Company Institute, 2002 General Membership Meeting*, U.S. Securities & Exchange Commission, Washington, DC (May 24, 2002) (challenges we face regarding US capital markets, SEC's role and the solutions it envisions, SEC initiatives in the mutual fund industry), available at http://www.sec.gov/news/speech/spch562.htm.

16. *Speech by SEC Chairman: Commencement Address, St. John's University School of Law*, U.S. Securities & Exchange Commission, Queens, NY (June 2, 2002) (personal observations about the legal profession), available at http://www.sec.gov/news/speech/spch564.htm.

17. *Speech by SEC Chairman: Remarks Before the New York Financial Writers Association*, U.S. Securities & Exchange Commission, New York, NY (June 13, 2002) (important relationship between the SEC and the financial press, especially during troubled times), available at http://www.sec.gov/news/speech/spch567.htm.

18. *Speech by SEC Chairman: Proposed Rules to Create a Framework for a Public Accountability Board*, U.S. Securities & Exchange Commission, Washington, DC (June 20, 2002) (discussion of SEC's proposal for a comprehensive system of rigorous private-sector regulation of the accounting profession), available at http://www.sec.gov/news/speech/spch569.htm.

19. *Speech by SEC Chairman: Remarks before the Economic Club of New York*, U.S. Securities & Exchange Commission, New York, NY (June 26, 2002) (SEC's proposed framework for oversight of accounting profession, CEO and CFO certification, improvements at the FASB (*e.g.* independence, timeliness in addressing issues), retooling disclosure requirements, and far-reaching corporate governance changes), available at http://www.sec.gov/news/speech/spch573.htm.

20. *Statement by SEC Chairman: On Fannie Mae/Freddie Mac*, U.S. Securities & Exchange Commission, Washington, DC (Jul. 12, 2002) (Fannie Mae and Freddie Mac subjecting themselves to SEC disclosure requirements; partnership between government and private sector), available at http://www.sec.gov/news/speech/spch574.htm.

21. *Speech by SEC Chairman: On the Passage of S. 2673, Public Company Accounting Reform and Investor Protection Act of 2002*, U.S. Securities &

Exchange Commission, Washington, DC (Jul. 15, 2002) (moving one step closer towards meaningful and effective oversight of accounting regulation in America), available at http://www.sec.gov/news/speech/spch575.htm.

22. *Speech by SEC Chairman: Remarks Before the National Press Club*, U.S. Securities & Exchange Commission, Washington, DC (Jul. 19, 2002) (SEC's achievements in 2001-2002 post-Enron, WorldCom and 9/11 disasters), available at http://www.sec.gov/news/speech/spch577.htm.

23. *Statement by SEC Chairman: Proposal of Regulation AC*, U.S. Securities & Exchange Commission, Open Meeting, Washington, DC (Jul. 24, 2002) (discussion of recommendation by the Division of Market Regulation that SEC propose a rule to require analysts to certify that research reports they issue represent their actual views and to provide disclosures as to whether they have received compensation for the opinions expressed in those reports), available at http://www.sec.gov/news/speech/spch578.htm.

24. *Speech by SEC Chairman: Remarks Before the Annual Meeting of the American Bar Association's Business Law Section*, U.S. Securities & Exchange Commission, Washington, DC (Aug. 12, 2002) (personal lessons learned in returning to the public sector, aspects of S-Ox that have special significance to lawyers), available at http://www.sec.gov/news/speech/spch579.htm.

25. *Speech by SEC Chairman: Remarks at the September Symposium On Corporate Governance and Accounting Reform*, U.S. Securities & Exchange Commission, Women in Housing and Finance, Washington, DC (Sept. 20, 2002) (SEC's major tasks under S-Ox, *e.g.* creating regulatory regime for accounting profession, disclosure and governance reforms), available at http://www.sec.gov/news/speech/spch584.htm.

