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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

In re JOHNSON & JOHNSON DERIVATIVE LITIGATION This Document Relates To: ALL ACTIONS.	No. 3:10-cv-02033-FLW-DEA MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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SECONDARY AUTHORITIES

Lead Plaintiffs Minneapolis Firefighters' Relief Association, the Hawaii Laborers Pension Fund and Jeanne M. Calamore (collectively, "Plaintiffs") respectfully submit this Memorandum of Law in Opposition to the Motion to Dismiss the Consolidated Amended Complaint (the "Complaint").[1]

I. Preliminary Statement

Corporate directors who knowingly permit longstanding or pervasive violations of regulation or law must face personal liability, even if they did not personally profit from the violations or misconduct. In contrast, a board should not be held liable for an isolated unforeseen misstep by a single rogue employee who contradicts the board's directives. This derivative action arises from the prolonged, pervasive illegal conduct in Johnson & Johnson's ("J&J" or the "Company") core manufacturing and marketing activities and the knowing failure of the Director Defendants, over multiple years and in the face of dozens of red flags, to call a halt to systemic wrongdoing in J&J's core business activities. Under these unique facts, this Motion should be denied.

J&J's principal business is manufacturing, marketing and distributing over-the-counter ("OTC") and prescription health care products. Despite operating through a

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[1] The Individual Defendants filed a 2.5 page, single-spaced letter brief on February 21, 2011 where they purport to reserve a right to file subsequent motions to dismiss. They never sought such permission, have missed the deadline for raising such arguments, and therefore should be deemed to have waived arguments beyond those already briefed.

labyrinth of wholly-owned subsidiaries, J&J's business operations are centrally managed at the parent level. A majority of the J&J board of directors (the "Board") have served in that capacity since 2003. As the Complaint details, these long-tenured Board members, and those who joined more recently, received a constant and clear stream of material "red flag" warnings of illegal conduct affecting each aspect of J&J's business. The Board consciously did not intervene and put a stop to the pervasive illegal conduct. Consequently, Plaintiffs adequately plead that the Director Defendants breached their duty of good faith and loyalty, and that demand on the Board is excused.

As the Complaint alleges, since 2003, the Board learned over 90 times that the Company's drug manufacturing practices and corporate-approved drug marketing strategies did not comply with applicable laws and regulations. ¶¶278-285.[2] These "red flags" all carried the same message of systemic misconduct, and came from multiple credible sources, including: no less than 22 state and federal government subpoenas or investigative demands; no less than six warning letters from the U.S. Food and Drug Administration ("FDA"); no less than 14 complaints filed by various State Attorneys General or the U.S. Department of Justice ("DOJ") regarding illegal

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[2] In this memorandum, "¶" refers to the corresponding paragraph in the Complaint. Capitalized terms have the same meaning as in the Complaint.

conduct; no less than four whistleblower or *qui tam* suits alleging illegal business practices, and no less than 12 recalls relating to many of J&J's best-selling products.

Defendants were plainly informed of the misconduct through the normal operation of internal reporting channels. And each time they executed annual U.S. Securities and Exchange Commission ("SEC") filings, the Board was reminded of many of these allegations of widespread criminality. ¶¶279-282. Critically, the red flags listed in the Complaint reflect only what Plaintiffs' investigation has uncovered. Only discovery will show how much more the Board really knew and chose to ignore.

Defendants' refusal to engage in good faith oversight over J&J's manufacturing practices led to J&J's distribution to consumers of dangerous health products. For example, in 2008, J&J's Board learned that OTC drugs manufactured at J&J's Fort Washington, Pennsylvania facility and its Las Piedras, Puerto Rico facility were contaminated with a pesticide that caused widespread gastrointestinal distress in consumers. ¶106. Mandatory drug manufacturing laws, referred to as "current Good Manufacturing Practices" ("cGMP"), required J&J to immediately investigate the complaints to determine the root cause of the contamination and take corrective and preventive actions to protect the public from exposure to unsafe drugs. Defendants ignored J&J's cGMP requirements. In January 2010, the FDA complained that:

> The Agency is concerned about the response of Johnson & Johnson (J&J) to this matter. . . . J&J did not take appropriate actions to resolve these issues. Corporate management has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management

> at J&J nor at McNeil Consumer Healthcare assured timely investigation and resolution of these issues.

¶109.

In April 2010, J&J was compelled to withdraw massive quantities of OTC drugs from the market, including household names like Children's Tylenol, Motrin, Rolaids and Benadryl. By December 2010 – almost three years after receiving the complaint – the FDA issued an inspection report noting that J&J had still not initiated a comprehensive action plan regarding the pesticide contamination. ¶¶116-118. The pattern of the FDA complaining about drug manufacturing problems and J&J's directors' and officers' lack of response was nothing new. The FDA had complained of a pattern of inadequate responses to manufacturing problems as far back as 2004, observing that J&J only engaged in "specific spot fixes," refused to "take a systematic approach to comprehensively cover the corrections," and had failed to "adequately deal with true preventive actions." ¶87.

Defendants' decision to turn a blind eye to J&J's manufacturing misconduct raised serious health and safety concerns, and exposed the Company and its shareholders to material regulatory, financial and reputational harm. Many of those risks have already materialized, with congressional and regulatory investigations into J&J's product recalls, the forced closure of one of the Company's principle manufacturing facilities, lost profits in the hundreds of millions of dollars and major

adverse press coverage. The Company recently entered into a Consent Decree with the DOJ and many other investigations continue.

While permitting the erosion of good manufacturing practices within its core Consumer segment, Defendants also oversaw, over a multi-year period, J&J's systematic violation of FDA drug marketing regulations, allowing its two other business segments – Pharmaceutical and Medical Devices and Diagnostics – to sell a wide range of powerful prescription drugs and medical devices illegally. Any Board member paying the slightest bit of attention before and since 2003 could not help but see that J&J's top-down drug marketing strategies violated the drug marketing laws by systematically marketing J&J drugs for uses the FDA never approved. *See* §II.A.

For example, between 1993 and 2009, J&J marketed Risperdal (a powerful anti-psychotic) for treating elderly patients with dementia and Alzheimer's disease, including by paying tens of millions of dollars in illegal kickbacks to a nursing home pharmacy. The FDA never approved Risperdal for treating elderly patients with dementia or Alzheimer's disease. In fact, the FDA warned that using Risperdal for these patients increased the risk of patient death. ¶¶168-170, 173-183, 191.

Risperdal was not an isolated violation. J&J's top-down drug marketing violations affected many of the Company's most important revenue drivers. Through J&J marketing messages inconsistent with FDA rules, false medical journal articles and payments of millions of dollars in illegal kickbacks, J&J also marketed Topamax, a powerful psychiatric drug and key revenue driver, for non-approved uses in children

(¶¶193-201, 203-205), Natrecor (an intravenous heart medication) for the non-approved treatment of outpatients, despite known safety risks (¶¶169, 178, 224), and J&J's biliary stents for non-approved use as vascular stents, despite learning that this practice resulted in a large number of aneurisms, amputations and deaths. ¶¶241-251. Risperdal, Topamax, Natrecor and biliary stents were among J&J's blockbuster products. From 2003 through 2009, J&J generated ***$23.6 billion*** in revenues from Risperdal alone. ¶50.

Defendants knew that J&J was systematically marketing numerous drugs for uses that were not approved by the FDA, despite known safety risks, as reflected in their execution of Form 10-Ks, and by the multiple federal and state regulatory subpoenas and requests for documents, employee grand jury testimony, subpoenas, *qui tam* and State Attorneys General complaints, and congressional requests for information that were brought to their attention by J&J's senior management. ¶¶279-285. Indeed, the Director Defendants specifically tracked usage data for J&J's top selling drugs and knew that J&J was generating billions of dollars in annual revenue from unapproved uses, including uses causing serious public harm. ¶¶166-167, 202. Instead of halting J&J's illegal activity, Defendants disregarded dozens of clear and material "red flags" of systemic wrongdoing and, in bad faith, permitted it to continue.

In their Motion, Defendants rewrite the Complaint, ignoring the detail that ties Defendants to affirmative knowledge of the underlying problems. It is not enough for

a defendant to set up and knock down a "straw man" complaint. The Complaint on file provides all the detail this Court needs to fairly deny Defendants' motion.

