Raising the Bar:
How Enterprise Risk Management Can Enable the Effective Transformation of the Pharmaceutical Industry
April 2008
Executive Summary

The pharmaceutical industry is facing a perfect storm of change. Within the next five years, an estimated additional $60 billion in blockbuster drugs will go off patent and face competition from generic drug manufacturers as the world’s leading pharmaceutical companies struggle to replenish depleted drug pipelines. Meanwhile, both the industry and the FDA have come under greater scrutiny over the safety of approved drugs taken by millions of patients each day.

Pharmaceutical companies are seeking to meet these challenges by transforming themselves into leaner, more efficient organizations, partnering with biotechnology firms to gain access to promising new therapies, downsizing their operations, and outsourcing many traditionally internal functions, including financial, clinical, and sales operations. But transformation contains inherent risks over and above the normal risk profile of the industry. This white paper addresses those risks and offers recommendations on what pharmaceutical companies can do to manage them and raise the performance bar.

Background

Over two years ago, KPMG’s Pharmaceuticals Practice published a white paper titled **Pressure Points: Risk Management in the Pharmaceuticals Industry** that focused on the sector’s ability to manage major risks such as patent expiration, reimportation, price controls, dwindling pipeline productivity, changing science, and compliance issues particularly around sales and marketing practices.

To address future risk management issues, we recommended that the sector change from its historic focus on detecting and correcting risk. It needed to adopt a more proactive approach aimed at anticipating and preventing negative outcomes, as well as enhancing the likelihood of positive ones. With the assistance of Professor S. P. Kothari, now Deputy Dean, and Gordon Y Billard Professor of Management at MIT's

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Sloan School of Management, and Associate Professor Wayne Guay at the Wharton School of the University of Pennsylvania, we conducted an analysis to demonstrate the impact of extreme events on shareholder value. The findings showed the pharmaceuticals industry was as much as 50 percent riskier than the overall Standard & Poor's (S&P) 500.

On closer analysis, we found that positive and negative events had a dramatic effect on shareholder value and reputation. What’s more, extreme negative events often had their roots in operations and in decisions with strategic importance that were not made at the right level. Our research showed that the underlying processes for risk management varied widely among companies. In conclusion, we recommended that companies undertake a complete assessment of their risk management framework as well as their risk assessment and risk management processes.

Current State

The pharmaceutical industry continues to transform in waves. During wave one over the past two years, major drug makers announced more than 40,000 layoffs. In the beginning of 2008, we had a second wave of cost-cutting when three more major pharmaceutical companies announced major transformation initiatives. The expected savings per company ranges from $900 million to $4 billion on an annual basis by 2010, although the $4 billion figure may include other cost-cutting programs as well. Against this backdrop, we conducted a new analysis of what pharmaceutical companies are doing to manage risk and to see if they had heeded our advice and made progress on assessing and managing their risks within the wider context of industry transformation and enterprise risk management (ERM).

At first glance, the industry has made considerable progress in improving risk management, with many companies taking the first steps in assessing their risks and communicating their assessment more effectively to the board. However, our analysis suggests that not all major companies in the industry have taken all the steps necessary to develop and integrate more proactive risk management processes into their business culture. In addition, there appears to be a considerable gap about understanding risk management processes between the executives who run companies and the directors who oversee them.

According to a 2006 survey of company directors and business executives, only 63 percent of company directors in 2005 felt they had a complete or good understanding of the risks facing their companies, a figure that improved to 75 percent last year. However, very few, even recently, said that they understood the process by which risk was managed and mitigated.

ERM is about ensuring that there is such a process and that it is communicated to the board along with management accountability and responsibility for key risks. In summary, there are still companies with insufficient systematic means for identifying risks that result from gaps between their functional silos and across the levels of the organization. They also have limited tools for identifying emerging risks.

“In 2006, 63 percent of directors felt they had an understanding of their company’s risks, while executives say that only 18 percent of directors understand their company’s risks.”

1 Source: February 2006 McKinsey Quarterly Survey
**Top of Mind Concerns**

Conversations with CFOs at leading pharmaceutical companies suggest that a number of "top of mind" concerns have preoccupied their attention. Besides compliance with Sarbanes-Oxley, a few of the questions have included:

- **Are we an overregulated industry?** The cost of getting a product to market is so high that companies may be increasingly unwilling to make the necessary R&D investment to develop new products.
- **How do we address patent legislation?** Current patent protection laws are causing products to expire more quickly, resulting in high upfront investments and shorter paybacks.
- **Where’s competition coming from?** Generics are major forces, but increasing competition is coming from companies investing in biological products.
- **What do we do with excess capacity?** Many companies built up production facilities and distribution centers based on the blockbuster model. With pharmaceutical companies struggling to develop new drugs and blockbusters coming off patent, there could be excess capacity throughout the pipeline.
- **How do we structure capital to add value?** CFOs wrestle with the question of what to do with company financials to increase value. Should they assume more debt? Issue more stock? Or buy back more stock?
- **Where’s the best place to invest overseas?** Companies are increasingly looking at populous countries with growing middle class and lower labor costs, especially Brazil, China, India, and Russia, to produce products more cheaply as well as to develop new markets.