26. *Speech by SEC Chairman: Remarks Before the Council of Institutional Investors' (CII) Fall Conference*, U.S. Securities & Exchange Commission, New York, NY (Sept. 23, 2002) (various challenges we all face at this time, the SEC's important role and the solutions it envisions, and the critical role CII plays in SEC's efforts to restore investor confidence and improve functioning of the capital markets), available at http://www.sec.gov/news/speech/spch582.htm.

27. *Speech by SEC Chairman: Remarks before the U.S. Department of Justice Corporate Fraud Conference*, U.S. Securities & Exchange Commission, Washington, DC (Sept. 26, 2002) (elements of an effective partnership between the SEC and the DOJ), available at http://www.sec.gov/news/speech/spch585.htm.

28. *Speech by SEC Chairman: Remarks at the Financial Times' Conference on Regulation & Integration of the International Capital Markets*, U.S. Securities & Exchange Commission, London, UK (Oct. 8, 2002) (discussion of S-Ox and its implementation for all companies—foreign and domestic, emphasis of the need for cooperation among global regulators), available at http://www.sec.gov/news/speech/spch588.htm.

29. *Speech by SEC Chairman: A Single Capital Market in Europe: Challenges for Global Companies*, Conference of the Institute of Chartered Accountants of England and Wales, Brussels, Belgium, U.S. Securities & Exchange Commission (Oct. 10, 2002) (discussion of S-Ox and its implementation for all companies—foreign and domestic, emphasis of the need for cooperation among global regulators), available at http://www.sec.gov/news/speech/spch589.htm.

30. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, Securities & Exchange Commission, Washington, DC (Oct. 16, 2002) (introductory remarks to the SEC's proposal of significant new rules pursuant to S-Ox), available at http://www.sec.gov/news/speech/spch590.htm.

31. *Speech by SEC Chairman: Remarks at the Directors' Education Institute*, Duke University, Securities & Exchange Commission, Durham, NC (Oct. 22, 2002) (personal thoughts on the role of corporate directors, discussion of S-Ox and other SEC reforms), available at http://www.sec.gov/news/speech/spch594.htm.

32. *Speech by SEC Chairman: Remarks at the Securities Industry Association Annual Meeting*, U.S. Securities & Exchange Commission, Boca Raton, FL (Nov. 8, 2002) (discussion of professional standards necessary for private sector to ensure investor confidence, recap of achievements during Chairmanship), available at http://www.sec.gov/news/speech/spch603.htm.

33. *Speech by SEC Chairman: Noah Krieger Memorial Lecture*, U.S. Securities & Exchange Commission, Brown University, (Nov. 18, 2002) (importance of public service) http://www.sec.gov/news/speech/spch111802hlp.htm.

34. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Dec. 11, 2002) (relief for internet investment advisers, repeal of the trade-through disclosure rule, enhanced portfolio disclosure), available at http://www.sec.gov/news/speech/spch121102hlp.htm.

35. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Dec. 18, 2002) (introduction to the consideration of two recommendations from the Division of Corporation Finance to make the SEC's processes more efficient, including exemptions from the registration requirements for standardized options and electronic filing of insider ownership reports), available at http://www.sec.gov/news/speech/spch121802hlp.htm.

36. *Speech by SEC Chairman: Remarks at Mutual Fund Directors Forum*, U.S. Securities & Exchange Commission, Washington, DC (Jan. 8, 2003) (personal observations on how to address challenges facing the mutual fund industry from the perspective of independent directors and from the SEC's perspective), available at http://www.sec.gov/news/speech/spch010803hlp.htm.

37. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Jan. 8, 2003) (investment company transactions with portfolio and subadviser affiliates, standards relating to listed company audit committees), available at http://www.sec.gov/news/speech/spch010803bhlp.htm.

38. *Speech by SEC Chairman: Remarks at Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Jan. 15, 2003) (introduction to three recommendations before the SEC from the Division of Corporation Finance, including Regulation G, Regulation BTR and two new types of disclosures in annual reports to implement Sections 406 and 407 of S-Ox), available at http://www.sec.gov/news/speech/spch011503hlp.htm.

39. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Jan. 22, 2003) (introduction for considering the adoption of four final rules related to the Sarbanes-Oxley, including: Form N-CSR and rules enhancing the independence of auditors of public companies, requiring public companies to provide a discussion of off-balance sheet arrangements in their MD&A and specifying information auditors must retain subsequent to the completion of an audit), available at http://www.sec.gov/news/speech/spch012203hlp.htm.

40. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Jan. 23, 2003) (introduction to the discussion of various recommendations, including a recommendation from the General Counsel to adopt rules setting forth minimum standards of professional conduct for attorneys who represent public companies before the Commission, and pair of recommendations from the Division of Investment Management regarding proxy voting by

investment companies and investment advisers), available at http://www.sec.gov/news/speech/spch012303hlp.htm.

41. *Speech by SEC Chairman: Alan B. Levenson Keynote Address*, U.S. Securities & Exchange Commission, Securities Regulation Institute, Coronado, CA (Jan. 29, 2003) (overview of what the SEC has been up to, SEC's attorney conduct rules, and observations about public service.), available at http://www.sec.gov/news/speech/spch012903hlp.htm.

42. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Feb. 4, 2003) (custody of investment company assets with U.S. securities depositories and compliance programs of investment companies and investment advisers), available at http://www.sec.gov/news/speech/spch020403hlp.htm.

43. *Speech by SEC Chairman: Remarks at the Commission Open Meeting*, U.S. Securities & Exchange Commission, Washington, DC (Feb. 6, 2003) (introducing recommendations from the Division of Market Regulation to adopt final rules implementing the dealer provisions of the Gramm-Leach-Bliley Act and to adopt Regulation AC), available at http://www.sec.gov/news/speech/spch020603hlp.htm.

44. *Speech by Former SEC Chairman: Orange County Public Company Forum* (Feb. 26, 2004) (importance of governance and transparency), available at http://www.kaloramapartners.com/SpeechDetails.aspx?SpeechId=25.

45. *Speech by Former SEC Chairman: Keynote Address, SEC Historical Society Annual Meeting,* New York, NY (June 9, 2005) (impressions and personal recollections of the events of 9/11), available at http://www.kaloramapartners.com/SpeechDetails.aspx?SpeechId=33.

Published Articles (in ascending date order)[2]

1. *Public Statement by SEC Chairman Harvey Pitt: How to Prevent Future Enrons,* "Op-Ed" for WALL STREET JOURNAL (Dec. 11, 2001) (suggestions for modernizing the disclosure system to make it more meaningful and intelligible to average investors), available at http://www.sec.gov/news/speech/spch530.htm.

2. Harvey Pitt, *Auditing Reform Can't Wait for Congress to Act*, WALL STREET JOURNAL, Pg. A18 (Oct. 7, 2003) (discussion of SEC's proposal to create a new system of strong and independent private-sector regulation, through a Public Accountability Board) [not publicly available—WSJ subscription required].

3. Harvey Pitt, *A Fresh Look at Executive Compensation*, COMPLIANCE WEEK (Oct. 7, 2003) (considerations for directors and officers to keep in mind when reviewing compensation policies and procedures) [not publicly available—Compliance Week subscription required].

4. Harvey Pitt, *Dealing with Employee Complaints*, COMPLIANCE WEEK (Oct. 21, 2003) (suggested approaches for responding to complaints of potential wrongdoing), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=1.

5. Harvey Pitt, *The Coming Storm: Mandatory Expensing of Stock Options*, COMPLIANCE WEEK (Dec. 16, 2003) (expensing stock option plans and what boards and managements need to review in their stock option grant policies and procedures), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=4.

6. Harvey Pitt, *Facing Our Corporate Governance Mistakes*, CORPORATE BOARD (Jan. 1, 2004) (corporate governance dos and don'ts), available at http://www.kaloramapartners.com/SpeechDetails.aspx?SpeechId=16.

