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McNeil, a Johnson & Johnson Subsidiary FDA Case Study

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ABSTRACT

This case study provides a detailed five-year review of one of Johnson & Johnson's important subsidiaries, McNeil Consumer Healthcare. The research presents summaries from the Food and Drug Administration (FDA) inspection reports, out-of-compliance findings, and warning letters for the period between 2007 and 2011. It also relies on a class action lawsuit and a judicial consent decree within this timeframe to further understand the relationship between Johnson & Johnson and McNeil. The case study focusses on problems in the manufacturing and quality assurance at McNeil, and how Johnson & Johnson may have exacerbated McNeil's production failures.

Keywords: FDA, CAPA, cGMP, enforcement, warning letters, pharmaceuticals

FOOD AND DRUG ADMINISTRATION CASE STUDY

Monk v Johnson & Johnson et al. (2013) is often regarded as a world-class pharmaceutical corporation, noted for its quality consumer products. Yet during the five-year period from 2007 and 2011, one of its principal subsidiaries, McNeil Consumer Healthcare, underwent a series of massive product recalls. The Food and Drug Administration (FDA), which is the principal regulatory agency for the U. S. bio-pharmaceutical (BP) industry, has cited McNeil numerous times during this period for violations of its statutes. This places in question not only the reputation of Johnson & Johnson, but also whether their products are safe, effective, and manufactured in accordance with "cGMP," the current Good Manufacturing Practice (FDA, 2004a).

As part of this case study, the research reviewed the FDA's judicial consent decree to close a McNeil manufacturing plant, and impose stringent external supervision. In addition, the researchers had access to public documents: congressional investigative transcripts about McNeil's recalls, and a class action lawsuit on behalf of Johnson & Johnson shareholders. The paper explores these documents to evaluate Johnson & Johnson's role in determining why McNeil's could not meet the FDA's cGMP standard (FDA, 2008b). The central question asked throughout this paper is, what part did Johnson & Johnson's management play in McNeil product recalls?

Surprisingly, previous researchers have not fully investigated these events. The two main academic investigations of quality assurance (QA) in the pharmaceutical sector are Adis's risk studies (2007, 2008) of the PB industry, and Marcher and Nickerson's (2006) review of quality systems. Both were sector evaluations, rather than case studies.

BACKGROUND: JOHNSON & JOHNSON CONSUMER HEALTHCARE

Johnson & Johnson is a global conglomerate with a market capitalization of more than \$160 billion. The company describes itself as the “Johnson & Johnson Family of Companies.” It consists of four divisions: consumer, pharmaceutical, medical device and diagnostic. McNeil is an important Johnson & Johnson pharmaceutical subsidiary with two large manufacturing facilities: one at Las Piedras, PR and other at Ft. Washington, PA, which is also its headquarters. In 2004, McNeil had annual sales of US \$2.1 billion and 2600 employees. Both sites are responsible for the manufacture, packaging and distribution of popular over-the-counter (OTC) products, including Tylenol and Motrin.

The quality melt down at McNeil described in this study took place from 2007 to 2011. It is critical to note that in January 2007, Johnson & Johnson began its \$16.6 billion acquisition of the Pfizer Consumer Healthcare business. Pfizer’s product lines (Zyrtec, Listerine, Sudafed and Benadryl) became part of the Johnson & Johnson Healthcare Products Division of McNeil-PPC, Inc.

McNeil faced the manufacturing challenge of incorporating Pfizer products, manufacturing processes, and employees. This was particularly true of the Ft. Washington and Las Piedras manufacturing sites where management was tasked with merging and integrating these new product lines cost-effectively, while maintaining pharmaceutical quality. However, in this merger it seems that the management goal of containing costs ran counter to the FDA’s objective of achieving best practices, as measured through cGMP inspection reports. These cGMP guidelines are the basis for quality systems and mandated industry best practice regulations (CDER, 2009).

Throughout this acquisition timeframe, there were significant QA problems at the Las Piedras and Ft. Washington sites. For instance, in the period from 2008 to 2010, the FDA in conjunction with McNeil recalled more than 100 million bottles of Motrin and Children’s Tylenol from the distribution channel (FDA, 2011b). The scale of this Tylenol recall of child medication is one of the largest recorded by the FDA. Further investigations by the FDA revealed additional QA breaches such as children’s medications contaminated with metallic particles. These violations and gross QA failures mandated an expanded recall of 136 million bottles of pediatric medications.

