REPORT OF THE SPECIAL COMMITTEE OF THE BOARD OF DIRECTORS OF JOHNSON & JOHNSON

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PART ONE

INTRODUCTION

From February through November, 2010, the Board of Directors of Johnson & Johnson ("J&J" or the "Company") received a series of demand letters from J&J shareholders. The letters demanded, *inter alia*, that the Board investigate alleged wrongdoing and initiate litigation against certain current and former J&J officers and directors for alleged breaches of fiduciary duty, and that the Board take further remedial actions as well. Other J&J shareholders, ostensibly on behalf of the Company, have filed a series of derivative complaints in the United States District Court for the District of New Jersey and the Superior Court of New Jersey that largely mirror the allegations in the demand letters. The gravamen of the demand letters and the derivative complaints is that the named J&J officers and directors breached their fiduciary duties owed to the Company by permitting a variety of improper activities to occur across various business segments, and by ignoring "red flags" that such conduct was occurring.

Specifically, the demand letters and derivative complaints describe an array of alleged wrongdoing, including that J&J: (1) paid improper "kickbacks" to Omnicare, Inc., the largest U.S. pharmacy for nursing-home patients, to induce Omnicare's purchase and recommendation of J&J's drugs for use in nursing homes; (2) engaged in improper "off-label" promotion of certain drugs or products for uses not approved by the federal Food and Drug Administration ("FDA"); (3) had insufficient quality controls and practices at several of its pharmaceutical manufacturing plants in violation of federal regulations, ultimately leading to product recalls, Congressional and federal criminal investigations, and a Consent Decree with the U.S. Department of Justice; (4) marketed a hip replacement system, while knowingly concealing its design defects; (5) improperly paid inducements to surgeons to use hip and knee replacement and reconstructive products made by DePuy Orthopaedics, Inc., a J&J subsidiary; and (6) "bribed"

foreign medical professionals and the Iraqi government to prescribe and/or purchase J&J's products in violation of the Foreign Corrupt Practices Act.

On April 22, 2010, following receipt of the first three shareholder demand letters, the J&J Board of Directors adopted a resolution creating a special committee (the "Special Committee") comprised of the four independent, outside directors who had most recently joined the Board: Michael M.E. Johns, Anne Mulcahy, William D. Perez and Charles Prince. The Special Committee was asked to review, analyze and investigate the allegations recited in the shareholder demand letters, and to recommend to the Board what actions, if any, should be taken in the best interests of the Company.

The Special Committee retained independent legal counsel, Lowenstein Sandler PC ("Lowenstein"), to assist the Committee with its investigation. After receipt of additional shareholder demand letters and the filing of several derivative complaints, the Board of Directors expanded the Special Committee's mandate on June 15, 2010 to include the investigation, review and analysis of the allegations asserted in the new letters and derivative complaints, as well as any subsequently-received demand letters or subsequently-filed derivative complaints.

With the assistance of Lowenstein, the Special Committee conducted an extensive investigation into these matters over the course of the past year. The investigation included interviews of some 57 current and former J&J employees, members of the J&J Board of Directors Audit Committee, in-house counsel, industry consultants, and outside counsel from eight different law firms representing the Company and/or its subsidiaries in the respective investigations and litigations to which they have been subject. The Special Committee submitted multiple document requests to J&J; through Lowenstein, it also accessed the databases compiled by outside counsel (comprising over 21 million pages of documents) and collected and created a

separate database of more than one million pages. J&J and its outside counsel cooperated fully throughout the Special Committee's investigation.

The principal issues that the Special Committee sought to resolve, given the allegations in the demand letters and derivative complaints, were whether any wrongdoing had occurred, whether that wrongdoing constituted or was the result of a breach of fiduciary duty, whether it was in the best interests of J&J to initiate litigation against one or more individuals responsible for the wrongdoing or breach of fiduciary duty, and whether J&J should take any other remedial actions. The Special Committee then had to decide whether it was in the best interests of J&J: (1) to accept or reject, in whole or in part, the shareholder demand letters; and (2) to take over the derivative litigation, seek its dismissal, or stand on the sidelines and let individual shareholders pursue their claims on behalf of the Company.

In conducting its investigation and analysis, the Special Committee considered: (1) the underlying shareholder allegations and the merits of the potential legal claims for breach of fiduciary duty against J&J officers and directors; (2) the cost, time, and effort in pursuing litigation, weighed against the likelihood of recovery; and (3) intangible costs caused by any such litigation, including factors such as the distraction and disruption to employees, officers and the Board, the impact on J&J's efforts to remediate the Company's manufacturing issues and the other issues identified in the shareholder allegations, and the effect that a derivative litigation would have on J&J's business as a whole, including the potential for additional exposure in pending litigation and/or criminal investigations.

As outlined below, based on its year-long investigation, the Special Committee has concluded that the allegations in the demand letters and derivative complaints do not warrant litigation by or on behalf of the Company. This conclusion is based on the findings of the Special Committee with respect to the merits of the allegations, as well as the attendant costs,

distractions and disruptions to the Company represented by potential litigation. The Special Committee therefore recommends to the Board of Directors that the Company take whatever steps are necessary or appropriate to reject the various shareholder demands and seek dismissal of the derivative actions. Out of an abundance of caution, the Special Committee recommends that Chairman and Chief Executive Officer William C. Weldon not participate in the Board's deliberations, which should take place in executive session. There is no evidence that Mr. Weldon engaged in or had knowledge of any wrongdoing. But because he is a part of management and the balance of the Board is comprised of directors whose independence is unassailable, it would be preferable if he were excluded from the discussion and decision-making. Finally, the Special Committee recommends that the Board of Directors establish a new Regulatory and Compliance Committee responsible for oversight of the Company's Health Care Compliance and Quality and Compliance systems and issues.

The following report includes (1) a summary of the shareholder allegations and the Special Committee's investigation, (2) the applicable legal standards relevant to the Committee's investigation, and (3) the Committee's ultimate findings and recommendations.

PART TWO

SUMMARY OF THE ALLEGATIONS AND THE INVESTIGATION

I. The Shareholder Demand Letters And Derivative Complaints

The first shareholder demand letter was sent to the J&J Board of Directors on February 17, 2010. In the following months, the J&J Board received six additional demand letters and two supplemental demand letters from shareholders. Each letter demanded that the Board initiate litigation against certain current and former J&J officers and directors for alleged breaches of fiduciary duties. The demand letters are summarized as follows:

	Date	Shareholder	Shareholders' Attorneys
1	Feb. 17, 2010 July 7, 2010 [supplement]	Leslie Katz, Jeffrey Tarson and Joan Tarson	Abraham Fruchter & Twersky LLP
2	March 23, 2010	NJ Building Laborers Annuity, NJ Building Laborers Pension Funds	Milberg LLP
3	April 15, 2010 July 22, 2010 [supplement]	Glenn Bassett	Prickett, Jones & Elliott
4	May 20, 2010	Martha Copeland	Greenfield & Goodman LLC
5	May 26, 2010	Dan Miran	Weiss & Lurie
6	June 17, 2010	Scott L. Lerner	Greenfield & Goodman LLC
7	Nov. 12, 2010	Michael Waber	Federman & Sherwood

The first three demand letters received were based on allegations stemming from a civil complaint filed on January 15, 2010 by the U.S. Department of Justice ("DOJ") in the United States District Court for the District of Massachusetts. That complaint alleged violations of the federal Anti-Kickback Statute and the False Claims Act by J&J and two of its subsidiaries, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson Health Care Systems, Inc., in connection with purported "kickbacks" paid by those entities to Omnicare, Inc. ("Omnicare"), a pharmacy serving nursing homes. The essence of the DOJ's civil complaint, and thus the essence of the demand letters, was that from 1999 to 2004, J&J and its subsidiaries allegedly provided kickbacks in the form of market share rebates and grants, as well as cash payments, to Omnicare -- on the condition that Omnicare engage in "active intervention programs" pursuant to which Omnicare purchased and recommended J&J's drugs to Omnicare's elderly nursing-home patients. The main product in the program cited by the DOJ was the antipsychotic drug Risperdal. The DOJ alleged that Omnicare, at J&J's behest, launched a "Risperdal Initiative" program whereby Omnicare pharmacists persuaded physicians to prescribe Risperdal despite

purported clinical risks in switching a stabilized and elderly patient from one antipsychotic drug to another.

The next three demand letters (received from shareholders Martha Copeland, Dan Miran, and Scott Lerner) cited the allegations from the Omnicare litigation, but also asserted additional claims, all apparently based on disclosures in J&J's annual Form 10-K reports to the Securities and Exchange Commission ("SEC"). The additional allegations focused on: (1) J&J's alleged off-label promotion of Topamax, Risperdal, Natrecor and Biliary Stents; (2) the alleged bribery of medical professionals in Greece and elsewhere in violation of the Foreign Corrupt Practices Act ("FCPA") by DePuy International Limited; (3) the $84.7 million settlement of federal civil and criminal kickback charges relating to DePuy Orthopaedics, Inc.'s alleged inducements to surgeons to use its hip and knee replacement and reconstructive products; (4) an alleged concealment of defects in a DePuy Orthopaedics, Inc. artificial hip implant system; and (5) alleged systemic violations of FDA regulations (current Good Manufacturing Practices), which led to the receipt of FDA Warning Letters, product recalls, the closure of a plant, and Congressional and criminal investigations.

The supplemental demand letter on behalf of shareholders Leslie Katz, Jeffrey Tarson and Joan Tarson, dated July 7, 2010, added allegations that J&J had "consistently" violated FDA regulations and engaged in purported "off-label marketing practices" with respect to Topamax, Risperdal, Natrecor and Biliary Stents. The latter allegation essentially mirrors the Copeland, Miran and Lerner demand letters; the former is based on (1) a January 15, 2010 Warning Letter issued by the FDA and directed at McNeil-PPC, Inc. ("McNeil"), a J&J subsidiary, (2) the results of an FDA inspection of McNeil's Fort Washington, Pennsylvania manufacturing plant, (3) the closure of that plant and the recall of over-the-counter ("OTC") medications manufactured there, and (4) the circumstances under which another product (Motrin) was

withdrawn from the market. The supplemental demand letter on behalf of shareholder Glen Bassett, dated July 22, 2010, similarly cited the recent recalls of OTC medications manufactured by McNeil, the "shuttering" of the Fort Washington plant, and press reports of the results of an inspection of McNeil's Lancaster, Pennsylvania plant that indicated "systemic oversight problems . . . which the J&J Board is unable or unwilling to correct." The final demand letter (received from shareholder Michael Waber) also focused on the McNeil manufacturing issues and recalls, including an alleged "phantom recall" of certain adult Motrin products in 2009.

In total, the shareholder letters demanded that the J&J Board conduct a thorough investigation of the allegations set forth in the letters; that the Board initiate legal action on behalf of J&J against certain officers and directors for purportedly breaching their fiduciary duties in allowing the conduct described in the letters to occur and/or failing to prevent it from occurring (including seeking monetary damages from the individual officers and directors); and that the Board undertake a comprehensive review and overhaul of the Company's corporate governance, compliance, risk management, and internal control practices and systems.

Meanwhile, on April 21, 2010, Jeanne M. Calamore filed a putative derivative complaint in the United States District Court for the District of New Jersey (Civil Action No. 10-2033 (FLW)). Other shareholders followed suit, filing five additional derivative complaints in the District of New Jersey: (1) *Carpenters Pension Fund of West Virginia v. Weldon, et al.*, Civil Action No. 10-2275 (FLW), filed May 5, 2010; (2) *Feldman v. Coleman, et al.*, Civil Action No. 10-2386 (FLW), filed May 6, 2010; (3) *Hawaii Laborers Pension Fund v. Weldon, et al.*, Civil Action No. 10-2516 (FLW), filed May 14, 2010; (4*) Ryan v. Weldon, et al.*, Civil Action No. 10-3147 (FLW), filed June 18, 2010; and (5) *Minneapolis Firefighters' Relief Association, et al. v. Weldon, et al.*, Civil Action No. 10-3215 (FLW), filed June 24, 2010. None of those shareholders made a demand on J&J's Board of Directors before filing suit.

A motion to consolidate the various derivative actions was granted on August 17, 2010. The Court consolidated the cases into one action -- *In re Johnson & Johnson Derivative Litigation*, Civil Action No. 10-2033 (FLW) -- and appointed co-lead counsel (Bernstein Litowitz Berger & Grossman, LLP; Morris and Morris LLC; Carella, Byrne, Cecchi, Olstein, Brody & Agnello, P.C.; and Robbins Geller Rudman & Dowd LLP). The Court further ordered that all subsequently-filed derivative actions would be subject to the consolidation order.

Despite the consolidation of the derivative complaints, one of the shareholders who served a demand letter on the Board, Martha Copeland, filed a complaint in the District of New Jersey on December 1, 2010.[1] Ms. Copeland's complaint alleged that the J&J directors used their control of J&J and its corporate voting process to effectuate and/or directly participate and/or aid and abet violations of Section 14(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated by the SEC to perpetuate themselves in office as directors of the Company, thereby permitting the directors to unjustly enrich themselves and/or otherwise damage J&J at its shareholders' expense. In addition, the Copeland complaint charged the J&J directors and J&J's CEO, Mr. Weldon, with gross negligence in the management of J&J, arising from allegedly systemic and pervasive breaches of fiduciary duty. The breach of fiduciary duty allegations in Ms. Copeland's complaint were similar to the allegations set forth in her May 20, 2010 demand letter.[2]

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[1] By Order dated January 19, 2011, the Court consolidated Ms. Copeland's action with the consolidated derivative action. On February 23, 2011, however, Ms. Copeland filed a motion to re-designate and unconsolidate her action from the consolidated derivative action. That motion is currently pending before the Court.

[2] The one exception is that Ms. Copeland's complaint did not include any allegations relating to violations of the FCPA, which had been included in her demand letter.

On December 17, 2010, the lead plaintiffs in the consolidated action filed a Consolidated Amended Complaint (the "Consolidated Complaint") against ten of the members of J&J's Board of Directors who were serving at the time that the first action was originally filed, as well as six current or former officers of the Company. The Consolidated Complaint in large part mimics the allegations made in the shareholder demand letters, although it provides a lengthier summary of the allegations (it includes 97 pages and 322 separate paragraphs).[3] The Consolidated Complaint alleges that J&J fostered a "culture of legal non-compliance," and describes the various issues that the Company has encountered over the past several years. Among other things, the Consolidated Complaint cites the quality and compliance problems encountered by McNeil and the violations cited by the FDA at McNeil's Las Piedras, Puerto Rico and Fort Washington, Pennsylvania plants; the recall of over 200 million bottles of J&J's OTC medications in 2010; the alleged "phantom recall" of adult Motrin products in 2009 and the subsequent Congressional investigation of that recall; the supposedly improper off-label promotion of products; and the purported kickback schemes involving Omnicare and DePuy Orthopaedics, Inc.

The plaintiffs claim that the named defendants breached their fiduciary duties by allegedly overlooking an array of "red flags" that should have put them on notice of the Company's purported systemic and widespread violations of the law. In particular, the plaintiffs allege that the "red flags" include: (1) FDA Warning Letters and additional violation notices identifying supposedly unlawful marketing practices or public health and safety violations; (2) six *qui tam* complaints detailing J&J's purported unlawful activities; (3) twelve subpoenas or informational inquiries from Congress and federal prosecutors regarding marketing and safety

[3] In September 2010, another shareholder, Michael Wolin, filed a derivative complaint in the Superior Court of New Jersey, Middlesex County, Chancery Division, which mirrors the claims in the Consolidated Complaint with respect to the McNeil recalls and Motrin product withdrawal.

issues; (4) six inquiries from State Attorneys General on the same topics; (5) "numerous" federal and state government complaints seeking civil and criminal relief; and (6) two criminal pleas accepted by J&J subsidiaries.

Based on the government warnings, inquiries, and complaints described in the Consolidated Complaint, the plaintiffs allege that J&J's officers and directors should have taken steps to address the Company's purported violations of federal and state laws and regulations. According to the Consolidated Complaint, the failure of J&J's officers and directors to take such remedial actions constituted a breach of the defendants' obligations of good faith and loyalty in the administration of J&J's affairs. The plaintiffs therefore seek a judgment requiring the named defendants to pay J&J the amounts "by which it has been damaged or will be damaged by reason of the conduct complained of herein." The plaintiffs further seek a judgment directing J&J "to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its shareholders from a recurrence of the damaging events described herein." The plaintiffs also seek reasonable attorneys' fees, expert fees and other reasonable costs and expenses.

On February 21, 2011, the defendants filed a motion to (1) dismiss the Consolidated Complaint on the grounds that the plaintiffs failed to make the requisite pre-suit demand on the J&J Board, or, in the alternative, (2) stay the action pending the outcome of the Special Committee's investigation. That motion is pending before the Honorable Freda Wolfson.

The shareholders who sent the first demand letter to the Board -- Leslie Katz and Jeffrey and Joan Tarson -- filed a motion on July 17, 2010 to intervene in the derivative litigation and have their counsel appointed as lead counsel. The Court denied that motion without prejudice. Subsequently, Leslie Katz and Jeffrey and Joan Tarson re-filed their motion to intervene on April

19, 2011, which motion is also pending before the Court. The substantive allegations of the proposed complaint from Katz, *et al.* essentially track their demand letters with respect to violations of FDA manufacturing regulations and the federal Anti-Kickback Statute, as well as alleged off-label marketing. In addition, a new claim, for violation of Medicaid Best Price Rules (which is part of the Omnicare allegations), is separately pled.

Finally, two additional derivative complaints have recently been filed in the District of New Jersey, and a third one was filed in the Superior Court of New Jersey, based on a recently-announced Deferred Prosecution Agreement between the DOJ and J&J, its subsidiaries, and operating companies -- relating to violations of the FCPA involving payments to medical officials in Greece, Romania and Poland and to a government agency in Iraq: *Wollman v. Coleman*, Civil Action No. 11-2511 (FLW) (District of New Jersey); *Cafaro v. Coleman*, Civil Action No. 11-2652 (FLW) (District of New Jersey); and *Clark v. Coleman*, Docket No. MID-C-116-11 (Middlesex County, Ch. Div.).[4] On May 23, 2011, the defendants in the *Wollman* and *Cafaro* cases wrote to the Court and requested that it consolidate those two cases into the Consolidated Action under the Court's August 17, 2010 consolidation order.

II. Formation And Mandate Of The Special Committee

On April 22, 2010, in response to the first three demand letters, the J&J Board of Directors adopted a resolution creating a Special Committee "to investigate, review, and analyze

[4] The *Wollman* and *Cafaro* complaints contain conclusory allegations of violations of federal securities laws based on a purported failure of the J&J Proxy Statements to disclose material facts regarding the FCPA investigation and the Company's purported lack of internal controls. Similarly, the *Copeland* complaint alleges that the director defendants failed to disclose "the extent to which [the directors] were responsible for the wrongdoings" alleged in the complaint. The Consolidated Complaint does not include any such claim; similar claims have been rejected as unactionable by the U. S. Court of Appeals for the Third Circuit. *See General Elec. Co. v. Cathcart*, 980 F.2d 927 (3d Cir. 1992). Moreover, J&J has made robust disclosure of the existence and status of the various governmental investigations and litigations that are the subject of the various derivative complaints and demand letters.

the facts and circumstances surrounding the allegations raised in, and recommend any appropriate or necessary actions, if any" in connection with the three letters. The Board resolution specifically authorized the Special Committee:

> to (i) retain for and on behalf of the Corporation, and at the sole expense of the Corporation, independent legal counsel, financial advisors, accountants, or other consultants and advisors as may be required; (ii) incur expenses on behalf of the Corporation in connection with its activities; (iii) seek interviews with any employee, officer, director, agent, or advisor of the Corporation, or any other person, as may be appropriate; (iv) have access to information of the Corporation which the Special Committee believes would assist it in its work; and (v) communicate on behalf of the Corporation with the shareholder(s) making the demand or their agents or representative from time to time as it may deem reasonably necessary[.]

The Board resolution appointed Charles Prince as Chairman of the Special Committee, and appointed Michael M.E. Johns, Anne Mulcahy, and William D. Perez as members. Those individuals were chosen by the Board because they were the four outside directors who had most recently joined the Board at the time the Special Committee was formed.

Although the Special Committee was authorized to investigate the allegations in the demand letters, the Board resolved that it "retains and shall exercise full authority to take final action on behalf of the Corporation" with respect to the demand letters. As such, the Board directed the Special Committee to report its activities, findings and recommendations to the Board, including its advice as to whether any Board member should not participate in the Board's deliberations and actions regarding these matters.

On June 15, 2010, in light of the additional shareholder demand letters and derivative complaints that had been received and filed, the Board adopted a resolution to expand the authority of the Special Committee to investigate, review, and analyze any new allegations that had been made in the recently-received demand letters and recently-filed shareholder derivative

lawsuits, along with any subsequently-received demand letters and/or subsequently-filed derivative complaints.

III. The Special Committee Investigation

By resolution dated June 2, 2010, the Special Committee agreed to retain Lowenstein to assist the Committee in investigating the allegations raised in the demand letters and the derivative actions. At the investigation's outset, the Special Committee instructed Lowenstein to identify the allegations at issue and then to collect and review relevant documents from within J&J and to interview relevant J&J employees and former employees. Because the demand letters and derivative allegations are rooted in alleged breaches of fiduciary duty by J&J officers and directors, the Special Committee focused its analysis on the conduct of those individuals, but also looked beyond the named individuals to consider whether any other officers or employees of J&J and/or its subsidiaries had engaged in any wrongdoing.

At the Special Committee's direction, Lowenstein met several times, both telephonically and in person, with counsel representing the J&J demand shareholders. The purpose of those meetings was to update the shareholders' counsel on the status of the Special Committee's investigation and to ensure that the shareholders' counsel had every opportunity to bring any particular allegations or concerns to the Special Committee's attention. The shareholders' counsel did not raise any new allegations or provide any additional information regarding the demands during those meetings.

Throughout the investigation, the Special Committee met formally, either in person or telephonically, eleven times. During those meetings, which were attended by Douglas S. Eakeley and, on one occasion, by Gavin J. Rooney (both of whom are Members of Lowenstein), the Committee received reports and summaries of the applicable legal standards and the information that was being obtained and analyzed, discussed the issues, and outlined areas that

should be developed further. Ultimately, the Special Committee discussed its factual findings, conclusions, and recommendations, and agreed upon the text of this report for presentation to the J&J Board of Directors.

In the course of the investigation, Lowenstein created a database of more than one million pages. Much of the document production came directly from J&J, in response to a series of formal document requests and follow-up inquiries. J&J also made available to Lowenstein the various outside law firms that were either defending J&J and/or its subsidiaries in litigation or responding on behalf of J&J and/or its subsidiaries to requests/subpoenas by the SEC, DOJ, or Congress in the course of various investigations. The outside firms made available to Lowenstein the databases they had assembled in representing J&J and/or its subsidiaries, which in the aggregate contained more than 21 million pages of documents, along with presentations made to and by the government, briefs, deposition transcripts, hearing transcripts and court decisions.

The documents reviewed by Lowenstein included:

- Minutes of the meetings of the J&J Board of Directors and its Committees, dating back to 1998;
- Presentations to the J&J Board of Directors and its Committees, and related meeting materials;
- Minutes of the meetings and meeting materials of the J&J Compliance Committee and Triage Committee, including the Sensitive Issues Log;
- Corporate documents describing J&J policies and procedures, including its Credo, Policy on Business Conduct, Code of Business Conduct and Ethics for Members of the Board of Directors and Executive Officers, and the charters of the Committees of the Board of Directors;
- Corporate documents describing Health Care Compliance and/or Quality and Compliance, including "Bright Lines," the International HCC Framework, the International Compliance Guide, the International Health Care Business Integrity Guide, the Quality Management Systems Policy, and the Escalation Procedure;

- Documents relating to "Perspectives on Decentralization" and the Corporate Center Review;
- FDA Warning Letters and Inspectional Observations Form 483s and J&J's responses thereto and internal analyses thereof;
- Results of internal and external audits of the McNeil manufacturing facilities at Fort Washington and Las Piedras;
- September 27, 2007 DePuy Orthopaedics, Inc. Deferred Prosecution Agreement and Corporate Integrity Agreement, federal Monitor reports and documents reflecting implementation;
- April 22, 2010 Ortho-McNeil Pharmaceutical, Inc. Settlement Agreement, April 26, 2010 Ortho-McNeil Pharmaceutical, LLC, Plea Agreement, April 27, 2010 Ortho-McNeil Pharmaceutical, Inc. Corporate Integrity Agreement and documents reflecting implementation;
- March 16, 2011 McNeil-PPC, Inc. Consent Decree;
- April 6, 2011 Johnson & Johnson, Inc., Consent Judgment, April 8, 2011 Johnson & Johnson, Inc. Deferred Prosecution Agreement, and April 8, 2011 DePuy International Ltd. Civil Recovery Order;
- Marketing materials;
- Pleadings, deposition transcripts, Congressional hearing transcripts, briefs and judicial decisions in relevant civil litigation; and
- Presentations and submissions to the government, and presentations by the government, in connection with ongoing investigations.