As a backup plan, Defendants insist that they have created a "Special Committee," and that they should now be trusted to right the corporate problems Defendants created. First of all, Defendants have made sure that the Special Committee has no authority to bring claims on behalf of the Company, undermining its pertinence to this Motion as a matter of well-established precedent. *See* §V. Moreover, three of the four supposedly "independent" committee members suffer from their own disabling conflicts and cannot be trusted to pursue the claims here with any vigor. *Id.* Even if these fatal problems could be cured (and they cannot), by urging this Court to trust them to decide the fate of this Action, Defendants are taking a position in direct conflict with the "Consent Decree of Permanent Injunction" the Company entered into with the DOJ and FDA on March 15, 2011, enjoining J&J subsidiary McNeil and two of its senior executives from continuing to distribute adulterated drugs at three different plants in violation of numerous statutes. ("Consent Decree," attached as Ex. 1 to the Declaration of James E. Cecchi in Support of Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Consolidated Amended Complaint ("Cecchi Decl.") filed concurrently herewith). Exasperated by J&J's refusal to take affirmative curative action, the DOJ averred in its Complaint for Permanent Injunction, filed on March 10, 2011:

> Between 2009 and present, FDA representatives have participated in numerous meetings and teleconferences with McNeil officials, and representatives from McNeil's parent company, Johnson & Johnson, in order to convey the seriousness of the violations found by FDA investigations and FDA's belief that significant improvements are needed to bring McNeil's facilities into compliance with the law. . . .
>
> FDA also issued a Warning Letter to McNeil's Consumer Healthcare Division on January 15, 2010, identifying the CGMP violations found during FDA's inspection of the Law Piedras facility from October 2009 to January 2010. The Warning Letter, a copy of which was also sent to McNeil's parent company, Johnson & Johnson, emphasized the serious nature of the CGMP violations . . . and stated that failure to correct the violations could lead to regulatory action, including an injunction. The President of McNeil's Consumer Healthcare Division responded . . . promising that corrective and preventative actions would be implemented . . . ; however, as noted, sufficient corrections were not made.

("DOJ Complaint," attached as Cecchi Decl., Ex. 2, ¶¶20-21).

It is ironic that Defendants here tell this Court to trust them to right the ship, while the DOJ and FDA have made it clear that they have no faith in J&J's ability or willingness to do so. The Consent Decree commits J&J to invasive regulatory oversight, including ***at least five years of FDA inspections and compliance oversight*** at the Fort Washington, Pennsylvania, Lancaster, Pennsylvania and Las Piedras, Puerto Rico facilities. Cecchi Decl., Ex. 1 at 26-27. The reason for this onerous oversight is apparent from the DOJ Complaint, where the government stated that absent the permanent injunction, and "***unless restrained by this Court, Defendants***

will continue to violate the Act, 21 U.S.C. § 311(a) and (k), in the manner here alleged." *Id.*[3]

In sum, this derivative action involves a Board that managed and oversaw a corporation systemically engaging in prolonged and pervasive illegal behavior in core aspects of its business. The Board was told, repeatedly and from a wide range of reliable sources, that the Company's legal violations were putting lives at risk, may result in government intervention, and were not being timely cured. The Board's utter indifference and disregard for its duty to intervene in this illegal conduct should cause this Court to ask: "Where were Defendants while J&J's hard-earned reputation was destroyed?" "Why didn't the Board halt the illegal conduct even as the red flags mounted?" Defendants' motion to dismiss should be denied, and discovery should commence in order to answer these critical questions.

II. Factual Allegations

A. Inadequate Manufacturing Processes and Illegal Marketing Practices Are Integral to J&J's Core Business

1. J&J's Extensively Regulated Business

J&J's core business – the manufacturing and marketing of drugs and medical devices – is heavily regulated under the Federal Food, Drug, and Cosmetic Act

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[3] Emphasis is added and citations are omitted throughout unless otherwise indicated.

("FDCA"), 21 U.S.C. §301 *et seq.*, and rules and regulations promulgated thereunder. ¶¶54-72. The FDA monitors compliance with cGMP – minimum requirements for the methods, facilities and controls used by drug manufacturers, like J&J, in manufacturing, labeling and packaging of their products. ¶57; 21 C.F.R. §211 *et seq*. The Company's officers and directors have an overriding obligation to ensure that any recall arising from cGMP violations is carried out effectively and with candor. ¶¶60-82. The FDCA further requires that after a drug is proven safe and effective for a specific use, the FDA-approved use and dosage must be described on the drug's official label. ¶¶61-63. To protect the public, the FDCA prohibits drug companies from marketing drugs for unapproved or "off label" uses. ¶¶61-64, 68-69, 73.

Compliance with cGMP and the drug marketing laws is expensive. ¶70. Considerable funds must be invested in maintaining manufacturing facilities and quality controls, and proving that a drug's specific use is safe and effective for treating people requires expensive clinical trials. ¶¶65, 81, 152, 157. Drug companies derive immediate and substantial financial benefits, however, from deliberately under-investing in their drug manufacturing facilities, from avoiding resulting recalls or carrying them out in secret, and from marketing drugs for uses that were not approved by the FDA. ¶¶65, 91, 101.

Drug companies also have a short-term incentive to give gifts and money to healthcare providers to encourage prescriptions (in violation of the federal anti-kickback statute), and to provide price discounts to private purchasers that are hidden

from Medicaid (in violation of the "best price rule" of the Medicaid drug rebate statute). ¶65. Recognizing this tension, the Office of the Inspector General of the Department of Health & Human Services ("OIG") published "Compliance Program Guidance" in the Federal Register in May 2003, explaining the importance of senior management's role in identifying the "root cause" of any violations and the need to take "decisive steps to correct the problem." ¶¶77-78.

Violations of cGMP and drug marketing regulations endanger the lives of patients relying on the Company's products. Non-compliance with cGMP and marketing regulations may result in significant regulatory action, including FDA warning letters, civil enforcement actions, and injunctions. ¶¶60, 78-80. If violations are repeated or deliberate, they may also result in criminal prosecution and federal debarment. ¶¶58-60.

2. J&J's Widespread and Prolonged Violations of Drug Marketing and Anti-Kickback Laws

J&J is organized into three business segments – Consumer, Pharmaceutical and Medical Devices & Diagnostics – which are operated through its subsidiaries, such as McNeil, Janssen, DePuy and Cordis. ¶¶47-48. Between 2003 and 2010, some of J&J's most important products included Risperdal, Topamax, and Natrecor, as well as biliary stents and orthopedic hip and knee replacements. ¶¶47-52. Each of these products generated substantial revenues. For example, from 2003 through 2009, J&J

generated ***$23.6 billion*** in revenues from Risperdal and another ***$12.5 billion*** in revenues from Topamax, alone. ¶50.

Defendants implemented and approved a simple strategy to illegally promote off label prescriptions of J&J products. J&J's illegal promotion practices were remarkably consistent and similar across different drugs and medical devices promoted by different J&J divisions. *See, e.g.*, ¶¶169, 195-201, 220-225, 242-247. J&J's unlawful practices required substantial financial resources, thereby reflecting a Company-wide business strategy implemented with Defendants' knowledge and support. ¶¶167, 174, 180, 202.

For example, between 1993 and at least 2009, J&J marketed the anti-psychotic drug Risperdal off label for treating elderly patients with dementia, PTSD or Alzheimer's disease. ¶¶168-170. J&J's scheme involved payment of tens of millions of dollars in kickbacks, including to Omnicare (the largest nursing home pharmacist in the country) to drive Risperdal prescriptions in nursing homes, significant kickbacks to "key opinion leaders" to publicly endorse off label uses of Risperdal, and the ghost-writing of articles for medical journals supporting off label uses of Risperdal. ¶¶168-170, 177-180, 183, 255-269. J&J's kickbacks to Omnicare included millions of dollars in rebates hidden from Medicaid in violation of the best price rule. ¶¶261-263.

J&J's illegal promotion of Risperdal was wildly successful and sales skyrocketed. ¶171. By 1997, Risperdal was the top selling antipsychotic in the U.S. *Id.* In 1999, the FDA sent a warning letter demanding that J&J immediately stop

marketing Risperdal for elderly patients, noting that there was "little to no data" supporting J&J's claims that such treatment was safe and effective. ¶173. In 2002, the FDA notified J&J that it was ***limiting*** the approved use of Risperdal to the treatment of schizophrenia in adults. ¶175. The Board closely tracked drug usage data and knew as of 2003 that a majority of Risperdal was prescribed off label. ¶¶167, 180, 202.

The Director Defendants ignored these warnings and did not stop J&J's widespread strategy of actively promoting Risperdal for the treatment of elderly patients suffering from dementia and other off label uses. ¶¶169-170, 183. Tellingly, in 2006, Risperdal sales topped $4.2 billion – a 17.8% increase over 2005. ¶190. In 2007, Risperdal revenues further increased to $4.7 billion. *Id.*

As a result, J&J faces substantial criminal and civil liability in connection with its off-label promotion of Risperdal. In 2009, Omnicare agreed to pay $98 million to resolve the DOJ's allegations, admitting key facts regarding J&J's role in the illegal kickback scheme to increase off-label prescriptions in nursing homes. The DOJ's criminal and civil investigation into J&J's promotion of Risperdal is open and active.[4]

[4] By Order dated February 25, 2011 (Cecchi Decl., Ex. 3), the district court for the District of Massachusetts denied the Company's motion to dismiss this action.