McNeil faced other recalls and QA problems during this timeframe. It also had to recall Zyrtec, Motrin, Benadryl and adult Tylenol. The QA failure with adult Tylenol was caused by the chemical breakdown of a protective coating on wooden transport pallets, causing a generally moldy odor. This substance was then absorbed by drug containers and their pharmaceutical contents.

Normally, if a cGMP violation is found, FDA issues an out-of-compliance Form 483 inspection report and the manufacturer works with the Agency to remediate the problem. If it is a flagrant violation, which has the potential to endanger the consumer, the Agency mandates a product recall. ‘Endangering’ means that there is a reasonable probability that the use of, or exposure to an out-of-compliance drug will cause significant harm or death. McNeil’s recalls during this timeframe were mainly Class I, the most serious category.

After four years of out-of-compliance findings, field alerts and product recalls, the FDA took legal action against McNeil. The FDA’s Consent Decree of Permanent Injunction (United States v.

McNeil-PPC., Inc., 2011) alleged that McNeil and certain corporate officers were responsible for cGMP violations in the life-cycle production of drugs. This specifically included the manufacturing, processing, packing, labeling, holding and distributing of their drug products. The decree named the McNeil Corporation of New Jersey, and key defendants such as the VP of Operations and the VP of Quality Control. The decree permanently restrained and enjoined McNeil to curtail activities at Las Piedras and close the Ft. Washington plant until its cGMP status was re-certified. McNeil consented to the decree without admitting or denying the allegations, yet immediately closed the Ft. Washington facility. Part of the decree forced McNeil to hire external cGMP consultants to provide guidance, oversight and remediation of the site violations. The decree also states that McNeil has to operate in coordination with, and under the appropriate oversight of Johnson & Johnson, the parent company.

It did not end there. The intense news coverage of the massive recall of popular OTC drugs prompted the U. S. Congressional sub-committee to investigate how both the FDA and McNeil, and by extension Johnson & Johnson, had not been able to prevent these QA failures. Prompted by the congressional investigation, the FDA released McNeil site inspections reports, which were previously unavailable. With these released reports, researchers were able to see how on one hand the FDA evaluated McNeil's QA problems during this period, and on the other, how management failed to actively remedy the problems.

CLASS ACTION LAWSUIT—JOHNSON & JOHNSON

To better understand management's inaction, the research turned to a securities fraud class action lawsuit, filed in 2011 on behalf of purchasers of the Johnson & Johnson common stock. It is the plaintiff's claim that Johnson & Johnson was responsible for conscious and reckless decisions from October 14, 2008, through July 21, 2010, (Monk v. Johnson & Johnson et al., 2011). This corporate malfeasance contributed to the product recalls, FDA warnings, and eventual court enforced plant closure. The lawsuit provided an important area of research since it initiated the release of documents and other information that would normally not have been made available. This provided a trove of new information, which the plaintiffs used to further their legal argument.

The legal argument focuses on Johnson & Johnson's \$16.6 billion acquisition of the Pfizer Consumer Healthcare business in January 2007. This event triggered an executive decision to integrate product lines and reduce costs across business segments in order to recoup the investment. The following are the plaintiffs' claims:

- Johnson & Johnson denied McNeil funding for essential staff and capital improvements to successfully integrate the Pfizer product line
- Johnson & Johnson's management made these decisions while consciously and recklessly disregarding known deficiencies already outlined by the FDA
- Quality control (QC) for OTC medicines was one of the principal cost cutting areas
- McNeil's experienced QC staff was fired or replaced with less qualified employees
- McNeil QC was then transferred to the Johnson & Johnson Consumer Division although its staff lacked the necessary pharmaceutical training or background

- This reckless and undisciplined cost-cutting impaired QC, and is the root cause for product defects, widespread recalls, and potential injury to the consumer

The second argument made by the plaintiffs relates to the degree of knowledge that makes an individual legally responsible for the consequences of his act (scienter). The plaintiffs made the allegation that corporate individuals at McNeil and Johnson & Johnson were fully aware of the reckless failure to support the integration of manufacturing product lines. This was particularly evident in the cost cutting of the QC unit. It is obvious that without QC it is impossible to maintain cGMP standards. The degree that these individuals are legally complicit are demonstrated by the out-of-compliance Form 483, product recalls, and plant closure.