Also as part of the investigation, Lowenstein interviewed some 35 witnesses, several of them more than once, for a total of 39 interviews. Members of the Special Committee participated in a number of the interviews. Lowenstein also met with and/or communicated telephonically with some 17 lawyers from nine different law firms, as well as with five J&J in-house counsel. And Lowenstein reviewed the deposition transcripts of six witnesses taken in the *Natrecor* civil litigation.

In short, over a period of approximately one year, the team of Lowenstein lawyers, paralegals and other legal staff devoted over 10,000 hours to assisting the Special Committee in its investigation.

PART THREE

APPLICABLE STANDARDS FOR THE COMMITTEE'S INVESTIGATION

As explained above, the Special Committee must decide whether to accept or reject, in whole or in part, the shareholder letters demanding that the J&J Board of Directors sue certain officers and directors for breach of fiduciary duty, and whether to take other remedial action. The Special Committee must also decide whether to intervene in and take over the derivative litigation, seek its dismissal, or stay on the sidelines and let the plaintiffs proceed derivatively on behalf of J&J. The pertinent legal standards and factors for such an analysis are set forth below.

I. Relevant Legal Standards

A. Board Independence And Disinterestedness

It is well settled that board members participating in a response to a shareholder demand should be independent and disinterested with respect to the subject matter at issue. *See In re PSE&G S'holder Litig.*, 173 N.J. 258, 286, 289-91 (2002). If the board members reviewing a shareholder demand are not independent and disinterested, the board's decision is not entitled to the protection of the modified business judgment rule. *Id.* at 282, 286.

Under the law, a director is "independent" with respect to a particular issue if he or she is capable of voting on the basis of "'the corporate merits of the subject before the board rather than extraneous consideration or influences.'" *PSE&G*, 173 N.J. at 290 (quoting *In re Prudential Ins. Co. Derivative Litig.*, 282 N.J. Super. 256, 276 (Ch. Div. 1995)). As the New Jersey courts have recognized, "[t]he question of independence flows from an analysis of the factual allegations pertaining to the influences upon the directors' performance of their duties

generally, and more specifically in respect to *the challenged transaction*." *Fagin v. Gilmartin*, 2007 WL 2176482 at *5 (N.J. Ch. Div. July 19, 2007) (citation omitted) (emphasis in original). In considering whether the personal or professional connections among directors deprive the directors of their independence, the question is whether "those relationships or purported conflicts would impair the Board's ability to make an independent decision based on an informed factual presentation." *Id.* at *6. Therefore, the "focus [is] on impartiality and objectivity." *In re Oracle Corp. Derivative Litig.*, 824 A.2d 917, 938 (Del. Ch. 2003).

Conclusory allegations are not sufficient to challenge the independence of a director under New Jersey law. *In re PSE&G*, 173 N.J. at 281. Thus, a director does not lose his or her independence simply because the director has personal friendships with other directors, has outside business relationships with other directors, or has served on the board of another corporation that engaged in a transaction that is the subject of the investigation. *Fagin*, 2007 WL 2176482, at *6.

A director is "disinterested" with respect to a particular issue if he or she has undivided loyalties and does not stand to receive from the challenged vote a personal financial gain that is not equally shared by the shareholders. *Fagin*, 2007 WL 2176482, at *5. A director may be "interested" -- as opposed to "disinterested" -- with respect to a corporate decision if the "decision will have a materially detrimental impact on a director, but not the corporation and the stockholders." *Rales v. Blasband*, 634 A.2d 927, 936 (Del. 1993). However, a director is not deemed to be "interested" simply because the director "approved the challenged transaction or because a shareholder alleges that the director would be reluctant to sue a fellow [director]." *PSE&G*, 173 N.J. at 290. As with the inquiry into director independence, "conclusory allegations that directors participated in and knew of the alleged wrongdoing or were direct

beneficiaries of the wrongdoing are insufficient[.]" *Prudential*, 282 N.J. Super. at 277 (citation and internal quotation marks omitted).

In the course of the investigation, the Special Committee and its counsel carefully considered whether they and the other outside directors of J&J's Board of Directors were independent and disinterested with respect to the subjects of the investigation. Notwithstanding the Consolidated Complaint's conclusory assertions that the directors breached their fiduciary duties and are therefore potentially liable to the Company, the allegations in the *Copeland* derivative complaint that members of the Special Committee are "biased," "disabled from investigating," and "conflicted," and the allegations in the *Cafaro* and *Wollman* complaints that the directors are "compromised from fairly evaluating the derivative claims," the Special Committee members and counsel do not have any doubt as to their independence or disinterestedness or that of any other outside director. They have no personal interests that would render them incapable of deciding the corporate merits of the issues presented; nor (for the reasons discussed below) do they believe they are exposed to any meaningful risk of personal liability for the claims asserted. Each Special Committee member affirmed his or her willingness to proceed diligently and objectively with the investigation, and to consider fairly whether it would be in the best interests of J&J to initiate or continue litigation against individual officers or directors if the investigation concluded that such litigation was warranted.

B. The Fiduciary Duties Of Care And Loyalty

Directors and officers are considered fiduciaries of a corporation, and the two basic duties that each owes to a corporation are the common law duties of care and loyalty.

In New Jersey, the standard of care is defined in the following terms: "Directors and members of any committee designated by the board shall discharge their duties in good faith and with that degree of diligence, care, and skill which ordinarily prudent people would exercise

under similar circumstances in like positions." *N.J.S.A.* 14A:6-14. This requires a director or officer to make an informed business decision before taking action. More specifically, the duty of care requires officials to be attentive and to inform themselves of all material facts reasonably available to them regarding a decision before taking action. Liability for breach of the duty of care is measured by a standard of "gross negligence." *In re PSE&G*, 173 N.J. at 291 (observing that shareholder committee report found no evidence of "gross negligence" on the part of the board); *Resolution Trust Co. v. Hovnanian*, 1994 U.S. Dist. LEXIS 19359, *21 (D.N.J. Oct. 13, 1994) (noting that New Jersey applies a "gross negligence" standard to directors' duty of care).

Here, however, it should be noted that J&J's Certificate of Incorporation provides that no director or officer "shall be personally liable to the Corporation or its stockholders for damages for breach of any duty owed to the Corporation or its stockholders," as permitted by New Jersey law. Under the New Jersey Business Corporations Act, *N.J.S.A.* 14A:1, *et seq.*, a corporation is permitted to limit or eliminate liability through its certificate of incorporation, except for acts or omissions (1) in breach of the duty of loyalty; (2) not in good faith or in knowing violation of the law; or (3) resulting in receipt of an improper personal benefit. *N.J.S.A.* 14A:2-7(3). Accordingly, by virtue of the terms of J&J's Certificate of Incorporation, J&J's directors and officers cannot be held personally liable for a breach of the duty of care unless such breach is so extreme as to constitute a breach of the duties of good faith or loyalty. *See N.J.S.A.* 14A:2-7(3).

But as explained above, the J&J Certificate of Incorporation does not insulate J&J's directors and officers from a breach of the duty of *loyalty*. The duty of loyalty requires that the best interest of the corporation and its shareholders take precedence over any material interest possessed by a director or officer and not shared by the shareholders generally. This duty is violated by "an act or omission which that person knows or believes to be contrary to the best

interests of the corporation or its shareholders in connection with a matter in which he has a material conflict of interest." *N.J.S.A.* 14A: 2-7(3).

The fiduciary duty of loyalty is not limited to cases involving financial or other cognizable fiduciary conflict of interests. It also encompasses cases where the fiduciary fails to act in good faith. As one court explained, the failure to act in good faith may result in liability because the requirement to act in good faith "is a subsidiary element, *i.e.*, a condition, of the fundamental duty of loyalty." *Stone v. Ritter*, 911 A.2d 362, 370 (Del. 2006) (citation omitted). Put differently, "[a] director cannot act loyally towards the corporation unless she acts in the good faith belief that her actions are in the corporation's best interest." *Guttman v. Huang*, 823 A.2d 492, 506 n.34 (Del. Ch. 2003).

The duties of care and loyalty also obligate a board of directors to "exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations, so that it may satisfy its responsibility." *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 969 (Del. Ch. 1996). However, "the duty to act in good faith to be informed cannot be thought to require directors to possess detailed information about all aspects of the operation of the enterprise." *Id*. at 971.

The Delaware Supreme Court has explained that director "oversight" liability can be established where:

> (a) the directors utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention. In either case, imposition of liability requires a showing that the directors knew that they were not discharging their fiduciary obligations. Where directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities, they breach

> their duty of loyalty by failing to discharge that fiduciary obligation in good faith.

Stone, 911 A.2d at 370 (emphasis in original).

The "oversight" standard therefore requires the existence of "red flags" -- and bad faith on the part of the board by consciously disregarding its responsibilities and failing to address inadequate systems or controls. The Delaware Supreme Court, however, has cautioned that a bad outcome does not equate with bad faith: in the absence of red flags that are ignored, "good faith in the context of oversight must be measured by the directors' actions to assure a reasonable information and reporting system exists and not by second-guessing after the occurrence of employee conduct that results in an unintended adverse outcome." *Id.* at 373 (citation and internal quotation marks omitted).

II. Other Factors Considered By The Special Committee

In determining how to respond to derivative allegations, the Special Committee also considered not only the likelihood of success on the merits in any litigation (*i.e.*, whether J&J would ultimately prevail on claims for alleged breaches of the duty of care and/or the duty of loyalty by directors or officers), but also the impact on J&J of pursing litigation as a whole -- positive or negative. The judgment as to whether a particular lawsuit should be initiated or maintained can involve a balancing of many different factors, including, among others, commercial, public relations, employee relations and legal considerations. In this case, the Special Committee considered the following additional factors.

A. Impact On Pending Or Potential Litigation

As described in more detail below, J&J continues to be subject to lawsuits and government investigations in connection with some of the same matters raised by the shareholder allegations. Thus, if the Company adopts derivative litigation, statements made by the Company

or its representatives in pleadings, depositions, or at trial could be deemed admissions and used against the Company in collateral litigation. In addition, to the extent that J&J takes positions in litigation against present or former officials and prevails, the result could be used against J&J and the Company could be prevented from taking an inconsistent position in collateral litigation.

B. Indemnification

J&J's By-laws mandate that the Company, "[t]o the full extent permitted by the laws of the State of New Jersey," indemnify any director or officer "who was or is involved in any manner . . . in any threatened, pending or completed investigation, claim, action, suit or proceeding, whether civil, criminal, administrative, arbitrative, legislative or investigative . . . by reason of the fact that he or she is or was a director or officer of the Corporation . . . ." *N.J.S.A.* 15A:3-4(c) permits indemnification of a corporate agent, *inter alia*, "if the agent acted in good faith and in a manner which the agent reasonably believed to be in or not opposed to the best interests of the corporation." The indemnified director or officer is entitled to indemnification against expenses (including legal fees), judgments, fines, penalties and settlements paid or reasonably incurred. Thus, if derivative litigation is pursued by the Company against certain officers and directors, J&J may be required to advance each of the named defendants all reasonable expenses incurred in defending the action. The expenses and amounts paid in a settlement may also be subject to indemnification, depending on the nature of the conduct at issue.

C. Application Of Insurance

The Special Committee also considered the application of insurance and whether J&J's insurance policy would apply if the Board adopted the derivative litigation and brought the claims itself. The Company's policy contains a standard "insured against insured" exclusion, pursuant to which damages incurred by the Company as a consequence of wrongful acts of an

insured officer or director may not be recovered under the policy, leaving only the personal assets of the officer or director as a source of compensation. However, the policy also contains an exception to the exclusion, in the case of a derivative complaint brought by shareholders who are not insured under the policy.

D. Time And Expense Of Litigation

Any litigation pursued by or on behalf of J&J would involve a substantial commitment of time and resources. Although many of the claims asserted derivatively appear to be duplicative of claims asserted in other litigation against the Company and/or its subsidiaries, J&J would nonetheless have to devote substantial resources to prosecuting the derivative claims.

E. Effect On J&J's Business Operations

The Special Committee also considered the potential detrimental effect that litigation could have on J&J's business and operations. Litigation against current or former directors or officers might damage employee morale and the Company's relationship with its employees. In addition, a derivative litigation could cause distractions and negatively impact the Company's focus on remedial measures, including compliance with the March 11, 2011 McNeil Consent Decree, discussed below.

PART FOUR

FACTUAL FINDINGS OF THE SPECIAL COMMITTEE

I. Background On Johnson & Johnson

J&J is a global pharmaceutical, medical devices, and consumer packaged goods company that was founded in 1886. It was incorporated on November 10, 1887 and family-owned until listed on the New York Stock Exchange in 1944. J&J is a "family of companies," comprised of more than 250 operating companies in 57 countries, and has approximately 114,000 employees worldwide. J&J's brands include numerous well-known household consumer products such as

the Band-Aid line of bandages, Tylenol medications, Johnson's baby products, Neutrogena skin and beauty products, Listerine mouthwash, and Acuvue contact lenses. The Company's corporate headquarters are located in New Brunswick, New Jersey.

J&J has several important corporate governance documents. First, J&J is a credo-based company. Robert Wood Johnson, the former Chairman from 1932 to 1963 and a member of the Company's founding family, crafted the J&J "Credo" in 1943. The Credo challenges J&J to put first the needs and well-being of the doctors, nurses, patients, and customers that it serves. It also sets forth the Company's responsibilities to its employees, the local and global community, and its shareholders. A number of witnesses have observed that the Credo is a living document that continues to shape and influence the J&J culture.

Second, J&J's Policy on Business Conduct sets forth the Company's commitment to conduct its business affairs with integrity and comply with governing laws and regulations, and is binding on all J&J directors, officers and employees. J&J requires the management teams of its operating companies to certify their compliance with this Policy on an annual basis.

Third, the Code of Business Conduct and Ethics for Members of the Board of Directors and Executive Officers sets forth the requirements for directors and officers with respect to conflicts of interest, fair dealing, gifts, compliance with laws and regulations, use of non-public information and disclosure, and use of Company funds.

A. Management Approach And Organization

J&J has a decentralized operating model. With more than 250 operating companies located throughout the world, J&J views its decentralized model as an asset and fundamental to the success of its broadly-based health care business. This model allows each of its individual operating companies to function in a small company setting, while drawing upon the resources of a Fortune 50 company.

J&J's operating companies are organized into three business sectors: (1) Consumer, (2) Pharmaceutical, and (3) Medical Devices and Diagnostics ("MD&D"). The Consumer sector manufactures and sells a broad range of products used in the baby care, skin care, oral care, wound care, and women's health care fields, as well as nutritional and OTC pharmaceutical products. The Pharmaceutical sector manufactures and sells products in the following areas: anti-infective, antipsychotic, contraceptive, dermatology, gastrointestinal, hematology, immunology, neurology, oncology, pain management and virology. The MD&D sector product line includes a broad range of products distributed to wholesalers, hospitals and retailers used principally by physicians, nurses, therapists, hospitals, diagnostic laboratories and clinics.

Each business sector is led by a Worldwide Chairman, who also heads the respective sector's Group Operating Committee ("GOC"). The GOCs, which are comprised of senior managers, oversee and coordinate the activities of the domestic and international operating companies within the sectors. Each operating company is led by a company Chairman, President, General Manager or Managing Director, who, in turn, reports directly, or through a line executive, to the sector Worldwide Chairman and GOC leader.

In addition to the business sector GOCs, J&J also has a Corporate GOC. That GOC is responsible for overseeing and managing the Corporate Center and administrative functions at J&J, including, among other things, compliance, information technology, finance, legal and human resources (the "Corporate Center").

In 2010, J&J's worldwide revenues totaled approximately $61.6 billion, with net earnings of approximately $13.3 billion. The operating profits for each business sector in 2010 were as follows: Consumer -- $2.3 billion; Pharmaceutical -- $7 billion; and MD&D -- $8.3 billion.

B. Executive Management

Mr. Weldon is the current Chairman of the Board and CEO of J&J. He assumed those responsibilities in April 2002, and previously served as Worldwide Chairman, Pharmaceuticals Group, and Vice Chairman of the Board of Directors.

J&J's Executive Committee is the principal management group responsible for the overall operations and allocation of the resources of the Company. The Executive Committee oversees and coordinates the activities of the Company's three business sectors. Ultimately, it reviews financial results and develops strategies and initiatives for long-term growth.

C. Board Of Directors

J&J's full Board is currently made up of eleven members, ten of whom are "independent" under the rules of the New York Stock Exchange. The Board appoints senior management of the Company, provides oversight of management, and forms Board committees to assist in fulfilling its obligations. In conjunction with J&J senior management, the Board discusses and oversees the strategic direction and major developments within J&J's various businesses.

J&J has six standing Board committees: (1) Audit Committee, (2) Compensation and Benefits Committee, (3) Nominating and Corporate Governance Committee, (4) Finance Committee, (5) Public Policy Advisory Committee, and (6) Science and Technology Advisory Committee. The Audit Committee assists the full Board with oversight of Health Care Compliance ("HCC") and Quality and Compliance ("Q&C") (jointly, "Compliance"), as described in the next section. The Audit Committee meets formally at least four times per fiscal year, and holds separate private meetings regularly with the Vice President of Internal Audit, the independent auditors, the General Counsel, the Chief Compliance Officer and the Chief Financial Officer to discuss Compliance updates, issues, and concerns. Before each Audit

Committee meeting, the Directors receive information packages detailing the various issues to be discussed when they convene.

The Audit Committee monitors Compliance by receiving regular reports on J&J's Compliance programs, major legal matters, and findings by regulatory authorities or agencies. It also oversees the Company's system for escalating and handling significant sensitive issues and employee complaints. Moreover, the Audit Committee discusses with senior management the audit risk assessment process and results of the Corporate Internal Audit Department's activities, as well as reports from the Compliance Committee.

II. J&J's Corporate And Board Oversight Of Compliance

At J&J, HCC and Q&C encompass separate and distinct areas. HCC involves the collective set of laws, regulations and industry standards impacting the research and clinical development, promotion, and marketing of health care products and services. Thus, the term HCC covers a wide array of activities, including topics such as payments or gifts to health care professionals or government officials, marketing and promotion of drugs and medical devices, government contracting, and privacy.

Q&C, in turn, relates to all regulated and non-regulated quality functional areas, such as: (1) quality assurance, including oversight of manufacturing plants and suppliers; (2) quality control, including clinical and laboratory testing; and (3) compliance with FDA regulations, including independent audit, escalation management, and health authority interactions. As a result, it encompasses J&J's oversight and quality management of products and services, as well as sites and operating companies.

A. Evolution Of Corporate Oversight Of Compliance

The operating companies, business sector GOCs, and the Corporate Center share responsibility for, and oversight of, Compliance at J&J. In light of J&J's decentralized operating

model, primary responsibility for Compliance has always resided at the operating company level, with varying degrees of oversight by the Corporate Center over time. J&J's rationale for this approach is that the personnel closest to the ground are most knowledgeable about the business and must take full responsibility for the quality of its operations and products. Compliance cannot simply be imposed from above; it must start at the manufacturing and procurement levels.

1. Pre-Corporate Center Review (1990s-2006)

J&J strengthened its corporate oversight of Compliance in the late-1990s to early-2000s. At that time, the Technical Resources Group, along with J&J's Law and Corporate Internal Audit Departments, oversaw Compliance at the corporate level. In 1999, the Law Department issued guidance documents called "Brightlines," which provided guidance on allowable marketing, promotional, and sales practices under the domestic health care regulatory and fraud and abuse laws. "Brightlines" have been revised periodically to incorporate new guidance documents and updates. To oversee and reduce compliance risks, J&J also began to use and/or improve upon various assessment tools and processes. For instance, J&J has utilized the Management Awareness and Review Systems ("MAARS") since at least 2000. MAARS receive input from four primary sources: (1) self-assessments completed by the operating companies; (2) business analyses; (3) joint assessments/internal audits; and (4) testing and monitoring. These inputs are then translated into a management action plan ("MAP") to address Compliance risks or violations. The MAP promotes accountability at the operating company level by setting priorities and identifying resource plans with specific measurable actions and completion dates.

The Corporate Internal Audit Department performs the internal audit function within J&J. The scope of that Department has expanded over time from reviews and assessments of financial controls and integrity to include government contract compliance reviews, reviews of major contracts with key vendors, HCC reviews, FCPA reviews, sensitive issues investigations, for-

cause investigations, and assignments from the Triage Committee. Corporate Internal Audit conducted its first HCC audits in 2003 and began performing regular HCC audits in 2004. Corporate Internal Audit also completed its first pilot FCPA audit in 2006 and has been performing routine FCPA audits since 2007.

On May 3, 2003, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") issued Compliance Program Guidance for Pharmaceutical Manufacturers (the "OIG Guidance"). The OIG Guidance reflected the government's increased focus on fraud and abuse in federal health care programs. It provided a voluntary set of guidelines that set forth seven elements of an effective compliance program. In accordance with the OIG Guidance, J&J issued the U.S. Health Care Compliance Framework ("HCC Framework") in July 2004. The HCC Framework was designed to provide further guidance to the U.S. operating companies on the elements of J&J's HCC program. The HCC Framework built upon Brightlines and had the approval of the Executive Committee. It required each major U.S. operating company to (1) develop written HCC policies, (2) appoint a compliance officer ("HCC Officer") and establish an HCC Committee, (3) establish a documented annual training process, (4) develop open communication between management and employees regarding HCC concerns, (5) audit and monitor HCC, (6) develop a documented enforcement and disciplinary action policy, and (7) utilize a system to address HCC issues.

Several significant corporate organizational changes followed in 2004. Technical Resources Group was renamed Technical Resources and Compliance ("TRC"), and the head of TRC, Brenda Davis, was appointed Corporate Compliance Officer, reporting directly to Russell Deyo, J&J's Chief Compliance Officer and General Counsel. Moreover, in March 2004, J&J established the Worldwide Office of Health Care Compliance (the "Worldwide HCC"), which was intended to increase corporate oversight of HCC.

That same year, J&J restructured the corporate quality governance organization to reflect the global nature of J&J's business as well. The previous corporate quality organization, Quality & Compliance Services, was renamed Quality & Compliance Worldwide ("Q&C Worldwide").

In addition, J&J replaced its Regional Quality Councils with the Global Quality Council ("GQC") and Global Quality Operating Groups aligned with the three business sectors. The GQC was comprised of senior quality heads and representatives from the sectors. It met three times per year and its roles and responsibilities fell into four categories: (1) governance (ensuring a unified Q&C direction aligned with business strategies), (2) talent management, (3) risk management, and (4) outreach. The Global Quality Operating Groups' roles and responsibilities fell within the same four categories, and they undertook projects as requested by the GQC.

With the domestic Compliance programs under way, J&J focused on its international operating companies in 2005. In May 2005, J&J issued the International HCC Framework (the "International Framework"), the International Compliance Guide ("International Guide") and International Compliance Guide Questions and Answers. The International Guide provided a set of common *minimum* standards for interactions with health care professionals abroad. Mirroring the U.S. Framework, the International Framework set forth the seven elements of J&J's international HCC program.

2. Corporate Center Review (2007-2008)

After ramping up its corporate oversight of Compliance in the preceding years, J&J restructured the Corporate Center in early 2007, pursuant to a Corporate Center Review ("CCR") conducted in 2006 with the assistance of the consulting firm McKinsey & Co., Inc. The purpose of the CCR, among others, was 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. As a result of the CCR, J&J reorganized the Corporate Center and streamlined its role both structurally and functionally. The objective of the restructuring was to "shift accountability for compliance risks to GOC/Franchises," while reducing the burden on the operating companies and sustaining "enterprise-wide Quality & Compliance performance levels." The roles of the Corporate Center, GOCs and operating companies were clarified and refined to improve efficiency, effectiveness and accountability for Compliance risks. In essence, the corporate Compliance philosophy became "pull not push." The corporate Compliance organizations no longer "pushed" themselves onto the operating companies, but responded to requests for assistance or advice from the operating companies.

Following the CCR, Worldwide HCC staff was reduced by 25%, from 16 to 12, and various tasks that the corporate organization once handled transitioned to the GOCs and operating companies. Worldwide HCC now concentrated on a core set of six primary responsibilities: (1) partnering with the Law Department and business leaders to develop global HCC policies and procedures; (2) providing independent oversight through *focused* audits and partnering with the Law Department and Corporate Internal Audit to support the HCC and FCPA audit programs; (3) informing J&J's senior management and the Board about enterprise-wide HCC information and critical issues; (4) managing certain enterprise-wide services; (5) providing technical, regulatory and compliance expertise; and (6) shaping the external environment. At the same time, the operating companies retained full responsibility for implementing and ensuring compliance by developing company-specific HCC policies and standard operating procedures. In addition, the GOCs and operating companies became responsible for managing the HCC self-assessment process, performing routine MAP reviews, preparing new general HCC training modules, and overseeing the annual certification process.

