

Expect the unexpected: Reduce corporate exposure and create value through supply chain risk management

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Supply chain problems have significantly impacted pharmaceutical and medical products manufacturers recently, leading to billions of dollars in lost market cap, recalls, regulatory settlements, and other costs. However, most companies in the sector still do not have a systematic approach for assessing and managing such threats. We have developed a five-part framework to identify and mitigate supply chain risks in a proactive way. By following the elements in this strategic approach, pharmaceutical and medical products manufacturers can substantially reduce or eliminate supply chain problems due to unforeseen events. As a result, these companies can gain an edge over competitors, with more stable production capacity and better financial performance.

Supply chain risks to companies in the pharmaceutical and medical products sector have risen steadily in recent years, driven by a range of factors. Increased offshoring and outsourcing, along with more sophisticated production technology, have made supply chains in the sector far more complex, leading to a greater potential for disruptive

events. Regulatory compliance changes have also played a role, as has convergence between pharma companies and makers of medical products. At the same time, competitive and pricing pressures have reduced the margin of error for production problems. Pharmaceutical and medical products manufacturers face greater capital intensity and cost pressures, leading to lower inventories and a reduction in dual sourcing. As a result, they are less prepared today to mitigate supply chain risks.

Such risks manifest themselves in several ways. At a minimum, component and product costs can spike during supply-demand imbalances, destabilizing business plans and overall financial performance. More substantial, however, are outright shortfalls in components or production materials, which can limit production and create a significant impact on public health. Recent reports indicate a current shortage of some cancer drugs, especially for certain low-margin generic versions, forcing doctors to delay or ration treatment¹. The FDA lists a range of supply chain risk issues that are currently causing drug shortages, including greater-than-expected demand, manufacturing delays, commodity shortages, and supply issues², among others.

Quality and compliance issues are an additional source of risk, potentially triggering recalls or adverse regulatory actions. While these events have obvious public-health ramifications, they can also result in large share-price declines for companies in the sector. A recent McKinsey study of medical products companies determined that supply chain risk events are the second-largest contributors of large monthly declines in share price, resulting in drops of 10 percent or more when compared to the S&P 500 over the same time period (Exhibit 1). These incidents can put substantial shareholder value at risk. In the United States, product recalls alone cost shareholders more than \$25 billion a year in market cap, assuming \$2 million in costs per recall; about 1,100 recalls a year; and a stock multiple of 12 times earnings.

The past year has seen several such incidents. 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 market³. GlaxoSmithKline PLC agreed to pay \$750 million for quality issues⁴. And 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 share⁵. This is not the first such experience for

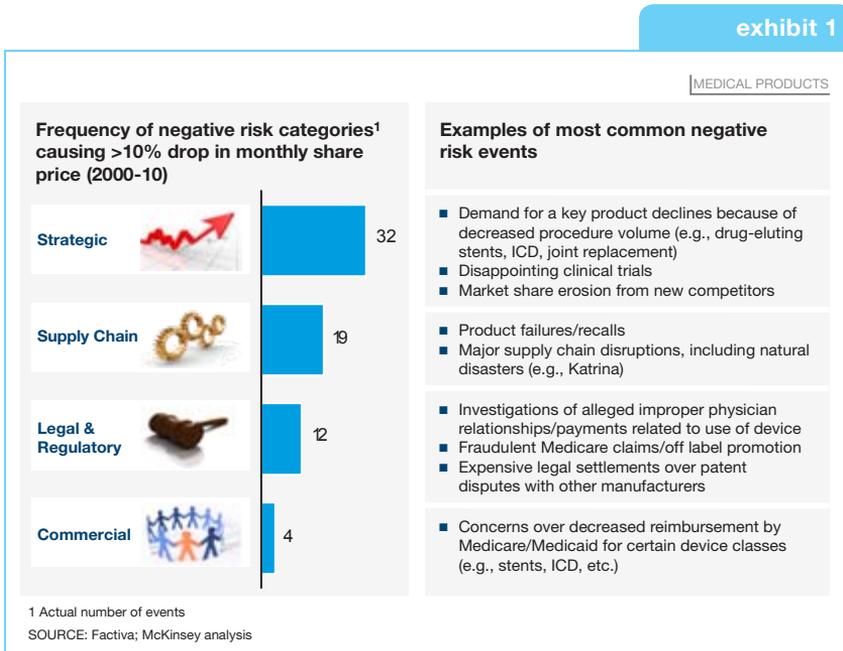
1 Debra Sherman and Julie Steenhuisen, "U.S. cancer drugs shortage has doctors scrambling," *Reuters.com*, June 7, 2011.