When the defendant Johnson & Johnson appealed the second argument, the judge concluded that a compelling inference of scienter can be drawn and upheld for the following plaintiffs:

- Defendant Goggins, Johnson & Johnson Worldwide Chairman of the Consumer Group. She was responsible for manufacturing and sales for McNeil's OTC medicine business. Goggins was responsible for creating financial targets for the Consumer Group. She recklessly imposed aggressive cost cuts on McNeil, including its quality assurance department, in order to boost the Company's growth and profitability. Goggins recklessly disregarded the fact that her aggressive cost containment efforts adversely impacted QC and created a brittle manufacturing environment. In sum, Goggins admitted to the Congressional Committee that she and others at Johnson & Johnson knew about quality control failures at McNeil during the first half of 2009
- Defendant Caruso, Johnson & Johnson's chief financial officer. He was fully aware of the problems at the manufacturing sites. He was fully briefed by the FDA about QC issues at McNeil, but chose to not to address these issues in any public statement or at best he tried to camouflage their meaning. More to the point, by not addressing the issues of cost-cutting and QA, Caruso was part of the problem, not the solution. The end result was that the CFO's policies contributed to QC deficiencies, and led directly to recalls, and the failures at McNeil.

While this finding is not guilt, it points to Johnson & Johnson's overarching involvement in the cost cutting activities at McNeil, and its knowledge of its negative consequences. Johnson & Johnson in the end chose to be part of a settlement with the plaintiffs, and pay \$22.9 million to end the litigation.

CURRENT GOOD MANUFACTURING PRACTICE

To understand McNeil's manufacturing weaknesses it is important to have a working knowledge of the FDA's cGMP, which provides oversight and guidance through QA protocols (International Society for Pharmaceutical Engineering (ISPE), 2008). This assures that OTC and prescribed drugs have the required quality, potency and efficacy.

The oversight tasks include examining quality control log books, testing potency and purity, and tracking consumer complaints. The FDA enforcement includes out of compliance findings, warning letters for serious infractions and field alerts, followed by ordering recalls. The Agency's protocols (FDA, 2003b, 2004a) define best practices for QA site inspections. Any violation triggers an increasing level of regulatory response, from increased inspections to consent decrees.

This is a risk based approach to reduce the probability of hazards to the consumer. It is fully described in cGMP for the 21st Century (FDA, 2004a) guidelines. The cGMP methodology focuses on manufacturing production plants with the highest risk priority, based on best practices, and QA protocols. The determination of risk drives the inspection process. The severity of the hazard determines if warning letters and recalls are necessary (FDA, 2008c). "The model is based on a risk-ranking and filtering method that is well-recognized, objective and rigorously systematic. The Agency believes that this methodology makes the best use of its limited surveillance and enforcement resources, while maximizing the impact of those resources on the public health" (FDA, 2004a). To achieve these QA standards, the manufacturer's active participation is critical (FDA, 2004b).

This research study compares McNeil's risk management performance against the cGMP regulations. To evaluate corporate performance, this research turned to the concepts of corrective and preventative actions, often referred to as CAPA. Best practices with CAPA are the core of problem prevention, containment and remediation. Therefore, both the manufacturer and the FDA have the same standards for achieving industrial strength manufacturing. (COSO, 2004). CAPA as described in CGMP is the risk scorecard for evaluating manufacturing performance. This is reflected in such QC tasks as record keeping and product sampling. (FDA, 2003a; ICH, 2005, 2006).

Over time, the FDA records manufacturer's site performance using these risk management statistics (ICH, 2007a, 2007b; FDA, 2008d):

- Compliance history of the company and facility
- Management's CAPA activities
- Complexity of the manufacturing process
- Complexity of the product
- Therapeutic importance of the product
- Number and significance of quality defects (e.g., recalls)

The FDA has now placed online McNeil site inspection history, permitting researchers to review and evaluate McNeil's CAPA performance, and indirectly Johnson & Johnson's level of support.