Like Worldwide HCC and other parts of the Corporate Center, Q&C Worldwide's organization and functions were streamlined following the CCR. Q&C Worldwide headcount was reduced by 35%, from 43 to 28, and the organization no longer had responsibility for implementing the oversight processes used to monitor and ensure Q&C at the operating company level, which were instead moved to the operating companies and GOCs. The primary responsibilities of Q&C Worldwide became (1) identifying emerging regulations and industry practices affecting Q&C; (2) providing expertise through technical and regulatory consulting in support of operating companies dealing with global regulatory agencies; (3) establishing compliance policies and coordinating a decision-making forum to allow quality leaders to network and collaborate on common themes; (4) developing talent; and (5) creating visibility of compliance risk by providing independent oversight through *focused* risk assessments and rolling up enterprise-wide information.

Shortly after the CCR, J&J appointed a new Chief Compliance Officer in 2007. J&J also created a new Compliance Committee, which was chaired by the Chief Compliance Officer and comprised of senior leaders from several corporate functions (*i.e.*, Corporate Internal Audit; Human Resources; the Law Department; Worldwide Operations; Q&C Worldwide; Worldwide HCC; Environment, Health and Safety; and Privacy) and the three sector Chief Compliance Officers. The Compliance Committee is responsible for approving sector-specific and corporate policies, procedures and programs, and reports to the Executive Committee and the Audit Committee of the Board of Directors. The Compliance Committee also oversees HCC, Q&C, environment, health and safety, privacy, anti-corruption laws and regulations, and compliance with the regulatory requirements of health authorities.

In addition, J&J formed the Triage Committee in 2007. The Triage Committee consists of the J&J Chief Compliance Officer, as well as the members of the Compliance Committee who

represent Corporate Internal Audit, Security, the Law Department, and Human Resources. It was established to assure that serious issues were reported to and addressed by senior management in a timely fashion. A "serious issue" includes violations of law by management or multiple employees or that might involve a loss greater than $500,000. In 2009, J&J also began to characterize all potential violations of FCPA or local anti-corruption laws as serious sensitive issues. The Triage Committee has two standing weekly meetings, during which decisions are made as to which issues should be investigated and by which office. All significant matters reported to Corporate Internal Audit are placed on the Sensitive Issues Log.

In line with their responsibilities after the CCR, the corporate Compliance organizations issued or updated certain important policies. On October 10, 2007, the Law Department and Worldwide HCC issued the International Health Care Business Integrity Guide (the "HCBI Guide"). The HCBI Guide incorporated and expanded upon the International Guide, and contained enterprise-wide standards for compliance with a number of law and regulations (including the FCPA). The J&J Global Quality Community, with the approval of the GQC and Compliance Committee, also substantially revised the Quality Management Systems Policy ("POL-005" or "Quality Policy") in November 2007 to align with international standards and global developments. The revised policy outlined the expectations of a compliant quality management system, but did not provide prescriptive requirements for J&J operating companies to follow.

Pursuant to POL-005, each J&J operating company was required to (1) establish a quality management system that meets the POL-005 standards, regulatory requirements and any voluntary standards; (2) establish a risk management system that meets applicable regulatory requirements; (3) establish and effectively execute a documentation system to assure the planning, operation and control of the quality management system; (4) ensure that the quality

management system is maintained and that customer needs and regulatory requirements are met; (5) identify and provide necessary resources, including infrastructure and trained personnel; (6) establish processes for research, design and development appropriate for meeting customer and regulatory requirements; and (7) establish various policies and processes for measurement, analysis and reduction of Q&C risks.

At the end of 2008, J&J issued the Escalation Procedure, which requires that the Vice President of Corporate Internal Audit be notified within three business days of any significant violations of J&J policy or law. Such violations may be uncovered as the operating companies review, test and monitor their internal controls over compliance policies and programs, or they may be identified through letters, hotline calls or reporting by employees directly to the Law Department, Corporate Internal Audit, line management or other corporate staff. Corporate Internal Audit ensures that there is a timely investigation and resolution of potential violations and it reports on such matters to senior management and, where appropriate, the Audit Committee.

3. Post-Corporate Center Review (2010-2011)

Beginning in approximately January 2010, J&J reorganized and strengthened its corporate and enterprise-wide Compliance functions. In particular, in January 2010, after a months-long internal, cross-sector study named "Project Rubik," Chairman and CEO Mr. Weldon announced the transition to an enterprise-wide coordination of the supply chain. As a result, Ajit Shetty, Corporate Vice President, Worldwide Operations, assumed responsibility for the J&J Supply Chain, and reports to J&J Vice Chairman Alex Gorsky, who, in turn, reports to Mr. Weldon.

Part of the organizational design for the J&J Supply Chain includes a new operating model for Q&C. Headed by Kathryn Wengel, who was appointed J&J Chief Quality Officer and

reports directly to Dr. Shetty, the operating model creates a single framework for quality across J&J, with one common set of Q&C elements and quality standards by product types. Although all units will align to common standards in applicable areas, individual quality systems execution and responsibility will remain with the operating companies.

To lead this new Q&C operating model, J&J announced the selection of a Quality & Compliance Leadership Team (the "Q&C Leadership Team") in August 2010. The Q&C Leadership Team sets the objectives of the enterprise Quality organization and provides leadership, oversight and support to enterprise Quality functions. In addition, its role includes establishing compliance standards and overseeing and deploying enterprise level processes to assess compliance risks.

Under the Q&C operating model, each business sector now has a Chief Quality Officer ("CQO"). The CQOs have responsibility for developing Q&C strategy, performing oversight and achieving quality results for their sectors. The CQOs report directly to the J&J Chief Quality Officer and have a "dotted line" reporting relationships to their respective Worldwide Chairmen. In addition, business-based Q&C leaders will report into their business heads directly and have a "dotted line" relationship with sector CQOs. Lastly, the Q&C Leadership Team includes members with cross-sector responsibilities: Enterprise Regulatory Compliance, Enterprise Quality Systems, Enterprise Customer & Logistics Services/Market Quality, Enterprise Operations Readiness & Convergence, Sterile Process Technology, Enterprise Quality Strategy, Enterprise Strategic Quality Leadership, GCP/GLP/PV Quality, and Information Technology Q&C.

Through the new Q&C organizational design, J&J also realigned and expanded the Enterprise Regulatory Compliance and Audit organization. This change is meant to improve the inspection readiness of operating companies and to ensure robust mandatory independent

assessments. It will involve a two-tier audit program (Enterprise Regulatory Compliance and Sector) designed to assess quality processes against J&J recognized standards from top-down and bottom-up approaches, as well as to provide transparency of issues to multiple levels of management. The Enterprise Regulatory Compliance audit schedule has been formulated to audit all sites on a three-year rotation, with high risk sites being audited more frequently. Any significant issues found through these audits will be escalated and reported to senior management.

Most recently, on March 31, 2011, J&J issued a new Quality Policy entitled "POL-001," which supersedes POL-005 and was approved by the J&J Chief Quality Officer. Among other things, POL-001 mandates that each J&J operating company undertake responsibility for the "quality of, and meeting the applicable requirements for, the products that it develops, manufactures and/or markets, and for products it manufactures or supplies for non Johnson & Johnson companies." In addition, each operating company must: (1) establish a quality system that meets the requirements of POL-001, the applicable regulatory requirements, and the requirements of any voluntary compliance or certification standards; (2) design a quality system to provide sufficient visibility and triggers to assure safety, efficacy, and quality products throughout their full lifecycle; (3) provide the necessary resources for the implementation, maintenance, and improvement of the quality system; (4) define the roles and responsibilities necessary to ensure compliance with POL-001; (5) identify the processes needed for the quality system together with the criteria and methods for the operation and control of these processes; and (6) maintain written agreements defining responsibilities when one J&J operating company produces product and/or provides services for another operating company.

J&J also created one integrated, enterprise-wide Office of Health Care Compliance & Privacy ("OHCC&P), led by J&J's Chief Compliance Officer, Willy Vanbuggenhout. The

mission of OHCC&P is to "[i]mplement and maintain effective and efficient compliance programs that facilitate sustainable & compliant growth in partnership with our businesses and protect the reputation of Johnson & Johnson for integrity and patient care." The broad scope of OHCC&P, among other things, covers issues dealing with: FCPA, False Claims Act, off-label promotion, Anti-Kickback Statute, corporate integrity agreement/deferred prosecution agreement implementation, and all interactions with health care providers and government officials. In sum, OHCC&P is responsible for providing infrastructure and guidance across J&J that effectively prevents and/or detects violations of law, regulations, policies and codes of conduct.

The strategic priorities of OHCC&P are to: (1) strengthen global compliance; (2) advance talent, leadership & capabilities; and (3) achieve operational effectiveness, efficiency and compliance. To meet these priorities, OHCC&P provides the following:

- Compliance oversight and governance -- develops and deploys standard policies and procedures, monitoring, communication, and training, as appropriate; and drives continuous improvement through corrective action processes and MAPs.
- Visibility to compliance risks through assessments.
- Timely and appropriate resolution of critical compliance issues.
- Monitors compliance-related incentives and disciplinary actions.
- Shapes the external compliance-regulatory environment.
- Partners with the businesses to ensure a culture of compliance, as well as to advance compliance talent, leadership and capabilities.

In conjunction with the reorganization of HCC and Q&C, the Compliance Committee has expanded and clarified its mission to: (1) coordinate, oversee and facilitate exchange of expertise and knowledge among the Compliance functions represented; (2) review and provide input into reports to the GOC, Executive Committee, Audit Committee and/or Board; (3) escalate Compliance issues, when appropriate, to relevant management or governing body; (4)

review and discuss emerging Compliance concerns and recommend actions, as appropriate; (5) synchronize and leverage, where possible, Compliance requirements, tools and actions to manage the treatment of Compliance risks; (6) provide input, as appropriate, into J&J's Enterprise Risk Management and sustainability programs; and (7) recommend models of business partnership to Compliance functions.

The Compliance Committee membership now includes the J&J Chief Compliance Officer, Integration Leader, four Corporate and Sector HCC Officers, Vice President of Internal Audit, Corporate Secretary, Corporate Vice President of Worldwide Operations, Chief Quality Officer, and representatives from the Law Department and Human Resources. The frequency of Compliance Committee meetings has increased from quarterly to quarterly full day meetings with full membership in preparation for GOC, Executive Committee, and Audit Committee meetings, and a standing committee meeting every two months by telephone.

B. Board Oversight Of Compliance

The Board, primarily through the Audit Committee, monitors and oversees Compliance at J&J. The Audit Committee receives updates on significant changes or issues relating to the Compliance oversight systems, which are usually presented by representatives of the corporate Compliance organizations or the Legal Department. Corporate Internal Audit also conducts compliance audits (including HCC and FCPA-specific audits) and presents reports at Audit Committee meetings. The Corporate Internal Audit reports submitted to the Audit Committee typically include information about audit results, recent trends and risks, audits that resulted in inadequate conclusions, and sensitive issues. The Compliance Committee also regularly reports to the Audit Committee on its activities, such as the results of risk assessments and the metrics and procedures used to oversee J&J's Compliance operations. And the Law Department at every

meeting provides the Audit Committee and Board of Directors with reports and updates on on-going government investigations and significant legal proceedings.

In turn, the full Board receives Compliance reports from the Audit Committee, Executive Committee, representatives of the corporate Compliance organizations, Legal Department, and senior management at its regularly-scheduled and special meetings. The Audit Committee reports to the full Board after each Committee meeting, and reviews with the Board any significant issues or concerns implicating Compliance. The Board also periodically receives reports directly from corporate Compliance representatives and GOC leaders with respect to J&J's Compliance systems, changes to the Compliance organizations, Compliance issues and risk assessments. In addition, the General Counsel or other members of the Law Department usually update the full Board on the status of important legal matters involving Compliance issues as they unfold.

At the February 14-15, 2011 Board of Directors meeting, J&J senior management presented a "Board Risk Oversight Plan" which described J&J's approach to enterprise risk management, confirmed the responsibility of the Board for the oversight of risk management, and set the schedule for presentation of reports to the Board during the year. Of particular relevance here, the Chief Compliance Officer and Chief Quality Officer will present reports on HCC and Q&C to the Audit Committee every quarter. There will also be quarterly reporting by the Law Department to both the Audit Committee and full Board on matters of significance. The full Board will meet at least annually with key members of management who oversee risk in their respective areas of responsibility. In addition, the Audit Committee will continue to meet in private sessions with the Chief Financial Officer, General Counsel, Chief Compliance Officer, Vice President of Corporate Internal Audit, and representatives of the Company's independent

auditors at the conclusion of every regularly scheduled Audit Committee meeting where aspects of risk management are discussed.

III. J&J's Quality And Compliance Issues

A. FDA Regulation Of Prescription And OTC Drugs

The manufacture of prescription and OTC drugs is regulated by the Federal Food, Drug and Cosmetic Act (the "FD&C Act"), 21 U.S.C. § 301 *et seq*. The FD&C Act requires, among other things, that all drug products be manufactured in conformance with current Good Manufacturing Practices ("cGMP"). Drug products that do not satisfy these criteria are considered "adulterated."

The FDA is responsible for enforcement of the FD&C Act, and has promulgated regulations that require drug product manufacturers to employ "systems that assure proper design, monitoring, and control of manufacturing processes and facilities." The FDA's cGMP regulations are intended to "assure the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories." The FDA does not differentiate between the manufacture of OTC medications and prescription medications, treating both as drugs subject to the same cGMP requirements.

The FD&C Act and the FDA regulations are sparse on the specifics of what constitutes cGMP. The FD&C Act states only that manufacturers of drug products must employ cGMP. The FDA's implementing regulations, in turn, are only marginally more specific -- requiring, for example, that laboratory facilities be "adequate," that manufacturing facilities be "of suitable size, construction and location," and that certain equipment be used "when appropriate." The

FDA asserts that this level of generality provides a flexible approach "to allow each manufacturer to decide individually how to best implement the necessary controls . . . ."

The FDA enforces cGMP compliance by, among other ways, periodic inspections of manufacturing facilities. If FDA inspectors find "observed problems" with any aspect of the facility or operations, they are required to provide the facility's top management official with their observations (usually at the conclusion of the inspection) on an Inspectional Observations form known as Form FDA 483 (the "483"). Such observations are just that; they are not violations. Inspections that do not result in a 483 with one or more observations are increasingly unusual. "When a company receives a Form 483, it usually submits a written response to the FDA disputing or explaining the inspector's observations, or promising to correct the problem if the company agrees that it exists." *Fujisawa Pharm. Co. Ltd. v. Kapoor*, 16 F. Supp. 2d 941, 943 (N.D. Ill. 1998).

If the FDA is dissatisfied with a company's response to a 483, or if the FDA inspector finds conditions that deviate sufficiently from cGMP, the FDA may issue a "Warning Letter" which, if not addressed promptly and adequately, may lead to an enforcement action. According to the FDA's website, a Warning Letter "is an official notice to a regulated business establishment that objectionable conditions or practices have been identified in their operations, that corrections are expected, and that failure to correct the deficiencies may result in further FDA actions." All FDA Warning Letters are publicly available on the FDA's website.

FDA enforcement actions for cGMP violations vary and include requesting voluntary recalls, injunctions or seizures. The FD&C Act defines drug products manufactured outside of cGMP as "adulterated," and attaches criminal liability for selling adulterated drugs. Although there are many 483s issued every year, criminal charges are rare and are typically misdemeanor violations, but may be upgraded to felonies where there is evidence of intent.

Historically, the FDA has sought to enforce cGMP violations through consent decrees. While the exact terms vary, consent decrees often require an immediate plant shutdown, inspection by an independent cGMP consultant, correction of all cGMP deficiencies, FDA inspections, FDA approval to resume manufacturing, and payment of the FDA's costs. While the FD&C Act does not provide for monetary penalties for cGMP violations, in 1998 the FDA began seeking the disgorgement of profits from sales of purportedly adulterated drugs. For instance, in May 2002, the FDA entered into a consent decree with Schering-Plough Corporation which required Schering-Plough to pay $500 million as a disgorgement due to alleged cGMP violations at several of Schering-Plough's facilities.

In recent years, the FDA under the Obama Administration has sharply increased its enforcement activities, as the FDA has hired significant numbers of new inspectors, conducted an increased number of facility inspections, issued greater numbers of Warning Letters, and projected an overall tougher compliance profile.

B. Quality Issues At McNeil OTC

The quality issues faced by J&J in the latter part of 2009 and continuing into 2011 arose principally (although not exclusively) out of operations at two of McNeil's OTC plants, in Fort Washington, Pennsylvania and in Las Piedras, Puerto Rico.

1. The Motrin Recall

McNeil manufactures Motrin IB at Las Piedras, and it is distributed in various packaging presentations. On October 23, 2008, McNeil discontinued the sale of Motrin IB packaged in 8-count vials ("Motrin 8's") due to poor sales. On November 20, 2008, caplets from two lots of Motrin 8's failed dissolution testing. The FDA was notified via a Field Alert Report. A root cause analysis was performed (although no root cause was determined), and dissolution samples

were taken from other lots. A Field Alert Report was submitted on December 18, 2008 to follow up on the status of the issue.

On January 22, 2009, in another follow-up Field Alert Report, McNeil informed the FDA that a medical assessment concluded "that the use of Motrin IB caplets from these lots is not likely to cause an increased risk of serious adverse health consequences." After a discussion between the San Juan District Office and the Site Quality Leader at McNeil's Las Piedras facility, a further follow-up Field Alert Report was submitted on March 23, 2009. That Report provided:

> In order to confirm that neither affected lot is available at the store level, a third party has been contracted to perform an in store assessment. A statistical sampling of twenty-five (25) percent of all stores across the US that received these batches will be visited. If this assessment confirms that there is no product from batches SCH003 and SCH004 at the store level, a recall will be considered not necessary due to unavailability in the market; otherwise a recall of these Motrin batches will be recommended to be performed. The assessment is expected to be completed by April 15, 2009.

The third-party assessment took place in April 2009. It found that, in fact, a small amount of inventory from the two lots remained on shelves. On April 20, 2009, according to a McNeil Record of Regulatory Quality Authority Contact, the Las Piedras QA Manager called the Director of the San Juan District Office "to confirm the strategy to be followed to complete the product retrieval due to the Motrin dissolution failure on two batches." The QA Manager informed the Director that it was McNeil's "intention . . . to continue visiting the retail stores to collect all the product and that decision was based on the low volume . . . . [The District

Director] agreed with the strategy."[5] McNeil was advised to contact the recall coordinator to document evidence of the retrieval process.

The following day, McNeil submitted another Field Alert Report, reporting:

> As stated in the previous Field Alert Report follow-up issued on March 23, 2009, in order to confirm the availability of Motrin batches SHC003 and SHC004 at the retail level, a statistical sampling of approximately ten (10) percent of all stores across the US that received these batches were visited (250 stores out of 2000). The assessment performed demonstrated that, on a statistical basis, a low amount of product (approximately 1% of the batches) is potentially still at the retail level. The product from the subject lots found in the stores was removed during the visits. Visits to the remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found.
>
> A Health Hazard assessment has indicated that the use of Motrin IB caplets of the above batches is not likely to cause an increased risk of serious adverse health consequences. In addition, a review of our complaint history indicates that neither affected lots have had complaints registered against them from November 1, 2008 through April 13, 2009.

McNeil did not advise the FDA that the product that had been removed during the initial visits had been purchased by the third party conducting the assessment. Nor did it advise the FDA that the removal of the product during the subsequent visits would also be purchased. Although Mr. Weldon in his September 30, 2010 Congressional testimony acknowledged that this was a "mistake," there does not appear to have been any intention to mislead the FDA.

The Product Purchase & Ship Instructions that McNeil sent to the third-party contractor (Inmar Field Analysts) instructed, in part: "DO NOT communicate to store personnel any information about this product. Just purchase all available product. If you are questioned by store personnel, simply advise that you have been asked to perform an audit and refer them to

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[5] An e-mail message to McNeil management touted this agreement with the FDA as "a major win for us as it limits the press that will be seen."

Amanda Harper at [telephone number]."[6] In her September 30, 2010 Congressional testimony, Ms. Goggins expressed her belief that "McNeil should have handled things in a more straightforward manner with the retail stores," and that, "were we to do this over, we would certainly be more transparent, particularly with the store personnel." Mr. Weldon testified to similar effect.

In July 2009, after several attempts to contact the San Juan District Office recall coordinator, McNeil was finally able to establish contact with the recall coordinator. In response to inquiries about how to document the retrieval process, the recall coordinator advised McNeil that the process should be documented as a recall. McNeil therefore submitted recall documentation on August 5, 2009, reporting that its representatives had removed all marketed product found at retail.[7]

2. The B. Cepacia Issue

In 2008, the FDA had inspected the Fort Washington and Las Piedras plants and issued 483s, but the observations (three at Fort Washington, two at Las Piedras) were not considered significant by McNeil. On June 4, 2009, however, after again inspecting Fort Washington, the FDA issued a 483 with six observations, three of which were deemed significant by McNeil and related to what became known as the "B. cepacia" issue.

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[6] Unbeknownst to McNeil, Inmar Field Analysts retained a subcontractor to purchase the Motrin 8's remaining on the retail shelves. That subcontractor's instructions to the field (of which McNeil was unaware) provided in pertinent part: "THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT! If asked, simply state that your employer is checking the distribution chain of this product and needs to have some of it purchased for the product."

[7] In February 2010, McNeil advised the San Juan District Office that it had decided to recall another Motrin lot as a precautionary action, even though retained samples of the lot had not failed periodic testing during the prior 18 months.

Avicel RC-591 ("Avicel") is a raw material used to manufacture pharmaceutical excipients or suspensions. McNeil used Avicel as a suspending matrix in 14 formulas of Tylenol. McNeil obtained Avicel from an outside vendor, FMC BioPolymer ("FMC"). Over the course of a two-month period in early 2008, McNeil received five separate drums of Avicel from FMC that were all produced from the same FMC vendor lot. Of those drums, the first, third, and fourth were accepted. The second drum, received on February 15, 2008, was rejected due to defective liners. When testing was performed on the fifth drum, received on April 7, it revealed the presence of Burkholderia cepacia ("B. cepacia"), a gram negative microorganism. No B. cepacia was detected in the first, third, and fourth drums, nor was any found in finished product manufactured using the Avicel from those three drums.

McNeil's Quality Assurance management decided to hold all shipments of finished product manufactured using Avicel from the accepted drums pending the results of an investigation. The investigation focused on FMC, and found that the Avicel manufacturing process was hostile to bacteria growth and that the Avicel processing steps were in a state of control. Concurrently, McNeil performed additional studies that confirmed the absence of B. cepacia in the finished product and concluded that the health risk from B. cepacia contamination in the finished product would be remote. As a result, McNeil released the product manufactured from Avicel drums 1, 3 and 4.

In the June 4, 2009 Fort Washington 483, the FDA faulted McNeil for manufacturing and distributing approximately 57 lots of Infants' and Children's Tylenol using Avicel from the drums that did not test positive for gram negative bacteria, but that came from the same FMC vendor lot. The FDA considered this a failure to reject a lot that did not meet specifications. McNeil's response to the 483 explained what had occurred and what actions were being taken to minimize the possibility of receipt of contaminated Avicel in the future. McNeil concluded that

the released product was safe and did not pose any health risk. At a meeting on July 30, 2009, the FDA Philadelphia District nonetheless advised McNeil that it disagreed with this assessment and that a recall would be appropriate. McNeil accordingly issued a recall.

3. The "Musty Odor" Issue

In August 2008, consumer complaint trending revealed an atypical number of complaints of an uncharacteristic odor in two lots of Tylenol Arthritis Pain Caplets ("Tylenol Pain Caplets"). Distribution of the identified lots was halted and an investigation was launched into the cause of the complaints. The FDA was not informed via a Field Alert Report because the standard operating procedure then in effect did not require alerting the FDA with respect to complaint trends.

Microbiological testing was performed on bottles, caps, liners and tablets from the implicated lots. No microbiological contamination was found. A complaint profile review determined that the odor complaints were limited to the two identified lots and that adverse event reports for those lots were not atypical. An organoleptic panel convened for the investigation concluded that the odor in returned complaint samples was subjective and sporadic. After October 2008, uncharacteristic odor complaints dropped off significantly, and the trend returned to baseline. Based on the decreased complaints and the investigation findings, McNeil determined there was no product contamination issue and it discontinued its investigation.

However, in the summer of the following year, another trend of uncharacteristic odor complaints was identified for two lots of Tylenol Pain Caplets manufactured in 2009. The two lots were placed on hold, and an investigation into the cause was commenced.

McNeil sought the help of a third-party expert to try to determine what was causing the unusual odor. It retained Microanalytics, a forensic laboratory with unique testing capabilities that employs non-traditional and highly sensitive equipment and methodologies. On September

11, Microanalytics identified the likely cause of the musty odor as a chemical known as 2, 4, 6 tribromoanisole ("TBA"). The level of TBA detected in returned complaint samples was minute -- between 0 and 3,000 parts per trillion. Microanalytics subsequently determined that the TBA causing the musty odor resulted from the breakdown of a preservative chemical used to treat wood pallets on which packaging materials are stored.