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**Why the Limited Focus on Risk Management?**

It’s no surprise that improving the risk management process has not been at the top of management’s agenda over the past several years. The decline of blockbuster growth, problematic pipelines, growing threats and opportunities from globalization, and potential new therapies have caused pharmaceutical companies to focus more on changing an outdated business model. In addition, compliance with the Sarbanes-Oxley Act of 2002 (S-O), particularly Section 404, required considerable resources that might have been deployed elsewhere. And return on investment in ERM remains difficult to prove. All of these challenges, however, are the very reasons why risk management should have been at the top of management’s agenda.

With the assistance of professors Kothari and Guay, our updated analysis suggests that the pharmaceuticals industry is still riskier than the overall S&P 500, and, as is well known, the industry’s aggregate market performance has lagged the S&P 500 for several years. There is an urgent need to raise the bar and improve performance: to support a risk management process that is designed not only to minimize adverse events but also to facilitate well-controlled and timely entrepreneurial risk taking, aimed at profitable growth.

**Organizational Transformation**

With numerous factors impacting pharmaceutical companies, the industry is clearly challenged by the need to transform its business model. In fact, we now see pharmaceutical companies responding to this challenge by focusing on three business goals simultaneously:

1. **Reducing costs**
2. **Restructuring the pipeline**
3. **Mobilizing the organization**

We see a variety of strategies for achieving these goals, and a range of initiatives, or programs, to carry them out. In fact, the specific strategic initiatives carry out, drive, and define the transformation strategies. We recognize the critical importance of transformation and believe that there are risks inherent in the strategies and in the implementation of their programs that need to be adequately identified and controlled, to avoid the potential for costly and embarrassing surprises.

It is also important to note that we are not recommending a zero tolerance for risk. We believe risk management should look to avoid the obvious negative events, such as fraud and misrepresentation, while actively enhancing the organization’s willingness to take entrepreneurial business risks and invest from time in time in what may turn out to be a dry well or a gusher.
Transformation Has Its Own Risks

Pharmaceutical companies are vulnerable to risks arising from transformation. On the one hand, companies may fail to execute their transformation strategies successfully and fail to deliver on the results they have promised to the marketplace. Despite their best efforts, some companies may not be able to realize all the savings that they expect from cost-cutting measures. A recent KPMG International Study has shown that, on average, companies across a broad spectrum of industries are achieving only 59 percent of the savings they expected from cost-savings programs.

At the same time, management may be distracted by the transformational activities and put at risk the ongoing operations of the enterprise during the transformation. Questions may also arise about management’s ability to drive the radical changes in the business model and in the culture that are required, given the traditional focus on research and marketing. In addition, we believe that cost-cutting measures may inadvertently strip away some of the controls that had been implemented under the detect-and-correct approach, creating new risks related to transformation. Besides these more general issues, there are myriad specific risks that are obstacles to successful execution of the transformational programs: variable risks in operations and compliance are capable of bubbling up to become more significant than they ought to be.

How does your company perform on cost reduction?

<table>
<thead>
<tr>
<th>% savings target achieved</th>
<th>% survey respondents</th>
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<tbody>
<tr>
<td>Under 50%</td>
<td>35%</td>
</tr>
<tr>
<td>50% - 60%</td>
<td>20%</td>
</tr>
<tr>
<td>60% - 70%</td>
<td>15%</td>
</tr>
<tr>
<td>70% - 80%</td>
<td>10%</td>
</tr>
<tr>
<td>80% - 90%</td>
<td>5%</td>
</tr>
<tr>
<td>90% - 100%</td>
<td>0%</td>
</tr>
<tr>
<td>Always hit or exceed</td>
<td>2%</td>
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Only 8% of businesses reach or exceed their targets for cost-savings initiatives!