¶¶188, 192. J&J also faces liability from pending State Attorneys General Complaints alleging off-label marketing of Risperdal.[5] ¶¶169-170, 192, 271-272.

J&J implemented the same strategy of simultaneously promoting products for uses that were not approved by the FDA and payment of substantial kickbacks to key opinion leaders and other healthcare providers with respect to other blockbuster drugs and major medical devices. *See, e.g.*, ¶¶199-201, 220-222, 224-225, 247. For example, J&J promoted Topamax for twenty four different unapproved uses – including various psychological disorders in children – using non-scientific articles in medical journals to convince doctors that Topamax was safe and effective for these disorders, and paying substantial illegal kickbacks to key opinion leaders and doctors who prescribed Topamax and publicly advocated such off-label use to the medical community. ¶¶195-201. The Board knew as of 2003 that ***eight out of every ten Topamax prescriptions in the U.S. were off label***. ¶¶167, 202. From 2002 through 2008, J&J's annual Topamax sales increased 400% – from $687 million to more than $2.7 billion. ¶202. Criminal and civil lawsuits in connection with J&J's illegal

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[5] Defendants' argument that the Risperdal off label scheme ended in 2004 (Johnson & Johnson's Brief in Support of Its Motion to Dismiss or, in the Alternative, Motion to Stay ("Def. Br.") at 36) is belied by the particularized allegations of the Complaint (*see, e.g.*, ¶¶168-191) and is premised on the Defendants' interpretation of selected materials extraneous to the Complaint. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) ("As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings.").

scheme are underway. In April 2010, J&J agreed to pay $81.4 million in criminal and civil fines, and to have a subsidiary plead guilty, to resolve allegations of the Company's off label promotion of Topamax. ¶207.

J&J likewise actively promoted Natrecor – a drug that was only approved for treating patients suffering from acute heart failure – for the unapproved use of treating regularly scheduled patients outside the hospital ("outpatients"). Defendants approved this strategy, despite the fact that the FDA had expressly denied any such approval for Natrecor because of safety concerns. ¶209. In January 2005, J&J estimated that Natrecor's off-label outpatient sales had increased by 173% for 2004 and would continue to increase by another 81% for 2005. ¶229.

In June 2005 a panel of cardiology experts recommended that J&J expressly warn doctors against using Natrecor for outpatient treatment because of significant safety concerns. ¶¶232-233. Defendants ignored this recommendation and continued J&J's top-down efforts to promote the off-label outpatient use of the drug. In fact, J&J did not stop marketing Natrecor for clear off-label use until the federal healthcare programs announced that they would no longer pay for the use of Natrecor for outpatients. ¶¶234-238. As a result, J&J was forced to take a $440 million write-down due to declining Natrecor sales and remains exposed to substantial liability for this illegal scheme. ¶¶238-239.

J&J also illegally marketed medical products. The consistency of J&J's illegal methods across product lines is telling. For example, J&J promoted its biliary stents

for the unapproved, much more highly-regulated use as vascular stents, including by funding studies in medical journals supporting the off-label use, and providing doctors with promotional materials supporting the off-label use of biliary stents to treat vascular disease. *See, e.g.*, ¶¶242, 247. As with Risperdal and Natrecor, J&J was warned that its illegal practices were dangerous to human health. In the case of J&J's biliary stents, *The American Journal of Therapeutics* reported in 2008 that one million biliary stents were used off-label from 2003 to 2006 and that as a result, deaths and serious injuries (including aneurisms and amputations) had occurred. ¶¶249-250. Defendants remained unfazed and continued the illegal practices anyway. Again, J&J now faces substantial liability, including from a pending DOJ investigation and complaint filed by the U.S. Attorney's Office ("USAO") in Massachusetts. ¶253.

Similarly, J&J implemented a scheme to increase the sales of hip and knee replacement products by paying substantial illegal kickbacks to orthopedic surgeons. ¶275. The scheme increased short-term sales while exposing the Company to criminal and civil liability. In 2007, J&J paid $84.7 million and caused a subsidiary to plead guilty to violating the federal Anti-Kickback Statute. ¶¶274, 277. Unfazed even by a criminal guilty plea, in August 2010, the FDA again caught J&J promoting hip replacement systems without FDA approval. ¶¶135-141, 283.

These pervasive illegal promotional and marketing schemes were implemented and actively pursued at J&J over many years and were directed to the Company's

biggest selling drugs and medical devices. J&J's senior management and Board were aware of and allowed J&J's systemic illegal promotion practices. ¶¶167, 278-279.

B. J&J's Widespread and Prolonged Violations of cGMP

Reflecting the same focus on increasing short-term profits regardless of J&J's legal obligations and the long-term interests of the Company and its shareholders, Defendants also implemented a Company-wide strategy to cut costs and abandon oversight despite systemic breakdowns in J&J's manufacturing quality controls. ¶¶94, 97, 107-109, 112, 114, 121-122, 128, 139. This strategy, involving numerous J&J products at different manufacturing facilities, violated J&J's cGMP obligations. *Id.*

As with J&J's violations of the drug marketing laws, J&J's cGMP violations were remarkably consistent throughout the Company, thereby reflecting a conscious business strategy that was implemented with Defendants' knowledge and support. For example, J&J received a large number of consumer complaints in 2008 that its OTC drugs had a musty-mildew smell causing gastrointestinal distress. ¶106. J&J's products were contaminated with a pesticide and flame retardant called 2,4,6 Tribromoanisole ("TBA"). *Id.* J&J first denied there was a problem, and then pursued a half-hearted and inadequate investigation. ¶¶86-87, 91-92, 107-112. The Company consistently failed to take adequate or effective corrective actions. As the FDA explained in a January 15, 2010 Warning Letter, J&J's inadequate response violated cGMP:

> [T]he timing and depth of your investigative efforts regarding uncharacteristic odor complaints were insufficient to meet good manufacturing practice. Your firm's management . . . was not proactive in response to consumer complaints. . . . Quality problems must be thoroughly investigated, root causes determined, and appropriate corrective and preventive actions implemented as quickly as possible to limit exposure of the public to substandard drugs.

¶108.

The FDA minced no words in blaming J&J's senior management for the Company's improper response to the complaints, stating:

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

¶109.

Following the January 15, 2010 FDA Warning Letter, J&J was forced to recall large quantities of Benadryl, Motrin, Rolaids, Simply Sleep, St. Joseph Aspirin, and Tylenol that were manufactured at J&J's Las Piedras facility. ¶283. However, reflecting the deficient corporate culture detailed in the March 10, 2011 DOJ Complaint, Defendants still did not take the Company's legal obligations to comply with cGMP seriously. On December 10, 2010 – almost three years after J&J first received the odor complaints, and one year after J&J received the FDA Warning Letter noting J&J's inadequate investigation and response to the TBA contamination –

the FDA issued a Form 483 Inspection Report with respect to the Fort Washington facility. ¶¶115-116. The FDA inspection report noted that J&J had ***still not*** initiated a comprehensive action plan regarding the TBA contamination, had ***still not*** identified trends associated with TBA, had ***still not*** developed a specific plan concerning TBA contamination at the Fort Washington facility, and had ***still not*** evaluated consumer complaints. ¶¶116-118. Moreover, the FDA inspection report identified a large volume of products that J&J knew were contaminated with TBA but that J&J – in direct breach of its legal and ethical obligations – simply did not recall at all. ¶120.

The TBA contamination is merely one example of Defendants' decision to ignore J&J's cGMP obligations, causing J&J to receive multiple warnings and suffering multiple, unprecedented recalls:

- Between 2004 and 2007, J&J initiated more recalls than any of the other top ten pharmaceutical companies. Each of these recalls was based on regulatory action by the FDA. ¶¶88, 90.

- In August 2007, an internal report prepared for J&J's senior management again warned about widespread cGMP violations at J&J's manufacturing facilities going back to at least 2005. ¶91.

- In 2008, J&J engaged in the "phantom recall" of the children medication "Motrin." ¶¶95-102.

- In 2009, J&J recalled 21 different infant and children's products after an FDA inspection of the Fort Washington facility found contamination of the products with the *B. capacia* bacteria. ¶282.

- In 2010, J&J recalled more than 200 million products, reducing J&J's revenues by approximately $600 million. ¶¶152, 156. The recalls included 135 million bottles of children's and infants' products because of quality and safety problems; 13 million packages of Rolaids because

> of contamination with wood and metal particles; 12 million of packages of Mylanta; nine million bottles of Tylenol because of labeling inaccuracies; four million bottles of Benadryl because of manufacturing "insufficiencies;" and 93,000 orthopedic hip replacements because one out of every eight patients who had received one of the recalled devices had to undergo revision surgery within five years of receiving it. J&J also recalled 100,000 boxes of contact lenses, only to secretly expand that recall five-fold to 492,000 boxes two months later. ¶¶123-150, 283, 285.