On September 18, 2009, McNeil submitted a Field Alert Report to the FDA with respect to the musty odor issue. As the investigation progressed through the remainder of 2009, McNeil submitted several follow-up Field Alert Reports.[8] It initiated its first recall due to TBA on November 6, 2009. That recall included five lots -- the two identified in 2008, the two identified in August 2009, and an additional lot identified as having an abnormal complaint trend in September 2009. On December 18, McNeil expanded the recall to include an additional 59 lots.

Meanwhile, the FDA initiated an inspection of Las Piedras on October 22, 2009. The inspection concluded on January 8, 2010 with the issuance of a seven-observation 483. Most significant were the four observations relating to the TBA issue.[9] The FDA faulted McNeil on several counts:

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[8] In a November 13, 2009 Field Alert Report, McNeil disclosed that "[a] Health Hazard Evaluation was performed and showed an atypical volume of adverse events associated with the five product lots reporting nausea, vomiting, diarrhea and belching. The evaluation suggests that the observed symptoms are related to the odor or the etiology of the odor in the affected bottles. No adverse event reports were categorized as serious due to the symptoms related to uncharacteristic odor or taste. No adverse event reports were categorized as unexpected."

[9] The other 483 observations addressed (1) inadequate investigation of the root cause of the failure of the Motrin-8 batch to meet dissolution specifications; (2) the potential inability of cleaning and maintenance controls to prevent product mix-ups and contamination (this was subsequently supplemented on February 3, 2010 following an inspection on January 27-28 and February 3, 2010); and (3) McNeil's classification of some 123 "mix-up" related consumer complaints as "isolated events" rather than as a recurring observation reflecting the potential for product mix-up. Although significant and requiring upgrades of plant, equipment and

- Upon identifying in 2008 a trend of musty odor complaints for two lots of Tylenol Pain Caplets, and confirming the presence of musty odor, McNeil discontinued its investigation of the matter prematurely without determining the cause of the odor;

- After receiving similar complaints and adverse event reports in 2009 and identifying a trend in August, no Field Alert was initiated until September 18, 2009;

- After identifying the cause of the musty odor as being proximity to chemically-treated wood pallets, McNeil did not extend its investigation to other products with packaging components that may have been affected and that had received complaints of a musty odor; and

- Internal Standard Operating Procedures were not followed in pursuing the investigation.

On January 15, 2010, based upon the results of the investigation finding that wood pallets were the source of the TBA contamination, McNeil initiated a broad recall of 537 lots of various OTC products. On the same day, the FDA took the unusual step of issuing a Warning Letter to McNeil without awaiting McNeil's response to the January 8, 2010 Las Piedras 483.[10] The Warning Letter tracked the 483's TBA observations and informed McNeil that serious cGMP deficiencies observed during the recent Las Piedras inspection caused McNeil's products to be adulterated pursuant to the FD&C Act. In addition, the Warning Letter noted concerns that J&J did not act appropriately to resolve some of these issues as it became aware of the FDA's concerns. The letter requested a response within 15 working days and the scheduling of a meeting to discuss remediation and further involvement by J&J management.

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operations, these observations did not find their way into the January 15, 2010 Warning Letter, which was devoted exclusively to the TBA issue.

[10] The alacrity and severity of the FDA's response seems to have been animated by the fact that, at the time, little was known about TBA and it was unclear whether it posed any gastrointestinal or other health risk to humans. J&J promptly and thoroughly investigated the safety implications of TBA, including the evaluation of potential health hazards by an external expert, the conduct of toxicological studies, and the reassessment of adverse events. It concluded (and reported to the FDA) that TBA was "an odor issue, not a safety issue."

McNeil responded to the Warning Letter and 483 in separate letters dated February 5, 2010. The response to the Warning Letter explained:

> In McNeil's experience, many of the challenges raised by this particular investigation were unique. Only after we engaged Microanalytics, an external forensic laboratory, that has unique testing capabilities, did we determine that TBA was a likely source of the uncharacteristic odor. After McNeil confirmed the source of the odor, we were able to launch a comprehensive investigation focused specifically on how TBA could have entered the McNeil supply chain.
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> * * * *
>
> Our next challenge was to determine how TBA could have entered the supply chain. This stage of the investigation led us to review multiple potential sources of contamination, including, but not limited to caps/liners, bottles/resins, pallets, manufacturing/packaging lines, bulk product, and ingredients. We also conducted extensive literature searches and worked with toxicology experts to help us better understand the chemical and how to evaluate its potential toxicity. From this, we learned that there was no toxicity data available for TBA. Relevant Health Hazard Evaluations ("HHEs") were developed and provided to FDA. The scope of the investigation widened significantly before it narrowed. Each time our knowledge increased, we expanded our search for affected or potentially affected products.
>
> Based on this comprehensive forensic investigation, we traced TBA from certain bottles to wood pallets, and then, more specifically, to wood used to build the pallets that were sourced from Brazil and treated with 2, 4, 6-tribromophenol ("TBP"). From the literature, we know TBP can lead to the formation of TBA under certain environmental and handling conditions. Once we confirmed via analytical testing that these wood pallets were treated with TBP and were likely the primary cause of the TBA, we expanded our review to include other sites that had received these pallets and decided on January 14, 2010 to initiate the very broad recall of any potentially impacted products.

McNeil's response to the Warning Letter also outlined a corrective action plan that included enhancements to the Quality System, organizational changes and senior management oversight, as well as a remediation plan with respect to TBA and wood pallets. The response noted that Dr. Veronica Cruz had been appointed Vice President of Quality Assurance and that

she would lead a comprehensive assessment of the McNeil quality system and develop "a plan that would continue to strengthen our focus on complaint vigilance, corrective and preventive actions ('CAPAs') and quality systems." The 30-page response to the 483 addressed each observation individually, and also promised corrective actions.

On February 19, 2010, management from both McNeil and J&J met with FDA representatives. McNeil presented an overview of its investigation into the TBA issue along with its corrective action plan to address the cGMP issues in both the January 8, 2010 483 and the January 15, 2010 Warning Letter. There was a follow-up meeting on March 30, 2010, in which McNeil described the toxicological studies that were under way to determine whether TBA presented any health risks. At a further meeting with the FDA on May 14, 2010, McNeil presented the results of its toxicological studies, reporting that exposure to TBA presents a *de minimis* gastrointestinal risk, and that the sensitivity of humans to the musty smell makes TBA an odor issue, not a safety issue.

4. The Closing Of Fort Washington, Related Recalls, And Additional 483 Observations

On April 8, 2010, small black particles were observed in 3 out of 24 bottles of Infants' Tylenol coming off a filling line at Fort Washington. The particles were subsequently determined to be comprised of acetaminophen, nickel, chromium, tin, and bismuth. The FDA was notified of the discovery of particles on April 14 via a Field Alert Report. On that same date, McNeil voluntarily shut down Fort Washington's liquids manufacturing lines pending an investigation into the matter. A subsequent investigation determined that metal-on-metal wear of the pistons in equipment on the bottling line was the probable source of the particles.

FDA inspectors arrived at Fort Washington on April 19, 2010 for a general cGMP inspection. During the investigation, McNeil submitted both a follow-up Field Alert and a final

Field Alert explaining that liquids manufacturing was shut down at Fort Washington and that McNeil would be initiating a liquids recall. On April 30, solids manufacturing was also shut down at McNeil, putting a stop to all manufacturing activities at the plant. On the same day, McNeil announced a recall of all unexpired lots of OTC children's and infants' liquid products manufactured at Fort Washington. The recall notice (which was approved by the FDA) explained that the recall was being initiated because some of the products may not meet required quality standards, and that it was "not being undertaken on the basis of adverse medical events."

Also on April 30, the FDA wrapped up its inspection and issued a 20-observation 483. One of the observations noted that a failure to validate manufacturing processes had caused the manufacture of three "super potent" batches of Infants' Tylenol. This issue resulted from a change in the process of mixing particular flavors of Infants' Tylenol at the end of 2009, pursuant to which McNeil moved from manufacturing 500 gallon batches to 1000 gallon batches. Ten batches were manufactured using the new process over a five-month period. Three of those batches were rejected for being out of specification because they had elevated levels of the active ingredient.[11] These batches were never marketed to consumers.

On May 7, 2010, a conference call was held with the FDA regarding solids manufactured at Fort Washington. McNeil took the position that, although it had ceased production of solids at Fort Washington, a recall of those products was not necessary. McNeil later voluntarily recalled many solids manufactured at the Fort Washington plant.

McNeil's May 20, 2010 59-page response to the Fort Washington 483 addressed each observation and more generally described the Quality overhaul under way at McNeil. In a cover

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[11] The specification called for active ingredient assay to be in the range of 92.0% to 108.0%; the three out-of-specification batches contained active ingredient assays of 111.6%, 119.7% and 123.7%.

letter accompanying the response, McNeil explained that, prior to the end of the Fort Washington inspection, it had retained an outside consultant, the Quantic Group, Ltd. ("Quantic"), and that Quantic was helping McNeil develop a comprehensive action plan (the "Action Plan") by July 15, which McNeil would share with the FDA.[12] As the letter explained, the Action Plan would address governance and management controls, training and culture of compliance, full assessment and improvements, product assessments, and interim communication with the FDA.

On July 15, 2010, McNeil submitted its Action Plan to the FDA, outlining "McNeil's extensive plan to address quality, facilities, and operational and process controls to ensure long-term, sustainable compliance." Also addressed were "interim controls to ensure product quality is maintained throughout the remediation period." The Action Plan was single-spaced and 38 pages in length (with seven attachments, including five exemplar Protocols between McNeil and Quantic). The Action Plan consists of eight major components:

i. Regulatory Commitments and other Immediate Actions

ii. Governance, Management Controls and Cultural Transformation

iii. Product Quality and Process Integrity

iv. Interim Controls, Third Party Support and Mentoring

v. Facilities and Equipment

vi. Quality System Improvement Plan

vii. Fort Washington Restart Plan

viii. FDA Communication Schedule

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[12] Quantic is a recognized industry expert with significant experience with quality and compliance issues, including remediation planning and implementation. It has worked for a number of major pharmaceutical companies confronted with consent decrees.

In the Action Plan, McNeil committed to "cultural transformation" as a long-term strategy, with "Quality and Compliance First" as the Company's "first business imperative." McNeil also committed to report quarterly on its progress in meeting its 483 commitments and monthly on its progress in implementing the Action Plan. J&J senior management and Quantic officials have expressed confidence that the Action Plan will be accomplished in a timely fashion, to the satisfaction of the FDA. And although the FDA as a matter of practice does not formally approve remediation plans, it has at least tacitly accepted the "holistic" approach described in the Action Plan and the periodic updates on implementation progress.

In addition to the remediation steps described in the Action Plan and McNeil's responses to the 483s, J&J has initiated a number of organizational and personnel changes aimed to promote quality, compliance and performance. Some of these steps (including the new enterprise-wide Supply Chain, the new Q&C organization, and new Q&C policies and standards) have been discussed above in the section on Q&C compliance. Other personnel and organizational changes were described in the Action Plan (including changes in the Quality Assurance and Operations functions at the McNeil home office and its sites, as well as new Quality Assurance and Management personnel).

In February 2011, Jesse Wu, the current Worldwide Consumer Group Chairman, announced a new organizational model for the Consumer Group, effective April 4, 2011. Of particular relevance for purposes of this report, Mr. Wu reported in a message to "Consumer Colleagues" that, "[i]n order to give focused attention to quality and compliance, and the critical task of restoring our McNeil Consumer Healthcare brands, the U.S. OTC business will be a separate organization," reporting to a new Company Group Chairman (Pat Mutchler, an experienced and highly-regarded J&J senior manager). In March 2011, Mr. Wu and Kathryn Wengel (J&J's Chief Quality Officer) announced the appointment of Georgia Keresty, Ph.D., to

the position of Chief Quality Officer and Vice President, Quality & Compliance, Regulatory Affairs and Medical Safety, for the J&J Consumer Group of Companies. With the appointment, Dr. Keresty also becomes a member of the Consumer Group GOC. In April 2011, Mr. Mutchler announced the appointment of Denice Torres as President of McNeil Consumer Healthcare.

5. Subsequent Events

Fort Washington has been closed since April 30, 2010. The remainder of 2010 and the first half of 2011 saw continued recalls and efforts at remediation. In particular, the TBA recall was expanded on June 15, 2010, July 8, 2010, October 18, 2010, and March 29, 2011. After further internal compliance reviews pursuant to the Action Plan, other voluntary recalls have been announced relating to foreign material, uncharacteristic texture, and potential process deficiencies.[13] In addition, since the closure of Fort Washington, the FDA has issued additional 483s following subsequent inspections of Fort Washington, Las Piedras, and the McNeil's plant in Lancaster, Pennsylvania. McNeil responded to each of the observations in the 483s, describing the corrective actions it had taken or planned to take.

6. The Consent Decree

On March 10, 2011, McNeil, Veronica Cruz (the Vice President of Quality for the McNeil Consumer Healthcare Division), and Hakan Erdemir (Vice President of Operations, OTC Products, for the McNeil Consumer Healthcare Division) (collectively, the "McNeil Defendants"), entered into a Consent Decree of Permanent Injunction with the United States of America (the "McNeil Consent Decree"). The McNeil Consent Decree resolves all claims asserted in a Complaint for Permanent Injunction, filed the same day by the government, which

[13] In terms of quantity, the TBA-related recalls and the Fort Washington liquids and solids recalls constitute by far the bulk of the recalls initiated by McNeil during 2009-2011. Other, more limited, recalls included recalls due to label legibility and thin-walled bottles. Again, there was no indication that the causes for the recalls involved heightened health risk.

charged the McNeil Defendants with violating the FDA's cGMP regulations by causing the adulteration of drugs, and introducing adulterated drugs into interstate commerce.[14] The McNeil Consent Decree recites that the McNeil Defendants have consented to its entry, "without admitting or denying the allegations in the Complaint, and disclaiming any liability in connection herewith." Notably, the McNeil Consent Decree does not require McNeil to disgorge any profits or shut down its operations at Las Piedras and Lancaster; nor does it include J&J as a party defendant.

The McNeil Consent Decree enjoins production at Fort Washington until McNeil's "methods, facilities, and controls used to manufacture, process, pack, label, hold and distribute drugs at [FW] are established, operated, and administered in conformity with CGMP . . . ." To that end, the McNeil Defendants are required to retain an independent expert (the "cGMP Expert"), who must conduct a comprehensive investigation of Fort Washington, evaluate the adequacy of the facilities, equipment, manufacturing processes and quality assurance/quality control program, and certify to the FDA that all cGMP deviations have been corrected and that "Defendants' methods, facilities, processes, and controls . . . [at Fort Washington] are and, if properly maintained and implemented by Defendants, will continuously remain in conformity with applicable laws and regulations." The McNeil Defendants are also required, among other things, to establish adequate management controls and an effective training program and qualification practices, implement laboratory controls and building and facility control systems, and have processes in place to ensure the qualification of suppliers and the quality of purchased materials. Operations at Fort Washington may recommence once the FDA notifies the McNeil

[14] The McNeil Consent Decree does not resolve other potential liability for the Company, and explicitly carves out potential criminal charges, False Claims Act claims, common law claims, and debarment and/or exclusion penalties.

Defendants that they appear to be in compliance with the requirements of the McNeil Consent Decree. The McNeil Consent Decree expressly authorizes the cGMP Expert to rely upon the work performed at Fort Washington before the entry of the Decree.

Production at Lancaster and Las Piedras is not enjoined. The McNeil Defendants must retain a cGMP Expert to conduct a comprehensive inspection of both plants and report on any cGMP observations. The McNeil Defendants and the expert must then develop a work plan to address all observations, which work plan is to be approved by the FDA. The cGMP Expert shall verify the completion of each step of the work plan and produce quarterly progress reports until complete. The FDA may then inspect and verify that the work plan is complete. Failure to complete any work plan step on time may result in penalties of $15,000 per day. Until the FDA certifies that Lancaster and Las Piedras appear to be in compliance with cGMP requirements, it will not issue export certificates for the products made at those plants. While the work plan is in process, McNeil may continue to manufacture and release product, provided that the cGMP Expert conducts record reviews of selected batches of product and certifies that any deviations found do not adversely affect product quality.

The McNeil Consent Decree also provides that once all three plants have completed the above process, the McNeil Defendants must retain an auditor to conduct audit inspections at all three plants at least every six months for the first year, and annually thereafter for four additional years. Audit results must be reported to the McNeil Defendants and the FDA. If there are any deviations found, the FDA may extend the audit period, and all deviations must be corrected within 30 days or less. Failure to correct deviations on time may result in penalties of $15,000 per day. The auditor will review actions taken to address deviations and report to the FDA.

Other than the penalties for failure to comply timely with the McNeil Consent Decree or the work plans, or failure to correct deviations noted by the auditor in a timely fashion, the

McNeil Consent Decree does not impose any fine or other financial penalty. If the McNeil Defendants maintain the three plants in a state of continuous compliance for 60 months after satisfying all of the obligations imposed by the McNeil Consent Decree, they may apply to the Court for relief from the decree.

The McNeil Consent Decree builds upon the Action Plan, and essentially calls for an end-stage evaluation of whether McNeil is fully and reliably compliant with all cGMP requirements. As with the Action Plan, senior management and Quantic (the designated "cGMP Expert") have expressed confidence that McNeil and J&J will be able to comply fully and in a timely fashion with the McNeil Consent Decree. Quantic reports that McNeil is on schedule with compliance with the McNeil Consent Decree. J&J senior management have fully supported the McNeil remediation and compliance efforts with major infusions of capital and personnel. And as previously noted, J&J has reinforced and enhanced the Q&C organization and operation at the corporate level.

7. Root Causes

Although the demand shareholders and the derivative plaintiffs claim that J&J's quality problems were "systemic," they were largely confined to McNeil OTC. There appears to be no single cause for the developments at McNeil. Senior management never issued any directives to the effect that quality should be sacrificed for production; nor did anyone report to senior management that McNeil was in jeopardy of significant regulatory intervention because it was out of compliance with cGMP. The Special Committee finds that there was no breach of any fiduciary duty by senior management or the Board of Directors. McNeil and J&J employees appeared to have been acting in what they believed to be the best interests of the Company. And McNeil's and J&J's Q&C organizations, policies and procedures did not present any obvious

weakness or inadequacy that should have been corrected by senior management or the Board of Directors.

Nonetheless, and with the benefit of hindsight, it appears that several different factors may have contributed to the series of recalls, FDA Warning Letter, 483 observations, and, ultimately, the McNeil Consent Decree. McNeil had a string of successive leaders in a short period of time who may not have had sufficient understanding of what was taking place at the plant level -- although when Peter Luther took over as President of McNeil in February 2009, he introduced quarterly quality reviews and requested more substantive quality presentations. But issues began to arise before the reporting got into full gear.

At the plant level, there seemed to be a lack of attention to product quality by some non-quality personnel (especially in Engineering and Operations), which at times produced an adversarial relationship between Quality personnel and Operations. Periodic headcount freezes and an emphasis on production volume may have contributed to this situation. In addition, some equipment was outdated and insufficient.

J&J's acquisition of Pfizer Consumer Healthcare ("PCH") in December 2006 had a major impact on McNeil OTC, as PCH's OTC product lines were added to those of McNeil. PCH was J&J's largest acquisition to date, bringing to J&J over 3000 Stock Keeping Units of products. Given that 25% of PCH's total sales were of products made at manufacturing sites that would not be conveyed to J&J, product lines were added to Fort Washington and Las Piedras, increasing the volume and complexity of their operations and distracting from quality system improvements. Q&C headcount may not have increased sufficiently to adjust to this added complexity. Las Piedras, in particular, was not equipped for the changes needed as a result of the PCH acquisition.

A virtual hiring freeze in 2008-2009 made it difficult to hire additional McNeil Quality personnel. There was no compliance group within the McNeil Quality organization to conduct internal cGMP audits; such audits were performed by personnel from other plants. There was a single Quality Site Leader for Fort Washington and Lancaster during 2009 and part of 2010; the Quality Site Leader position at Las Piedras was open for more than four months during 2009. Although the Vice President for Quality of McNeil OTC (Robert Miller) was well regarded, he spent a significant amount of his time focusing on other matters (the integration of PCH into McNeil OTC in 2007-2008, and the enterprise-wide supply chain initiative (Project Rubik) in 2009). Two of his senior direct reports were out on sick leave for part of 2009.[15]

Although the FDA's inspection of the McNeil plants during 2006-2009 resulted in few observations of significant noncompliance, the internal audits conducted by the McNeil Quality organization and by one outside consultant in 2007 revealed some cGMP issues that went uncorrected for long periods of time. The observations resulting from the internal audits were supposed to be incorporated into Management Action Plans ("MAPs"), which were periodically reported to the McNeil Management Board, but the MAPs were incomplete, and the due dates for corrective actions were frequently postponed, yielding the impression that everything was under control.

Nonetheless, a January 22, 2009 report of an internal audit of Las Piedras, while rating that site overall as "marginal," noted that "[t]he site has made marked improvement from the 2007 inspection" (when it was rated "unsatisfactory"). Similarly, an October 15, 2009 report of

[15] Mr. Miller was not available for an interview by the Special Committee. Despite his unavailability, the Special Committee was able to gain what it considers to be an accurate and adequate perspective on the McNeil cGMP issues.

an internal audit of Fort Washington rated that site as "satisfactory" and noted that it had "demonstrated an impressive track record of improvement over the previous two audits . . . ."

After the PCH acquisition closed in December 2006, it was integrated into the Consumer sector; McNeil was also transferred from the Pharmaceutical sector to the Consumer sector. Unlike the GOCs of the Pharmaceutical sector and the MD&D sector, the Consumer GOC did not appoint a Chief Compliance Officer ("CCO") until June 2008. That CCO (Frank Konings) was only responsible for HCC, and did not sit on the Consumer GOC. Instead, McNeil OTC's Vice President of Quality (Mr. Miller) and McNeil Consumer's Vice President of Quality (Santosh Jiwrajka) reported to the Chief Technology Officer of the Consumer sector, Richard D'Souza, who was a member of the Consumer GOC. Mr. D'Souza was not trained in Quality and Compliance, and did not consider himself to be a "Quality" person. However, once the "musty odor" issue developed, he became intensively involved in the efforts to identify its cause and potential safety ramifications.

The quarterly reports that the Consumer GOC received with respect to Q&C at McNeil contained only retrospective metrics -- the number of inspections by health care authorities, the number of significant observations resulting from those inspections, and the number of product recalls. The results of the internal audits of the Fort Washington, Las Piedras and Lancaster plants were not included in those reports, although the McNeil Management Board did receive MAPs based upon those audits.

Internal audit results were, however, included in a new analytical model developed by the Q&C Worldwide organization in early 2007, which was designed to provide a proactive view of operating company Q&C risk on a plant by plant basis. Q&C Worldwide prepared charts, entitled "QScan Manufacturing Attribute Scores by Site," which contained a score from 1 to 10 for each of ten rated attributes -- one of which was "Focused Assessments/Internal Audits." The

individual ratings were then averaged to create a total score by site. A score of 7 or higher (color-coded red) indicated a critical condition. QScans during 2008 and 2009 for Fort Washington and Las Piedras reported critical (red) scores under the category "Focused Assessments/Internal Audits." However, when those scores were averaged with the other nine attributes being evaluated, the average totals dropped below the critical zone. Neither the Consumer GOC nor the Board of Directors received the QScans for the individual McNeil sites; instead, they received the combined average of each plant's average QScan, plus the range of individual plants' average QScans.

Thus, for example, the Compliance Committee and Audit Committee received Compliance Risk Assessments from the three J&J sectors during the course of the years 2008 and 2009. The Consumer sector presented at the September 8, 2008 Audit Committee meeting, reporting a "positive track record on key metrics": (1) of the 21 recalls in the prior two years, 15 (or 71%) were related to PCH; (2) there were no Warning Letters or significant inspections; (3) 62% of FDA inspections were without any 483 observations; (4) there were zero sites in the red zone of the Proactive Scan, 67% in the green zone; and the average Proactive Scan score for the OTC drug sites was 3.8. No mention was made of the Proactive Scan scores for internal audits at Fort Washington and Las Piedras.

Similarly, in its September 14, 2009 presentation to the Audit Committee, the Consumer sector reported that there were no sites in the red zone and 63% in the green zone, with an average score across 38 sites of 3.6 (and a range of 2.3 to 5.0). The report also noted, however, that the June 2009 inspection of Fort Washington resulted in "one Major observation related to receipt/release of partial lots of excipients" [the B. cepacia issue]. Again, there was no mention of the Proactive Scan scores for internal audits at Fort Washington and Las Piedras.

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 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.