Reluctance to use high savings tools

<table>
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<tr>
<th>% savings target achieved</th>
<th>% seeing as important</th>
<th>Average savings</th>
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<tbody>
<tr>
<td>Under 50%</td>
<td>35%</td>
<td>7.00</td>
</tr>
<tr>
<td>50% - 60%</td>
<td>20%</td>
<td>6.50</td>
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<tr>
<td>60% - 70%</td>
<td>15%</td>
<td>6.00</td>
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<tr>
<td>70% - 80%</td>
<td>10%</td>
<td>5.50</td>
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<tr>
<td>80% - 90%</td>
<td>5%</td>
<td>5.00</td>
</tr>
<tr>
<td>90% - 100%</td>
<td>0%</td>
<td>4.50</td>
</tr>
<tr>
<td>Always hit or exceed</td>
<td>2%</td>
<td>4.00</td>
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Only 8% of businesses reach or exceed their targets for cost-savings initiatives!
Many companies may have been reluctant to invest in more extensive risk management programs because they believed that compliance with S-O offered a greater sense of security based on their providing documentation of controls enterprisewide. However, S-O is primarily intended to address issues in financial reporting. It does not necessarily address the controls over the root causes of financial issues in operations and compliance and may not fully satisfy the New York Stock Exchange’s requirement for board oversight of risk.

We believe that companies can build on their experience with S-O – the skills and the processes for documenting controls and identifying areas for improvement – in their approach to managing risks from operations, including regulatory compliance. We think they should view their operations in a comprehensive way across silos and bridge the gaps between the silos, taking into consideration security, controls, and compliance; the readiness and education of Internal Audit to assist in the process; and the potential tax implications on a global basis.

These fundamental requirements should be considered throughout the transformation. For example, a company should not leap forward into accelerating its Research & Development process without considering the implications for security in its IT infrastructure. Nor should it shut down company-owned plants without considering the implications for product quality and potential disruption of supply. A view to achieving cost reduction, growth, or organizational change cannot be one dimensional but needs to consider the adequacy and efficiency of security, controls, and compliance at every juncture and from end-to-end. The organization needs to have Internal Audit primed to assist in the documentation and ongoing monitoring. And it needs to consider not only the apparent benefits of the initiatives but also their potential costs in terms of tax liabilities. Our experience suggests that treating these factors as afterthoughts is both expensive and potentially risky.
CEO Challenge 2007: Top 10 Challenges
The Conference Board’s survey CEO Challenge 2007: Top 10 Challenges\(^{2}\) reports that execution is taking precedence over profit and top-line growth as a focus for CEOs around the world. Excellence in execution – a new category – and ensuring consistent execution of strategy by top management rank first and third, respectively, as greatest concerns. Sustained and steady top-line growth, which led the pack last year, now ranks second, with profit growth fourth and finding qualified managerial talent fifth.

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<tr>
<th>Relative Ranking</th>
<th>Cite challenge as being of “greatest concern”</th>
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<tr>
<td>1</td>
<td>Excellence in execution 38.4%</td>
</tr>
<tr>
<td>2</td>
<td>Sustained and steady top-line growth 36.8</td>
</tr>
<tr>
<td>3</td>
<td>Consistent execution of strategy by top management 31.8</td>
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<tr>
<td>4</td>
<td>Profit growth 28.4</td>
</tr>
<tr>
<td>5</td>
<td>Finding qualified managerial talent 27.2</td>
</tr>
<tr>
<td>6</td>
<td>Customer loyalty/retention 26.3</td>
</tr>
<tr>
<td>7</td>
<td>Speed, flexibility, adaptability to change 25.4</td>
</tr>
<tr>
<td>8</td>
<td>Corporate reputation 23.7</td>
</tr>
<tr>
<td>9</td>
<td>Stimulating innovation/creativity/enabling entrepreneurship 18.7</td>
</tr>
<tr>
<td>10</td>
<td>Speed to market 18.2</td>
</tr>
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*Weighted by regional representation in global GDP (Asia, 21.7 percent; Europe, 35.1 percent; the United States, 28 percent; and other, 15.2 percent). GDP data from the International Monetary Fund, World Economic Outlook Database, September 2006.

In addition, rating agencies such as Standard & Poor’s and Moody’s are expecting the industry to demonstrate its effectiveness at risk management while Congress may add pressure for proactively and systematically managing drug safety as well as preventing conflicts of interest. For example, recent legislation amending the Federal Food, Drug, and Cosmetic Act (Public Law 110-85) provides for new drug-safety regulations, strengthens the FDAs enforcement powers, requires greater disclosure of private and public clinical research and agency decision-making, and calls for a computerized system to identify drug risks. It also takes steps to reduce the FDAs reliance on outside advisors with potential financial conflicts of interest and creates a new program to review drug companies’ advertising.

Conclusion
At the beginning of the decade, most pharmaceutical companies could afford a detect-and-correct approach to enterprisewide risk. But that approach is no longer sustainable during a period of rapid transformation. In fact, it may leave them exposed and vulnerable to even greater risks.