7. Harvey Pitt, *New Year's Resolutions For Independent Directors*, COMPLIANCE WEEK (Jan. 27, 2004) (suggestions for independent directors on how to fulfill their duties and limit their liability in the wake of accounting scandals, S-Ox and an era of increased regulation and enforcement), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=5.

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[2] Websites have been provided for all publicly available articles. A password is required to retrieve articles that appear in certain publications, such as Compliance Week, Wall Street Journal and FT.com. As indicated, these materials are therefore not publicly available.

8. Harvey Pitt, *Certifying Internal Controls—A Trap for the Unwary?,* COMPLIANCE WEEK (Feb. 24, 2004) (S-Ox § 404 and how it requires companies to approach internal and external audit functions), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=13.

9. Harvey Pitt, *Directorial Activism In The Face Of Alleged Or Actual Officer Misbehavior*, COMPLIANCE WEEK (Mar. 30, 2004) (the need for outside directors to adopt a program to deal with issues of potential corporate wrongdoing), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=11.

10. Harvey Pitt, *The Critical Importance, and Changing Face, of Corporate Transparency*, COMPLIANCE WEEK (Apr. 27, 2004) (governance approaches public companies should consider implementing), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=9.

11. Harvey Pitt, *Risky Business: Assessing And Managing Risk*, COMPLIANCE WEEK (June 2, 2004) (steps directors can take to ensure a continuous and effective process for identifying, assessing and managing risk), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=10.

12. Harvey Pitt, *Practical Guidance On Being Worth One's "Salt"*, COMPLIANCE WEEK (Jul. 7, 2004) (practical guidance on how to assure that your company's executives are worth their compensation), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=14.

13. Harvey Pitt, *The Changing Landscape Of Internal Corporate Investigations,* COMPLIANCE WEEK (Jul. 27, 2004) (recent SEC enforcement cases highlight the high-bar required for internal investigations), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=15.

14. Harvey Pitt, *Enhanced D&O Responsibilities For Compliance, Ethics*, COMPLIANCE WEEK (Aug. 24, 2004) (discussing new and refined 'tone at the top' obligations that corporate directors and officers will want to consider in advance of S-Ox's implementation), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=18.

15. Harvey Pitt and Suzanne Dans, *The Brave New World of Sarbanes-Oxley*, CRITICALEYE.NET (Sept.--Nov. 2004), available at http://www.kaloramapartners.com/pdfs/ceye-sep04-pitt_dans1.pdf.

16. Harvey Pitt, *Instilling A Corporate Culture Of Integrity, Ethics And Compliance—Setting The Tone At The Top*, COMPLIANCE WEEK (Sept. 28, 2004) (practical suggestions corporate leaders can consider to establish a "culture of discipline" and integrity), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=16.

17. Harvey Pitt, *How To Be An Effective Director As Standards Change*, COMPLIANCE WEEK (Oct. 26, 2004) (practical suggestions to assist directors in understanding how they can be effective and in finding the correct balance between the unacceptable extremes of complete abdication to management and an adversarial relationship), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=17.

18. Harvey Pitt, *The Mythical Pendulum Isn't Swinging Back the Other Way*, COMPLIANCE WEEK (Nov. 23, 2004) (reasons why it's in corporations' self-interest to look beyond specific legislative and regulatory mandates and think about effecting real governance and transparency reforms) [not publicly available—Compliance Week subscription required].

19. Harvey Pitt, *Helping Independent Directors Be Constructively Proactive*, COMPLIANCE WEEK (Dec. 21, 2004) (ways in which directors can be constructively proactive), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=19.

20. Harvey Pitt, *Whither Directors' Personal Liability?* COMPLIANCE WEEK (Jan. 25, 2005) (prudent steps directors should consider before declining to serve on a public company board, or deciding to resign from a public company board on which they presently sit), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=22.

21. Harvey Pitt, *Conflict Of Interest Lessons From Financial Services*, COMPLIANCE WEEK (Feb. 22, 2005) (steps for management and compliance officers to effectively patrol against conflicts of interest), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=21.

