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Supply Chain Risks: Causes & Mitigation Strategy for the Medical Device Companies

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SUPPLY CHAIN RISKS: CAUSES & MITIGATION STRATEGY

For the Medical device Companies

Table of Contents

Figures and Tables 2

Introduction..... 4

Literature Review..... 6

 Impacts of Risks..... 10

 Mitigating Risks..... 13

Research Methodology 16

 Theoretical framework:..... 16

 Research Design: 17

 Sample: 17

Importance of the research..... 18

Limitation and key assumptions 18

Abbreviations 19

References..... 19

Figures and Tables

Figure 1 : The Global Risks Interconnections Map 2016..... 6

Figure 2 Impact of Supply Chain Risks 12

Figure 3 Four Speheres of Supply Chain 14

Abstract

'How Supply Chain Disruptions at Medtronic can be reduced?'. The objective of this research is to profile the risk involved with the external procurement and what risk mitigation strategy need to be in place to avoid any disruptions in the supply chain.

To limit the scope of the research, Focus will be only on the buy items used for building the capital equipment at Medtronic. For research, data is gathered by doing creating the survey which will be distributed among the external suppliers and by doing interviews with people from different functions.

Introduction

The world has become the very competitive place to do the business; Technology is changing the way the business is done. There are many businesses competing each other over a very small margin. To do so Companies have collaborated with the suppliers and vendors across the globe, which makes their supply chain more complex than ever. While doing that one cannot avoid the challenges like —rising and falling of product requirement, varying market uncertainty and changes —we can see that businesses are facing constant supply chain risk.

Before we profile supply chain Risks, their impacts, and mitigation strategies, we need to know what supply chain risk management is. APICS, the organization for operations and supply chain professionals, provides this definition: "The variety of possible events and their outcomes that could have effect on, services, funds,. And information resulting in some level of quantitative or qualitative loss for the supply chain."

Also Dr. Robert Trent of Lehigh University has a slightly different definition in his new book, Supply Chain Risk Management: An Emerging Discipline. "It is the implementation of strategies to manage every day and exceptional risks along the supply chain through continuous risk assessment with the objective of reducing vulnerability and ensuring business continuity. "We like to think of SCRM as the intersection of supply chain management and risk management".

The objective of this research paper is to assess the different risks, how businesses can create the risk profiles and quantify them so that it can be used to prioritize risk management efforts

Supply Chain Risks: Causes & Mitigation Strategy

and finally the different mitigation strategies that can be used to overcome any type of supply chain risk. The scope of this research could be too broad so for research purpose, the focus will be on capital medical device companies. The plan is to gather information research purpose from the vendors I am currently working in my position as Sr. Supply Chain Planner. Medical device field is seeing lot of growth opportunities in next 5 years. BRIC countries have tremendous opportunity for the growth but at the same time there many challenges also.

From MRI machines to pacemakers to syringes, the medical devices field is varied and diverse, presenting a wide range of supply chain challenges from company to company, and product to product. Many hi-tech medical device companies have excelled in supply chain efficiency, by borrowing strategy and best practice from the hi- tech and electronics field. Other medical device manufacturers are more aligned with traditional pharmaceutical companies in terms of their supply chain, lagging slightly behind the cutting edge of operational excellence.