2 "Current Drug Shortages," U.S. Food and Drug Administration website, October 20, 2011.

3 Debra Sherman, "Boston Scientific's ICD recall may result in asset sale," *Reuters.com*, April 1, 2010.

4 Justin Blum, Andrew Harris, and David Voreacos, "Glaxo Agrees to Pay \$750 Million to Settle Defective Drug Suit," *Bloomberg.com*, October 27, 2010.

5 "Johnson & Johnson's Profit Falls 12%, Hurt by Series of Recalls" Associated Press, *NYTimes.com*, January 25, 2011



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 share⁶.

Although most companies in the sector have risk management programs in place, they are typically siloed and functionally based. For example, companies may have business continuity management (BCM) programs for individual manufacturing sites that focus on recovering from disruptive events, measures within the procurement organization to mitigate sourcing risks from suppliers, or compliance and audit management initiatives in the quality organization. Yet, there is little if any coordination among these efforts. Furthermore, most BCM plans typically specify similar time-to-recover goals for manufacturing sites without explicitly considering the relative importance of the products being produced or the likelihood of bad events, and they often fail to include proactive steps to mitigate the risks from such events.

In this context, 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

⁶ Ross Kerberand and Jeffrey Krasner, "Johnson & Johnson Missing Out on Stent Sales," *Boston.com*, August 19, 2004.

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.

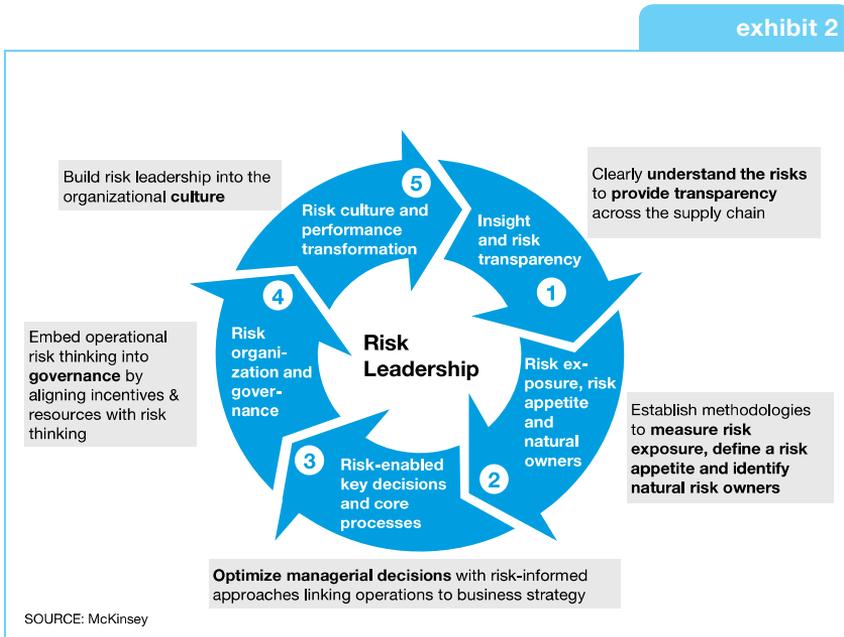
Accordingly, we believe that:

- Companies in the healthcare sector can systematically identify risk at all steps in the end-to-end supply chain, and rigorously quantify their exposure by considering: the likelihood of a particular source of risk; the business impact from that risk; and the preparedness to mitigate it.
- Risk mitigation and preparedness strategies should be differentiated based on the relative importance of different products and sites.
- Risk management must go beyond the traditional scope of business continuity management—that is, preparing for recovery *after* bad events—to more proactively reduce the likelihood and negative consequences of such events.
- Companies should explicitly account for risk when making strategic decisions.
- While healthcare companies must still implement quality and compliance management systems, a risk-informed approach can enhance the effectiveness of those systems. This approach can reduce both the risk of conventional quality and compliance issues, and—if those risks develop into full-fledged recalls and regulatory actions—the impact of those events on the company's operations.
- In addition to the focus on negative risk, companies must consider and plan for the upside opportunities of supply chain uncertainties, such as greater-than-expected demand for vaccines, opportunities stemming from supply disruptions that impact a competitor, and new product introductions that ramp faster than forecasts.