8. Allegations Against J&J Board Of Directors And Senior Management

The shareholder demand letters and/or derivative complaints allege that senior management and the Board of Directors are liable for the Q&C problems that afflicted McNeil. Thus, for example, the November 12, 2010 demand letter on behalf of shareholder Michael Waber, asserts:

> Given that the recalls have implicated the Company's core products, the [current and/or former executive officers and directors of J&J, defined as the "Individuals"] must have known of, yet recklessly disregarded, the problems in these products and the FDA's concerns. Indeed, the Individuals have breached their fiduciary duties by failing to properly implement and maintain sufficient quality controls over the Company's drug manufacturing practices. Moreover, the Individuals breached their fiduciary duties by permitting a "phantom recall" of Motrin products, which failed to disclose the contamination problems to the public.

Contrary to those allegations, and as previously discussed, J&J had a robust Q&C organization, with policies and procedures in place that should have averted the McNeil Q&C issues. The Audit Committee and full Board were periodically apprised of the state of Q&C, and were provided with risk assessments for each of the Company's business sectors at a level of detail appropriate for a decentralized company with 250 subsidiaries.

Moreover, senior management and the Board of Directors were unaware of the quality issues that were developing at McNeil. Again, as previously noted, prior FDA inspections of the McNeil plants had been free of significant 483 observations. The reports provided to the Consumer GOC, Executive Committee, and Audit Committee with respect to Consumer sector Q&C were generally positive. When the Fort Washington 483 was issued in June 2009 with significant observations concerning the B. cepacia issue, Consumer sector Chair Colleen Goggins demanded an explanation and remediation plan, both of which she received. As the musty odor/TBA issue developed later in the year, the initial Field Reports were submitted to the FDA, and the first of several recalls announced, senior management became increasingly involved and sought out the expertise and assistance of the corporate Q&C Worldwide organization and Microanalytics. Overall, J&J management's response to the quality issues as they arose was affirmative: identifying the causes of the problems, assuring they presented no health or safety risk, remediating where necessary or desirable, and doing everything necessary to safeguard the public and reassure the FDA.

The Special Committee also finds no culpability at the McNeil management level. McNeil officials acted in what they considered to be the best interests of the Company. The Q&C problems seem to have developed inadvertently, rather than deliberately. McNeil was making progress in improving conditions at Fort Washington and Las Piedras. No decisions were made to sacrifice Quality for production or profits.

The first formal notice the Audit Committee or the Board received of significant Q&C issues at McNeil was provided at the February 8-9, 2010 Audit Committee and Board of Directors meetings.[16] At the latter meeting, Ms. Goggins was joined by Ms. Wengel, Vice President Q&C Worldwide, and Desiree Ralls-Morrison, McNeil Vice President of Law, OTC and Nutritionals. The minutes of the Board meeting reflect that

> Ms. Wengel presented a timeline of the events, actions of the Company and communications with the FDA commencing with the first indication of an unusual odor in several products beginning in 2008. She explained in detail the investigations conducted by the Company and the conclusions reached. She explained the discussions with the FDA which led to the limited product recall in late 2009 and the more recent, broader product recall. She also explained the warning letter issued by the FDA, and the Company's plans to respond to that letter.

At the June 14, 2010 Board of Directors meeting, there were extensive presentations by Ms. Goggins, J&J Counsel and outside counsel with respect to the product recalls, the suspension of operations at Fort Washington, and the ensuing Congressional investigation. The meeting minutes reflect that Ms. Wengel then

> updated the Board on the status of activities at the Fort Washington facility and discussions with the FDA. She explained that the Company had retained an independent consultant to assist in the remediation efforts at the facility and advised that the Company had submitted its response to the 483 report issued by the FDA. Ms. Wengel described the quality assurance practices and processes at the factory, as well as the oversight roles at the Group Operating Committee and Corporate levels. She described several senior management changes that were made at McNeil before the recall, as well as changes that are being implemented in Corporate oversight.

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[16] There is no indication that senior management or the Board was aware of the withdrawal of the two lots of Motrin 8's from the market in 2009 because of failure to meet dissolution specifications. As previously noted, the product was withdrawn because it failed to meet dissolution specifications; it was not "contaminated." And although the matter received a great deal of press attention when it was presented in the course of Congressional hearings in 2010 as a "phantom recall," McNeil expressly advised the San Juan District Office of how it intended to proceed and how it actually proceeded.

Subsequently, the Audit Committee and Board received regular updates on the status of the Company's recalls, remediation efforts and organizational changes relating to Quality and Compliance.

C. Quality Issues At Other J&J Operating Companies

1. DePuy ASR™

DePuy Orthopaedics, Inc. ("DePuy") is a J&J company whose business is the manufacture and marketing of orthopaedic devices and supplies, including artificial hip and knee replacement parts. DePuy is the responsible U.S. entity for the design, manufacture, labeling, distribution, marketing and sale of the ASR™ XL Acetabular Hip System and the ASR™ Hip Surface Replacement Femoral Head Component. The latter was approved for use with an Acetabular component only outside the United States and was introduced in 2003. The ASR™ XL Acetabular Hip System was available worldwide in 2004 and in the United States commencing in 2005. In November 2009, DePuy announced that it was discontinuing production of its ASR™ platform, due to declining demand and the need to allow the company to focus on delivering next generation hip technology.

On August 24, 2010, DePuy recalled both products after a review of data from the United Kingdom's National Joint Registry ("NJR") indicating that the number of patients requiring a revision (a second hip replacement surgery) was higher than data previously reported. The total number of ASR™ products implanted worldwide is approximately 93,000. As part of the recall, DePuy announced that it would cover reasonable and customary costs of testing and treatment associated with the recall, including revision surgery if necessary. Such expenses for five years have been estimated at $184 million and the cost of revisions for seven years post implant has been estimated at $326 million. The ASR™ platform is the subject of a significant number of

products liability/personal injury complaints that have been filed in the United States as well as various other countries.

The United Kingdom and Australia have national joint replacement registries that capture various data related to the implantation of joint replacement devices. The registries enable the monitoring of outcomes of the devices. In the Fall of 2007, the Australian Orthopaedic Association ("AOA") released a report with data collected from the Australian National Joint Replacement Registry ("NJRR") for the period September 1999 through December 2006. In the report, the ASR™ Resurfacing prosthesis (not the ASR XL) was determined to have a higher than anticipated rate of revision.

Based on its investigation of the AOA data, DePuy concluded that the primary causes of the revisions were femoral neck fractures in the resurfacing device, due to patient selection and surgical technique. At a meeting in September 2007 with Australia's regulatory agency for medical devices and drugs, which DePuy had requested to discuss the ASR™ Resurfacing revision rate data, DePuy agreed to issue a safety alert in the form of a "Dear Doctor" letter to stress the "importance of correct patient selection and appropriate surgical technique[,]" including cup selection, when using the ASR™ system.

DePuy continued to monitor surgeons using the system following the distribution of the safety alert in October 2007, implemented a training program, and performed Health Hazard Risk Evaluations ("HHEs") on the ASR™ in 2008 and 2009. The results of the 2008 HHE were basically consistent with DePuy's initial investigation that the primary causes of revision were patient selection and surgeon technique. The results of the 2009 HHE indicated that the ASR™ revision rates were consistent with the rates for other large head, monoblock, metal on metal systems. In 2008 and 2009, DePuy distributed brochures, reminding surgeons of the importance of proper implantation angle and patient selection.

In November 2009, DePuy announced that it was discontinuing production of its ASR platform, due to declining demand, and would focus instead on developing the next generation of hip technologies to better meet the needs of patients and surgeons. The decision was not related to trends in complaints or abnormal revision rates.

In January 2010, DePuy conducted another HHE following the release of the latest data from the Australian registry in September 2009. The HHE noted that "[r]ecent published and unpublished data suggests that [the revision rate] may be higher in cohorts where a large proportion is female or has small acetabulae. These data suggest the smaller heads (less than 50mm diameter) are associated with a higher risk of revision (up to 8-9% at three years)." The HHE concluded that the revision rates were higher than expected and "significantly higher" than for conventional total hip replacement. In March 2010, DePuy sent a "Dear Doctor" letter and Field Safety Notice to remind surgeons, among other things, of the proper implantation angle and to ensure proper patient selection.

In mid-summer 2010, DePuy received as yet unpublished data from the NJR which revealed for the first time ASR™ revision rates outside the range of other large-headed metal on metal devices. On August 26, 2010, based on the recently revealed U.K. data, the DePuy Quality Review Board decided to recall both the ASR™ and the ASR™XL.

In a "Dear Colleagues" message on August 27, 2010, MD&D Sector Chair Alex Gorsky reported:

> [O]n August 26, DePuy Orthopaedics voluntarily recalled the ASR™ XL Acetabular System and the ASR™ Hip Resurfacing System used in hip replacement surgeries worldwide. New data showed that a relatively high number of ASR patients required a second hip replacement procedure, called a revision surgery, over a five-year period. The majority of ASR hip replacement surgeries have been successful, and previous data had shown lower revision rates, in line with other devices in its class. In 2009 DePuy decided to discontinue the ASR hip as a result of declining demand, so very few devices remain in the market. Nonetheless, this

> recall is naturally concerning for patients, their family members, and surgeons, as it is for us. We are committed to assisting those who received an ASR hip by paying for the cost of follow-up monitoring and treatment, including revision surgeries, associated with the recall.

At the September 13, 2010 meeting of the Board of Directors, Mr. Gorsky presented a report on recent regulatory actions in the MD&D Sector, including the voluntary recall of the ASR™ systems.

The Amended Consolidated Complaint alleges, among other things, that the Board breached its fiduciary duties by "ignoring" the recall of the ASR™ XL and the ASR™ Resurfacing System. (ACC ¶ 278). But the Board was apprised by senior management of the recall and remedial efforts undertaken by DePuy, as well as the reasons for the recall. We find no evidence of any breach of duty under the circumstances.

2. DePuy TruMatch Personalized Solutions System And Corail Hip System

In August 2010, the FDA sent DePuy a Warning Letter regarding two of its products: TruMatch Personalized Solutions System ("TruMatch") and Corail Hip System. The Warning Letter claimed that DePuy did not receive premarket approval or clearance for the TruMatch product and it was thus adulterated and misbranded under the FD&C Act.[17] The FDA noted that

[17] The FDA classifies medical devices into three categories based on the level of control necessary to ensure safety and effectiveness. Class I devices do not require premarket approval but are governed by "general controls" such as they must "be manufactured under a quality assurance program" and "be suitable for the intended use." Class II devices are those that require general controls and "special controls." Class I and Class II devices are further categorized as either "with exemptions" or "without exemptions." If the device is not exempt, then the device manufacturer must file a premarket notification with the FDA. A premarket notification, also known as a "510(k)," is required before a manufacturer may market a medical device. Devices cleared through this process must be "substantially equivalent" to a device in the marketplace prior to May 28, 1976 -- a "predicate device." The FDA will respond with a "clearance letter" indicating that the submitted device is cleared for marketing for the stated indications. Conversely, Class III devices must be FDA-approved through the Premarket Approval (PMA) process, similar to the New Drug Application process.

the Corail Hip System was cleared for marketing through the 510(k) premarket notification process for specific indications, including for cementless use only. The FDA claimed that DePuy's Corail webpage contained either an explicit or implicit promotion that "represent[s] a major change or modification in the intended use" of the device and necessitated a new premarket notification.

The Consolidated Complaint (at Paragraphs 135 to 137) cites the Warning Letter as an example of a "fundamental control breakdown[] across all of [J&J's] business segments." The evidence does not support that claim.

(a) Corail Hip System

On September 8, 2010, DePuy responded to the FDA's August 19, 2010 Warning Letter, reporting that it had removed Corail promotional materials from its website to review and delete any statements found objectionable by the FDA, and instructed its sales representatives to remove Corail promotional materials and cease distributing them until new marketing materials could be created. DePuy also maintained that it "never intended these statements [in the promotional materials] to be construed as a new intended use or condition that the device treats. These statements describe the technical experience with the device when used in accordance with its labeled indications, based on scientific research findings as reported in the published literature." The FDA replied in December 2010, to the effect that DePuy's response to the Warning Letter "adequately resolves the issues concerning the Corail Hip System."

(b) TruMatch

DePuy also addressed the TruMatch issue in the September 2010 letter. TruMatch is a four-step process that is designed to assist surgeons with knee replacements. First, a CT scan is taken of the patient's leg. Second, that scan is sent to DePuy for the creation of a 3D model based on the scan. Next, DePuy analyzes the model and creates a personalized guide for the

surgeon for the implantation of the knee replacement. Finally, the guides are sent to the surgeon for the actual replacement surgery. TruMatch is only available with Sigma Knee Replacements. DePuy asserted that TruMatch was 510(k) exempt because it was either an orthopedic manual surgical instrument or a template for clinical use and therefore did not need to be cleared for marketing by the FDA through its 510(k) submission process.

The FDA in its December 2010 response disagreed with DePuy's characterization of the TruMatch. First, the FDA claimed that, due to TruMatch's exclusivity with the Sigma Knee Replacement, it was not an orthopedic manual surgical instrument because it was not generic. Second, according to the FDA, TruMatch could not be considered a template for clinical use because it guides the cutting of a patient's tissue rather than the marking of tissue prior to cutting and because the guide is designed for a selected implant rather than for selecting an implant size or position.

At a meeting between the FDA and DePuy on January 28, 2011, DePuy explained why DePuy believed that TruMatch was a Class I exempt product (based on its similarity to standard manual templating systems). This appears to have been a valid (indeed strong) legal/regulatory position. However, DePuy proposed that, if the FDA was not convinced, then DePuy was prepared to submit a 510(k) but requested that the device be available to current registered customers. DePuy agreed not to promote TruMatch to new customers until such time as it was cleared through the 510(k) process. DePuy also pledged that it would submit a Premarket Approval application for TruMatch if it decides to use TruMatch with another knee implant. The FDA accepted the proposal, but emphasized that until such time as the device is cleared/approved, the Warning Letter would not be closed out.

3. Acuvue Contact Lenses Recall

Vistakon, a division of Johnson & Johnson Vision Care Inc., manufactures the 1-Day Acuvue® TruEye™ disposable contact lenses sold in the United States, Asia, and Europe. On August 18, 2010, after receiving consumer complaints in Japan of stinging or pain after insertion of the lenses, J&J recalled the product in Asia and Europe. The Company also suspended shipments of the affected lots. Approximately 100,000 multipacks of the lenses were recalled in 26 countries in Asia and Europe, although the recall was primarily in Japan. Upon investigation, J&J determined that the cause of the discomfort came from an incomplete rinsing process on a manufacturing line located in Ireland, which was promptly corrected. There were no reports of any long term health consequences, which were considered unlikely.

On October 28, 2010, the Company expanded the recall to a total of nearly 500,000 multipacks, less than 1 percent of the contact lenses manufactured worldwide by the Company. The expanded recall was announced in Japan, where 75 percent of the multipacks were sold. Field Safety Notices were sent to regulatory agencies in the affected countries, advising that: "continued complaint monitoring indicates no increase in health-related complaints related to this product variation. While these reports, along with the findings from the company's continued testing, indicate a lower likelihood of the occurrence of stinging than the earlier recalled lots, Johnson and Johnson Vision Care is taking this action as a precaution . . . ." The expanded recall was not announced in the U.S. because the Acuvue® TrueEye™ lenses made for the U.S. are made with a different material, and the U.S. market was consequently unaffected.

The Consolidated Complaint (at Paragraph 134) alleges that "[t]he serious facts regarding the initial Acuvue Recall in August 2010 were well known to the Board, yet, . . . the Board took no real action to effectively manage the circumstances of the expanded recall in October. To the

contrary, the expanded recall was designed much like the Phantom Recall -- to take place in the dark." The evidence does not support that claim.

At the September 10, 2010 Board of Directors meeting, Mr. Gorsky reported on the August Vision Care voluntary recall, explaining that an investigation had been initiated due to an emerging customer complaint trend, that the decision to recall was based on the risk of severe ocular discomfort and associated medical symptoms, and that the root cause of the problem had been identified as an incomplete rinsing process on one manufacturing line in Ireland. Mr. Gorsky provided an update on the strategy for the Vision Care expanded recall at the Board of Directors meeting on October 21, 2010. Notice of the expanded recall was publicly announced in the country most affected, and duly provided to the regulatory authorities in all countries in which the product had been distributed. In short, this was a relatively isolated event that was properly managed, with the Board being appropriately informed by management of the issue and its resolution.

IV. Health Care Compliance Issues

A. Off-Label Investigations

Several demand letters and shareholder complaints raise issues pertaining to investigations and/or *qui tam* suits under the False Claims Act, alleging "off-label" promotion of three drugs (Risperdal, Natrecor, and Topamax) and one medical device (biliary stents). Risperdal and Natrecor are the subject of pending grand jury investigations; the DOJ investigation of Topamax was resolved in the spring of 2010; and biliary stents are the subject of a pending *qui tam* action in which the United States has chosen not to intervene. Following a general discussion of off-label promotional issues, we examine each issue separately below and then state our general conclusions.

1. Off-Label Promotion

The FDA will approve a drug for particular indication(s) following a review of its safety and efficacy. 21 U.S.C. §§ 331(d) and 355(b). The FDA regulates medical devices in a similar fashion, requiring premarket approval for such devices. 21 U.S.C. § 360 *et seq.* As a general matter, manufacturers may not market their drugs or devices for indications not approved by the FDA, which can result in a drug being deemed "misbranded" within the meaning of the FD&C Act. 21 U.S.C. §§ 331(a) and (d). However, physicians can -- and often do -- prescribe drugs and employ devices in such an "off-label" manner. 21 U.S.C. § 396. In fact, "off-label" use of FDA-regulated products "is an accepted and necessary corollary" to FDA's regulatory scheme." *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 350 (2001). Indeed, in some contexts off-label use represents the standard of medical care. *United States ex rel. Polansky v. Pfizer*, No. 04-CV-0704, 2009 WL 1456582, *6 (E.D.N.Y. May 22, 2009).

The rules regarding off-label promotion are nuanced. For example, while as a general matter a pharmaceutical manufacturer may not provide physicians with unsolicited journal articles discussing off-label use of their drugs, the manufacturer may do so if the physician first requests a copy. 21 U.S.C. § 360aaa-6(a). Moreover, manufacturers may also disseminate unsolicited copies of certain peer-reviewed articles regarding off-label use if they follow the FDA's "Good Reprint Practices."

Advertisement and promotion of drugs falls within the jurisdiction of FDA's Division of Drug Marketing, Advertising and Communication ("DDMAC"). Pharmaceutical companies must submit copies of their promotional materials to DDMAC for review. While DDMAC does not necessarily review all submissions due to resource constraints, if DDMAC reviews a submission and believes there is a violation, it will provide notice and an opportunity to correct through a Warning Letter, an Untitled Letter, or other correspondence.

As a general matter, off-label promotion was not the subject of government enforcement action until 2002, when Pfizer announced that DOJ had convened a grand jury to investigate allegations that it had promoted Neurontin for off-label use. Pfizer subsequently announced a settlement of that investigation in 2004, in which it pled guilty to two felony counts of misbranding, agreed to pay $430 million in civil fines and criminal penalties, and entered into a Corporate Integrity Agreement.

The Neurontin matter represented the first in a wave of investigations by DOJ against a series of leading drug and device makers. Many of these investigations were accompanied by *qui tam* actions by relators suing under the FCA. Some of the larger off-label settlements include:

- Schering-Plough's 2006 agreement to pay $435 million, plead guilty to making false statements in response to an FDA Warning Letter, and enter into a Corporate Integrity Agreement to resolve claims related to Temodar and Intron-A;

- Pfizer's September 2009 agreement to pay $2.3 billion, plead guilty to a misbranding count, and enter into a Corporate Integrity Agreement to resolve claims related to four different drugs (Bextra, Geodon, Zyvox, and Lyrica);

- Allergan's September 2010 agreement to pay $600 million, plead guilty to misdemeanor misbranding, and enter into a Corporate Integrity Agreement to resolve Botox claims;

- Forest Lab's September 2010 agreement to pay of $313 million, plead guilty to misdemeanor misbranding, and enter into a Corporate Integrity Agreement to resolve claims related to Celexa;

- Novartis' September 2010 agreement to pay $422.5 million, plead guilty to misdemeanor misbranding, enter into a Corporate Integrity Agreement to resolve claims related to Trileptal; and

- Elan Pharmaceuticals' December 2010 agreement to pay $203 million, plead guilty to misdemeanor misbranding, and enter into a Corporate Integrity Agreement to resolve claims related to Zonegran.

Moreover, many of the settlements have focused on "atypical" antipsychotics (a class of drugs which includes Risperdal). In September 2008, Bristol-Myers agreed to pay $515 million and enter into a Corporate Integrity Agreement to resolve claims of off-label promotion for Abilify, although the company did not plead guilty to any crime. In January 2009, Eli Lilly agreed to plead guilty to a felony count of misbranding, pay $1.415 billion in civil and criminal penalties, and enter into a Corporate Integrity Agreement to resolve claims of off-label promotion of Zyprexa. As noted above, in September 2009 Pfizer entered into a settlement that included (among other drugs) its atypical antipsychotic, Geodon. And in April 2010, AstraZeneca agreed to pay $520 million and enter into a Corporate Integrity Agreement to resolve claims that it marketed Seroquel for off-label uses.

Prosecutors pursuing off-label investigations wield a potent weapon in the form of the potential debarment of the drug or device maker if it is adjudged guilty at trial. Different federal laws require or permit the disqualification of companies convicted of a felony or misdemeanor from participating in government-sponsored payment plans, including Medicare, Medicaid, and other federal health care programs. Such a threat of debarment "is a literal death knell for many pharmaceutical companies," and therefore "even the threat of criminal prosecution can be a powerful incentive for a company to resolve pending civil and criminal investigations on terms favorable to the government simply to avoid the risk of exclusion." Allison D. Burroughs, et al., *Government Theories of Prosecution*, 65 Food & Drug L.J. 555, 558 (2010).

While the threat of debarment underscores the importance of off-label compliance, it also suggests that a pharmaceutical company may pay substantial sums to settle questionable allegations rather than risk trial. Indeed, in 2001 TAP Pharmaceuticals paid $875 million to resolve an investigation into alleged fraudulent drug marketing practices. Following TAP's guilty plea, the individual TAP executives who were separately charged were all acquitted at

trial. Similarly, in 2005 Serono pled guilty to a felony offense and paid $700 million to end an investigation into whether it marketed Serotism for off-label use; but again, the individual Serono employee-defendants who allegedly implemented the off-label marketing scheme were all acquitted at trial.

2. Risperdal

Risperdal (risperidone) is an "atypical" antipsychotic drug, marketed by Janssen Pharmaceutica, Inc. ("Janssen") (now Ortho-McNeil-Janssen Pharmaceuticals Inc. ("OMJPI")), that FDA approved for sale in late 1993. In January 2004, J&J received a subpoena from the DOJ, seeking documents relating to alleged off-label promotional practices for Risperdal. A criminal investigation remains pending today.[18] The core allegation at issue in the DOJ investigation is that between 1999 and 2005 Janssen engaged in off-label promotion by marketing Risperdal to physicians for the treatment of elderly, demented patients in nursing homes. Janssen did, indeed, employ an Elder Care Sales Force during the period 1998-2005 that marketed the drug to physicians practicing in the nursing home setting. Accordingly, the Special Committee examined whether the manner in which Janssen did so contravened the labeled indication for Risperdal.

Significantly, Risperdal has had two distinct labeled indications and, therefore, Janssen's promotional practices must be examined for each of these separate periods. When the drug was

[18] The DOJ investigation has also spawned a number of other suits by a number of states and private third-party payors. While most of those suits remain pending, some have been dismissed in favor of Janssen and J&J. Two (in Louisiana and South Carolina) have resulted in jury verdicts adverse to Janssen, premised on claims that Janssen failed to warn, and misled the public, about the health risks of Risperdal. The Louisiana verdict awarded $257.7 million to the State's Attorney General against Janssen and J&J, who have appealed. The South Carolina Court of Common Pleas entered a penalty order on June 3, 2011, assessing penalties against Janssen of $327.1 million, based upon the jury verdict of liability. Janssen plans to challenge the order and, if unsuccessful, to appeal the verdict and penalty order.

initially approved by FDA in late 1993, the FDA approved it for "the management of the manifestations of psychotic disorders" ("MMPD"). As such, Risperdal's approved indication dealt with the symptoms that a psychotic patient might present -- such as delusions, excitement, grandiosity, conceptual disorganization, hallucinatory behavior, suspiciousness/persecution, and hostility. However, in September 2000, FDA sent a letter to Janssen "asking" that it change the labeled indication from MMPD to the "treatment of schizophrenia." The FDA sent similar letters to all antipsychotic manufacturers. This requested change in the labeled indication was not based upon any new clinical data, but instead represented a change of philosophy at the FDA as to how to label appropriately anti-psychotic medications -- *i.e.*, by symptoms or by disease state of the populations studied in the clinical trial used to support the approval of the drug. Janssen agreed to change the Risperdal label in January 2002, and the change itself was implemented in March 2002.