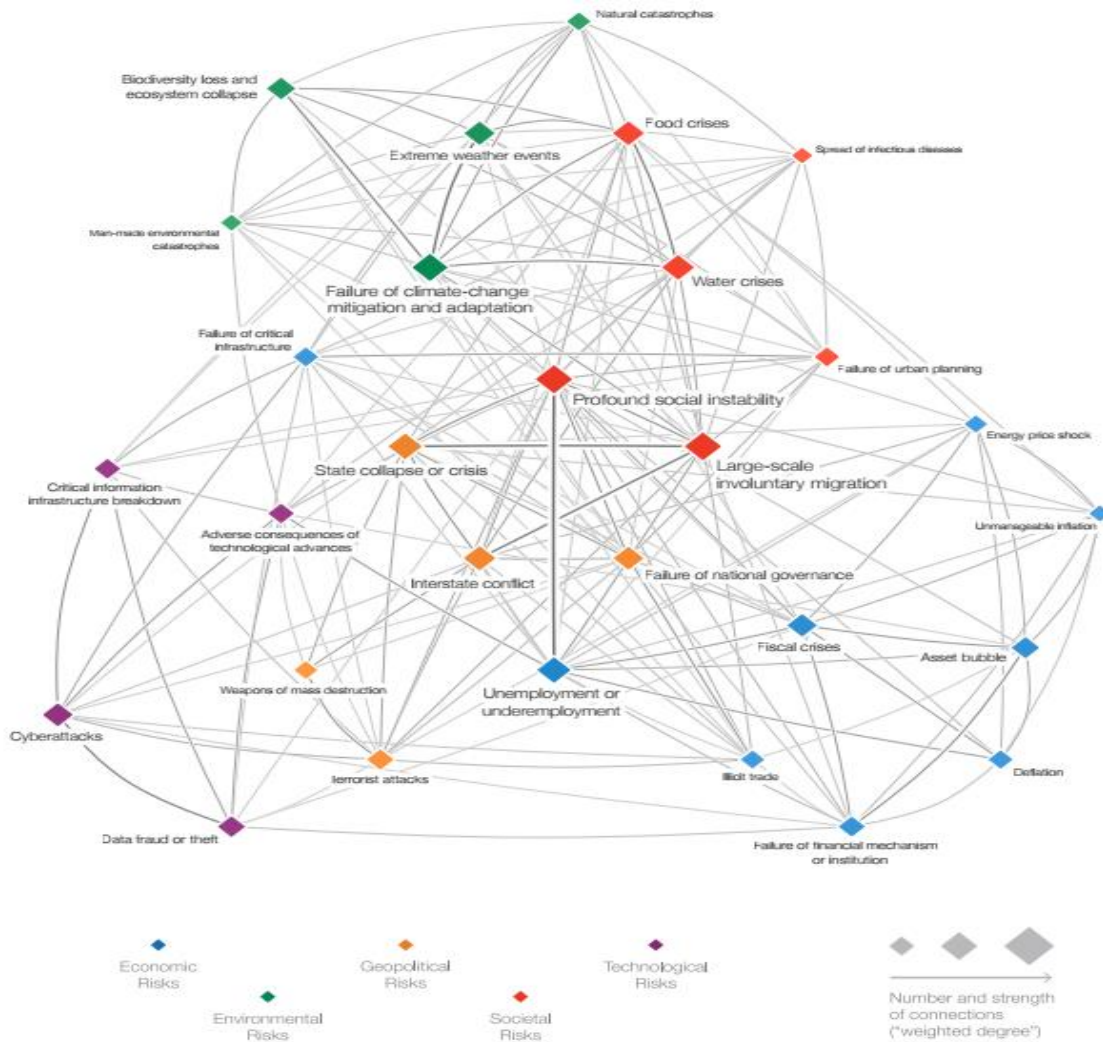
So in this research paper we set out to explore the causes and Mitigation Strategy for Supply Chain Risks by finding answers to following question:

'How Supply Chain Disruptions at Medtronic can be reduced?'

Literature Review

There are lot of research paper and articles written on the Supply Chain Risks Management.

Figure 1 : The Global Risks Interconnections Map 2016



The World Economic Forum categorizes the global risks as— Economic, Environmental, Geopolitical, Societal, and Technological. This world view, as shown in Figure 1, depicts their assessment of risks, scope/ scale, and dependent relationships. With that as a backdrop, we

Supply Chain Risks: Causes & Mitigation Strategy

can also profile global uncertainties such as parts shortages, counterfeiting, labour strike, natural disasters, supplier failure, bankruptcy, terrorism, and child labour issues, currency fluctuations, and many more. We can classify the Supply chain risk into four major

1. Supply- These are upstream disruptions caused by failure of the supply base to deliver on time, delivery quality, sustain financial integrity, and maintain compliance and resiliency.
2. Demand- These are downstream disruptions caused by problems in the distribution flows, actions of competitors, product failures, customer insolvency, warehouse and distribution centre issues, demand volatility, transportation lead times, pricing issues, credit issues, and much more.
3. Process- Originating within an organization and its own four walls, these include time delays, system glitches, quality issues, inventory shortages, capacity shortages, equipment issues, demand errors, accounts receivable and payables processing, intellectual property management, supply chain security, and supply chain visibility.
4. Environmental Landscape - This is by far the largest and most dynamic area of supply chain disruptions. In this growing arena, the major threats are natural disasters, currency exchange rate fluctuations, country rules, regulations and customs requirements, political volatility, transportation and global trade issues, banking and global finance, capital availability, social media, terrorism, natural