22. Harvey Pitt, *The Changing Standards by Which Directors Will be Judged*, ST. JOHN'S LAW REVIEW (Mar. 23, 2005) (discussing the changing liability landscape for corporate directors), available at http://testwww.stjohns.edu/media/3/2d852f38d5b64d77862bd5052622fb30.pdf.

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24. Harvey Pitt, *Two-Way Street: How Executives Should Work With The Board*, COMPLIANCE WEEK (Apr. 26, 2005) (suggestions for how directors can establish a good working relationship with the executive officers of the company) [not publicly available—Compliance Week subscription required].

25. Harvey Pitt, *Anticipating The Concerns of Your Institutional Investors*, COMPLIANCE WEEK (May 31, 2005) (approaches corporate managers should consider as they think about their relationships with institutional investors) [not publicly available—Compliance Week subscription required].

26. Harvey Pitt, *The Gathering Storm In Retirement Funds,* COMPLIANCE WEEK (June 28, 2005) (suggestions for areas that trustees should consider evaluating on a periodic basis in order to ferret out—and then address—problems or issues that may be lurking in their retirement funds) [not publicly available—Compliance Week subscription required].

27. Harvey Pitt, *Summertime Compliance: Responding to Changes in Climate and Enforcement*, COMPLIANCE WEEK (July 26, 2005) [not publicly available—Compliance Week subscription required].

28. Harvey Pitt, *Caveat Emptor: Merger Considerations for Public Cos.*, COMPLIANCE WEEK (Aug. 30, 2005) (list of alphabet soup of regulatory concerns that boards will have to grapple with in considering whether to acquire/merge with another company) [not publicly available—Compliance Week subscription required].

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30. Harvey Pitt, *Best Practices For Small- And Mid-Cap Companies*, COMPLIANCE WEEK (Oct. 25, 2005) [not publicly available—Compliance Week subscription required].

31. Harvey Pitt, *Effective Ways For Companies To Avoid Murphy's Law,* COMPLIANCE WEEK (Nov. 29, 2005) (reflecting on mistakes we've seen good companies grapple with—or successfully avoid—over the past two-and-a-half years), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=41.

32. Harvey Pitt, *Sorting Through Probabilities, Possibilities For 2006*, COMPLIANCE WEEK (Jan. 3, 2006) (sorting through the probabilities and possibilities on what companies are likely to be contending with in 2006), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=29.

33. Harvey Pitt, *Trials And Tribulations of Enron and S-Ox*, FORBES.COM (Jan. 23, 2006) (reviewing Enron and addressing the benefits and drawbacks of S-Ox), available at http://www.forbes.com/2006/01/20/enron-sarbox-pitt-commentary-cx_hlp_0123harveypitt.html.

34. Harvey Pitt, *Fine Print: SEC Penalty Plan Explains Price Of Fraud*, COMPLIANCE WEEK (Jan. 31, 2006) (how to avoid or reduce the magnitude of SEC corporate penalties, including incorporating lessons and recommendations from SEC's recent statements, the U.S. Sentencing Commission's Federal Sentencing Guidelines, and the SEC's 2001 *Seaboard* release), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=27.

35. Harvey Pitt, *Executive Compensation: Spend It Carefully*, COMPLIANCE WEEK (Feb. 28, 2006) (discussing the wake of escalating concerns about executive compensation and various ways companies can stay ahead of the issue), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=24.

36. Harvey Pitt, *The Principles vs. Prescriptive Rules Debate*, COMPLIANCE WEEK (Mar. 28, 2006) (issues that businesses must confront in coming to terms with prescriptive and principles-based accounting rules and policies), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=26.

37. Harvey Pitt, *Make SOX Fit*, WALL STREET JOURNAL, pg. A12 (Apr. 13, 2006) (addressing need for imbuing S-OX with fewer burdens, while providing the same measure of protection to investors that its framers intended) [not publicly available—WSJ subscription required].