These warnings and recalls were the foreseeable and foreseen result of the Defendants' improper decision to cut costs and budgets rather than curing J&J's systemic cGMP violations. ¶¶153-155. The Company's consistent failure to adequately address these major and endemic problems has resulted in the filing of the DOJ Complaint and the Company entering into an uncontested Consent Decree. *See, e.g.*, DOJ Complaint, ¶¶19-20, 22. The DOJ Complaint makes clear that J&J was kept fully informed by the FDA of the problems at McNeil through, *inter alia*, meetings, teleconferences and a Warning Letter. *Id.*, ¶¶20-21. Despite years of warnings, the DOJ determined that a permanent injunction was necessary because "***unless restrained by this Court, Defendants will continue to violate the Act***, 21 U.S.C. §§331(a) and (k)." *Id.*, ¶22.

C. Defendants Received Many Red Flags Over a Multi-Year Period

Even if a hypothetical board could somehow remain innocently ignorant of problems of this magnitude at a company they are supposed to manage, these Defendants are not that rare bird. Since at least 2003, Defendants had actual notice of

multiple "red flags" about J&J's widespread, illegal sales and marketing practices and systemic violations of cGMP, in flagrant violation of federal drug marketing and manufacturing laws. As the Complaint details, off-label marketing and manufacturing red flags included, *inter alia*, close tracking by the Board of skyrocketing revenues from off-label sales of certain drugs with very circumscribed FDA approvals; numerous federal and state regulatory subpoenas and witness testimony subpoenas; *qui tam* and State Attorneys General complaints; congressional inquiries and requests for documents, FDA warning letters and violation notices; internal reports; a history of major recalls, internal budgets and annual strategic plans positioning key drugs for unapproved uses; press reports; major problems at and the eventual shuttering of material manufacturing plants; and multimillion dollar criminal fines and civil settlements. ¶¶84-163 (manufacturing issues), 164-277 (marketing issues).

These red flags, received by the Director Defendants quarter after quarter, year after year, demonstrated that major problems – occurring across all three of the Company's core segments and involving blockbuster drugs, medical products and critical OTC products – were pervasive, longstanding and continued unchecked.

1. Red Flags for the Period 2003-2005

In 2003 and 2004, seven of the ten Director Defendants were on the Board – Defendants Coleman, Cullen, Langbo, Lindquist, Mullin, Satcher and Weldon. ¶¶29-30, 32-34, 37. In addition to these seven directors, Director Defendant Johns joined

the Board in 2005. ¶31. From 2003 through 2005, red flags relating to pervasive wrongful conduct began to accumulate, including:

- Two FDA warning letters regarding false and misleading Risperdal warnings, as well as the unlawful marketing of Topamax (¶280, bullets 4, 6);

- Seven subpoenas from various USAOs and the OIG relating to the unlawful marketing of Risperdal, Topamax, Natrecor and Procrit, illegal sales and marketing of drugs to Omnicare, and contractual relationships with surgeons involved in hip and knee replacements and reconstructive surgery (¶280, bullets 2-3,9; ¶281, bullets 1-2, 5-6);

- Five requests for documents from the criminal division of the USAO, New York Attorney General, and U.S. Senate Finance Committee concerning off-label marketing of Risperdal, Topamax and four other J&J drugs, and the Company's use of the "nominal price exception" in calculating the "best price" for Medicaid rebates (¶280, bullets 1, 5, 8; ¶281, bullet 7);

- A request by a USAO for assistance in obtaining subpoenaed testimony of Ortho-McNeil witnesses before a grand jury (¶280, bullet 10); and

- A letter from the Department of Health and Human Services relating to misleading claims about risks of Duragesic (¶280, bullet 7).

Importantly, many of these red flags were reflected in the March 11, 2004 and March 14, 2005 Form 10-Ks, reviewed and executed by Director Defendants Coleman, Cullen, Langbo, Lindquist, Mullin, Satcher and Weldon. ¶¶279-280.

2. Red Flags for the Period of 2006-Present

In addition to the eight above-named Director Defendants, each of whom continued on the Board during 2006 to the present (save for Director Defendant Langbo, who left the Board in April 2010), the two remaining Director Defendants

Prince and Perez joined the Board in 2006 and 2007, respectively.[6] ¶¶35-36. From 2006 to the present, the Director Defendants continued to receive an avalanche of additional red flags indicating continued pervasive and wrongful conduct, including:

- A recall of Motrin without warning the public of health and safety risks associated with this popular OTC pain medication (the "Phantom Recall") (¶282, bullet 25);

- 12 product recalls involving certain of J&J's best-selling drugs and devices, including Tylenol, Benadryl, Motrin, Rolaids, Mylanta, Simply Sleep, St. Joseph Aspirin, and ASR replacement hips resulting from cGMP violations (¶282, bullets 33-35; ¶285, bullets 4, 8, 14-16, 19-22);

- Two congressional hearings at which J&J senior executives were called to testify regarding product recalls and J&J's lack of quality controls as required by cGMP (¶285, bullets 12, 17);

- A plant closure due to unaddressed cGMP violations (McNeil's Fort Washington, Pennsylvania plant) (¶285, bullet 10);

- Four FDA warnings letters regarding issues including the improper disclosure of risks relating to Natrecor, illegal marketing of Ultram ER painkiller, deficiencies in the Company's clinical investigations protocol, and the handling of the musty, mildew odor complaints resulting from contamination of J&J products with a pesticide (¶282, bullets 10, 29, 31; ¶285, bullet 3);

- 11 subpoenas from various USAOs, the DOJ and the U.S. Senate Finance Committee relating to the unlawful marketing of Risperdal, Topamax, Natrecor, Procrit, payments of illegal kickbacks to doctors, manufacturing and marketing issues with orthopedic devices and biliary

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[6] Despite having been on the Board during periods when much of the wrongdoing occurred, Director Defendants Johns, Prince and Perez were nonetheless named to the Board's Special Committee to investigate the demand letters and the derivative litigations.

stents, and suspected non-compliance with the "best price" rule (¶281, bullets 11-13; ¶282, bullets 2-4, 15-16, 21, 26, 28);

- 14 complaints filed by various State Attorneys General and the DOJ concerning J&J's systemic off-label promotion of Risperdal, Topamax, and Natrecor throughout the country (¶282, bullets 1, 5, 8, 19, 22, 24);

- A criminal complaint filed by Department of Health and Human Services relating to the payment of illegal kickbacks (¶282, bullet 7);

- Four *qui tam* actions regarding the illegal marketing of Risperdal and Topamax (¶281, bullet 14; ¶282, bullet 12, 27);

- Seven separate requests for information from different congressional committees concerning the Phantom Recall, the unlawful promotion of Risperdal, Procrit, and stents, J&J's use of educational grants and continuing medical education funds as illegal kickback to doctors (¶281, bullet 10; ¶282, bullets 11, 14, 17-18; ¶285, bullet 13);

- Four investigative demands served by various State Attorneys General around the country relating to the illegal marketing of Risperdal, financial relationships between the Company and orthopedic surgeons, and potential violations of the "best price" rule (¶281, bullet 9; ¶282, bullets 9, 20; ¶285, bullet 5);

- A corporate integrity agreement between OIG and J&J's Ortho-McNeil Janssen Pharmaceuticals division (¶285, bullet 6);

- J&J's agreement to pay $81.5M in fines to resolve allegations of the illegal promotion of Topamax (¶285, bullet 7); and

- A $257.7 million adverse jury verdict relating to the Company's repeated violations of Louisiana's Medical Assistance Programs Integrity Law (¶285, bullet 18).

Significantly, many of the above red flags were reflected in: (1) the March 14, 2006 Form 10-K, reviewed and executed by Director Defendants Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Prince, Satcher and Weldon, (2) the February 21,

2007 Form 10-K, likewise reviewed and executed by all of the Director Defendants but Perez, (3) the February 26, 2008 Form 10-K, reviewed and executed by all of the Director Defendants, (4) the February 20, 2009 Form 10-K, reviewed and executed by all of the Director Defendants, and (5) the March 31, 2010 Form 10-K, reviewed and executed by all of the Director Defendants. ¶¶279, 281-282. These Form 10-Ks also included a discussion of historical regulatory actions, subpoenas, document requests, investigations and congressional inquiries for prior years, directly showing the knowledge of the Director Defendants. *Id*.

Virtually all of the red flags were reported to the Board after the OIG published its Compliance Program Guidance in May 2003, warning that "[d]etected but uncorrected misconduct can endanger the reputation and legal status of the company," including federal debarment. ¶¶77-79. Despite the known risk that J&J could face criminal prosecution, possible federal debarment, and potentially crippling civil fines and damages awards, Defendants decided not to intervene, consciously facilitating J&J's illegal promotion practices in violation of their fiduciary duties of good faith and loyalty under New Jersey law. ¶278.