Supply Chain Risks: Causes & Mitigation Strategy

resources, climate, and much more. I'm sure it's obvious by now that there are enough risks to go

So as all the major Medical Device companies are continually seeking to reduce the costs and devise new strategies for profitable growth. With huge potential growth opportunities in global markets, most of the Companies are getting increasingly concerned about their supply networks and the financial impacts of globalization. It's obvious by now that there are enough risks to go around whether you are in operations, supply chain, management, marketing, finance, or any other business discipline. And, it's normal for anyone to raise the question that why medical device companies are facing these challenges more than ever

First, because five-year medical device compound annual growth rate (CAGR) in mature markets is estimated to be 7.5% vs. an emerging markets rate of 15%. So more medical device companies are operating and selling in regions of the world they've never operated in before, everyone's supply chains have become more complex. These companies are adding more and manufacturing facilities, warehouses, DCs, contractor facilities, ports of call, suppliers, and much more. With this added complexity, the probability of some type of disruption is increased almost exponentially! Therefore, supply chain visibility is one of the key critical success factors associated with good supply chain risk management.

Second, in medical device companies there is not that high scope for organic growth so companies are focusing on acquisition of other business of interest. E.g. – Medtronic in year 2015 acquired Covidien in \$40 Billion deal. This is also a major reason to make the supply chain more complex. Also in medical device companies the strategy is to grow horizontally which leaves no option but to outsource the stuff. This approach has

Supply Chain Risks: Causes & Mitigation Strategy

demonstrated improvements in top line revenue growth, cost management, and asset turnover rates, especially in a fast growing global environment. With this approach, comes risk. As a company outsources several supply chain functions or expands its supply chain complexity, risks tend to manifest themselves, including longer lead times, inadequate supply chain visibility and coordination, exposure to political instability, regulatory, and currency surprises.

Third, the operations and supply chain profession has developed and used Just-in-Time (JIT) inventory techniques, along with Lean and Six Sigma methodologies, in an effort to increase throughput or velocity, reduce process variability, and remove non value added workflow. These techniques have been very successful, especially if a company is measuring supply chain excellence through efficiencies and effectiveness. However, many industries have been so successful leveraging these techniques they have actually increased their risks that are associated with stock outs and supply chain disruptions of high magnitude because they have little or no ability to absorb a risk event.

And finally, As major medical device companies are acquiring other companies as part of acquisition and merger, companies try to leverage the Spend. So companies try to take the business and work more and more with the strategic suppliers for both direct and indirect materials, This provides assumed "leverage" for the company by becoming a larger force in that supplier's backlog, which, overtime, will presumably provide better pricing, delivery, and quality. What's wrong with this picture? The methodology has manifested itself into a very risky supply equation, because many companies have narrowed their supply base, placing themselves in a "Single- Sourced" environment and therefore

Supply Chain Risks: Causes & Mitigation Strategy

increasing their supplier risk exposure. And in medical device industry due to high regulations qualifying the new suppliers sometimes take months and months.

So from different resources we know what are some of the causes of the Supply chain disruptions but still there are following unknowns about the specific causes for Medical Devices Challenges :

- **How the negative risk events are affecting Supply chain**
- **Why Big companies are still failing to address the Supply Chain Risks even after they have risk management program**

Impacts of Risks

There are four types of risks. These are: hazard, financial, operational, and strategic.

- Hazard Risk - Includes natural disasters, property damage, and liability torts.
- Financial Risk - Asset risk, pricing risk, currency risk, and liquidity risk.
- Operational Risk - Product failure, warranty, product integrity, customer satisfaction, and reputational risk.
- Strategic Risk - Competition, capital availability, compliance, social norms, mores, and social media.