38. Harvey Pitt, *Crafting Effective Disclosure, Even When It Hurts*, COMPLIANCE WEEK (Apr. 25, 2006) (tips for helping companies say the right words and take the right angle in the Information Age), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=25.

39. Harvey Pitt, *The Next Big Scandal*, FORBES.COM (May 26, 2006) (addressing options backdating and suggesting best practices regarding compensation grants and recordation), available at http://www.forbes.com/2006/05/25/hpitt-column-stockoption-cx_hp_0526nextbigscandal.html.

40. Harvey Pitt, *On The Road To Global Governance Standards*, COMPLIANCE WEEK (May 31, 2006) (list of issues that the future will bring for corporations as we move toward global markets and harmonization of regulatory regimes), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=28.

41. Harvey Pitt, *Lessons of the Stock Options Scandal*, FINANCIAL TIMES (June 2, 2006) (options backdating and suggested solutions for the Board of directors and its compensation committee in addressing the issue),

available at http://www.kaloramapartners.com/SpeechPF.aspx?SpeechId=42.

42. Harvey Pitt, *Sarbanes-Oxley is an Unhealthy Export*, FINANCIAL TIMES, London Ed1, Page 21 (June 21, 2006) (difficulties S-Ox presents for multi-national companies and suggesting a solution to modify S-Ox to allow the SEC to give comity to comparable regulatory systems without requiring them to replicate every facet of S-Ox), available at http://www.kaloramapartners.com/SpeechDetails.aspx?SpeechId=41.

43. Harvey Pitt, *A Risk-Based Approach To Section 404*, COMPLIANCE WEEK (June 27, 2006) (tips for implementing a top-down approach, which is more effective at controlling risks), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=31.

44. Harvey Pitt, *Covering Up Naked Shorts*, FORBES.COM (Jul. 11, 2006) (Companies must take to the initiative to uncover problems and prevent future crises), available at http://www.forbes.com/2006/07/11/leadership-harve-pitt-cs_hp_0711coveringupnakedshorts.html.

45. Harvey Pitt, *Essentials For An Ethical Corporate Culture,* COMPLIANCE WEEK (Jul. 25, 2006) (exploring ways companies can develop ethical corporate cultures, and keep themselves from becoming the next cautionary tale), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=30.

46. Harvey Pitt, *Over-Lawyered at the SEC*, WALL STREET JOURNAL, (Jul. 26, 2006) (SEC's failures a result of an over-reliance on lawyers instead of economists and analysts), available at http://www.kaloramapartners.com/SpeechDetails.aspx?SpeechId=40.

47. Harvey Pitt, *Dollars and Sense*, FORBES.COM (Aug. 14, 2006), (suggestions for rational process in determining and explaining executive compensation), available at http://www.forbes.com/2006/08/12/leadership-SEC-compensation-cx_hp_0814pitt.html.

48. Harvey Pitt, *Finding A Cure for the Compensation Blues*, COMPLIANCE WEEK (Aug. 29, 2006) (rules of thumb addressing major issues arising from the stock option grant scandal and requirements contained in the SEC's new compensation disclosure rules), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=35.

49. Harvey Pitt, *Document Creation, Retention, and Destruction Policies*, COMPLIANCE WEEK (Sept. 26 2006) (things companies should keep in mind in adopting or revamping their policies on document creation, retention,

and destruction), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=36.

50. Harvey Pitt, *Learning The Lessons Of Hewlett-Packard*, COMPLIANCE WEEK (Oct. 31, 2006) (fundamental lessons to be learned from HP's woes), appears on Kalorama's website at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=37.

51. Harvey Pitt, *What to Do When The SEC Comes Calling*, COMPLIANCE WEEK (Jan. 3, 2007) (the discrete time periods to consider in responding to an SEC inquiry or investigation) [not publicly available—Compliance Week subscription required].

52. Harvey Pitt, *SOX 404 Redux: It's Groundhog Day*, COMPLIANCE WEEK (Feb. 27, 2007) (steps that managements should consider in order to successfully implement new S-Ox 404 procedures), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=38.