III. Argument

A. The Legal Standard for Demand Futility

In deciding a motion to dismiss, "the court is required to accept as true all allegations in the complaint, and all reasonable inferences that can be drawn therefrom, and to view them in the light most favorable to the non-moving party." *In*

re Cendant Corp. Derivative Action Litig., 189 F.R.D. 117, 127 (D.N.J. 1999). Rather than dissecting the Complaint into component parts, the Court must review Plaintiffs' allegations as a whole and examine the totality of the circumstances. *Id.* at 128-29.

A plaintiff in a derivative suit who did not make a demand on the board of directors must state with particularity why demand was futile and therefore excused. *See* Fed. R. Civ. P. 23.1. To assess whether demand was futile, the Court "must decide 'whether, under the particularized facts alleged, a reasonable doubt is created that: (1) the directors are disinterested and independent, and (2) the challenged transaction was otherwise the product of a valid exercise of business judgment.'" *In re PSE&G S'holder Litig.*, 173 N.J. 258, 279 (2002) (quoting *Aronson v. Lewis*, 473 A.2d 805, 814 (Del. 1984)). If either prong is satisfied, demand is excused. *Id.*

B. Demand Is Excused Because the Board's Approval of Illegal Business Strategies Is Not a Valid Business Judgment

Corporate directors cannot act beyond their lawful powers, and their conscious decision to allow illegal conduct is not a "valid exercise of business judgment." *Aronson*, 473 A.2d at 814; *see also Miller v. AT&T*, 507 F.2d 759, 762 (3d Cir. 1974) (business judgment does not insulate directors from liability for willful violation of federal statute); *Desimone v. Barrows*, 924 A.2d 908, 934 (Del. Ch. 2007) ("it is utterly inconsistent with one's duty of fidelity to the corporation to consciously cause the corporation to act unlawfully"); *Metro Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 131 (Del. Ch. 2004) (explaining that "a

fiduciary may not choose to manage an entity in an illegal fashion, even if the fiduciary believes that the illegal activity will result in profits for the entity").[7]

As an initial matter, J&J asserts that the second prong of *Aronson* does not apply in this case because Plaintiffs do not challenge any specific decisions or actions of the J&J Board. Def. Br. at 16-17. Wrong. A fair reading of the Complaint shows that Plaintiffs squarely challenge the Board's conscious decisions to save costs by allowing illegally deficient manufacturing process and secret recalls, and to increase revenues by allowing the illegal promotion of blockbuster drugs and medical devices. *See* §II. The second prong of the *Aronson* test applies "in the context of director action," whether that takes the form of affirmative action or "***a conscious decision to refrain from acting***." *Aronson*, 473 A.2d at 813; *Rales v. Blasband*, 634 A.2d 927, 933 (Del. 1993); *In re Abbott Labs. Derivative S'holders Litig.*, 325 F.3d 795, 809 (7th Cir. 2003) (same). Moreover, even if Defendants were correct that this case

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[7] *See also Ryan v. Gifford*, 918 A.2d 341, 354 (Del. Ch. 2007) (excusing demand because "[t]he board had no discretion to contravene the terms of the stock option plans . . . [which] raise[s] a reason to doubt that the challenged transactions resulted from a valid exercise of business judgment"); *Cal. Pub. Emps.' Ret. Sys. v. Coulter*, No. 19191, 2002 Del. Ch. LEXIS 144, at *34 (Del. Ch. Dec. 18, 2002) ("the business judgment rule may not be invoked to shelter unauthorized actions of a board of directors"); *Kahn ex rel. DeKalb Genetics Corp. v. Roberts*, 679 A.2d 460, 465 (Del. 1996) ("The business judgment rule normally protects all lawful actions of a board of directors, provided they were taken in good faith . . . .").

should be decided under the *Rales* test, the Complaint more than meets that standard, as discussed below.

Defendants also argue that this action should be dismissed for lack of demand because "[t]here are no particularized allegations that the Board knew of any red flags in advance of the alleged misconduct, let alone particularized allegations that the Board egregiously failed to take action in response to the purported red flags." Def. Br. at 22. Again, not true.

First, a fair reading of the Complaint as a whole shows that it is replete with detailed allegations about a flood of red flags informing the Board that J&J was systematically flaunting the federal drug manufacturing and marketing laws for the better part of a decade. ¶¶278-285. Nor were these violations trivial. *See United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 226 (3d Cir. 2005) (explaining that "protecting consumer health and safety is a primary purpose of the FDCA").

As the Third Circuit Court of Appeals explained in *In re Tower Air, Inc.*, 416 F.3d 229 (3d Cir. 2005):

> Whether the officers' behavior is construed as an egregious decision or as unconsidered inaction, that allegation is troubling. Under no circumstances should aircraft maintenance problems be ignored. Lives are on the line. . . . We can imagine few things ***more*** egregious. The officers' alleged passivity in the face of negative maintenance reports seems so far beyond the bounds of reasonable business judgment that its only explanation is bad faith.

Id. at 239 (emphasis in original).[8]

Second, the Complaint alleges that the red flags resulted from Defendants' conscious decision to boost profits by: (i) cutting costs and budgets despite the reported Company-wide breakdown of J&J's manufacturing quality controls; and (ii) promoting numerous J&J drugs and devices for uses that were not approved by the FDA, including by paying tens of millions of dollars in kickbacks. *See* §II. The Complaint also details how Defendants consciously allowed this strategy to continue despite receiving repeated warnings that it would endanger human health and expose the Company to the risk of criminal prosecution and federal debarment. *Id*.

In re SFBC Int'l, Inc. Sec. & Derivative Litig., 495 F. Supp. 2d 477 (D.N.J. 2007), ignored by Defendants, is on point. There, the derivative plaintiffs alleged that the company engaged in widespread ethical and legal violations over a period of three years, including using unethical drug testing practices and operating unsafe facilities, thereby "putting the safety of the human participants in the studies at risk and providing the client companies with inaccurate or falsified reports about the products being tested." *Id.* at 479-80. The FDA conducted inspections of the testing facilities and identified various improper practices, prompting the agency to issue at least seven Form 483 citations. *Id.* at 481.

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[8] Although not a derivative suit, the Third Circuit expansively analyzed the protections afforded directors by the business judgment rule. *See id.* at 238-42.

Echoing the Director Defendants here, the *SFBC* defendants claimed ignorance and argued that demand was not excused because the complaint did not adequately allege that the directors knew or should have known about the improper clinical practices or the unsafe testing facility. *Id.* at 485 (citing *Stone v. Ritter*, 911 A.2d 362 (Del. 2006), a case relied upon by Defendants). Judge Chesler squarely rejected that argument, because the complaint alleged "endemic mismanagement of the company, raising plenty of red flags concerning the improper and even possibly illegal practices in which the company was engaged." *Id.* "Moreover, the alleged misconduct related to the core of [the company's] business," and "not merely decentralized activity by employees of a far-flung enterprise of the company." *Id.* at 486 (distinguishing *In re Caremark Int'l*, 698 A.2d 959 (Del. Ch. 1996)). As Judge Chesler explained, ***the misconduct "appear[ed] to have been so endemic, with repeated documented violations filed by both the FDA and local authorities, that it [was] inconceivable that a board of directors properly performing its functions would not have known about the wrongdoing***." *Id.* at 487; *see also In re Veeco Instruments, Inc. Sec. Litig.*, 434 F. Supp. 2d 267, 278 (S.D.N.Y. 2006) (excusing demand because it was "not a case where the directors had 'no grounds for suspicion' or 'were blamelessly unaware of the conduct leading to the corporate liability'").

Judge Jed S. Rakoff's recent decision in *In re Pfizer Inc. S'holder Derivative Litig.*, 722 F. Supp. 2d 453 (S.D.N.Y. 2010), is also instructive. There, derivative plaintiffs alleged that the directors ignored numerous red flags raised by guilty pleas,

criminal and civil fines, FDA warning letters and *qui tam* lawsuits, about widespread violations of the drug marketing laws, and consciously took no action to stop the systemic misconduct. *Id.* at 460. The *Pfizer* defendants, like Defendants in this case, argued that these red flags could not establish demand futility because the complaint purportedly failed to detail what each individual director knew and did in response to the information. *Id.* at 461-62 (discussing, *inter alia*, *In re Intel Corp. Derivative Litig.*, 621 F. Supp. 2d 165, 174 (D. Del. 2009)); *see also* Def. Br. at 22.