In recent years Medical Device Companies have seen lot of incidents of SC disruptions. Boston Scientific was forced to recall implantable defibrillators, causing its shares to fall 13 percent overnight. The company expects to lose \$5 million every day that the devices are off the marketⁱ. GlaxoSmithKline PLC agreed to pay \$750 million for quality issuesⁱⁱ. And

Supply Chain Risks: Causes & Mitigation Strategy

Johnson & Johnson recently experienced a series of product recalls caused by several manufacturing and supply chain events that resulted in a loss of more than \$900 million in annual revenue, not counting losses of goodwill and market shareⁱⁱⁱ. This is not the first such experience for the company. In 2003 and 2004, Johnson & Johnson experienced higher than-expected demand for a new drug-eluting stent, which—coupled with supply shortages due to manufacturing and quality issues as well as lower inventories—resulted in lost sales and loss of market share.^{iv}

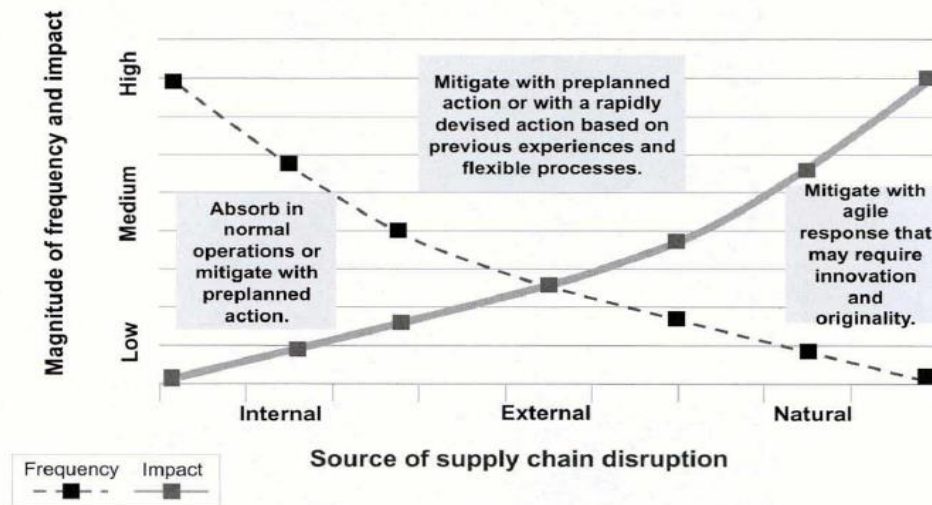
To better understand the key concept of risk management, we've utilized Dr. Richard Crandall's example he postulated back in 2012 in his monthly APICS magazine column. Figure 2 profiles that relationship.

The "Y" Axis profiles the magnitude and frequency of events, from low to high and is depicted by the dotted line. The " X " Axis depicts the cause of risk events. If you review the graph from left to right you will find SC disruptions within companies own supply chain. These are something called chronic risks and happen frequently with not that high impact on business. Next is caused by outside factors. These external disruptions emerge from contract manufacturers, suppliers, customers, third party logistics (3PLs), and more. These disruptions don't manifest themselves as often as chronic risks; rather, they tend to have a greater impact on the organization.

Supply Chain Risks: Causes & Mitigation Strategy

Figure 2 Impact of Supply Chain Risks

Figure 2 | Frequency and Impact of Supply Chain Risks



Reference: Richard E. Crandall, "Perceptions of Peril," APICS Magazine, 2012

And finally, there are the "Black Swan" events. What we call hazard risks, natural disasters, and man-made risk events, such as plant fires, explosions, and more. These events happen much less frequently, but tend to have a very large impact on the organization. Hurricane Katrina, the U.S. subprime mortgage crisis, the Thailand floods, earthquakes, droughts, and Hurricane Sandy are all black swan events. Below are some salient statistics regarding financial impacts on companies that have experienced a moderate-to severe supply chain disruption event.

- A 107% drop in operating income
- A 114% drop in return on sales
- A 93% drop in return on assets
- A 6.9% lower sales growth
- A 10.66% increase in cost and a 13.8% increase in inventories

Supply Chain Risks: Causes & Mitigation Strategy

Another study, including ongoing studies by Accenture, states that if you are a publicly held company and you experience a moderate-to-severe supply chain disruption, you can expect to realize a 7% to 10% reduction in shareholder value. As most of the medical device companies are publically traded, this could be very critical.