Our framework for supply chain risk leadership

We have developed a proprietary, end-to-end supply chain risk-management process and tool kit tailored to healthcare companies, in order to identify and proactively mitigate potential risks and deliver incremental value. This represents a substantial upgrade to the current risk-management practices at most companies in the sector, which are largely ad hoc and lack a comprehensive approach to implementation.

Our framework consists of five components (Exhibit 2).



1. Identify and evaluate risks across the end-to-end supply chain

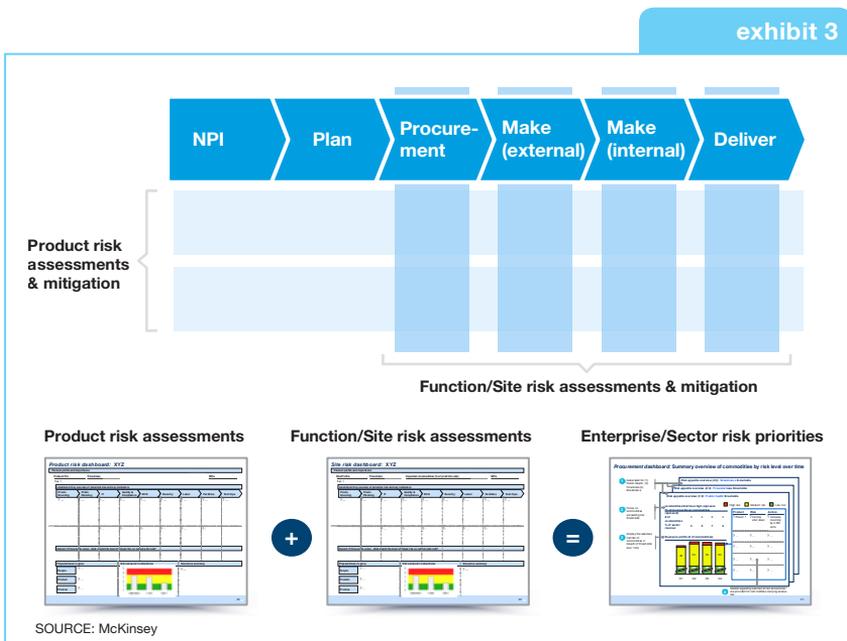
The ability to identify and evaluate exposure from sources of risk from their supply chains made a big difference to the fortunes of Nokia and its competitors. In March 2000, a fire broke out at a Philips plant in New Mexico—a supplier of semiconductor chips to cell-phone manufacturers including Nokia—forcing the plant to remain shut down for several months. The difference in outcomes for the customers of the New Mexico plant was dramatic—Nokia came out of the disruption stronger and gained market share, while some of its leading competitors were significantly weakened and lost market share⁷.

This difference was primarily due to Nokia's comprehensive supply chain risk-management program, which helped the company immediately—and accurately—estimate the impact of the shutdown on its business, and then react accordingly. Nokia switched orders to other Philips plants and to its Japanese and American suppliers, and redesigned chips to reduce its reliance on Philips products.

⁷ Amit Mukherjee, *The Spider's Strategy: Creating Networks to Avert Crisis, Create Change, and Really Get Ahead*, Financial Times Press, 2008.

Like Nokia, Cisco Systems also has an effective system to identify and evaluate sources of risk throughout its end-to-end supply chain⁸. The company maps all manufacturing partners, component suppliers, and logistics providers as nodes. It can then identify and evaluate sources of risk from each node, which it displays on a central crisis-management dashboard. In addition, Cisco uses a subscription-based service to obtain near real-time alerts about events that could affect the flow of goods from, to, and between suppliers. And it updates the resiliency of critical suppliers every six months through worst-case-scenario evaluations.

Nokia and Cisco offer object lessons for pharmaceutical and medical device companies that should adopt a multidimensional approach to understand the risks at all stages of the supply chain. To begin, the company should identify individual risks for each product, function, and site (Exhibit 3). Each source of risk must be evaluated based on its impact on the company's ability to meet its objectives—the “objectives-at-risk” approach. Specifically, those objectives include serving customer demand, obtaining supply, achieving cost targets, and complying with regulations.