RESEARCH METHODOLOGY

The researchers examined the inspection history for McNeil, focusing especially on cGMP and CAPA violations. This investigation was then expanded to include deficiencies that escalated into actual field alerts, recalls and plant closings. In the mind of the researchers, the fundamental question was whether Johnson & Johnson was actively engaged in the CAPA remediation.

Table 1 is an overview of the enforcement activities of FDA's CDER division (Center for Drug Evaluation and Research). This becomes helpful when describing McNeil and Johnson & Johnson's response to FDA oversight. The first column lists the common name used by the FDA, followed by a brief definition (FDA, 2008d). These are generally straightforward, though certain significant terms such as warning letters (WLs) will be further explained.

Category 1	FDA Corrective and Preventive Activities
EIR	Establishment Inspection Report: The EIR documents the inspection. The FDA guidelines calls for 2-4 year manufacturing inspection cycle, with added inspections based on risk determination.
Form 483	FDA Form 483: Summary of objectionable conditions listed in the EIR or related documents. These cite specific regulatory violations and are the basis for WLs.
WL	Warning Letters cite regulatory violations deemed significant. These violations may trigger enforcement if not promptly and adequately remediated.
Category 2	FDA and Manufacturer CAPA Remediation Activities
Field Alert	The FDA requires the manufacturer to issue a Field Alert when a hazard occurs in the manufacturing life-cycle. Field Alerts may lead to recalls.
Recall	Recalls remove the product from the market. Recalls may be the result of firm's own initiative, by FDA request, or by FDA's statutory authority
Category 3	FDA Enforcement
Consent Decree	Consent Decree of Permanent Injunction. A legal agreement by a defendant to cease all activities stipulated as being hazardous.
Plant Closing	An example is the voluntary plant closing by McNeil and Johnson & Johnson, immediately prior to the issuance of the consent decree.
Category 4	Congressional Investigative Activities
Congressional Investigation	Congressional Committee on Oversight and Government Reform's investigation of the FDA, McNeil and Johnson & Johnson.

Table 1: Review of Major FDA Activities.

Table 1 shows FDA activities in increasing importance, as determined by CAPA risk categories. For instance, CAPA Category 1 shows actions to correct and prevent manufacturing risks. As an example, the EIR records the outcome of a normal inspection. The next row is the Form 483 stating that the site had out-of-compliance conditions. The final entry in this CAPA category is the warning letters (WLs) for flagrant regulatory violations. The WL establishes the fact that prior notice was given to the manufacturer, and failure to voluntarily remove the hazard would lead to judicial action.

Category 2 is remediation. It identifies and alerts the retail distributors about drug batches that may pose a danger to consumer. This occurs when the manufacturer, in collaboration with the FDA, issues field alerts, followed by the determination to recall the products (FDA, 2011a).

The next grouping is Category 3. The most serious enforcement activities: consent decrees to halt manufacturing, followed by the judicial order to close the plant. When the normal CAPA actions (Form 483, WLs) have not caused the manufacturer to bring production into compliance, the Agency seeks a court ordered injunction to force compliance. The last category is a U. S. congressional investigation. This took place in this case because of the magnitude and significance of the recalls. Here, Congress chose to review the business interactions of the FDA, McNeil and Johnson & Johnson.

Of all the steps listed, the critical juncture occurs when the manufacturer fails to remedy the Form 483 quality control problems. CDER then issues a WL, which cautions the manufacturer about the significant regulatory violations and formally establishes prior notice. From the FDA perspective “(A) Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act” (FDA, 2012b). For a WL to be issued:

1. The violation reflects a history of repeated violations
2. There is a violation of cGMP in terms of manufacturing, ingredients, dosage, quality systems and oversight
3. The product contains harmful substances such as illegal pesticide residues
4. The product shows sub-potency, or super-potency

McNeil, with its numerous Form 483 violations, certainly deserved the WL that was issued in 2010. The WL also names Johnson & Johnson, the parent company. The WL is specifically concerned that neither Johnson & Johnson nor McNeil assured timely investigation and resolution of the QA violations and production failures.