Mitigating Risks

With the advent of our supply chains growing globally, becoming more complex, and inherently fraught with more risk, there are many new tools, techniques, and tactics emerging to mitigate, not eliminate, those risks. The many research suggests that a company should run what we call—"A Risk Appetite" session. We do it with many of the executive sessions before we actually work for companies. Why? Organizations have many diverse perceptions of risk, depending on where one resides in the company. We advocate these sessions to identify a company's risk appetite, before we identify, assess, mitigate, and help manage their risks.

There are four basic Risk responses a company can exhibit when it experiences a risk event or gets into a risk/reward project. They are:

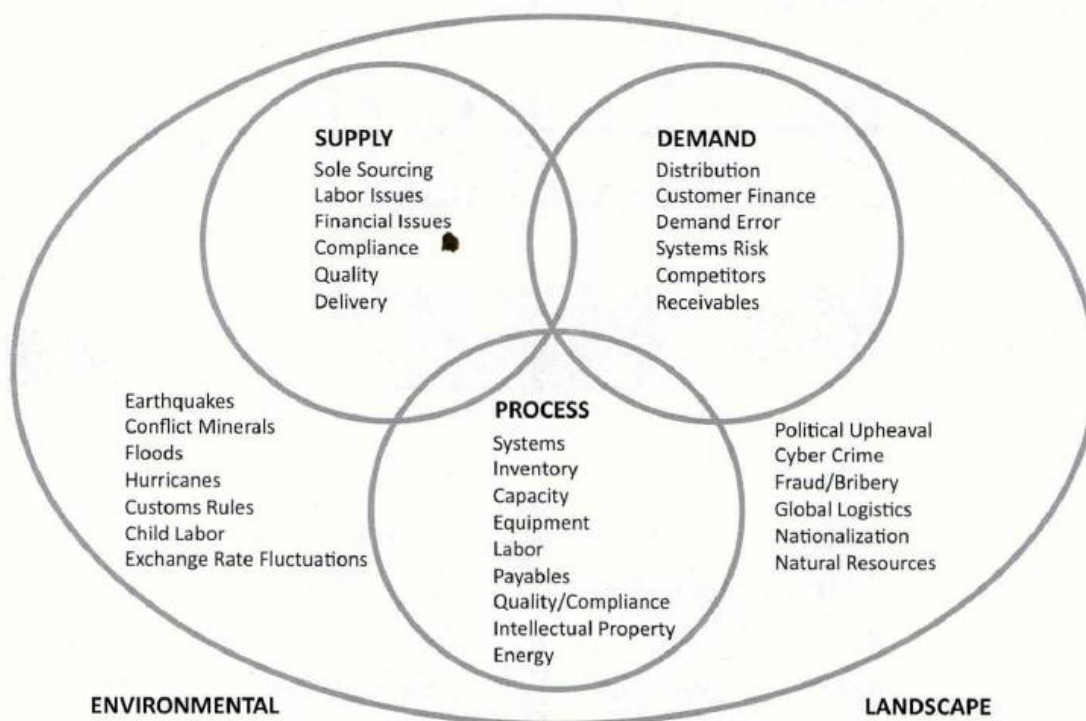
- **Avoidance** - The risks are too high so the company exits the activity producing the risk.
- **Acceptance** - The Company has run the numbers, understands the risk at hand, and accepts it.
- **Transfer or Pool** - The Company understands the risk and takes action to transfer some of the risk using partners, insurance, and other hedging mechanisms.

Supply Chain Risks: Causes & Mitigation Strategy

• **Mitigate** - The Company has identified the risk, its probability of occurrence and impact, and begins to utilize tools, techniques, and tactics to mitigate. Figure 3 provides a snapshot of specific risks within the four spheres of supply chain.

Figure 3 Four Spheres of Supply Chain

Figure 3 | Four Spheres of Supply Chain Risk



Some approaches to identify, assess, mitigate, and manage the risks.