In addition, for each of its top products, the company should systematically identify and then assess sources of risks for all functions along the end-to-end supply chain—from new product introduction (NPI) and commercialization to planning, procurement, manufacturing, and distribution.

To evaluate the exposure from each source of risk, management must use a standard evaluation approach that considers: the likelihood of occurrence for that risk; the impact it would generate on one or more supply chain objectives if it were to materialize; and the current level of preparedness in place to reduce the impact. Using quantitative leading indicators and trends of key performance indicators (KPIs) helps to determine the likelihood of individual sources of risk. A standard evaluation approach will enable management to make an apples-to-apples comparison of risks across products, functions, and sites, in order to identify the most immediate potential disruptions facing the company.

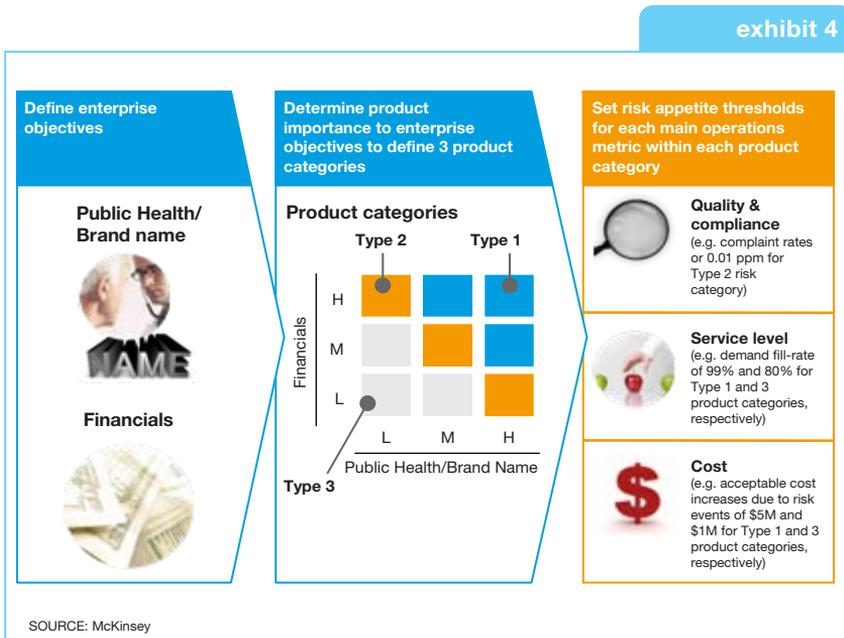
In the healthcare sector, this kind of quantitative approach is notably rare, a problem that is compounded by a comparatively wide range of supply chain risks, some unique to the sector. These include quality and compliance risks, patient safety, environmental health and safety, capacity at several stages of production, and the cost and supply of raw materials.

2. Define clear risk appetite across the enterprise and by product type

The appetite for risk will vary dramatically from one company to another, and even from one product to another within a company's offerings. For example, a company may have a substantially lower risk appetite for products that can adversely impact public health. That said, given the complexity of many companies' portfolios, management should specify risk appetite not by individual products but rather by product groupings. These groupings can be based on individual importance of products to one or more enterprise objectives, such as financials, public health, reputation, and brand name.

For example, a major healthcare company recently defined its risk appetite by categorizing the entire product portfolio into three types, with specific exposure thresholds for each. The company also categorized its production facilities into segments based on the type of products they manufactured. The site segmentation enabled the company to prioritize investments, properly allocate management attention among multiple facilities, more accurately determine the frequency and duration of quality audits, and better assess its overall business continuity preparedness.

The next step for each company should be to define risk appetite by setting exposure thresholds for each product type. These exposure thresholds can be pegged to supply chain metrics such as meeting demand (fill rate or service level), cost savings targets, or quality and compliance levels by product type (Exhibit 4). Defining risk exposure will enable managers throughout the organization to make quantitative and consistent decisions when faced with tradeoffs between risk levels and investment.



3. Use a risk-informed approach to making strategic decisions

Every strategic supply chain decision involves an element of managing uncertainty and risk. Companies that strive to optimize their production network must assess a range of factors, including labor, currency, material and logistical cost risks, disaster-related disruptions and supply shortages, and demand variability risks.