ANALYSIS

The problems at McNeil escalated and then culminated in the 2010-2011 period, in which the FDA received a court-ordered injunction decree against McNeil. The decree continually refers to Johnson & Johnson as the ultimate parent company, legally binding it to the injunction. Prior to consenting to the court injunction, McNeil voluntarily shuttered its Ft. Washington plant. In 2011, a congressional committee investigated the FDA-McNeil-Johnson & Johnson interactions. They initially reviewed CDER’s level of oversight, and McNeil-Johnson & Johnson response to its product recalls. The investigation then expanded to probe other CAPA areas.

This study follows a similar approach, reviewing the FDA-McNeil interactions. Table 2 summarizes the increasing level of FDA activities from EIR site inspections to product recalls, culminating in 2010 with 19 CDER actions. This represents a substantial increase in FDA activity accounting for 41 percent of the total CDER response.

It also shows the 2011 timeframe for the consent decree and congressional investigation. This chronological activity chart visually captures the intensity of the problem during the Johnson & Johnson acquisition and attempted integration of Pfizer into the McNeil operation.

While there were some Form 483 objectionable conditions in 2005-07, CDER seemed satisfied that McNeil was proactive in addressing and remediating them. In 2007, there were no inspections in spite of a field alert. FDA business as usual approach seems to imply a certain confidence in McNeil's ability to resolve QC problems.

Then in 2008 thru 2010 there were ten EIR inspections, causing CDER to issue eight Form, 483. CDER's EIR inspections determined that QA and CAPA weaknesses were the root cause of the manufacturing failures. In reviewing these EIR and Form 483 documents, one has to be struck by their comprehensive listing of QA problems. It seems as if McNeil moved from being a normal manufacturer to a rogue pharmaceutical corporation. The class action suit highlights this point that McNeil followed best practices until 2007. Then McNeil was overwhelmed by the incorporation of Pfizer products, followed by the staff reductions and the transfer of their QA department to Johnson & Johnson. The brittleness of operations became evident, as McNeil was no longer able to address the production pressure and the QA problems cascaded.

QA and CAPA methodologies are based on what Booch calls "industrial strength" processes (Booch, 1994), that is, sustainable manufacturing practices with 24/7 quality and reliability. Problems with quality rarely materialize out of the blue, but are triggered by events that expose the weakness of old manufacturing sites, inexperienced staff, and insufficient budgets. The Pfizer acquisition was the trigger for a series of field alerts and recalls, since McNeil could no longer control the manufacturing processes. Where was Johnson & Johnson during this transition?

By 2011, the structural weakness of McNeil operations could no longer be ignored. The FDA obtained a court injunction to shutter the Ft. Washington plant, and place Las Piedras under external cGMP supervision.

However, CDER's approach is also somewhat questionable since it only issued its first WL in 2010, well into the period of increased recalls and 483 objectionable conditions reports. A WL issued earlier might have prompted McNeil to take action, and moved Johnson & Johnson to fund the necessary modernization and staffing at McNeil, which was necessary to address the Pfizer acquisition.

Without a WL with its ability to give prior notice of impending enforcement penalties, Johnson & Johnson was able to avoid taking corrective actions. Therefore, product defects increased in frequency and scale. In terms of blame, there is a strong argument to be made that both the FDA and McNeil-Johnson & Johnson shared blame at this stage, neither performed due diligence in following CAPA. CDER took multiple years before issuing a WL; McNeil did not or could not follow best practices; Johnson & Johnson was not proactive in supporting McNeil, and in fact contributed to its failures.

Yet, by the end of the 2011 study period, CDER acted with full authority, and met its regulatory role of oversight and enforcement required by cGMP. By this time, McNeil-Johnson & Johnson

had no alternative but to comply with the consent decree. As of January 2014, after spending \$100 million on the Ft. Washington plant, the FDA had still not recertified the plant and it remained shut.

Year	2005	2006	2007	2008	2009	2010	2011	Total
Category 1: CAPA Activities								
EIRs	2	3		2	2	6		15
Form 483	2	1		2	1	5		11
WLs						1		1
Category 2: CAPA Remediation								
Field Alerts	1		1		1			3
Recalls				1	5	5		11
Category 3: Enforcement								
Consent Decree							2*	2*
Plant Closing							1	1
Category 4: Investigative								
Congress Investigation						2*		2*
Yearly Totals	5	4	1	5	9	19	3	46
Yearly Percent	11%	9%	2%	11%	20%	41%	7%	100%

* Both plants are subject to the same consent decree and congressional investigations. The plants are listed twice, to show their involvement.