The *Pfizer* court rejected defendants' arguments, explaining that "demand futility is to be evaluated based on the facts of each particular case rather than through the invocation of rigid rules." 722 F. Supp. 2d at 461 (citing *Grobow v. Perot*, 539 A.2d 180, 186 (Del. 1988)). The court refused to draw an inference in favor of any of the defendants that they were unaware of the alleged pervasive wrongdoing *throughout* the company. *See id.* (citing *Abbott Labs.*, 325 F.3d at 806 ("Where there is a corporate governance structure in place, we must then assume the corporate governance procedures were followed and that the board knew of the problems and decided no action was required."). Under those circumstances, "nothing in either federal or Delaware law holds it insufficient for individual directors' knowledge and liability to be pleaded inferentially." *Id.* at 461-62 (citing *Abbott Labs.*, 325 F.3d at 809, and *McCall v. Scott*, 239 F.3d 808, 824 (6th Cir. 2001)); *see also Am. Int'l Grp., Inc. v. Greenberg*, 965 A.2d 763, 777 (Del. Ch. 2009), *aff'd sub nom.*, *Teachers' Ret. Sys. v. PricewaterhouseCoopers LLP*, 11 A.3d 228 (Del. 2011) (refusing to draw the

inference that a majority of the defendants were kept entirely in the dark about pervasive misconduct).

Finally, the seminal *Abbott Labs.* decision is also instructive. There, derivative plaintiffs alleged that the directors

> knew of the continuing pattern of noncompliance with FDA regulations and knew that the continued failure to comply with FDA regulations would result in severe penalties and yet ignored repeated red flags raised by the FDA and in media reports and ***chose not to bring a prompt halt to the improper conduct causing the noncompliance, nor to reprimand those persons involved, nor to seek redress for Abbott for the serious damages it has sustained***.

325 F.3d at 802-03. The *Abbott Labs.* plaintiffs argued (and the court eventually held) that board knowledge of the company's problems could be reasonably inferred based on "six years of noncompliance, inspections, 483s, Warning Letters, and notice in the press." *Id.* at 809. As the court explained:

> [T]he facts support a reasonable assumption that there was a "sustained and systematic failure of the board to exercise oversight," in this case intentional in that the directors knew of the violations of law, took no steps in an effort to prevent or remedy the situation, and that failure to take any action for such an inordinate amount of time resulted in substantial corporate losses, establishing a lack of good faith.

Id.

Here, the Complaint alleges that the Director Defendants, despite receiving upwards of 90 red flags over many years, consciously disregarded their fiduciary duties of loyalty and good faith by deliberately allowing ongoing illegal misconduct related to the core of J&J's business. *See* §II. As in *SFBC*, *Pfizer*, and *Abbott Labs.*,

this is not a case where a board of directors was justifiably unaware of discreet illicit schemes that hurt the company. Indeed, the allegations here are stronger than the ones in *Pfizer*, *SFBC* and *Abbott Labs.* because the misconduct took place over the better part of a decade, and involved:

- Manufacturing quality controls that did not comply with cGMP for years and at multiple facilities, resulting in hundreds of millions of contaminated and unreliable products being sold to the public, as well as massive public and secret recalls, and at least one instance of not recalling contaminated products at all (¶¶84-163);

- Systemic top-down promotion of numerous key drugs and medical devises for off label uses, generating billions of dollars in annual revenues while endangering the lives and wellbeing of millions of patients, including children and the elderly, and exposing the Company to criminal prosecution, federal debarment, and potentially devastating civil damages fines and awards (¶¶164-253);

- Payment of tens of millions of dollars in illegal kickbacks to nursing home pharmacies, doctors and key opinion leaders to increase sales while exposing the Company to criminal prosecution, federal debarment and significant civil damages fines and awards (¶¶254-277); and

- Hiding private purchaser discounts from Medicaid in violation of the "best price rule," exposing the Company to criminal prosecution, federal debarment, and civil enforcement actions (¶¶72, 280).

The Director Defendants, therefore, were not merely exposed to the incidental red flag that may come with operating any large business. Rather, the Director Defendants were subjected to a prolonged onslaught of warnings that the Company's core operations were breaking mandatory drug manufacturing and marketing laws, that were enacted to protect the public. The long duration of these violations (and, according to the DOJ, they are continuing today and will continue without a

permanent injunction) is by itself strong evidence of the Board's bad faith disregard of its duties. Consciously permitting J&J's illegal operations was not a protected business judgment, and demand is excused on this basis alone.

C. Demand Is Excused Because a Majority of the Director Defendants Face a Substantial Likelihood of Liability

Even if permitting illegal conduct was subject to the business judgment rule (and it is not), demand was not required because a majority of the Director Defendants were not disinterested and could not properly consider demand. *See SFBC*, 495 F. Supp. 2d at 487 (demand excused because "the directors have exposed themselves to liability by allegedly ignoring particularly flagrant and reprehensible wrongdoing"); *McCall v. Scott*, 250 F.3d 997, 1001 (6th Cir. 2001) (demand excused because directors faced substantial likelihood of liability for failing to intervene in a health care fraud based on the directors' prior experience, the existence of a federal investigation, civil allegations, and newspaper reports). Here, demand was futile because every Director Defendant served on the Board when the Board was informed about J&J's illegal operations and decided not to intervene.

As an initial matter, Defendant Weldon faces a substantial likelihood of liability due to his employment as CEO of the Company when the Action was initiated. ¶38. *See, e.g.*, *In re Cooper Cos. S'holders Derivative Litig.*, No. 12584, 2000 Del. Ch. LEXIS 158, at *17-*21 (Del. Ch. Oct. 31, 2000) (directors who also served as CFO/Treasurer and Vice President/General Counsel could not respond impartially to a

demand). J&J's Proxy Statement, filed on March 17, 2010, concedes that Weldon was not "independent" pursuant to the listing standards of the New York Stock Exchange. Cecchi Decl., Ex. 4 at 15. Moreover, Weldon joined the Board in 2001 and was therefore inundated with countless red flags demonstrating the misconduct throughout the relevant period. *See* §II.C.; *see also* ¶311. Weldon was, for example, the addressee of multiple FDA warning letters. ¶¶105, 181, 280, 282.

All of the remaining Director Defendants were members of the Board since at least 2007, and were similarly informed about numerous red flags concerning J&J's illegal manufacturing and marketing practices.[9] Six of the Director Defendants, constituting a majority of the Board, have served on the Board since 2003. *See* §II.C., *supra*; *see also* ¶¶303-308, 312-322. Thus, the Director Defendants were repeatedly placed on notice of illicit activities through the various FDA warning letters, the multiple government investigations, including criminal investigation and grand jury testimony subpoenas, numerous *qui tam* actions, class actions, and the clandestine "phantom recall" of over-the-counter drugs. Indeed, the Defendants signed the

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[9] Specifically, Defendant Coleman joined the Board in 2003 (¶29); Defendant Cullen joined the Board in 1995 (¶30); Defendant Johns joined the Board in 2005 (¶31); Defendant Langbo served on the Board from 1991-2010 (¶32); Defendant Lindquist joined the Board in 2004 (¶33); Defendant Mullin joined the Board in 1999 (¶34); Defendant Perez joined the Board in 2007 (¶35); Defendant Poon was on the Board from 2005-2009 (¶43); Defendant Prince has served on the Board since 2006 (¶36); and Defendant Satcher has served on the Board since 2002 (¶37).

Company's contemporaneous SEC filings discussing many of these red flags. ¶¶279-285.

Defendants' decision not to intervene in J&J's widespread misconduct violated their obligations of good faith and loyalty and exposes them to a substantial likelihood of liability. Put differently, Defendants' indifference to widespread illegal conduct constituted an "intentional dereliction of duty" and "a conscious disregard of one's responsibilities," each of which is "'properly treated as a non-exculpable, non-indemnifiable violation of the fiduciary duty to act in good faith.'" *Ryan v. Lyondell Chem. Co.*, No. 3176-VCN, 2008 Del. Ch. LEXIS 125, at *23 (Del. Ch. Aug. 29, 2008) ("*Lyondell*"). "Few Delaware cases attempt to define precisely what conduct reaches the level of actionable bad faith, but there is at least agreement that 'adopting a "we don't care about the risks" attitude concerning a material corporate decision' constitutes bad faith." *Brown v. Brewer*, No. CV 06-3731-GHK (SHx), 2010 U.S. Dist. LEXIS 60863, at *46-*47 (C.D. Cal. June 17, 2010) (quoting *In re Walt Disney Co. Derivative Litig.*, 825 A.2d 275, 289 (Del. Ch. 2003)). As a result, each of the Director Defendants faces a substantial likelihood of liability.

A majority of the Board engaged in even more egregious dereliction of duty by publicly undertaking special oversight responsibilities over J&J's core management processes – accepting seats on important Board committees – while not intervening when they learned that J&J's core operations were breaking the law. ¶297. Specifically, four Director Defendants – Defendants Coleman, Cullen, Langbo, and

Mullin – served on the Audit Committee during the Relevant Period and undertook to ensure the Company's compliance with applicable laws and regulations, including by monitoring compliance and reviewing reports from J&J's internal audit concerning management improprieties. ¶¶29-30, 32, 43, 297-298. Defendants Cullen, Lango, Mullin, and Prince served on the Nominating and Corporate Governance Committee and, as such, were required to oversee corporate governance matters. ¶¶30, 32, 34, 36, 297. Finally, Defendants Lindquist, Perez, and Satcher served on the Public Policy Advisory Committee and were regularly apprised of regulatory affairs and compliance matters affecting the Company.[10] ¶¶33, 35, 37, 297, 299. These committees were charged with reporting significant issues, such as the widespread misconduct alleged in the Complaint, to the full Board. ¶¶298-299.