A CPG company, for instance, recently confronted these issues. The company was seeking to better manage significant demand risks in its main U.S. market, along with cost and supply risks at its foreign manufacturing sites due to uncertainties in labor, currency, materials, and natural disasters. To that

point, the company had two manufacturing sites in a low-cost country (LCC), however those sites served only local and regional markets. The company optimized its manufacturing network to address these risks by investing in new capacity at one of the LCC facilities. This provided a dual production source, which not only mitigated downside risks from events such as natural disasters but also offered additional capacity to address upside opportunities in the United States. The company tested the idea with highly volatile products that required minimum investment (e.g., overtime). By adopting a long-term view to investing in capacity in this manner, the company reduced its exposure to external events while also generating a 16 percent improvement in risk-adjusted cost.

Similarly, a large pharmaceutical company faced risks in a high-margin segment of its business, due to supply threats such as shortages and disasters, and more significantly due to variable demand. To address these challenges, it needed to establish a flexible production capacity. The company conducted a comprehensive analysis to quantify all major risks and determine the scope of potential upside revenue opportunities. By strategically optimizing its flexible capacity, the company recognized an additional \$2.5 billion in sales over five years, an increase of 17 percent. Vaccine manufacturers face related capacity-planning challenges, given significant uncertainty in demand and the long lead times associated with production.

We recommend using a risk-informed approach to make strategic supply chain decisions, including network optimization, manufacturing footprint, supplier contracts, and inventory policies. This raises the degree of difficulty of such decisions, in that it adds an additional entering argument. Yet, we find that when explicitly accounting for risk, certain supply chain decisions—such as the level of inventory and dual sourcing, and the size of back-up manufacturing facilities, among others—can be vastly different from those determined by traditional practices, as shown in the examples above. This is particularly true in the healthcare sector, where rigorous supply chain risk-management programs are still relatively rare. Only by adopting a risk-informed approach will management be able to make more robust decisions that can withstand the inherent uncertainties of the future.

Finally, while companies most commonly seek to reduce their exposure to risk by determining the optimal set of mitigating actions, this is not universally true. In some cases, a company may find itself able to tolerate *greater* exposure for certain products, processes, and facilities. In this way, a rigorous risk-based approach not only can mitigate threats but also can unlock incremental value by freeing up resources of time and attention that had been devoted to keeping certain risks unnecessarily low.

4. Establish robust governance by embedding risk management into core processes

Risk management, by its very nature, is a cross-functional activity, as different functions within the supply chain can only identify and manage the sources of risks within their own realm. Because of that interconnectedness, establishing a cross-functional risk-management process is critical to success. This process must explicitly define the roles and responsibilities of the different supply chain functions, with clear lines of demarcation. In addition, the company must periodically reassess risks to ensure that its mitigation strategies remain appropriate to the changing dynamics of the market.

Given the scope and complexity of most companies in the sector, managing the sheer volume of information from this process becomes a challenge. A set of customized risk reports and dashboards can help. One major healthcare company is currently implementing a series of dashboards that can be customized to specific levels within the management structure. For example, the company compiles all of the top risks for a particular product and displays them on a single dashboard for that product's manager, while information for multiple products, functions, and/or sites can be displayed on a sector-level dashboard for risk officers and other senior leaders.

5. Create a risk culture in the organization

Our surveys of employees at several healthcare companies indicate that risk culture is an area with substantial room for improvement. At some companies, managers seem to reward firefighting more than the proactive steps taken to reduce risks. Other companies tend to punish dissent in the ranks, or fail to accommodate innovative, ground-level suggestions that are intended to improve results.

Developing the right culture is the key element of managing risk in any organization. Management should foster an open environment in which individuals feel empowered to discuss risks and potential disruptions, and even challenge line managers on specific decisions where appropriate. Individuals should be able to discuss bad news with the same candor as when discussing good news. And workers within the different supply chain functions should share actions and best practices across the boundaries of the supply chain. For example, an employee in manufacturing should be aware of, and be able to leverage, a mitigation action that has worked well in procurement. Establishing this culture requires a high degree of communication, in which management establishes the right set of incentives for individuals to respect rules and procedures and to work for the greater good of the organization.

Given that backdrop, we recommend a detailed assessment of a company's risk culture to identify gaps and address cultural issues head-on.

Getting started

Senior executives of healthcare companies can get started by asking the supply chain organization to identify the greatest sources of risk to the enterprise. This information should come through specific deliverables such as a heat map to describe the concentration of top risk sources across various supply chain functions, or an analysis of strategic investments that includes both conventional metrics such as expected net present value (NPV) and return on invested capital (ROIC), along with risk-adjusted measures such as standard deviation or worst-case NPV and ROIC.