Table 2: Summary of CDER-McNeil Activity (Ft. Washington and Las Piedras).

Table 3 highlights the specific and persistent cGMP violations (FDA regulations, Part 802–Quality Systems) at McNeil. For instance in Table 3, CDER reported violation d. “No written procedures for review of complaints, returned drugs, and conducting investigations” repeatedly in 2005, 2010, and 2011. cGMP states that un-remedied QA failures create a manufacturing breach and pose a system-wide threat. McNeil violations, because of their scope, severity and extended timeframe, constituted a manufacturing hazard, and a danger to the consumer. The FDA responded with increased CAPA inspections to meet these unresolved violations (See Table 2). Then in 2011, it determined that the conditions at McNeil were untenable and issued a Consent Degree and closed the Ft. Washington plant.

More specifically, Table 3 summarizes Form 483 violations from FDA reports of 2005-2006, and compares it with 2010 data. The final column is a summary of the Consent Decree of 2011. The FDA language in the table has been simplified for presentation. The table organizes the data into standard CDER categories: quality systems, packaging, laboratory, and facility and equipment systems. The table emphasizes McNeil’s non-conforming operations: weak QC and failure to adhere to best practices.

CDER repeatedly found that McNeil’s QC unit was not fully integrated into manufacturing, and consequently unable to supervise, audit, and support operations. This resulted in failure to document and investigate production anomalies, and more seriously the inability to follow through on customer complaints. Its investigations were not thorough, timely or complete. CAPA violations occurred throughout the reporting period and within all CDER categories. The consent decree re-emphasized these finding.

The author tried to determine exactly what took place between the events of 2005-2006 and 2011. One unlikely answer is that McNeil recognized and corrected the violations with the support of Johnson & Johnson. Then, unfortunately, due to circumstances beyond its control, McNeil lapsed and returned to failed practices and substandard production. A more likely answer, supported by the class action lawsuit, is that McNeil ignored or minimized the findings. Johnson & Johnson, in its effort to maximize profits, merged Pfizer into McNeil without first strengthening operations at McNeil.

Major Quality Assurance Functional Areas	CDER 2005-6	CDER 2010	Decree 2011
Quality Systems			
a. QA investigations are not always documented, nor are they timely or complete	✓	✓	✓
b. Unexplained discrepancies are not extended to other related drug products	✓	✓	✓
c. QC Responsibilities and procedures are not in writing nor fully followed	✓	✓	✓
d. No written procedures for review of complaints, returned drugs, and conducting investigations	✓	✓	✓
Packaging System			
e. Strict control is not exercised over labeling drugs	✓	✓	✓
f. Labeling and packaging materials are not sampled	✓	✓	✓
g. QC unit did not review and approve procedures for packaging and reprocessing	✓	✓	✓
Laboratory			
h. Batch production and control records do not include all necessary information	✓	✓	✓
i. Laboratory records do not include necessary information: description of the sample, its source or location, the quantity and date of the sample	✓	✓	✓
j. QC unit does not review or approve changes to equipment specifications or procedure	✓	✓	✓
Facilities and Equipment System			
k. Written procedures are not established and followed for the cleaning and maintenance of manufacturing equipment	✓	✓	✓
l. Representative samples are not taken of each shipment lot for testing or examination	✓	✓	✓

Table 3: QA Violations between 2005 and 2011.

The 2011 Consent Decree re-emphasizes these CAPA weaknesses. The decree, approved by McNeil and the FDA, develops a plan to address the shortcomings. McNeil is now legally committed to

- Develop a comprehensive, written QC program that ensures best practices

- Hire an external cGMP consultant to supervise compliance
- Have a QC Unit at its facilities that is adequately qualified, trained and staffed to evaluate cGMP compliance, and to prevent and promptly correct future CAPA deviations
- Assure continuous cGMP compliance with the CDER federal regulations relating to the safety, strength, quality, and purity of drugs
- Johnson & Johnson, the parent company, is obligated to coordinate and support these tasks

Based on this initial analysis it seems that without court action, McNeil was not able or not willing to meet its manufacturing obligations. It also is likely that in its drive for profits, Johnson & Johnson was actively unresponsive. Certainly according to the lawsuit findings, Johnson & Johnson was aware of the production and QC problems at McNeil.