MMPD was the operative indication when, in March 1998, Janssen launched the Elder Care Sales Force to promote several drugs (Risperdal, Propulsid, and Duragesic) in the long-term care market. Janssen employed a "symptoms-based" marketing theme, which focused on the kinds of psychotic symptoms that patients with dementia, schizophrenia, or other disease states might present. The government suggests that Janssen used this symptoms-based approach in order to market Risperdal off-label to demented patients. We conclude, however, that Janssen had a good-faith basis to market Risperdal to dementia patients who presented with psychotic symptoms because the MMPD indication allowed Janssen to market Risperdal for patients presenting with psychotic symptoms, irrespective of disease state.

This conclusion finds support in FDA communications. Indeed, FDA had earlier objected to sales materials that focused on a particular disease state (schizophrenia) even when the population used for the approval studies had been diagnosed with the same disease state. In

February 1994 correspondence, DDMAC objected to sales materials that addressed schizophrenia patients as "misleading" because Risperdal was "indicated for the management of the manifestations of psychotic disorders, and all efficacy claims should be limited to th[at] indication." In response to a later proposed extension of the Risperdal label to cover behavioral disturbances associated with dementia, FDA stated that this "would not really be an expansion of the basic claim for Risperdal, but rather, an extension of the population base supporting the claim." Similarly, at an August 1997 meeting, the head of the applicable FDA reviewing division told Janssen that Risperdal was already approved "generally for psychotic disorders" and there was "no convincing evidence that this symptomatology in the demented population [would be] distinct from that in other patient populations."

We also conclude that Janssen had a good-faith basis to believe that it could market Risperdal to physicians practicing in nursing homes, provided that Janssen did not claim any particular efficacy for elderly patients. Risperdal's label always included dosage information for the elderly, thereby demonstrating that FDA realized it would be prescribed for such patients. Indeed, FDA's stated concerns with marketing to the elderly focused on claims of efficacy specific to that population since Risperdal's approval studies involved a general population of subjects. In October 1994, DDMAC expressed "significant concerns" with a sales aid targeted at elderly patients, stating that "[a]dditional data from clinical trials would be required to support the geriatric use of Risperdal." Later in the 1990s, when Janssen launched the Elder Care Sales Force, it submitted sales materials to DDMAC which again focused on an elderly patient population. DDMAC responded with a January 1999 Untitled Letter, which stated that Janssen should not "state or imply that Risperdal has been determined to be safe and effective for the elderly population in particular" and that "presentations that focus on this population are

misleading in that they imply that the drug has been found to be specifically effective in the general population."

In other words, Janssen reasonably believed that a prohibition against claiming that Risperdal was "specifically effective" in the elderly does not mean that FDA forbade marketing to nursing homes at all, provided that Janssen limited its claims of efficacy to a general population (which would include the elderly, among other age groups). Significantly, Janssen received advice on this point from a J&J regulatory official who previously served as Division Director of DDMAC; she counseled that a marketing campaign that included nursing-home doctors was permissible, provided that Janssen's promotional message relied on a general patient population and refrained from making any specific claim of efficacy among the elderly.[19]

As explained above, on September 25, 2000, FDA requested that Janssen change the indication from MMPD to schizophrenia, which would move the indication from a symptoms inquiry to a disease-state inquiry. Janssen agreed to that change in January 2002, and implemented the change when FDA accepted the final labeling in March 2002. Our investigation suggests that Janssen could have moved more expeditiously to change the label, and indeed we note that other manufacturers changed their labels before Janssen did. Significantly, however, FDA lacked the legal authority to force Janssen to change the label (which is why it termed its September 25, 2000 letter a "request"). Given that Janssen could have simply refused to make the change at all, we cannot conclude that Janssen delayed doing so in bad faith.

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[19] In March 2005, FDA requested that all atypical antipsychotic manufacturers include in their labeling a "black box" warning of increased risk of mortality among dementia patients. FDA based this request not on any data particular to Risperdal, but rather upon a meta-analysis of many clinical studies of all antipsychotics.

Following the March 2002 label change, Janssen reformed its sales materials to eliminate the word "psychosis" and replace it with "schizophrenia," with the symptoms-based promotional message remaining essentially the same. Janssen also continued marketing Risperdal to physicians practicing in nursing homes through the Elder Care Sales Force.[20] The government contends that Janssen thereby marketed Risperdal off-label to dementia patients, when the indication had now been narrowed to schizophrenia patients.

The Special Committee concludes, however, that Janssen had a good-faith basis to pursue its marketing strategy after the March 2002 label change. Janssen did, in fact, change its sales aids to reflect the schizophrenia indication. While the materials continued their symptoms-based message, a substantial body of literature makes clear that psychiatrists treat schizophrenia by addressing symptoms. Importantly, DDMAC did not issue a Warning Letter, Untitled Letter, or make any comment at all concerning the revised sales aids following the label change. If DDMAC felt the revised sales materials contravened the new labeled indication, then presumably it would have issued such correspondence. Finally, statistics suggest that there was a sufficient schizophrenia market in nursing homes to warrant the Elder Care Sales Force's continued deployment to sell Risperdal in that setting, even after the label change (particularly when that sales force was also selling two other drugs).

We also note the dilemma presented by the change in the Risperdal label and the government's investigation of off-label promotion. As previously noted, prescription by doctors of drugs for off-label usage is permitted. Knowledge by a pharmaceutical company of that off-label usage is not a violation of the FD&C Act. Nor should such knowledge of off-label usage be equated with intent to promote for such usage. Nonetheless, the FDA-initiated change in the

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[20] Janssen disbanded the Elder Care Sales Force in 2005.

Risperdal label meant that a large number of prescriptions that had been consistent with an indication for MMPD were now technically off-label.

In sum, the Special Committee concludes that Janssen did not intentionally promote Risperdal for off-label usage, and had a good-faith basis for its marketing plans and efforts. As has been publicly disclosed, moreover, the Special Committee is well aware that J&J and Janssen have been engaged in settlement discussions with the government concerning the latter's investigation of alleged off-label promotion of Risperdal. The Special Committee has taken into account that there could be a sizable settlement resulting from those discussions. Nonetheless, and for the reasons previously discussed, the Committee does not believe it would be in the best interest of J&J to pursue claims relating to Risperdal on its behalf.

3. Natrecor

Natrecor (nesiritude) is a drug that treats congestive heart failure, and was formerly marketed by Scios, Inc. ("Scios"). FDA approved Natrecor for sale in the U.S. in 2001 with a labeled indication for the "treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity." J&J acquired Scios in April 2003; before that date, Scios was not affiliated with J&J. Natrecor is the subject of a pending grand jury investigation conducted by DOJ and parallel *qui tam* litigation in which the government has chosen to intervene. As an intravenous drug, Natrecor must be administered by a physician or other qualified health care provider in a health care facility.

DOJ's core theory is that Scios marketed Natrecor for off-label use during the 2001-05 period by promoting the drug for use in outpatient clinics as opposed to hospitals. FDA only approved Natrecor for use in acute cases, *i.e.*, where the patient experiences an immediate attack. It has not been approved for use in patients presenting with chronic congestive heart failure, whether for use as a preventative medication or otherwise. While Scios pursued clinical studies

to show efficacy among chronic patients, these studies ultimately proved unsuccessful. Our investigation revealed that Scios did, in fact, market Natrecor to physicians who practiced in outpatient clinics. Accordingly, the Special Committee focused its inquiry on whether the Natrecor label permitted Scios to do so.

After it was launched in 2001, Natrecor gained swift acceptance among cardiologists because it was viewed as a replacement for an older generation of drugs, inotropes, that had been employed to treat acute and chronic cases of congestive heart failure in both the hospital and outpatient setting. Around the time of Natrecor's launch, studies were published highlighting safety risks associated with inotropes, which induced many cardiologists to switch from inotropes to Natrecor. Accordingly, much of Natrecor's growth in the outpatient setting and for use among chronic patients occurred for reasons unrelated to Scios' marketing.

The controversy regarding Natrecor's use in the outpatient setting largely arose as a result of recommendations made by an independent panel convened in 2005. The panel, chaired by Dr. Eugene Braunwald, was assembled at the request of Scios in order to provide analysis and recommendations regarding potential safety issues with Natrecor that had been reported in medical journals earlier that year. While the panel largely dismissed the safety issues pending further study, it also issued a recommendation that Natrecor's use be "strictly limited to patients presenting to the hospital . . . as were the patients in the largest trial that led to the approval of the drug." Scios thereafter ceased its efforts to promote Natrecor to physicians practicing in clinics.

Contrary to the Braunwald Panel's recommendation, however, Natrecor's FDA-approved label was not specific to the location where the drug could be employed (provided, of course, that facilities were available to monitor blood pressure and otherwise permit the administration of an intravenous drug). Additionally, patients suffering from acute attacks do present in the outpatient setting. Patients with chronic congestive heart failure often have an existing

relationship with a physician practicing in a clinic, where they go from time to time for care; and in the event of an acute episode, such patients may therefore report to the clinic in lieu of the hospital emergency room. Indeed, demographically it appears that affluent, suburban patients often present to clinics with their acute episodes, while urban residents of lesser means who are not undergoing treatment will report to the hospital emergency room. Accordingly, the Special Committee concludes that Scios had a good faith basis to believe that outpatient clinics were an appropriate venue to market Natrecor for on-label use for acute patients.

It is also significant to the Special Committee's analysis that J&J bought Scios in April 2003. Indeed, following that acquisition, and at J&J's direction, Scios implemented a series of compliance-related reforms. Among other things, these reforms included moving the budget and responsibility for educational grant requests and the speakers' bureau from Marketing to Medical Affairs; confirming a "zero tolerance" policy for off-label promotion; reforming promotional pieces; and the "seconding" of a J&J regulatory lawyer to Scios to assist with compliance.

DOJ has focused its inquiry on particular practices, including payments to health care professionals for speaking about outpatient use of Natrecor and other CME programs, a program to educate physicians as to how to open new outpatient clinics, and a Scios-sponsored registry that allows physicians to record and analyze outcome patterns (including in any chronic patients). Significantly, many of these practices pre-dated the April 2003 J&J acquisition of Scios. Moreover, the registry was already being phased out when the DOJ subpoena was received; it was discontinued thereafter for business reasons. And the enhanced compliance procedures put into place following the acquisition resulted in the termination of the other practices before the opening of the DOJ investigation.

Accordingly, the Special Committee concludes that the evidence fails to support the claim that Scios marketed Natrecor for off-label use in bad faith. Moreover, after J&J's

acquisition of Scios in 2003, J&J took affirmative steps to enhance compliance with FDA regulations with respect to off-label promotion, and had a good faith basis for believing that outpatient clinics were an appropriate venue to market Natrecor for on-label use.

4. Topamax

Topamax (topiramate) is an anti-epileptic drug, marketed by Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") (now OMJPI), that FDA approved for sale in the United States in 1996 with an indication for the treatment of partial onset seizures in adults. Topamax was subsequently approved for additional indications, including for the treatment of migraines. In 2003, two relators filed a *qui tam* action alleging, among other things, that Ortho-McNeil promoted Topamax for off-label use among psychiatrists. DOJ also commenced a grand jury investigation. Both matters were resolved by an agreement reached in April 2010, whereby Ortho-McNeil agreed to pay approximately $75.4 million in civil and $6.1 million in criminal fines, plead guilty to a misdemeanor count of misbranding, and enter into a Corporate Integrity Agreement. The settlement concluded the controversy surrounding the alleged off-label promotion of Topamax; there are no other pending claims on that issue. In comparison with the other off-label settlements outlined above, the Topamax settlement amount was relatively modest.

The focus of the government's investigation into Topamax pertained to its promotion to psychiatrists and other non-neurologists. In the middle of 1999, Ortho-McNeil investigated adding psychiatrists to its call lists for Topamax (which previously had focused on neurologists). In October 2000, Ortho-McNeil began a co-promotional arrangement with Janssen to allow representatives to carry both Topamax and Risperdal on visits to psychiatrists, with Risperdal in the first position. Ironically, one of the multiple reasons Ortho-McNeil wished to detail psychiatrists arose from the activities of a competitor, Eli Lilly, whose sales representatives were

then promoting Topamax as a conjunctive prescription to boost Zyprexa sales. Zyprexa often causes patients to gain weight, which formed a barrier to physician acceptance of that antipsychotic. To counteract this side effect and promote physician acceptance of Zyprexa, Eli Lilly representatives suggested that psychiatrists also prescribe Topamax along with Zyprexa since Topamax induces weight loss. Ortho-McNeil was particularly concerned that the Eli Lilly sales force might not provide appropriate usage and dosing information for Topamax, which could be ameliorated through the co-promotional arrangement with Janssen. Moreover, the sales force was directed to promote Topamax "only when a physician has indicated a use in epilepsy." The co-promotion arrangement with Janssen was short-lived, as it ended in March 2001.

In September 2001, the FDA notified Ortho-McNeil that it was required to include a new warning label on Topamax packaging for acute myopia and secondary angle closure glaucoma. In response, Ortho-McNeil determined that it was "best positioned to deliver the information regarding the new prescribing update for TOPAMAX to all customers, including Psychiatry." Ortho-McNeil cautioned that it was "NOT a promotional strategy" and reminded that adding psychiatrists to the call plan "DOES NOT change our primary responsibility and measure of success to grow TOPAMAX use for the treatment of Epilepsy in the specialty of NEUROLOGY." Because research indicated that physicians would want to meet with the sales representatives regarding the label change (which was to be announced by a "Dear Doctor" letter), the call plan included psychiatrists "that are Medium to Very High prescribers of [anti-epileptic drugs]."

Significantly, while the DOJ investigation focused in part on the Janssen co-promotion arrangement and the inclusion of psychiatrists on the call lists, DOJ did not include that issue in the criminal Information which was ultimately filed as part of the 2010 settlement. Instead, the Information focused on a different issue entirely -- *i.e.*, the "Doctor for a Day" program. This

program was developed by the Ortho-McNeil sales force (not Ortho-McNeil management). Under the program, a neurologist accompanied a sales representative on a physician visit, and received an honorarium for doing so. During the visit, the sales representative would ask the neurologist to present information to the doctor being detailed. Psychiatrists formed approximately 10% of the call list for the Doctor for a Day program, with neurologists forming the remaining 90%. However, in the spring of 2002, the national sales director directed that psychiatrists be dropped from the Doctor for a Day visits once he became aware that psychiatrists were being visited.

Ortho-McNeil ended the Doctor for a Day program altogether in late 2003, before DOJ issued its first subpoena. Significantly, Ortho-McNeil did so as a result of a memorandum issued by J&J that, in turn, was prompted by the OIG Guidance that laid out standards for physician speakers' programs. In response to that memorandum, Ortho-McNeil ended the Doctor for a Day program since, under J&J policy, such speakers' programs could not be structured in a one-on-one (as opposed to a group) setting.

The Special Committee concludes that Ortho-McNeil management did not intentionally promote Topamax for off-label uses, and had a good faith basis for the Topamax marketing programs. And the Doctor for a Day program, which was not an initiative of management, ended as a result of enhanced compliance efforts by J&J.

5. Biliary Stents

Cordis Corporation ("Cordis") manufactures biliary stents, a Class II medical device. Cordis is presently a defendant in a *qui tam* action filed under the FCA against three major biliary stent manufacturers (also including Abbott Laboratories and Boston Scientific). Notably, the United States chose not to intervene in the action when it was unsealed in January 2010. In general terms, the *qui tam* complaint alleges that the defendants marketed the stents for use in a

cardiovascular setting when the devices are only approved for use in the bile duct. Cordis' motions to dismiss the *qui tam* case was granted, without opinion, and with leave for the Relator to amend some of his claims. It is not clear when the opinion will issue.

Off-label use of biliary stents in the cardiovascular setting is widespread in the medical community, and it has proven difficult to conduct a clinical study of biliary stents to prove efficacy and safety in the cardiovascular setting given the problems recruiting patients for the non-stent arm. In April 2001, FDA convened a Circulatory Systems Panel whose speakers explained that it was "more and more difficult ethically to randomize patients when they were getting more optimal results with stenting." Another speaker commented that "off-label devices are superior to the currently approved devices," which made it ethically difficult to "randomize the old technology and put patient[s] at some disadvantage or risk." Cordis has had a consistent and focused research plan that included a pursuit to obtain pre-market approvals and conduct clinical trials to expand and update indications for its stents.

It appears that the use of biliary stents for cardiovascular purposes is due to widespread physician acceptance as opposed to promotional activities by Cordis. An exception is an advertisement for biliary stents that Cordis placed in 1999 in the publication *Endovascular Surgery*. That advertisement resulted in a Warning Letter issued by FDA, finding that it made "an implied claim for vascular use . . . because it appears in a journal intended for vascular specialists." Cordis responded that the advertisement was placed in error, appeared in only a single monthly issue of *Endovascular Surgery*, and assured FDA that such advertisements would not recur.

The United States' decision to decline to intervene in the *qui tam* action is, in the Special Committee's judgment, evidential of the government's view of its merit. Moreover, while biliary stents have been the subject of informal requests for documents and a subpoena issued

under the Health Insurance Portability and Accountability Act ("HIPAA"), no grand jury has been convened to investigate claims of off-label marketing of biliary stents by Cordis.

Other than the inadvertent placement of the advertisement in Endovascular Surgery, which the FDA construed to "imply" a claim for vascular use, the Special Committee found no evidence of promotion of biliary stents for off-label usage.

6. Conclusions

Plaintiffs in the consolidated derivative action allege that "Defendants received many years of red flags reflecting systemic noncompliance with drug manufacturing and marketing laws." *Consolidated Compl.* ¶ 278. They point primarily to the receipt by J&J and/or its subsidiaries of subpoenas pursuant to the government's investigations of Risperdal, Topamax, Natrecor and Biliary Stents.[21] The J&J Board of Directors and Audit Committee were regularly advised that the Company was cooperating with the investigations. As previously noted, several of the subpoenas were received after the allegedly inappropriate off-label marketing practices had been discontinued. The Special Committee found no evidence to suggest that the Board became aware of illegal marketing activity and failed to take steps to prevent it.

Nor does the evidence suggest there was "systemic noncompliance" with FDA regulations prohibiting off-label promotion. To the contrary, reflecting changes at the J&J corporate level, the sales and marketing compliance systems at the subsidiary level have grown and strengthened over time, and particularly so following DOJ's settlement with Pfizer of the Neurontin investigation in 2004. Each subsidiary employed a Promotional Review Committee ("PRC"), a multi-disciplined committee composed of legal, regulatory, scientific, and other

[21] Plaintiffs also allege that J&J senior management and the Board were "fully aware" of Scios's alleged off-label promotion of Natrecor at the time of J&J's acquisition of Scios in February 2003. *Consolidated Compl.* ¶ 226. That allegation is without evidentiary support.

resources that reviewed, commented on, and ultimately approved all sales aids and written materials. J&J also "seconded" a regulatory attorney at each subsidiary, who provided advice and counsel to the subsidiary on the legal aspects of compliance while still reporting through the J&J Law Department. Directives from J&J also caused the subsidiaries to cease certain promotional activities later challenged by DOJ, such as J&J compliance initiatives at Scios following the acquisition and the cessation of the Doctor for a Day program at Ortho-McNeil.

A recurrent theme of the several off-label matters is the government's theory that promotion to a physician audience that would largely prescribe the drug in off-label manner violates the law, even if the sales message remained an on-label one. Indeed, this is the core theme of DOJ's theories regarding Janssen's marketing of Risperdal to doctors practicing in nursing homes, Scios' marketing of Natrecor to doctors in out-patient clinics, and Ortho-McNeil's marketing of Topamax to psychiatrists. While, as noted above, there are strong defenses to these theories, nevertheless one area of potential improvement would be the implementation of procedures whereby such marketing plans received advance review and input from the Regulatory and/or Law Departments. In the past, the sales aids that the Company planned to use received such review and approval by the PRC mechanism, but the marketing strategy of where to deploy them (whether nursing home, out-patient clinic, or psychiatrist's office) apparently did not receive such review.

B. Anti-Kickback Statute Issues

1. The Federal Anti-Kickback Statute ("AKS")

Enacted in 1972, the federal AKS is a criminal statute that serves to protect patients and the federal health care programs from fraud and abuse. Under the AKS, it is a felony to:

> knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . .[22]

The AKS prohibits a wide range of activity and establishes stiff penalties for violators. In addition to fines and imprisonment, conviction may lead to the automatic exclusion from federal health care programs, including Medicare and Medicaid. Moreover, irrespective of criminal conviction, the OIG and the Department of Health and Human Services ("DHHS") may initiate administrative proceedings to assess civil monetary penalties (which could result in treble damages plus $50,000 for each violation of the AKS), and the DHHS Secretary has the discretion to exclude violators from participation in the federal health care programs.

The broad reach of the AKS, however, is limited by: (1) the requisite level of intent needed to establish a violation, and (2) the statutory exceptions. *First*, the AKS is only violated when the offered remuneration is made "knowingly and willfully" for the purpose of inducing a referral or a purchase.[23] *Second*, Congress expressly carved out exceptions to the AKS' reach.[24] Among those exceptions are discounts that are properly disclosed and appropriately reflected in claimed costs and/or charges and payments to *bona fide* employees. In addition, OIG has promulgated regulatory Safe Harbors which protect proper and useful commercial arrangements that would otherwise be subject to criminal prosecution under the AKS. Business arrangements

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[22] 42 U.S.C. § 1320a-7b(b)(2).

[23] 42 U.S.C. § 1320a-7b(b); *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000), *cert. denied*, 531 U.S. 1015 (2000).

[24] 42 U.S.C. 1320a-7b(b)(3).

that strictly comply with Safe Harbor conditions are shielded from prosecution. On the other hand, practices that fail to comport with Safe Harbor requirements are not automatically deemed in violation of the law. Rather, those practices are evaluated on a case-by-case basis.

2. Federal Investigation Of DePuy And The Orthopaedic Industry

DePuy Orthopaedics, Inc. ("DePuy") is part of a larger group of entities known as DePuy, Inc., which J&J purchased for approximately $3.5 billion in November 1998. Following common industry practice, DePuy historically has relied upon the use of health care providers ("Consultants") who play an integral role in advancing medical technology and evaluating the safety and efficacy of products currently on the market. DePuy's interactions with Consultants have been generally limited to the following categories: (1) fee-for-service Consultants, (2) clinical research Consultants, (3) scientific research Consultants, (4) product development Consultants, (5) educational grants and charitable contributions, and (6) expenses or in-kind payments to Consultants.

In March 2005, DePuy became one of the targets of a broad-scale investigation of the orthopaedic industry by the United States Attorney's Office for the District of New Jersey (the "USAO"). As part of this investigation, the USAO issued subpoenas to DePuy and four other leading orthopaedic products manufacturers, who accounted for nearly 95 percent of the total hip and knee surgical implants market at the time. Although the USAO's investigation focused on agreements for the retention and compensation of Consultants ("Consulting Agreements"), it is important to note that Consulting Agreements were and remain common in the industry and are not *per se* illegal. The OIG, itself, has concluded that Consulting Agreements that mutually benefit the parties generally do not violate the AKS.[25] Rather, violations of the AKS hinge on

[25] *See* 54 Fed. Reg. 3088 (1989); 56 Fed. Reg. 35952 (1991).

the respective party's intentions.[26] Additionally, Safe Harbors -- such as the Personal Services and Management Contract Safe Harbor -- protect contractual arrangements with Consultants that meet the requisite criteria.[27]

In September 2007, the investigation culminated with the entry of Deferred Prosecution Agreements accompanied by the filing of criminal complaints against four companies, including DePuy. The complaint against DePuy (the "DePuy AKS Complaint") made one claim without any specific factual allegations: in the period between 2002 and 2006, DePuy allegedly conspired to violate the AKS by entering into contractual arrangements with various orthopaedic surgeons designed to induce the use and purchase of DePuy's hip and knee reconstruction and replacement products. Contemporaneously with the filing of the criminal complaint, DePuy signed a deferred prosecution agreement (the "DePuy DPA"). And, as part of a civil and administrative settlement with the OIG, DePuy entered into a corporate integrity agreement (the "DePuy Corporate Integrity Agreement") and agreed to pay $84.7 million in fines. In the Settlement Agreement, DePuy "denie[d] that it was engaged in any wrongdoing"; the Settlement Agreement also provided that the settlement constituted "neither an admission of any facts or liability by DePuy."[28]

As required, DePuy engaged the services of an independent monitor to oversee the company's compliance with the DePuy DPA. In late 2007, Debra Wong Yang, Esq. of Gibson, Dunn & Crutcher, LLP (the "Monitor") was appointed to fulfill this role. In discharging her

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[26] *Id.*

[27] 42 C.F.R. § 1001.952(d).

[28] The DPA provides that the prosecution was being deferred "[i]n light of the Company's remedial actions to date and its willingness to . . . (b) acknowledge responsibility for its behavior . . . ." However, DePuy was not required to admit any of the factual allegations in the criminal complaint.

duties, the Monitor conducted an investigation of DePuy's Consulting Agreements, which involved numerous trips to DePuy's headquarters, regular meetings and communications with DePuy representatives, interviews of hundreds of employees, and attendance at DePuy-sponsored events. In six separate quarterly reports to the USAO, the Monitor documented DePuy's progress over the course of the monitorship. In her final report to the USAO in March 2009, the Monitor concluded that DePuy had fully complied with the terms of the DePuy DPA, and the USAO subsequently filed an order dismissing the DePuy AKS Complaint with prejudice on March 30, 2009.