53. Harvey Pitt, *Rethinking U.S. Regulation: Can America Restore its Leadership in Global Capital Markets*, THE CHIEF EXECUTIVE (Mar. 1, 2007) (steps for rethinking our regulatory approach, created over 70 years ago, which stifles innovation, creativity and risk-taking) [not publicly available—Lexis/Nexis subscription required].

54. Harvey Pitt, *The FCPA—Best Practices for a New Climate*, COMPLIANCE WEEK (Apr. 24, 2007) (practical guidelines that companies may wish to heed in order to assure compliance with the FCPA's anti-bribery provisions), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=39.

55. Harvey Pitt, *Accounting for Uncertain Tax Liabilities*, COMPLIANCE WEEK (June 26, 2007) (fundamental questions audit committee members will need to consider and resolve when evaluating the company's tax position), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=40.

56. Harvey Pitt, Avoiding Murphy's Law: Tips for Boards and Management, COMPLIANCE WEEK (Aug. 8, 2007) [not publicly available—Compliance Week subscription required].

57. Harvey Pitt, *Learning the Lessons of the Sub-Prime Crisis*, COMPLIANCE WEEK (Oct. 30, 2007) (simple approaches that institutions can take to strengthen their risk-management systems), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=42.

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60. Harvey Pitt, *"For Want of a Nail": ERM for the Regulators*, COMPLIANCE WEEK (Apr. 29, 2008) (creating a governmental Risk Management Committee to avoid or ameliorate financial crises), available at http://www.kaloramapartners.com/ArticleDetails.aspx?Id=45.

61. Harvey Pitt, *Regulation That Achieves What We Need Today*, COMPLIANCE WEEK (June 24, 2008) (regulatory pendulums and what its recent trajectory means for public company executives) [not publicly available—Compliance Week subscription required].

62. Harvey Pitt, *Bringing Financial Services Regulation into the Twenty First Century*, YALE JOURNAL ON REGULATION (Summer 2008) (revolution brewing in our financial regulatory environment), available at http://findarticles.com/p/articles/mi_7780/is_200807/ai_n32287808/?tag=content;col1.

63. Harvey Pitt, *The Inevitable Move to IFRS: Getting Started*, COMPLIANCE WEEK (Aug. 26, 2008) (steps U.S. companies should consider in making the transition to IFRS as smooth as possible) [not publicly available—Compliance Week subscription required]

64. Harvey Pitt, *Transparency Key to Securities Markets' Comeback* (Oct. 28, 2008) (fair value accounting and suggested steps for companies to ensure maximum transparency in its pricing policies and procedures for assets that are subject to it) [not publicly available—Compliance Week subscription required].

65. Harvey Pitt, *Rules for Disclosing a CEO's Unexpected Absence*, COMPLIANCE WEEK (Feb. 24, 2009) (determining whether and how to disclose a CEO's absence to the investing public) [not publicly available—Compliance Week subscription required].

66. Harvey Pitt, *FIN 48 Turns Two, and Certainly Isn't All That Bad*, COMPLIANCE WEEK (Apr. 28, 2009) (need for boards and companies to reconsider their income tax risk tolerance and consider additional steps

to manage such risk effectively) [not publicly available—Compliance Week subscription required].

67. Harvey Pitt, *Retaining Ethical Cultures During a Weak Economy*, COMPLIANCE WEEK (June 30, 2009) (how companies can achieve good corporate governance and encourage ethical business behavior in turbulent times) [not publicly available—Compliance Week subscription required]

68. Harvey Pitt, Weder di Mauro roundtable: Better Regulators Needed, THE ECONOMIST (Oct. 2, 2009), available at http://www.economist.com/blogs/freeexchange/2009/10/weder_di_mauro_roundtable_bett.