This information will help catalyze a set of initial activities that ideally comprise the first steps of this framework. Companies should categorize all products into a few types and then define the risk appetite for each one, leading to an assessment of supply chain risks for the top products to determine the greatest sources of risk and the specific mitigation actions for each type. With this as a foundation, risk organizations can progressively become more sophisticated in the implementation of supply chain risk management.

In conclusion, implementing a holistic and comprehensive supply chain risk-management program can deliver a wide range of benefits, enabling companies to: understand the likelihood of certain risks, proactively and cost-efficiently mitigate those risks, and obtain incremental value by making risk-informed strategic supply chain decisions. However, management must understand that risk management is not a one-time activity. To deliver on this wide range of benefits, risk management must become an integral part of how the company operates.

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Case study: Hewlett-Packard

Hewlett-Packard Company has been implementing a comprehensive supply chain risk-management program since 2001, which has been written about extensively in industry and academic journals^{1,2}, primarily because the results have been so notable. Like most high-tech companies, HP faces a host of challenges. Short product life cycles in the sector create significant demand risks. Volatile component prices bring cost risks. And periodic mismatches in supply and demand for the industry—along with supply chain disruptions and quality issues—trigger component supply risks. To address these supply chain risks, HP developed and implemented a comprehensive supply chain risk-management program, which aligns well with portions of the five-part framework described above.

Supply chain uncertainties and risks linked to key objectives

HP has implemented the “objectives-at-risk” approach, which considers the risks to key supply chain objectives that the company considers most important: supply assurance, cost savings, and cost predictability. These three objectives are impacted by a range of variables, including component/product demand, component cost, and supply uncertainties, which HP quantifies using probabilistic scenarios. In evaluating demand, for example, the company uses the 10th, 50th, and 90th percentiles of the discrete demand

distribution to represent the low, base, and high scenarios of demand for HP products at any point in time.

Defining risk appetite and ownership using the probabilistic scenario approach

The probabilistic scenario approach lends itself nicely to the subsequent challenge of defining risk appetite. Taking demand analysis a step further, the 10th percentile (the “low” scenario) by definition implies that there is only a 10 percent likelihood of the actual demand being less than forecast. This defines the range of demand uncertainty that HP is willing to accept. That is, HP commits to buying that range of demand using a fixed quantity contract with suppliers. For the range of demand near the 50th percentile, where the uncertainty is higher, HP transfers that risk to the supplier using a flexible quantity contract. The supplier takes on this uncertainty because it may be cheaper for the supplier to manage across all of its customers.

Risk-informed strategies and decisions

Once HP has quantified the uncertainties impacting its supply chain objectives, it can then leverage pricing terms pegged to specific business objectives. For example, if the business objective is cost savings, HP uses a discounted pricing term. If the business objective is cost predictability, it uses either a fixed-price or price-cap pricing term. HP repeats this process for all of its products, and effectively winds up with a portfolio of structured contracts that are specifically tailored to maximize business objectives and manage risk due to demand, cost, and supply uncertainty.

1 Venu Nagali et al., “Procurement Risk Management at HP,” *INFORMS Interfaces Journal*, Vol. 38, Number 1, January 2008. Nagali is current at McKinsey and is one of the co-authors of this paper.

2 Patrick Scholler and Venu Nagali, “Calculated Risk,” *European Leaders in Procurement Magazine*, October 2007.

In the aggregate, HP's supply chain risk-management program delivered incremental value in excess of \$500 million during its first six years, across four key categories: (1) material cost savings of over \$425 million, as the risk-informed contracts enabled suppliers to lower their costs and risks of doing business with HP; (2) increased supply assurance for key components, particularly during market shortages, delivering an estimated \$50 million in additional margin; (3) improved cost predictability of components that have volatile costs, saving HP an additional \$50 million; and (4) lowered inventory costs by several percentage points as HP optimized inventory levels internally and at suppliers.

Of course, these results are not reproducible in all companies and across all sectors. Among other elements, HP took the governance element of risk management extremely seriously, implementing a rigorous business process that linked and defined the responsibilities of all elements of the supply chain—from procurement and planning to supply chain operations, finance, and marketing. However, this example shows what is possible through a comprehensive and integrated approach to supply chain risk management.