3. DePuy's Oversight Of Consulting Agreements

Given the lack of specificity in the DePuy AKS Complaint, the Special Committee's investigation has focused on the adequacy of the HCC oversight systems in place at DePuy to ensure that the company's use of Consulting Agreements complies with the AKS and other applicable laws and regulations. To that end, the HCC initiatives that DePuy has implemented before, during and after the monitorship are discussed in detail below.

(a) Pre- And Post-DPA And CIA (1998-2007)

When J&J acquired DePuy in 1998, the operating company did not have a centralized HCC program to regulate or monitor its use of Consultants. Less than a year after J&J purchased DePuy, the company issued its first set of standard operating procedures specifically addressing Consulting Agreements. In 2001, DePuy appointed a Director of HCC. The Director of HCC, along with his two direct reports, became informally known as the HCC Department. This group monitored HCC issues, including potential AKS violations. For example, the HCC Department conducted internal audits of DePuy's use of Consultants, and the Company took action to address issues that arose from those assessments. In addition, DePuy had a J&J co-located regulatory attorney on site to assist with HCC matters, and the Company Group Chairman was

required to certify DePuy's compliance on an annual basis with J&J's Policy on Business Conduct.

In 2003, DePuy further revised and refined its standard operating procedures governing Consulting Agreements, and transferred direct oversight of the consulting approval process from Sales and Marketing to the Business Relations Department. DePuy also became a founding member of the Advanced Medical Technology Association ("AdvaMed"), and helped write the Code of Ethics for Interactions with Health Care Professionals (the "AdvaMed Code"). The AdvaMed Code went into effect in 2004.

As previously noted, after the OIG Guidance was promulgated in May 2003, J&J increased its corporate oversight of HCC. On October 3, 2003, J&J's Corporate Internal Audit department conducted a review to assess whether DePuy's HCC program complied with the seven elements prescribed by OIG. The review ultimately concluded that DePuy had made considerable effort to create an effective compliance program. Corporate Internal Audit followed this review with a more comprehensive audit in 2004. In July 2004, J&J issued the HCC Framework. Mirroring the OIG Guidance, this Framework set forth the essential HCC program elements that DePuy and each of the other operating companies had to implement.

After the federal investigation into the orthopaedic industry began in 2005, DePuy's HCC program underwent further development. DePuy expanded the size and responsibilities of its HCC personnel. DePuy appointed a Worldwide Vice President of HCC, who had direct line reporting to the Company Group Chairman. Thereafter, DePuy formalized the HCC Department in 2006, and appointed the first official DePuy Chief Compliance Officer in 2007.

In terms of structure and organization, DePuy changed the name of the Business Relations Department to the Department of Medical Affairs ("Medical Affairs"). Medical Affairs became responsible for pre-approving Consulting Agreements and paying invoices for

services rendered. DePuy also created several committees staffed by key personnel to oversee the various types of Consulting Agreements.

Moreover, in June 2005, Medical Affairs began a formal needs assessment to examine DePuy's use of Consultants. DePuy then later commissioned Polaris Management Partners ("Polaris"), a management consulting firm specializing in services that address compliance risks in the Life Science industries, to develop a fair market value methodology and pay rates for compensating Consultants and other health care providers. Importantly, the Polaris report validated DePuy's existing compensation scale for Consultants.

As it ramped up its oversight and monitoring of Consultant use, DePuy ended certain past practices that had been vulnerable to abuse industry-wide. For instance, DePuy stopped training its sales representatives in the operating room and prohibited Consultants from seeking compensation for operating room sessions attended only by DePuy employees and/or agents. Additionally, DePuy strengthened its HCC training efforts in general, and there were additional audits of DePuy's use of Consultants by the J&J Corporate Internal Audit Department.

In the September 2007 DePuy DPA, the USAO acknowledged that DePuy's alleged conduct had not adversely affected patient health or care, and that the Company had undertaken extensive actions and HCC reforms before entering into the DePuy DPA. Generally speaking, pursuant to the DePuy DPA, the Company was required to cooperate with federal investigators, inform employees and distributors of their obligations to report legal violations, implement compliance programs, and adhere to the AdvaMed Code. More specifically, the DePuy DPA mandated that DePuy continue or implement additional HCC initiatives, such as: (1) retention of an independent monitor to evaluate its compliance with the DePuy DPA; (2) establishment of the Office of the Chief Compliance Officer headed by the DePuy Chief Compliance Officer, who reports directly to the Depuy Chief Executive Officer and oversees the Company's day-to-day

compliance activities; (3) completion of an annual needs assessment; (4) requirement that all Consulting Agreements must be in writing, meet certain conditions, and be executed by DePuy's Chief Compliance Officer, President, Chief Legal Officer, and Vice President of Research and Development; (5) requirement that all Consulting Agreements entered after the DePuy DPA contain a provision compelling Consultants to disclose their relationship with DePuy to their patients; (6) enhancement of its training and education programs; and (7) implementation of certification requirements to promote HCC compliance.

Likewise, the terms and conditions of the DePuy Corporate Integrity Agreement, which expires in 2012, are similar to those of the DePuy DPA. Two significant differences, however, are that the Corporate Integrity Agreement provides stricter requirements for DePuy officers, directors, employees, agents, and independent contractors who are involved in the development, approval, management, implementation, use, or review of any consulting transactions and/or arrangements, and also requires DePuy to engage the services of an Independent Review Organization ("IRO") to review and assess annually the procedures the Company has enacted to try to ensure that its Consulting Agreements do not run afoul of the AKS.[29]

(b) Monitorship (2007-2009)

As noted above, DePuy retained the Monitor to assess and oversee its HCC compliance efforts in 2007. The Monitor issued six separate quarterly reports to the USAO documenting the company's progress. In those comprehensive reports, the Monitor expressly recognized the significant, and entirely legitimate, value that Consultants have afforded to DePuy and the rest of the orthopaedic industry. The Monitor also commended DePuy for its HCC improvements, and

[29] DePuy subsequently selected Ernst & Young as the IRO. In its initial report, Ernst & Young concluded that DePuy had implemented the Corporate Integrity Agreement's Arrangement Requirements. Based upon a random and selective testing of compliance with those Arrangement Requirements, Ernst & Young found a compliance rate of about 98%.

"noted a general commitment to health care compliance and compliance with the DPA at DePuy" since the monitorship began.

The Monitor indicated that DePuy appeared to have had weak compliance controls in the distant past and generally followed common industry practices in its use of Consultants. Importantly, however, the Monitor encountered no evidence that such conduct was continuing, or that it has occurred since DePuy made efforts to improve its compliance practices in recent years.

Nonetheless, the Monitor made various recommendations to facilitate further improvement, which DePuy has implemented. Thus, for example, DePuy increased the resources and expertise of its collective HCC organization, restructured its Committees, and created the Service Review Committee to review and approve service and payment requests. DePuy also revised its policies and procedures with respect to Consultants and Consulting Agreements to make them more practicable and comprehensible, and revised its Consulting Agreements templates.

Finally, at the Monitor's request, J&J also began taking a more active role in monitoring HCC at DePuy. In order to do so, J&J assigned two of its employees to work closely with DePuy senior management.

(c) Conclusions

The Consolidated Complaint (at Paragraph 282) cites the receipt by DePuy of a subpoena from the USAO as a "red flag" received by the Board of Directors that indicated "the ongoing pervasive wrongful conduct at the Company." However, the Board and Audit Committee were advised that the Company was cooperating with the investigation and that DePuy was one of several medical device manufacturers under investigation. The allegations in the criminal

complaint were conclusory in nature. DePuy undertook a variety of steps to enhance HCC compliance before and after entering into the DePuy DPA and Corporate Integrity Agreement.

Over the course of the monitorship, DePuy adopted the Monitor's recommendations, implemented numerous HCC initiatives on its own, and strengthened compliance measures it had previously put into practice to ensure that its consulting arrangements satisfy statutory and regulatory requirements. Ultimately, the Monitor found that DePuy not only complied with the terms of the DPA, but in certain instances, went above and beyond expectations to ensure the long-term health and sustainability of its compliance program. Therefore, the Monitor determined that DePuy -- with significant help from its parent company J&J -- had developed a robust HCC program to oversee and mitigate compliance risks associated with Consultants and Consulting Agreements.

In sum, the Special Committee finds no wrongdoing by the Board of Directors or management -- either at the J&J or DePuy level -- with respect to potential violation of the AKS.

4. Omnicare Issues

Several demand letters and shareholder complaints allege that J&J and its subsidiaries[30] caused Omnicare to submit false claims to the U.S. government from 1999 through 2004 as a result of kickbacks that Johnson & Johnson Health Care Systems, Inc. allegedly paid to induce Omnicare's purchase and recommendation of certain drugs for use in nursing homes -- in violation of the federal AKS[31], the Medicaid Drug Rebate Statute[32], and the False Claims Act

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[30] Johnson & Johnson Health Care Systems, Inc. ("J&JHCS"), Janssen Pharmaceutica Products, L.P. ("Janssen") and Ortho-McNeil Pharmaceutical Products, Inc. ("OMP") (now Ortho-McNeil-Janssen Pharmaceuticals, Inc. or "OMJPI").

[31] 42 U.S.C. § 1320a-7b(b)(2).

[32] 42 U.S.C. § 1396r-8.

("FCA")[33]. The alleged illegal kickbacks were in the form of: (1) market-share rebates conditioned on Omnicare engaging in "active intervention programs" for the drugs Risperdal, Propulsid, Levaquin, Procrit, Duragesic, and Ultram; (2) the purchase of data from Omnicare identifying physician prescribers of antipsychotics, among other products, which the government alleges was a covert rebate; and (3) various grants, educational funding, and meeting sponsorship fees paid to Omnicare.

These allegations derive from two civil FCA lawsuits brought by relators and various states that are currently pending in the United States District Court for the District of Massachusetts (the "Omnicare Litigation").[34] The DOJ first began investigating J&J and its subsidiaries' relationship with Omnicare in 2004. The DOJ did not pursue criminal or civil enforcement action against the Company or its subsidiaries under the AKS; however, the United States did intervene in the Omnicare Litigation on January 15, 2010 and named J&J, J&JHCS, and OMJPI as defendants.

The Omnicare litigation remains pending, although many of the claims brought by the relator-plaintiffs and states have been dismissed. The District Court denied the defendants' motion to dismiss the government's FCA claim because it determined that (1) a failure to disclose the terms and conditions for achieving rebates under the Omnicare drug supply agreements may have been a violation of the AKS, and (2) a violation of the AKS could have resulted in Omnicare submitting false claims for Medicaid and other government reimbursements because Omnicare certified that it had complied with federal and state anti-kickback statutes when filing such claims.

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[33] 31 U.S.C. § 3729 *et seq.*

[34] *United States of America ex. rel. Bernard Lisitza and David Kammerer v. Johnson & Johnson*, Civil Action Nos. 07-10288-RGS and 05-11518-RGS (D. Mass.).

(a) Rebates And Reporting Requirements In The Pharmaceutical Industry

The Omnicare Litigation challenges the practice of providing discounts and market-share rebates in connection with drug supply agreements. It is important to note that rebates and discounts for pharmaceutical products are not *per se* illegal. In carving out exceptions to the AKS, Congress explicitly "ensure[d] that the practice of discounting in the normal course of business transactions would not be deemed illegal."[35] Pertinent here, the AKS does not prohibit J&J from applying a "discount or other reduction in price" in its charges to Omnicare for pharmaceutical products, so long as "the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made . . . ."[36] Likewise, under the Regulatory Discounts Safe Harbor, a discount -- which is defined as "a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction" -- is permissible so long as the discount is fully and accurately reported, the buyer is informed of its disclosure obligations, and the seller refrains from impeding the disclosure obligations.[37]

Indeed, rebates are a commonplace and universally recognized practice in the health care industry and employed by both private and public health care providers. For example, the Medicaid program uses rebates and supplemental rebates, formularies, and preferred drug lists to encourage the use of preferred drugs. Moreover, in accordance with the Medicaid Drug Rebate Statute, Medicaid enjoys the benefit of rebates and prices on drugs that other large purchasers enjoy. In particular, for a brand name drug to be covered and reimbursed by Medicaid, the manufacturer is required to (i) report on a quarterly basis the drug's "average manufacturer

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[35] H.R. Rep. No. 95-393(II), at 53, reprinted in 1977 U.S.C.C.A.N. 3039, 3056 (emphasis added).

[36] 42 U.S.C. § 1320a-7b(b)(3)(A).

[37] 42 C.F.R. § 1001.952(h)(5).

price" and its "best price," and (ii) pay each state a quarterly rebate equal to the total number of drug units purchased by the state times the greater of (1) 15.1% of the drug's average manufacturer price or (2) the difference between the average manufacturer price and the best price.[38]

J&J, as a manufacturer, does not submit reimbursement claims to the government for the purchase of its drugs. Rather, J&J's statutory and regulatory reporting requirements pertain to its "average manufacturer's price" and its "best price" -- which would reflect any rebates/discounts given to its commercial customers. Omnicare, as a provider of pharmacy dispensing services to nursing homes, would submit reimbursement claims to Medicaid for the costs of the drugs that would likewise reflect their discounted price. Accordingly, the discounted costs of the drugs are disclosed to the federal government by both J&J and Omnicare.

(b) Alleged Kickbacks To Omnicare

(i) Rebates From The Drug Supply Agreements

J&JHCS and Omnicare entered into two Drug Supply Agreements in 1997 and 2000 (the "Agreements"), pursuant to which Janssen and OMP sold certain drugs to Omnicare.[39] In accordance with these agreements, J&JHCS paid quarterly rebates on enumerated products based upon their percentage of Omnicare sales within each drug class. Market share was determined by Omnicare's purchase of each drug in comparison to Omnicare's purchase of competing products.

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[38] 42 U.S.C. § 1396r-8(c)(1)(A). Effective January 1, 2010, the statutory minimum percentage changed to 23.1%.

[39] The Long Term Care Group from Janssen (now OMJPI) was primarily responsible for negotiating the Agreements and maintaining the relationship with Omnicare.

In addition, the Agreements provided for an "Annual Strategic Product Performance Rebate" on specific drugs that had an "Active Intervention Program (AIP) or Appropriate Use Program (AUP) applied in their favor." The AIP was defined as:

> a program, applied by [Omnicare] and accepted by J&J in writing, which is designed to appropriately shift market share to J&J's Product. Active interventions can include, but are not limited to, disease management initiatives, written correspondence to Participating Providers prescribing or dispensing pharmaceutical products, educating nursing home staff regarding [J&J's Products, [and] conducting clinical intervention programs through which consultant pharmacists recommend Supplier's Products when appropriate.

The AUP was defined as "a program applied by [Omnicare], and accepted in writing by Supplier, designed to cause the appropriate use of [J&J]'s Products." Omnicare agreed to promote the "appropriate and indicated uses" of the J&J products and to implement programs that would educate Omnicare staff and nursing home personnel about the J&J products in a "clinically appropriate" manner. The Agreement was amended on October 11, 2000 to eliminate the Annual Product Performance Incentive for Risperdal (the Annual Product Performance Incentives for Levaquin and Procrit had previously been removed).

As with any market-share rebate program, the larger the market share the larger the rebate. The Agreements clearly explained how the rebates would be calculated and included a performance matrix. Furthermore, the 2000 Agreement explicitly obligated Omnicare to disclose the rebates to Medicaid and Medicare "as required by applicable State and/or Federal regulations," and it also contained a "Best Price" provision that allowed a price adjustment both retroactively and prospectively if the discount exceeded the current Medicaid "Best Price" threshold.

The Agreements were reviewed by the J&J Legal and HCC departments before they were executed. As a general matter, the individuals involved in negotiating these Agreements were

familiar with and sensitive to the requirements of the AKS. The Long Term Care Group received training on the AKS and compliance with other health care laws and regulations on a regular basis. Neither the documents the Special Committee has reviewed nor the interviews it has conducted have revealed any specific concern in 1999-2004 that these Agreements, as drafted, violated the AKS. Nor is there evidence of a concern that the AIP would not meet the requirements of the statutory and safe harbor exceptions for acceptable discounts under the AKS. Notably, since approximately 2007, the Long Term Care Group no longer incorporates an AIP into its supply agreements with Omnicare -- or with any other long term care facilities

Whether the Agreements violated the AKS is a legal question currently being addressed in the Omnicare Litigation. Although the court denied the defendants' motion to dismiss the government's complaint, this is an area where reasonable minds may differ. The Omnicare Litigation defendants certainly have a *bona fide* basis for contending that the rebates were lawful.

(ii) Data Purchase Agreements As "Covert Rebates"

The OIG-promulgated Safe Harbors also include a "Personal Services and Management Contracts Safe Harbor" that permits commercial arrangements between manufacturers and health care providers if there is a signed, written agreement for a term greater than one year that specifies all of the services to be provided, the schedule for providing such services, and the aggregate compensation (which must be consistent with fair market value in an arms-length transactions). [40] Moreover, the contracted-for services must not violate any state or federal law

[40] 42 C.F.R. § 1001.952(d).

and must not "exceed those [services] which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."[41]

In October 2000, J&JHCS entered into a Consulting and Services Agreement ("CSA") under which it would purchase from Omnicare data identifying physician prescribers that it claims were critical to the Long Term Care Group's marketing activities. The CSA had a term of July 1, 2000 to April 1, 2004 and required J&JHCS to pay $450,000 for the first three months of the term and $300,000 per quarter thereafter. The government alleges that this was actually a "covert rebate" put into effect because J&J did not want to set a new Best Price that would require it to pay higher rebates to Medicaid. It further contends that the purchased data was not supplied by Omnicare on a quarterly basis as required by the Agreement; rather, Omnicare pharmacies "randomly" and "willingly" provided the Long Term Care Group with names of prescribing physicians as they had done prior to the Agreement.

Based upon the evidence reviewed by the Special Committee, it appears that:

- The CSA was a legitimate means to obtain marketing information that was not available elsewhere, as Omnicare did not sell its data to IMS or any another vendor until 2005. The Long Term Care Group needed this data in order to (1) channel the efforts of its Elder Care sales force to key physicians who have the greatest influence on drugs prescribed, and (2) to obtain timely information about its product performance in the marketplace and the effectiveness of its sales force's practices.

- The Long Term Care Group was receiving the physician data it needed from Omnicare -- albeit, the data was initially delivered in a manner other than that specified in the contract. The CSA called for the quarterly provision of a "national report [that] will list 200 competitive prescribing physicians for each J&J Strategic Brand." Instead, the Long Term Care Group received information on the high volume physicians from each individual Omnicare Pharmacy. J&JHCS considered this data from local pharmacies to be "more valuable" and, in 2003, amended the CSA's data provision requirements to reflect the type of data Omnicare had been

[41] *Id.*

providing. J&JHCS would not release payment to Omnicare for the physician data unless it had first verified receipt of the data.

- Compensation under the CSA was not volume-based or in any way contingent upon Omnicare's purchase and recommendation of J&J drugs. Moreover, the compensation for this data was based upon fair market value analyses that J&JHCS conducted using the cost of comparable data from a vendor (IMS) from which J&J purchased regularly.

- Even though J&JHCS considered its payments under the CSA to be "marketing fees" not subject to Best Price calculations, it maintains that the addition of these sums would still not have resulted in a Best Price violation in any quarter. But even if there had been a Best Price violation, that would not automatically result in a violation of the AKS.

(iii) Grants, Educational Funding And Sponsorship Fees

J&JHCS and Omnicare entered into an "Initiative Partnership Agreement" in 1999, pursuant to which J&JHCS paid Omnicare a $300,000 Program Fee to aid Omnicare in its development of intervention initiatives. The written agreement specifically stated that the Program Fee was not "tied to or conditioned on favorable formulary positioning or purchasing commitments [and] is not tied to volume or value of utilization of J&JHCS's products or services." This Agreement, like any other agreement for personal services, is reviewed by J&J's Law Department for compliance with all applicable laws before it is executed.

J&JHCS also provided Omnicare with grants for its health management programs and was one of the sponsors of Omnicare's annual meeting -- where it made presentations to Omnicare employees. It is not unusual for J&JHCS to make such investments in research and education, or to sponsor a meeting where a J&J subsidiary will be presenting. In March 2003, J&J revised its educational grant review process to formalize the manner in which grants were requested and reviewed in order to ensure compliance with the AKS. A formal request must be made; the request must be reviewed and approved by HCC; and all such payments are memorialized in a letter of agreement.

(c) Conclusion

To be liable under the AKS, a defendant must act "knowingly and willfully."[42] The defendants in the Omnicare Litigation believed in good faith that the payments made to Omnicare fell within the statutory discount exception and the regulatory Safe Harbors; their interpretation of the AKS is certainly a reasonable one.

The Special Committee Investigation has found no evidence that the defendants in the Omnicare Litigation knowingly and willfully entered into a rebate agreement that did not fall within the AKS discount exception and regulatory Safe Harbor. The court has interpreted the statutory exception to require the disclosure of not just the raw amounts of the rebates, but of the terms and conditions of the rebates -- here, the AIP. Notably, however, the court did not point to any case law in support of this interpretation, and such a requirement is not explicitly set forth in the text of the statutory or regulatory discount exceptions. To the contrary, an OIG advisory opinion suggests the opposite. But even if such a reporting requirement were feasible and ultimately becomes a requirement under interpreting case law, the Special Committee finds that it was reasonable for the defendants to believe they were complying with the AKS at the time J&JHCS entered into the Agreements with Omnicare. Importantly, J&JHCS no longer enters into rebate agreements that incorporate an AIP, so this should not be a concern in the future.

Likewise, the Special Committee has uncovered no evidence that either the CSA or the grants and educational funding provided to Omnicare constituted a knowing and willful violation of the AKS. The defendants have a *bona fide* basis for contending that the CSA falls within the personal services safe harbor. Indeed, any payments made to Omnicare under this Agreement were not linked to its purchase of J&J drugs or movement of market share. And it was also

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[42] 42 U.S.C. § 1320a-7b(b)(2).

objectively reasonable for the defendants to believe that the occasional educational grants and sponsorship fees afforded to Omnicare (which were standard in the industry, subject to review and approval from HCC, and not linked to the purchase of drugs) were lawful.

The demand letter submitted on behalf of the New Jersey Building Laborers Annuity and New Jersey Building Laborers Pension Funds alleges that "[e]ach of the members of the J&J Board, as a director, knew, and/or should have known, of the misconduct set forth in the DOJ [civil complaint]." As discussed above, J&J's defense on the merits of the Omnicare litigation is strong and proffered in good faith. The Board of Directors and Audit Committee were informed of the government's investigation and J&J's cooperation with that investigation; the Board was also advised of the government's subsequent intervention in the civil litigation and J&J's defenses to the litigation.

C. Alleged Violations Of The Foreign Corrupt Practices Act

As a result of a report by a whistleblower in early 2006, J&J with the assistance of outside counsel began an extensive investigation into potentially illegal payments to foreign medical officials in Greece and elsewhere. When the investigation revealed breaches of Company policies, senior management initiated an FCPA risk analysis review of foreign operations in South America, Europe and Asia, and presented the investigation findings to the Board of Directors with the recommendation, which the Board accepted and acted on, that the Company self-disclose its findings to the DOJ and the SEC, as well as through a press release to the general public.[43] Senior management also retained a second outside counsel firm to evaluate the Company's FCPA compliance systems,

In-house counsel provided regular updates to the full Board and the Audit Committee on

[43] The Company also referenced the self-disclosure and government investigation in every annual 10-K filed with the SEC since February 2007.

the status of negotiations with the government and improvements to FCPA compliance systems. In April 2011, the DOJ, SEC, and the U.K. Serious Fraud Office announced that they had resolved their investigations of the matters disclosed by J&J. The DOJ and J&J entered into a Deferred Prosecution Agreement (the "FCPA DPA"), which pertained to conduct that took place in Greece, Poland, Romania, and in connection with the United Nation's Oil-for-Food Program. The DOJ's announcement acknowledged the Company's self-disclosure, cooperation, and extensive compliance improvements as material to its decision to defer any prosecution. The DOJ did not require the Company to retain an independent compliance monitor.

Within approximately a month of the DOJ announcement, one law firm filed two putative derivative complaints in federal court, each on behalf of two shareholders, that asserted claims of breach of fiduciary duty based solely on the FCPA and the FCPA DPA. A third complaint was subsequently filed in the Superior Court of New Jersey, asserting similar allegations.

As discussed below, our investigation has not uncovered any evidence of a breach of fiduciary duty by any current officer or director of the Company. The FCPA DPA recites facts that implicate a former J&J executive and a former DePuy, Inc. executive with knowledge of the conduct in Greece. We do not believe it is in the best interests of the Company to pursue any potential claims against those two individuals.