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70. Roderick Hills, Harvey Pitt and David Ruder, *Don't Let Banks Hide Bad Assets*, WALL STREET JOURNAL (Nov. 18, 2009) (transferring accounting standards responsibility from the SEC to a systemic risk regulator. Such a radical move would have extremely negative consequences for our capital markets), available at http://online.wsj.com/article/NA_WSJ_PUB:SB10001424052748704782304574542134264068424.html.

71. Harvey Pitt, *The Board's Role in Bringing Legal Trouble to an End*, COMPLIANCE WEEK (Nov. 24, 2009) (rejection of SEC's proposed settlement with Bank of America and suggested approaches for corporations to consider in avoiding litigation) [not publicly available—Compliance Week subscription required].

72. Harvey Pitt, *Risk of Failing to Understand ERM Risks,* COMPLIANCE WEEK (Feb. 23, 2010) (understanding enterprise risk management and lessons to be learned from the case of Abdulmutallab, who boarded a Northwest flight from Amsterdam to Detroit with an incendiary device strapped to his body) [not publicly available—Compliance Week subscription required].

73. Harvey Pitt, The SEC's Dangerous Gamble, THE DAILY BEAST (Apr. 20, 2010), available at http://www.thedailybeast.com/articles/2010/04/20/betting-the-farm-on-goldman.html

74. Harvey Pitt, *Following the Road to IFRS Convergence*, COMPLIANCE WEEK (Apr. 27, 2010) (history of IFRS convergence and reasons why companies

should embrace IFRS now) [not publicly available—Compliance Week subscription required].

75. Harvey Pitt, *Learning From History on Financial Reform*, WALL STREET JOURNAL, pg. A19 (May 17, 2010) (points on financial reform implications, what we still need and don't have, and the need to consider history in implementing reform in order to avoid occurrence of past mistakes), available at http://online.wsj.com/article/SB10001424052748703460404575244810777765420.html.

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77. Harvey Pitt, *The Truth About Financial Reform: It's A Big Fat Failure*, DAILY BEAST (Jul. 14, 2010) (problems with the Dodd-Frank reform bill), available at http://www.businessinsider.com/ugly-truth-about-financial-regulatory-reform-2010-7.

78. Harvey L. Pitt & Roderick M. Hills, *The Politics of Congressional Ethics*, THE GADSDEN TIMES (Mar. 8, 2012), available at http://www.gadsdentimes.com/article/20120308/NEWS/120309783.

79. Harvey Pitt, *Opening Remarks, Insider Trading Debate*, THE ECONOMIST (May 2, 2012), available at http://www.economist.com/debate/days/view/834

80. Harvey Pitt, *Rebuttal Remarks, Insider Trading Debate*, THE ECONOMIST (May 7, 2012), available at http://www.economist.com/debate/days/view/835

81. Harvey Pitt, *Closing Remarks, Insider Trading Debate*, THE ECONOMIST (May 10, 2012), available at http://www.economist.com/debate/days/view/836

Exhibit C
List of Expert Testimony and Reports[1]

1. *San Antonio Fire & Police Pension Fund v. Amylin Pharmaceuticals, Inc.*, C.A. No. 4446-VCL (Del. Ch. Ct.) (2009).

2. *In re Fannie Mae Securities Litigation*, C.A. No. 1:04-CV-01639 (RJL) (D. D.C.) (2010).

3. *In re Pfizer Inc. Shareholder Derivative Litigation*, No. 09-CV-7822 (JSR) (S.D.N.Y.) (2010).

4. *Fairfax Financial Holdings Limited v. S.A.C. Capital Management, LLC, et al.*, No. MRS-L-2032-06 (N.J. Sup. Ct.) (2011).

5. *Goodman v. Genworth Financial Wealth Management, Inc.*, No. 09-CV-5603 (LDW) (E.D.N.Y.) (2012).

6. *In re Bank of America Securities, Derivative and ERISA Litigation*, 09 MDL 2058 (PKC) (S.D.N.Y.) (2012).

[1] All references to years are to the year in which Former Chairman Pitt provided the expert testimony and/or report.