Initially, CDER also seems to be a passive onlooker. How else could it be explained that CDER issued only one WL in 2010? Simply put, CDER did not meet an appropriate level of oversight when facing repeated QA failures and recalls at the McNeil plants. It only rose to the task in 2010-2011. CDER's weak enforcement matched McNeil's obstinacy. In spite of the risk based cGMP methodology, both the FDA and McNeil-- Johnson & Johnson failed to address best practices.

CONCLUSION

The CDER-McNeil business relationship was first characterized by inertia. Neither the FDA nor McNeil did anything about the failed processes and recalls. This may be in part because the FDA faces a monumental task of monitoring the BP industry with limited fiscal and staff resources. Furthermore, this situation becomes worsened when a large corporation like McNeil fails to follow best practices. It also seems reasonable to say that Johnson & Johnson directly or indirectly colluded in the events as alleged in the lawsuit.

At the point when the cycle of 483 reports and product recalls began escalating, CDER changed its downward spiral of inaction, and began aggressive enforcement, concluding with a court injunction mandating cGMP. The decree specifically named Johnson & Johnson as the ultimate parent company and required its involvement. Since McNeil's failures were caused by Johnson & Johnson, then Johnson & Johnson was put on notice to cease resisting and actively support compliance. So depending on circumstances, CDER is an organization weighed by its constraints, or a proactive focused organization.

In today's business environment of interlocking corporations, with multiple business objectives and profit targets, QA may well become a victim. CDER has the necessary tools to escalate enforcement by establishing prior notice through WLs. When CDER fails to take this step, it is an open signal for the manufacturer to become passive. In the end, Johnson & Johnson had to remedy the faults, for they were corporate parent that failed to respond to FDA guidance.

cGMP and CAPA methodologies are based on the ability to guide, provide oversight and enforce. The fault may lie with CDER and its weak implementation of cGMP methodology. Since that time the FDA (FDA, 2012a) has updated its current mission to deal with this problem:

In May 2011 a new streamlined enforcement process for seizures and injunctions was implemented. The new process increases collaboration at an early stage in the process of case development; reduces paperwork by removing redundant and unnecessary documentation; removes a bias toward inaction by making the process less daunting and more collaborative; provides a mechanism for continuous improvement in case development; and shortens approval times.

Through additional analysis, the research intends to continue to explore the CAPA issues that have dogged McNeil, Johnson & Johnson and CDER. In particular, the research will explore the functions of the new FDA Office of Pharmaceutical Quality (OPQ) to see if it changes the dynamics of the BP industry.

REFERENCES

- Adis, W. (2007). A risk modeling framework for the pharmaceutical industry. *Communications of the IIMA*, 7(1), 1-11.
- Adis, W. (2008). Pharmaceutical risk control systems. *Communications of the IIMA*, 8(2), 1-9.
- Booch, G. (1994). *Object-oriented analysis and design with applications*. Reading, MA: Addison-Wesley.
- CDER. (2007). *Center for Drug Evaluation Research update: Improving public health through human drugs*. Retrieved May 14, 2010, from <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/WhatWeDo/UCM121704.pdf>
- CDER. (2009). Guidance for the industry: Current good manufacturing practice for combination products. Retrieved April 10, 2010, from <http://www.fda.gov/CombinationProducts/default.htm>
- CDER. (2012). *Food and Drug Administration FY2012 congressional budget request*. Author. Retrieved December 14, 2012, from <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM248654.pdf>
- COSO. (2004). *Enterprise risk management—integrated framework: Executive summary*. Retrieved from http://www.coso.org/documents/coso_erm_executivesummary.pdf
- Food and Drug Administration (FDA). (2003a). *Guidance for industry part 11, electronic records; electronic signatures: Scope and application*. Washington, DC: Author. Retrieved April 11, 2011, from <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf>
- Food and Drug Administration (FDA). (2003b). *Strategic action plan: Protecting and advancing America's health*. Washington, DC: Author