1. The Foreign Corrupt Practices Act

The FCPA was enacted in 1977 to, *inter alia*, prevent the bribery of "foreign officials" by domestic corporations.[44] Generally speaking, the FCPA makes it unlawful to bribe foreign government officials to "obtain or retain business." For purposes of this report, the FCPA prohibits U.S. companies and citizens, or any person while in the United States, from making

[44] 15 U.S.C. § 78dd-1. *See also* S. Rep. No. 95-114, at 3-4 (1977); H.R. Rep. 95-640, at 4-5 (1977).

payments either directly, or indirectly through a third party, of anything of value to an employee of a foreign government, with the intent to obtain or retain business.[45] The FCPA also contains accounting provisions, commonly referred to as the "books and records" provisions, that require, *inter alia*, any company whose shares are publicly traded in the U.S. to "(1) . . . keep accurate books and records reflecting the transactions and dispositions of the assets of the [company], and (2) . . . maintain a reliable and adequate system of internal accounting controls."[46] These are designed to eliminate slush funds and off-book transactions that facilitate bribery.

The prohibitions of the FCPA also apply to officers, directors, employees, or agents of domestic companies, or those whose shares are publicly traded here. Furthermore, a parent corporation may be liable for violations by its subsidiary, where the parent authorized, directed, or controlled the activity in question.

2. Analysis Of Specific Allegations

Certain shareholders allege that J&J subsidiaries in Europe paid bribes to state health care employees in Greece, Poland, and Romania, and paid kickbacks to win contracts in Iraq under the United Nations' Oil-for-Food program. The shareholder-plaintiffs allege that these practices took place throughout the world and that J&J had inadequate procedures to prevent such practices. The Special Committee's investigation has determined that the underlying allegations were isolated instances and that there is no evidence to support the shareholders' allegations that this conduct was widespread, tolerated, or that the Company had inadequate controls.

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[45] 15 U.S.C. §§ 78dd-1, 78dd-2, 78dd-3.

[46] *S.E.C. v. World-Wide Coin Investments, Ltd.*, 567 F. Supp. 724, 748 (N.D. Ga. 1983). *See also* 15 U.S.C. § 78m(b).

(a) Greece

The Greek health care sector is a mix of public and private services. The majority of physicians in Greece, however, are employed by the Greek government and the majority of medical equipment consumption is by the public sector, mainly by public hospitals. Tenders for government purchases are issued by the Ministry of Health and Social Welfare, the Ministry of Development, and in the case of Military Hospitals, the Ministry of National Defense.

J&J acquired DePuy, Inc. in 1998. At that time, DePuy, Inc. served the Greek market through DePuy International, Ltd. ("DPI"), a Leeds, U.K., based subsidiary, which contracted with a Greek distributor, Medec, S.A. ("Medec"). J&J's existing Greek business was served through its subsidiary, J&J Hellas, S.A. ("JJH"), which reported to European umbrella management and distributed its products directly. After the acquisition, J&J initially decided to continue to use Medec to distribute DePuy, Inc. products in Greece and integrate the businesses at a later date.

Evidence indicates that prior to the DePuy, Inc. acquisition, Medec, and specifically its principal and owner, made improper payments to surgeons to induce sales, and that such practices were *de riguer* in Greece. We have found no evidence, however, that J&J was aware of this at the time of its acquisition of DePuy, Inc.

By March 1999, however, personnel at the European subsidiary that served as umbrella management for non-DePuy, Inc. subsidiaries in Europe became aware that Medec was making payments for "surgeon support." By early 2000, DPI personnel and the DePuy, Inc. franchise Worldwide Chairman agreed to terminate DePuy, Inc.'s relationship with Medec. However, the DePuy, Inc. franchise Worldwide Chairman reversed course and decided that DPI would acquire Medec and retain its owner as a consultant. Certain personnel at DPI, and potentially the franchise Worldwide Chairman, intended to find a business model that would allow DPI to

continue to sell through the consultant while keeping the sales practices at arms length. This included keeping Medec outside the Company's regular reporting lines to MD&D EMEA, the Europe/Middle East/Africa umbrella management organization. Ultimately, the acquisition was structured so that Medec, renamed DePuy Hellas ("DPH") after the acquisition, reported to DPI, rather than to MD&D EMEA.

In late 2004 and early 2005, DPI's President alerted U.S. personnel that DPH's use of a second consultant may not be compliant with Company compliance policies. That information passed through compliance channels, ultimately reaching DePuy Inc.'s HCC Officer. Over the course of 2005, DePuy Inc.'s HCC Officer discussed a transition to a business model that would not entail use of a consultant, but did not order DPH to immediately terminate its relationship with the consultant or investigate whether the consultant had violated Company policies or U.S. laws. By the end of 2005, all agreements with the consultant had been terminated.

In January 2006, J&J received a "whistleblower" email from a DPH employee that raised the allegations of improper payments by DPH and its consultant. J&J and its Corporate Internal Audit Department launched an investigation. Based on the results of that internal investigation, the Company retained an outside law firm to continue the investigation. The Company also launched a proactive review of its foreign operations in both the MD&D and Pharmaceutical sectors, conducting an FCPA risk analysis review of subsidiaries on three continents.

By February 2007, the Company's investigation determined that improper payments may have taken place but had stopped by early 2006. Management recommended and the Board authorized a voluntary disclosure to the DOJ and SEC, and further instructed the Company to publicly disclose the Greece investigation and a separate investigation in Poland (which is

discussed below), which J&J did after the close of the market on February 12, 2007.[47] That same day, the MD&D Worldwide Chairman, who had ultimate responsibility for DPI by virtue of its reporting upward through the MD&D sector, retired. A second firm was subsequently retained to assess FCPA compliance programs and recommend improvements.

(b) Poland

The Polish health care sector is a centrally-administrated national health care system where most doctors are government employees and most hospitals are government owned and operated. Most purchases of medical devices are through the tender process. Providers of medical supplies compete by submitting bids to tender committees associated with hospitals.

J&J's MD&D franchises in Poland report to a country-wide Managing Director (collectively, "MD&D Poland"). In November 2006, while J&J was investigating sales practices in the Greek market, Polish authorities informed J&J that they were investigating "the acceptance of pecuniary advantages" by public officials at public hospitals. The Company immediately investigated.

It had been MD&D Poland's practice to contract with health care professionals to perform lectures, workshops, or clinical trials. Prior to 2006, MD&D Poland did not require documentation that the services were actually performed. The Company's investigation determined that some of the civil contracts engaged health care professionals to influence pending tender offers, and that some of the contracted services may not have been performed.

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[47] After the Company made its voluntary disclosure to the DOJ and SEC, the DOJ informed the United Kingdom's Serious Fraud Office ("SFO") of the allegations and of the potential involvement of U.K. citizens. In December 2009, the SFO charged former-DPI executive Robert John Dougall, a United Kingdom national, with conspiracy to "mak[e] corrupt payments and/or giv[e] other inducements to medical professionals working in the Greek healthcare system . . . ." SFO Release, Dec. 1, 2009. Mr. Dougall agreed to cooperate with the SFO's investigation and, in April 2010, pled guilty and received a suspended sentence.

MD&D Poland would also sometimes sponsor a health care professional to attend a congress or symposium. The sponsorship expenses included registration fees, hotel and travel expenses, and meals. Payment was made directly to the organizer of the congress or a travel agency, not to the health care professional. The Company's investigation determined that some sponsorships were intended to influence pending tender offers.

There is no evidence that knowledge of these practices extended beyond MD&D Poland. The potential abuse of these practices was halted immediately upon commencement of the Company's investigation in late 2006.

(c) Romania

Romania's health care system is almost entirely state run with most physicians employed by the government and most hospitals owned and operated by the government. Health care costs are funded by the National Health Care Insurance Fund, to which employees and employers make mandatory contributions.

J&J pharmaceuticals are sold in Romania through Janssen-Cilag Eastern Europe ("JC-EE"), which was established in July 2005 as the sales and marketing organization responsible for the southeast European pharmaceutical markets. During the relevant time period, JC-EE maintained only a representative office in Romania ("JC Romania"), primarily for sales and marketing functions.

In June 2007, J&J received a report that one of its foreign subsidiaries' distributors had complained that a JC Romania sales representative was asking the distributor for envelopes of cash for a doctor. J&J immediately investigated and concluded that JC Romania employees and distributors had arranged to provide to physicians (1) cash payments and gifts, and (2) travel to conferences, in exchange for prescriptions for select J&J products. There is no evidence that

knowledge of these practices extended beyond JC-Romania, which has terminated this practice and undergone a restructuring.

(d) The United Nations Oil For Food Program

In August 1990, the United Nations ("U.N.") adopted a resolution prohibiting member nations from transacting business with Iraq, except for the purchase and sale of humanitarian supplies. In April 1995, the U.N. adopted a resolution that allowed Iraq to sell oil so long as the proceeds were used to purchase humanitarian supplies, including food and medicine, for the Iraqi people. Hence, the program became known as the Oil-for-Food Program ("OFF"). Payments made to the Iraqi government outside the OFF program were prohibited, and the U.S. Treasury enacted conforming regulations prohibiting U.S. companies from engaging in business with the Iraq government outside the OFF program.[48]

Two J&J subsidiaries, Janssen Pharmaceutica A.V. in Belgium and Cilag A.G. International in Switzerland, sold pharmaceutical products to the Iraqi government through Cilag's office in Lebanon, JC-Lebanon, which in turn used an independent agent to distribute products in Iraq. In approximately August 2000, the Iraqi government surreptitiously demanded that suppliers of humanitarian goods pay a kickback, usually valued at 10% of the contract price, to the Iraqi government. From approximately December 2000 to March 2003, JC-Lebanon's agent apparently made payments to the Iraqi government on 18 contracts.

3. The Deferred Prosecution Agreement

In April 2011, the DOJ and J&J entered into a FCPA DPA, pursuant to which the Company agreed to cooperate with the DOJ for a period of three years, pay a fine of $21.4

[48] 31 C.F.R. § 575.201 *et seq.*

million, continue to implement its FCPA compliance program, report on its compliance implementation, and accept responsibility for the conduct described above. In exchange, the DOJ agreed it would file a criminal information against only DePuy, Inc. and only for the conduct that took place in Greece. The FCPA DPA recited that this was specifically on account of the Company's "voluntar[y] and timely" disclosure of the conduct, thorough investigation, full reporting to the DOJ, full cooperation with the DOJ, and substantial remedial measures. The Company also agreed to pay the SEC $48.6 million in disgorged profits, pursuant to a Judgment to which the Company consented without admitting or denying the allegations in the SEC's complaint. And DPI agreed with the U.K. SFO to enter into a Civil Recovery Order and pay a fine of 4.829 million pounds sterling.

The statement of facts incorporated in the FCPA DPA indicate that the conduct in Greece, Romania, Poland, and during the OFF program, would constitute violations of the FCPA's books and records provisions. However, the FCPA DPA does not state that J&J's internal controls were inadequate, or that J&J directly misstated its financial statements. Rather, the FCPA DPA states that J&J's financial statements were inaccurate because they incorporated the statements of the implicated foreign subsidiaries. The criminal information alleged that the conduct in Greece violated the anti-bribery provisions of the FCPA.

4. Conclusions

The *Cafaro* derivative complaint alleges that, "when faced with a known duty to act, *i.e.*, ensuring J&J's compliance with the Foreign Corrupt Practices Act ('FCPA'), defendants breached their duty of loyalty by failing to cause J&J to implement an internal controls system for detecting and preventing bribes to public doctors and administrators in Greece, Poland, and Romania and kickbacks to Iraq to win business there." Cafaro Comp., ¶ 3. To the contrary, the first notice the Board of Directors had of the improper payments made to Greek and Polish

medical officials came with management's report to the Board during the February 2007 Board meeting. The Board authorized J&J's voluntary self-disclosure to the SEC and DOJ, and received periodic reports thereafter about both the Company's internal investigation and the government's. The Audit Committee and Board also received periodic reports on the Company's enhanced FCPA compliance efforts.

Paragraph 4 of the FCPA DPA recites that the DOJ entered into the Agreement in consideration of several factors, including:

> b. J&J conducted a thorough internal investigation of [the misconduct described in the Information and Statement of Facts].
>
> c. J&J reported all of its findings to the Department.
>
> d. J&J cooperated fully with the Department's investigation of the matter.
>
> e. J&J has undertaken substantial remedial measures . . . .

In addition, it should be noted that J&J's internal investigation, audits by its Corporate Internal Audit Department, and responses to whistleblower complaints uncovered other disparate issues in additional markets and businesses that J&J duly reported to DOJ and SEC. Pursuant to paragraph 7 of the FCPA DPA, the DOJ agreed "that it will not bring any criminal or civil case against J&J, its subsidiaries, or its operating companies related to the conduct of present and former directors, officers, employees, agents, consultants, contractors, and subcontractors . . . relating to any other conduct J&J disclosed to the Department prior to the date on which this Agreement was signed."

The SEC in its complaint alleges that "J&J failed to implement internal controls to detect or prevent bribery," and "failed to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions were executed in accordance with management's general or specific authorization; and (ii) transactions were recorded as

necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for its assets." *SEC Compl.*, ¶¶ 64, 75. As previously noted, J&J consented to entry of a final judgment without admitting or denying the allegations of the SEC's complaint.

Notwithstanding the SEC's allegations, it was J&J's controls that led to receipt of the whistleblower complaint in 2006 and consequent investigation. The Company has significantly enhanced its internal controls, including controls specifically focused on preventing or detecting violations of the FCPA, in the ensuing years, and has committed pursuant to the DPA to periodically review its existing internal controls, policies and procedures that include remediation and compliance measures described in the attachments to the DPA. J&J's independent outside auditors have confirmed the adequacy of J&J's internal accounting controls; the head of J&J's Corporate Internal Audit Department regularly reviews the adequacy of J&J's internal controls with respect to FCPA compliance. Indeed, in its press release announcing the Deferred Prosecution Agreement, DOJ reported that J&J was not required to appoint a monitor because of its "pre-existing compliance and ethics programs, extensive remediation and improvement of its compliance systems and internal controls, as well as the enhanced compliance undertakings included in the agreement."

The compliance lapses that led to the FCPA issues in Greece, Poland, Romania and the OFF program share a single common factor: a lack of corporate visibility into operating company compliance efforts. For Poland, Romania, and the OFF program, the issues arose and remained entirely within the operating companies. In Greece, a second factor contributed, however, to the length and scope of the FCPA issues, namely the delay in integrating DPH into the existing J&J Europe structure. While both of these factors were, in hindsight, correctible, and the resulting compliance problems avoidable, the evidence shows that the decisions

underlying these root causes were made in good faith and were reasonable at the time they were made. More importantly, there is no evidence that suggests that the Board and senior management breached their fiduciary duty to prevent such conduct with adequate risk management controls.

J&J's Board oversaw a global compliance system that was extensive and robust in many ways. 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. Our investigation indicates that this belief was reasonable at the time. The FCPA compliance failures occurred as a result of isolated instances of intentional misconduct by employees of foreign subsidiaries in markets where corruption was endemic. Although misconduct is always present as a risk, the Company's compliance organization and systems could reasonably have been expected to identify and stop such misconduct.

In Greece, however, several individuals, including at least one senior executive of DPI, were complicit. Similarly, in Poland and Romania, the Managing Directors of the respective operating companies failed to enforce corporate policy prohibiting payments to government officials. The Company's expectation that senior personnel would perform in accordance with corporate policy was not unreasonable. Moreover, the Company's investigation has demonstrated that this misconduct was not widespread, and the Board, senior management and Law Department have implemented enhancements to the Company's international compliance systems. There is no evidence that these beliefs and the resultant decisions were negligent -- much less reckless.

Likewise, there is no evidence of negligence at the Board and senior management levels with regard to the delay in integrating the Greek operations into the existing European structure. The purpose of integrating operations is to reduce costs through shared services and economies of scale. For the Greek operations, and a few others, the integration was delayed because any savings would have been exceeded by the costs, among others, of early termination of DPI's existing contractual obligations with Medec. There is no evidence to suggest that this decision was unreasonable or lacking in good faith.

PART FIVE

CONCLUSION AND RECOMMENDATIONS

In summary, the Special Committee finds that substantial enhancements have been made to the J&J HCC and Q&C systems and organizations over the past several years. The systems are designed to assure full compliance with all applicable laws and regulations, and include regular reporting to and monitoring by the J&J Board of Directors and its Audit Committee. The Board and Audit Committee devoted substantial amounts of time and effort to review compliance efforts and issues; there were no red flags or indications of systemic failure that were overlooked. As issues arose, they were appropriately addressed and resolved -- often with the expenditure of significant resources. The Special Committee also finds that no officer -- with the possible exception of the one former J&J officer and the one former DePuy, Inc. officer implicated by the FCPA investigation -- or director breached any fiduciary duty owed to J&J. With respect to the two former officers, the Special Committee concludes that it would not be in the best interest of J&J to initiate litigation against them.

Given the foregoing, the Special Committee believes that it is not in the best interests of the Company to pursue the derivative litigation currently pending or to initiate litigation based upon the demands made upon the Board by the demand shareholders. The Special Committee

therefore recommends to the Board of Directors that the Company reject the shareholder demands and take whatever steps are necessary or appropriate to secure dismissal of the derivative litigation. The Special Committee further recommends that the Board of Directors consider this report and its recommendations in executive session, without the presence jof management.

Without detracting in the slightest from the competence, dedication and hard work of the Audit Committee, the Special Committee also recommends that the Board of Directors 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 Corporate Integrity Agreement, the McNeil Consent Decree and Action Plan, and the FCPA DPA. This would permit the Audit Committee to focus on accounting, audit and financial issues while the new Committee focuses on Compliance systems and issues.

The Special Committee recommends that the Regulatory and Compliance Committee be authorized to retain outside expert consultants, to assist the Committee in its work as the need arises. Among other things, the Regulatory and Compliance Committee, in consultation with management and an expert consultant, should develop metrics and a report card that would provide insight into and perspective on J&J's Compliance systems and organizations. The new Committee should have an initial term of five years, commensurate with the McNeil Consent Decree. Members of the Special Committee will make themselves available to consult and confer with the members of the Regulatory and Compliance Committee, to provide the latter with the former's insights gained as a consequence of its investigation.

Dated: June 27, 2011

By: _ /s/ Charles Prince
Charles Prince (Chairman)

By: /s/ Michael M. E. Johns
Michael M.E. Johns

By: /s/ Anne Mulcahy
Anne Mulcahy

By: /s/ William D. Perez
William D. Perez

APPENDIX A
Glossary of Acronyms

Acronym	Full Description
AIP	Active Intervention Program
AKS	Federal Anti-Kickback Statute
AOA	Australian Orthopaedic Association
AUP	Appropriate Use Program
CAPA	Corrective and Preventive Actions
CCO	Chief Compliance Officer
CCR	Corporate Center Review
cGMP	Current Good Manufacturing Practices
CQO	Chief Quality Officer
CSA	Consulting and Services Agreement
DDMAC	FDA's Division of Drug Marketing, Advertising and Communication
DHHS	Department of Health and Human Services
DOJ	U.S. Department of Justice
FCPA	Foreign Corrupt Practices Act
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug and Cosmetic Act
GOC	Group Operating Committee
GQC	Global Quality Council
HCBI Guide	International Health Care Business Integrity Guide
HCC	Health Care Compliance
HHE	Health Hazard Risk Evaluation
IRO	Independent Review Organization
MAARS	Management Awareness and Review Systems
MAP	Management Action Plan
MD&D	Medical Devices and Diagnostics
MMPD	Management of Manifestation of Psychotic Disorders
NJR	National Joint Registry (U.K.)
NJRR	National Joint Replacement Registry (Australia)
OHCC&P	Office of Health Care Compliance & Privacy
OIG	Office of Inspector General
OFF	Oil-for-Food Program
OTC	Over The Counter
PCH	Pfizer Consumer Healthcare
POL-005	Quality Management Systems Policy
PRC	Promotional Review Committee
Q&C	Quality and Compliance
RG	Regulatory Group
SEC	Securities and Exchange Commission
SRC	Service Review Committee
TBA	Tribromoanisole
TRC	Technical Resources and Compliance

APPENDIX B
List of Witnesses Interviewed

1.	Ms. Tracy Acker	Former Director, Regulatory Affairs, Advertising and Promotion, Pharmaceuticals Group
2.	Ms. Minnie Baylor-Henry	Worldwide Vice President, Regulatory Affairs, Medical Devices & Diagnostics Group; Former Vice President, Global Regulatory Affairs, McNeil Consumer Healthcare
3.	Mr. Charles Chartier	National Regional Account Director, J&J Health Care Systems
4.	Mr. Douglas Chia	Corporate Secretary
5.	Dr. Mary Sue Coleman	Board Member and Member of Audit Committee
6.	Ms. Nancy Corkum	Worldwide Vice President, Health Care Compliance & Privacy Integration
7.	Mr. John Crisan	General Counsel, Consumer Group
8.	Ms. Veronica Cruz	Vice President, Quality Assurance, McNeil Consumer Healthcare
9.	Mr. James Cullen	Board Member and Chairman of Audit Committee
10.	Ms. Kris Curry	Vice President, Health Care Compliance, Pharmaceuticals Group
11.	Mr. Paul D'Eramo	Executive Director, Worldwide Quality & Compliance
12.	Mr. Richard D'Souza	Chief Technology Officer
13.	Ms. Saribel Estrada	Former Quality Site Leader, Las Piedras
14.	Mr. Gary Fair	Vice President, Corporate Internal Audit
15.	Ms. Colleen Goggins	Former Worldwide Chairman, Consumer Group
16.	Mr. Alex Gorsky	Vice Chairman, Executive Committee
17.	Mr. Freddie Jimenez	Assistant General Counsel
18.	Mr. Santosh Jiwrajka	Chief Quality Officer, Consumer Group
19.	Ms. Georgia Keresty	Chief Quality Officer and Vice President, Quality & Compliance, Regulatory Affairs and Medical Safety, Consumer Group

20.	Mr. Frank Konings	Vice President, Global Markets, Research & Development; Former Chief Compliance Officer, Consumer Group
21.	Mr. Peter Luther	President, McNeil Consumer Healthcare
22.	Ms. Ashley McEvoy	Former President, McNeil Consumer Healthcare
23.	Ms. Christine Poon	Former Worldwide Chairman, Medicines & Nutritionals Group
24.	Ms. Desiree Ralls-Morrison	Vice President, Legal Department, McNeil Consumer Healthcare
25.	Mr. R. Owen Richards	President, Quantic Regulatory Services, and Vice President, Quantic Group
26.	Mr. Marc Robinson	Company Group Chairman, OTC/Nutritionals/Wellness & Prevention, Consumer Group
27.	Ms. Kathy Schroeher	Former Associate General Counsel; Former Chief Compliance Officer
28.	Mr. Joseph Scodari	Former Worldwide Chairman, Pharmaceuticals Group
29.	Mr. Ajit Shetty	Vice President, Worldwide Operations, and Vice President Worldwide Supply Chain
30.	Mr. Willie VanBuggenhout	Vice President, Worldwide Office of Health Care Compliance & Privacy, and Chief Compliance Officer
31.	Mr. William Weldon	Chief Executive Officer and Chairman of Board of Directors
32.	Ms. Kathryn Wengel	Vice President, Worldwide Quality Compliance, Environment, Health & Safety, and Chief Quality Officer
33.	Mr. Donnie Young	Former Vice President, Worldwide Supply Chain
34.	Mr. Chris Zalesky	Vice President, Global Policy & Guidance, Worldwide Office of Healthcare Compliance & Privacy
35.	Ms. Megan Zoschg	Former Manager, Regulatory Affairs, Johnson & Johnson Pharmaceutical Research & Development

APPENDIX C

List of J&J In-House Attorneys Interviewed

1.	Mr. Joseph Braunreuther	
2.	Mr. William Craco	
3.	Mr. Russell Deyo	
4.	Mr. Harman Grossman	
5.	Mr. John O'Shaughnessey	

APPENDIX D
List of Outside Counsel Interviewed

1.	Mr. Thomas F. Campion	Drinker Biddle & Reath
2.	Mr. Scott Coffina	Montgomery McCracken
3.	Mr. Michael Conner	Barnes & Thornburgh
4.	Mr. Thomas Crocker	Alston Bird
5.	Ms. Diane Doolittle	Quinn Emanuel
6.	Mr. Eric Dubelier	Reed Smith
7.	Mr. Stephen Grossman	Montgomery McCracken
8.	Mr. Gerard Masoudi	Covington & Burling
9.	Ms. Kathleen McDermott	Morgan, Lewis & Bockius
10.	Ms. Ashley Mortabano	Quinn Emanuel
11.	Mr. Ethan Posner	Covington & Burling
12.	Mr. John Potter	Quinn Emanuel
13.	Mr. William Sarraile	Sidley Austin
14.	Mr. Richard Scheff	Montgomery McCracken
15.	Mr. Thomas Suddath, Jr.	Reed Smith
16.	Mr. Walter Timpone	McElroy, Deutsch, Mulvaney & Carpenter
17.	Mr. Robert Ullmann	Nutter, McLennan & Fish