Because the Complaint adequately alleges that at least a majority of the Board breached their fiduciary duties to act in good faith, a majority faces a substantial likelihood of liability and demand is futile.

D. Defendants Mischaracterize the Allegations in the Complaint and Cite Inapposite Authority

Fundamentally, Plaintiffs' Complaint alleges conscious and deliberate acts of misconduct by the Board. J&J's brief attacks something much different. It pretends

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[10] J&J's Chief Compliance Office in 2005 and 2006, Defendant Deyo, also sat on this Board committee, providing the Board with real time information regarding compliance problems and issues at the Company. ¶281.

that Plaintiffs merely allege negligent failure of oversight claims, or so-called "*Caremark*" claims. Def. Br. at 19. But Plaintiffs are not asserting that the Board was "blissfully unaware" of J&J's ongoing violations; no fair reading of the Complaint supports that conclusion. *See Caremark*, 698 A.2d at 969; *see also id.* at 971 (*Caremark* action "presents no occasion to apply a principle to the effect that knowingly causing the corporation to violate a criminal statute constitutes a breach of a director's fiduciary duty").

Likewise, Plaintiffs have also not "cherry-picked [a] list of issues" at a handful of subsidiaries, as asserted by Defendants. Def. Br. at 1, 11. Rather, the Complaint details the Director Defendants' conscious disregard for J&J's prolonged and widespread illegal business practices concerning J&J's core businesses: OTC drugs, prescription drugs, and medical devices.

J&J nevertheless relies heavily on cases involving passive failures to monitor. However, none of the cited cases involve: (i) allegations of company-wide illegal conduct, spanning numerous products during more than six years; (ii) receipt of numerous FDA warning letters; (iii) imposition of corporate integrity agreements; (iv) numerous state and federal government investigations; (v) guilty pleas to criminal conduct; (vi) significant adverse jury verdicts; and (vii) the filing of numerous *qui tam* complaints. *See* §II.

For example, in *King v. Baldino*, the court dismissed for failure to make a demand because the "plaintiff fail[ed] to plead particularized facts demonstrating that

the Board was aware of the actions of the alleged 'principal wrongdoers' and consciously failed to act in light of that knowledge." 648 F. Supp. 2d 609, 626 (D. Del. 2009), *aff'd*, No. 09-3834, 2010 U.S. App. LEXIS 25490 (3d Cir. Dec. 14, 2010). A comparison of the Complaint here – which contains 322 paragraphs of detailed allegations across nearly 100 pages – to the complaint dismissed in *King* – a 19-page document consisting largely of multi-page quotations from newspapers strung together with boilerplate allegations – makes clear the significant distinctions between the two cases. *See* Cecchi Decl., Ex. 5. As the *Pfizer* court explained in very similar circumstances:

> The allegations here dwarf by several orders of magnitude such cases as . . . *King v. Baldino*, 648 F. Supp. 2d 609, 623-26 (D. Del. 2009) (plaintiffs failed to plead demand futility with respect to allegations arising from pharmaceutical company's $425 million settlement for illegal off-label marketing, where plaintiffs pleaded no facts supporting inference that the board was aware of, *inter alia*, certain audit reports, data indicating the frequency of off-label prescriptions, or reports of increased sales of illegally promoted drugs).

722 F. Supp. 2d at 462 n.7.

Defendants' reliance upon *Fagin v. Gilmartin*, No. 03-2631 (SRC), 2004 WL 5835749 (D.N.J. Aug. 20, 2004), is equally misplaced. In *Fagin*, plaintiffs alleged that members of the Merck's board of directors had breached their fiduciary duties because a Merck subsidiary had inaccurately accounted for co-payment revenues and improperly curtailed the role of pharmacists in filling prescriptions. *Id.* at *3-*4. This is a far cry from the pervasive conduct in J&J's core business practices alleged here.

Moreover, Judge Chesler expressly found that the plaintiffs had pleaded only "conclusory allegations" as to why the directors were not "disinterested." *Id.* at *7-*10, *13. The plaintiffs did not challenge this finding on appeal. *Fagin v. Gilmartin*, 432 F.3d 276, 283 (3d Cir. 2005). Here, of course, the Complaint alleges much more than "conclusory allegations" and Plaintiffs do challenge the disinterestedness of J&J's Board. Indeed, the well-pleaded allegations in the Complaint are much closer to, and even more egregious than, the facts alleged in Judge Chesler's finding in *SFBC* that demand was futile. *See SFBC*, 495 F. Supp. 2d at 487.

In re Merck & Co., Inc. Derivative & ERISA Litig., No. 05-1151, 2006 WL 1228595, at *7-*17 (D.N.J. May 5, 2006), *rev'd*, 473 F.3d 393 (3d Cir. 2007), is also inapposite. There, plaintiffs alleged board inaction with respect to Merck's improper marketing of a single drug, Vioxx, as safe and effective. The *Merck* court found:

> Here, Plaintiffs' own allegations assert that Defendants approved and monitored Merck's marketing and sales plans despite receiving a "'body of scientific evidence which ***questioned*** the cardiovascular risk safety of Vioxx.'" (Compl.¶ 218(e)) (emphasis added). Plaintiffs have, therefore, failed to allege particularized facts that would suggest that the Directors' conduct was "egregious," or in bad faith.

Id. at *14 n.5. As in *Fagin*, the court found that plaintiffs' allegations with respect to futility of demand were "conclusory at best" (*id.* at *10), stating that:

> Plaintiffs do not plead with particularity any knowledge or action by the Board generally, or by the March 2004 Board specifically. The only allegation specific to the March 2004 Board is a letter sent by the FDA to Gilmartin in 2001 stating that the promotional campaign minimizes risks observed in the VIGOR study.

Id. at *14.

Here, the Complaint alleges unambiguous, systemic illegal business practices across all three of J&J's core business segments, and sets forth over 90 specific red flags informing the Board of this ongoing misconduct. In addition, the Complaint particularizes which Director Defendants were on the Board when each red flag was received, and alleges individualized knowledge based on, *inter alia*, the Director Defendants' signatures on multiple Forms 10-K. ¶¶279-285; *see also* §II.C.

Bronstein v. Austin, No. 07 C 3984, 2008 WL 4735230 (N.D. Ill. May 30, 2008), is also misplaced. There, the plaintiff did not allege any facts "that the underlying conduct render[ed] any of the directors interested" or any "particularized facts showing that at least half of the directors face[d] a sufficiently substantial threat of personal liability." *Id.* at *4. Moreover, the court found that the *Bronstein* plaintiff had also failed to adequately allege the board's bad faith because the FDA had expressly acknowledged defendants' efforts in addressing the underlying problem. *Id.* at *5. As discussed above, none of this is true here.

Markewich v. Collins, 622 F. Supp. 2d 802 (D. Minn. 2009), is also inapposite. Conceding that there was no conscious decision by the board not to intervene in misconduct, the *Markewich* plaintiff alleged that a majority of the board faced a substantial likelihood of liability because they were aware that "several hospitals and clinics were discontinuing the implementation of Fidelis lead" (a company product), that several adverse event reports were filed, and "did nothing to prevent or remedy

this situation and instead made fraudulent statements regarding the Fidelis lead." *Id.* at 805.

Applying Minnesota law, the court found that demand was not futile because the complaint did not plead sufficient facts to "support the inference of a 'sustained or systematic failure' of the Director Defendants to exercise oversight" and the *Markewich* plaintiff had failed to plead "the Director Defendants' knowledge of the issues they were required to prevent or correct, nor has she pleaded any facts indicating their knowledge of substantial inadequacies in the performance of their oversight duties." *Id.* at 811. This does not describe the Complaint here.

Here, Plaintiffs have asserted particularized allegations of sustained and systemic lawbreaking, sanctioned by the Board, which received constant reminders of the ongoing illegal conduct. Thus, the Complaint details at great length the issues that the Director Defendants consciously did not prevent and correct.

Intel is distinguishable for the same reason. There, the red flags to the board consisted of a $10 million arbitration award 16 years before the lawsuit, a "'preliminary'" finding by the European Commission that Intel had violated European Union antitrust law, a Korean antitrust investigation that did not result in any findings of liability until 6 months after the lawsuit was commenced, and a Japanese investigation that did not result in any liability. 621 F. Supp. 2d at 175-76. Analyzing these purported red flags, the court had no trouble finding that they were "not so severe that the Defendants now face a 'substantial likelihood of liability' for allegedly

ignoring them." *Id.* at 176 (distinguishing *SFBC*, *Veeco*, *McCall* and *Abbott Labs.* "because they all include a much more compelling collection of 'red flags'").