- Food and Drug Administration (FDA). (2004a). *Pharmaceutical cGMPs for the 21st Century: A risk-based approach: Final report*. Washington, DC: Author. Retrieved from <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswers/CurrentGoodManufacturingPracticescGMPforDrugs/ucm137175.htm>
- Food and Drug Administration (FDA). (2004b). *Risk-based method for prioritizing CGMP inspections of pharmaceutical manufacturing sites: A pilot risk ranking model*. Washington, DC: Author. Retrieved January 10, 2009, from http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4080b1_04_risk-based.pdf
- Food and Drug Administration (FDA). (2008a). *Code of federal regulations, Title 21: Quality system regulation*. Retrieved April 10, 2010, from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820>
- Food and Drug Administration (FDA). (2008b). Establishment inspection report (EIR). *Investigations Operations Manual*. Ors pp. 272-279. Author. Retrieved April 10, 2010, from <http://www.betterchem.com/portlets/iom/ChapterText/590.html>
- Food and Drug Administration (FDA). (2008c). *Factory inspections*. Washington, DC: Author. Retrieved January 10, 2009, from <http://www.fda.gov/CDRH/qsr/18inspn.html>
- Food and Drug Administration (FDA). (2008d). *Inspections, compliance, enforcement, and criminal investigations: Inspection reference, guides & field activities*. Washington, DC: Author. Retrieved April 10, 2010 from http://www.fda.gov/ora/inspect_ref/
- Food and Drug Administration (FDA). (2011a). *Code of federal regulations, Title 21: NDA—field alert report*. Washington, DC: Author. Retrieved December 14, 2012, from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.81>
- Food and Drug Administration (FDA). (2011b). *Safety: Archive for recalls, market withdrawals & safety alerts*. Retrieved December 14, 2012, from <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/default.htm>
- Food and Drug Administration (FDA). (2012a). *Fiscal Year 2012 Food and Drug Administration Justification of estimates for appropriations committees*. Author. Retrieved December 14, 2012, from <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM291555.pdf>
- Food and Drug Administration (FDA). (2012b). *Inspections, compliance, enforcement, and criminal investigations: 4-1 – Warning letters*. Retrieved December 14, 2012, from <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm>
- FOIA. (2008). Freedom of information act (FOIA). Retrieved December 11, 2010, from <http://www.fda.gov/foi/warning.htm>

International Society for Pharmaceutical Engineering (ISPE). (2008). GAMP® 5: Guide for Validation of automated systems in pharmaceutical manufacture. Retrieved December 11, 2013, from http://www.ispe.org/cs/gamp_publications_section/gamp_publications_overview

ICH. (2005). *Quality risk management* (Document ICH Q9). Geneva, Switzerland: Author.

ICH. (2006). *Guidance for industry: Q9 quality risk management*. Retrieved June 18, 2009, from <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073511.pdf>

ICH. (2007a). *Guidance for industry: Q10 pharmaceutical quality system*. Retrieved from <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0266-gdl0001.pdf>

ICH. (2007b). *Pharmaceutical quality system*. (Document ICH Q10). Geneva, Switzerland: Author. Retrieved from http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q10/Presentation/Q10_General_Presentation.pdf

Macher, J., & Nickerson, J. (2006). *Pharmaceutical manufacturing research project: Final benchmarking report*. Retrieved June 18, 2009, from <http://apps.olin.wustl.edu/faculty/nickerson/results/PMRPFinalReportSept2006.pdf>

Monk v. Johnson & Johnson, William C. Weldon, Dominic J. Caruso, Collene A. Goggins and Peter Luther, Civil Action No. 10-04841 (FLW) (DEA), (U.S. District Court of NJ, 2013). Retrieved from http://securities.stanford.edu/filings-documents/1045/JNJ10_01/20131121_r01x_10CV04841.pdf

United States of America v. McNeil-PPC, Inc., Veronica Cruz and Hakan Erdemir, No. 11-1745, (E.D. Pa. 2011). Retrieved December 14, 2012, from <http://media.npr.org/assets/blogs/health/images/2011/03/mcneilconsentdecree.pdf>