- Identify Risks. This can be accomplished with:
 - Better and more frequent communication with customers and suppliers;
 - Stronger contract verbiage with suppliers, contractors, and agents— especially auditing capabilities;

Supply Chain Risks: Causes & Mitigation Strategy

- Supply chain mapping of all nodes, suppliers, contractors, facilities, and customers;
 - Support of supply chain network using risk event real-time data;
 - Risk/reward methodologies; and - "What-if" scenario planning.
- Assess Risks. This can be accomplished with:
 - Classic heat maps, likelihood, and impact of risk; - New cloud-based supply chain maturity/risk heat map tools;
 - Value-at-Risk (VaR), Risk Priority Number (RPN), Failure Mode Effect Analysis (FMEA), Business Impact Analysis, and Insurance Risk Quantification;
 - Sentiment Analysis (social media);
 - Use of third-party research and marketing intelligence; and
 - Altman Z-Score for suppliers' financial health.
 - Mitigate Risks. This can be accomplished by:
 - Developing potential multiple supplier sources;
 - Developing and sustaining compliance governance infrastructure; and
 - Building out resiliency indexes for the entire supply chain.
 - Manage Risks. This can be accomplished by:
 - Committing to developing an enterprise risk management team;
 - Developing and sustaining a governance, risk, and compliance infrastructure;
 - Developing positions responsible for enterprise and supply chain risk; and
 - Committing to continually fund and maintain talent for the supply chain risk team.

Supply Chain Risks: Causes & Mitigation Strategy

There is a clear need for healthcare companies to implement comprehensive and rigorous supply chain risk-management programs, in order to manage increasing risks in a cost-effective way. While such practices are still relatively uncommon in the sector, companies can adopt best practices from other industries that have implemented a more comprehensive and forward-looking approach, such as those in the high-tech, automotive, apparel, and consumer product goods (CPG) verticals.

Research Objective

- **How Supply Chain Disruptions at Medtronic can be reduced?**
 - How medical device companies can systematically identify the risks
 - Redefining the scope of risk mitigation beyond traditional
 - Create framework for supply chain leadership

Research Methodology

For this research purpose Qualitative methodology will be used. There are many different pieces of information that are needed to collect. Two major sources of information: First – External Suppliers and Second People from different functions working within company

Theoretical framework: There are four basic Risk responses a company can exhibit when it experiences a risk event or gets into a risk/reward project. They are:

- **Avoidance** - The risks are too high so the company exits the activity producing the risk.
- **Acceptance** - The Company has run the numbers, understands the risk at hand, and accepts it.

Supply Chain Risks: Causes & Mitigation Strategy

- **Transfer or Pool** - The Company understands the risk and takes action to transfer some of the risk using partners, insurance, and other hedging mechanisms.
- **Mitigate** - The Company has identified the risk, its probability of occurrence and impact, and begins to utilize tools, techniques, and tactics to mitigate. Figure 3 provides a snapshot of specific risks within the four spheres of supply chain.

Research Design: There are hundreds of suppliers used for sourcing production material by the Medtronic. So there will be survey provided to them and question will be created to gather information about the following:

Operational Risk -

- Total capacity used to meet Medtronic monthly requirements
- The longest lead time

The questionnaire and survey questions will be developed to make sure the information required is gathered from the external suppliers

Sample:

- The plan is to collect the data by working with different sites of current company I am working and carrying a survey.
- Following Departments will be involved
 - Purchasing
 - Manufacturing
 - Product Development
 - Quality
 - Distribution

Supply Chain Risks: Causes & Mitigation Strategy

- There will be different survey that will be created for each department and questions would be collectively exhaustive but mutually exclusives.

- Some of the questions we are looking to get answer are as follows
 - When did the SC risk first appear?
 - How and why was it noticed?
 - Why did it not appear earlier?
 - To project the risk into the future, ask more questions:
 - What enables this risk to persist?
 - What dependencies (systems, processes, resources) does the risk have to maintain itself?

Importance of the research

Medtronic Sources the majority of the production material from outside suppliers.

The production is doubling every year and the growth is exposing the drawbacks in the supply chain

Recent supply gaps caused lot of the production shutdowns

Limitation and key assumptions

- This research limits to the Class A suppliers
- Make Items are excluded from the Risk analysis
- Research only focuses on the upstream disruptions caused by failure of the supply base to deliver on time, delivery quality, sustain financial integrity, and maintain compliance and resiliency.

Abbreviations

APICS - American Production & Inventory Control Society

SC – Supply Chain

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ⁱⁱⁱ ‘Johnson & Johnson’s Profit Falls 12%, Hurt by Series of Recalls’ Associated Press, NYTimes.com, January 25, 2011

^{iv} Ross Kerberand and Jeffrey Krasner, “Johnson & Johnson Missing Out on Stent Sales,” Boston.com, August 19, 2004.