In sum, unlike here, the cases cited by the Defendants did not involve a flood of serious, credible red flags from multiple sources informing the Board of prolonged, pervasive illegal conduct in the Company's core manufacturing and marketing activities. Rather, they involved conclusory allegations of misconduct in placeholder complaints, a few isolated red flags, or much more limited misconduct with respect to an isolated product. They are therefore not relevant for determining whether demand on the Board was futile.

IV. Defendants Cannot Hide Behind J&J's Certificate of Incorporation

Defendants' reference to the "Restated Certificate of Incorporation" of J&J is a red herring. Def. Br. at 20-21. First, use of an exculpatory provision in the charter is an affirmative defense that is "not amenable for pretrial disposition." *Emerald Partners v. Berlin*, 726 A.2d 1215, 1223 (Del. 1999); *see also Tower Air*, 416 F.3d at 242 (same).[11]

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[11] Defendants argue that the existence of an exculpatory provision imposes a higher pleading standard. Def. Br. at 20. Defendants are wrong. The exculpatory provision is irrelevant, since the underlying claims pleaded here either allege an absence of good faith, and therefore meet the applicable standard to establish demand futility, or they do not, and should be dismissed irrespective of the provision. In any event, the case Defendants cite for this proposition – *Kanter v. Barella*, 388 F. Supp. 2d 474, 479 n.9 (D.N.J. 2005), *aff'd*, 489 F.3d 170 (3d Cir. 2007) – does not impose a

Second, Plaintiffs allege that the Director Defendants breached their duty of good faith and loyalty to the Company and its shareholders. The alleged misconduct is non-indemnifiable and non-exculpable under New Jersey law. Indeed, N.J. Stat. Ann. §14A:2-7(3) does not act to shield the Director Defendants from liability where, as here, the Complaint alleges repeated and pervasive violations of drug manufacturing and marketing laws that subjected the Company to the risk of federal debarment, because such conduct evidences non-exculpable bad faith. *See* §II; *see also SFBC*, 495 F. Supp. 2d at 487; *Lyondell*, 2008 Del. Ch. LEXIS 125, at *23 ("a conscious disregard of one's responsibilities" is "'properly treated as a non-exculpable, non-indemnifiable violation of the fiduciary duty to act in good faith'"). Because Defendants' liability is premised on their violation of the duty of good faith, their reliance on N.J. Stat. Ann. §14A:2-7(3) is misplaced and, the motion to dismiss on this ground should be denied.

V. This Action Should Not Be Stayed Pending a Special Committee Investigation

Plaintiffs did not make a demand on the J&J Board. There is no reason for this Action to be stayed pending the outcome of an investigation by a Special Committee.

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higher pleading standard when defendants attempt to hide behind an exculpatory clause.

First, the Special Committee does not have an adequate mandate to warrant a stay. According to the Board resolution that created the Special Committee, the committee can make a "recommendation" as to how the Board should respond to the shareholder demands, but the Board "retains and shall exercise full authority to take final action on behalf of the Corporation with respect to the shareholder demands and the Shareholder Derivative Lawsuit." *See* Exs. 1 and 2 to the Declaration of Douglas S. Eakeley, Dkt. No. 105-3. In other words, the Special Committee is toothless and legally inadequate; *see also Szeto v. Schiffer*, No. 12,934, 1993 Del. Ch. LEXIS 264, at *10-*11 (Del. Ch. Nov. 24, 1993) (finding inapposite legal precedent supporting a stay for a fully empowered SLC because the committee in that case was "not authorized to 'take over control of the conduct of [the] action'"); *Biondi v. Scrushy*, 820 A.2d 1148, 1165 (Del. Ch. 2003) (denying motion for a stay in part because the board's "at best, begrudging and, at worst, inadequate, original delegation of authority to the HealthSouth SLC [was] ***a delegation that left the board litigating to dismiss the derivative suits at the same time as the SLC was supposedly considering their merits***"); *In re Par Pharm., Inc. Derivative Litig.*, 750 F. Supp. 641, 645 & n.8 (S.D.N.Y. 1990) (denying motion for a stay because committee "was not given full power to determine the Company's position but was merely authorized to investigate and report to the Board"); *Hirsch v. Jones Intercable, Inc.*, 984 P.2d 629, 638 (Colo. 1999) (same). The cases cited by Defendants in favor of a stay all involved SLCs

with an adequate mandate and are, thus, inapposite.[12] *See Par Pharm.*, 750 F. Supp. at 645 & n.8.

Second, Defendants request for a stay should also be denied because a majority of the members of the Special Committee faces a substantial likelihood of liability and is not disinterested. *See Sutherland v. Sutherland*, 968 A.2d 1027, 1029 (Del. Ch. 2008) (denying special litigation committee's motion to dismiss, noting that "moving party must prove that the SLC was 'like Caesar's wife . . . above reproach'"); *Lewis v. Fuqua*, 502 A.2d 962, 967 (Del. Ch. 1985) (same); *see also* 2 *Principles of Corp. Governance* §7.09(a)(1) (A.L.I. 2010) (SLC "should be composed of two or more persons, no participating member of which was interested in the action, and should as a group be capable of objective judgment in the circumstances").

Here, three of the four members of the Special Committee – Defendants Johns, Prince and Perez – are Defendants in this action and were informed about numerous red flags of the illegal practices in J&J's core business activities. Defendants Johns

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[12] *See Abbey v. Computer & Commc'ns Tech. Corp.*, 457 A.2d 368, 373 (Del. Ch. 1983) (SLC was granted full authority to determine what action to take); *In re InfoUSA, Inc. S'holders Litig.*, No. 1956-CC, 2008 WL 762482, at *2 (Del. Ch. Mar. 17, 2008) (same); *Rudolph v. Cummins*, No. H-06-2671, 2007 WL 1189632, at *1 (S.D. Tex. Apr. 19, 2007) (same, as reflected in SEC Form 8-K, cited in opinion); *In re UnitedHealth Grp. Inc. S'holder Derivative Litig.*, No. 06-CV-1216 (JMR/FLN), 2007 WL 803048, at *2 (D. Minn. Mar. 14, 2007) (same); *Strougo ex rel. Brazil Fund v. Padegs*, 986 F. Supp. 812, 815 (S.D.N.Y. 1997) (same); *St. Clair Shores Gen. Emps. Ret. Sys.*, No. 06 Civ. 688 (SWK), 2006 WL 2849783, at *3-*5 (S.D.N.Y. Oct. 4, 2006) (same).

has been a member of the Board since 2005. ¶31. Defendant Prince has been a member of the Board since 2006, including as a member of the Nominating and Corporate Governance Committee. ¶36. And Defendant Perez has been a member of the Board since 2007. As a result, the Special Committee is unable to represent the interests of J&J in this Action. *See In re KLA-Tencor Corp. S'holder Derivative Action*, No. C 06-03445 JW, slip op. (Dkt. No. 484) (N.D. Cal. Dec. 12, 2008) (denying SLC's motion to dismiss because SLC was not disinterested), attached as Ex. 6 to the Cecchi Decl.

Third, this Action should not be stayed because the Special Committee – made up of four current Board members – lacks independence due to their ongoing support for Defendants Weldon and Deyo, who are alleged to have engaged in the wrongdoing at issue in this Action. Recently, and subsequent to the filing of the Complaint, ***the Board praised Weldon***, stating that Weldon "met expectations during 2010" and exhibited "leadership" arising from the aftermath of recalls and regulatory scrutiny. *See* Cecchi Decl., Ex. 7 at 38. This praise, despite historic recalls and the acknowledged damage to the Company's reputation (*see id.* at 21-22, 38), was in connection with the Board's approval of Weldon's pay package exceeding ***$28 million*** and a merit-based raise. *Id.* at 39, 46. Additionally, the Board also recently praised Deyo's leadership and approved a compensation package for Deyo of nearly ***$9 million*** as well as a merit-based raise. *Id.* at 41, 46. Moreover, at present, all four members of the Special Committee – Prince, Johns, Mulcahy and Perez – constitute

the Compensation Committee that approved Weldon's and Deyo's compensation packages in the face of allegations that they participated in the wrongdoing. *Id.* at 21. The Special Committee's unequivocal support for Defendants Weldon and Deyo disables it from conducting a disinterested investigation into the alleged wrongdoing, in which both Weldon and Deyo are alleged to have participated. *See Biondi*, 820 A.2d at 1165 (denying a stay because the SLC lacked independence, as evidenced, *inter alia*, by comments from an SLC member that the CEO "did nothing wrong").

A stay of this action pending review by the legally inadequate and factually compromised Special Committee would be a waste of time, and should be denied.

VI. Conclusion

For the reasons set forth above, Plaintiffs respectfully submit that the Court should deny in its entirety Defendants' motions to dismiss the Complaint.

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Respectfully submitted,

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