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\(^{2}\) The Conference Board, October 2007, Research Report R-1406-07-RR
Although we have seen pharmaceutical companies make significant progress with risk identification and reporting, we believe they may be confronting new risks as they transform their organizations and may, in reducing costs, cut back vital controls. We recommend they take the next steps to implementing a more comprehensive framework for risk management that is integrated, anticipatory, and preventive in approach. One size will not fit all. Each company’s risk framework needs to take into account the implications and issues around the company’s strategies for transformation.

Recommendations

In our ongoing analysis of risk management in the pharmaceutical industry, we have been in regular discussion with senior executives at large and mid-size pharmaceutical companies. What we hear from these executives has led us to four recommendations for revitalization of their ERM program:

- **Revisit the purpose of ERM and its guiding principles with management and the board.** Top-level support is vital to the success of ERM. The organization needs to agree on the desired outcomes for ERM, to identify the guiding principles and the desired benefits and to shape their ERM program accordingly.

- **Reboot the risk assessments.** Consensus around the key risks at the C-Level is critical. Historically, risk assessments in pharmaceutical companies were good at reporting the past but insufficient to manage the business for the future. Now, a company’s risk profile may not represent the current and emerging threats to achieving its strategies, especially if it is a static profile. The business is not static, and change accelerates with transformation.

  The probabilities of individual risks also change so the likelihood of an adverse outcome may vary over time. Risk assessments may not necessarily pick up the emerging risks. In addition, the historic risk assessment may not have identified interrelationships among risks, creating a potential snowball effect, and the most current strategic point of view may not have been brought into the risk assessment.

  In the pharmaceutical industry, risk assessments have historically been backward looking, linked solely to operations and siloed. Companies need to reboot their risk assessments so they are forward looking, relevant to the current strategies, and recognize the interrelationships of risks across the enterprise.

- **Realign the risk management structure.** The ERM process needs to be sustainable to deliver value to the organization. While it is critical to align with the strategies and to achieve a consensus around key risks at the top of the organization, ERM needs structure and processes to make it part of doing business on the front lines. The structure needs to harmonize the views from the top down and the bottom up.
Pharmaceutical companies need a clear risk management structure with independence and accountability for the content, process, and compliance with companywide principles and policies. One model for consideration is a vertical risk management structure:

- **1st line of defense**: Operations, which is responsible for identifying, managing, and mitigating business risk. Operations owns the content of emerging risks and may be encouraged to focus more on entrepreneurial risk taking.

- **2nd line of defense**: The “standard setters” who own the process. They define the requirements for the risk management process and set policy.

- **3rd line of defense**: The auditors/enforcers who ensure that the first and second lines are functioning according to the policies and principles that have been developed.

The board, in turn, has responsibility for the governance over risk and needs sufficient comfort with the structure, process, and content of the ERM.

- **Reinforce the risk management process for identifying, managing, and mitigating risk.** Pharmaceutical companies need to step back now and ask how well their current risk management process is working. Is it designed to identify emerging risks, mitigate and monitor them, and communicate them to the appropriate levels for decision-making on a timely basis? Does the process ensure that there are common standards across the enterprise? Are there processes for communicating across silos and for bridging the gaps between functions, such as the hand-off from research and development to marketing and sales?

We believe that a more robust approach to managing risk can help reduce the likelihood of significant adverse events and create a culture that supports entrepreneurial risk-taking, balancing both value creation and the value preservation. Therefore, the purpose of this white paper, *Raising the Bar: How Enterprise Risk Management Can Enable the Effective Transformation of the Pharmaceutical Industry*, is to help identify and explore the risks inherent in transformation and to challenge the sector’s apparent sense of security that its current risk assessments and board communications are sufficient. We are in no way pessimistic about the industry’s prospects of success for transformation. We are looking to serve as a catalyst for companies in their ongoing efforts to balance risk and controls with performance improvement and, thus, help the industry in muting its downside events while enhancing the upside potential of well-informed risk-taking and the successful execution of transformation strategies.
Potential Market Volatility

In 2007, KPMG’s Pharmaceuticals Practice commissioned a new analysis of 33 top companies in the industry from Professor S. P. Kothari, Deputy Dean, and Gordon Y Billard Professor of Management at the MIT Sloan School of Management, and Wayne Guay, Associate Professor of Accounting at the Wharton School of the University of Pennsylvania. The objective of the analysis was to see if the market risk profile of the industry has changed since the publication of Pressure Points. Their findings, summarized in the following chart, indicate that the pharmaceuticals industry is still as much as 50 percent riskier than the S&P 500.

<table>
<thead>
<tr>
<th></th>
<th>Pharmaceuticals Companies</th>
<th>S&amp;P 500</th>
<th>Pharmaceuticals with one low point deleted</th>
<th>Pharmaceuticals with one low and one high point deleted</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flow scaled by assets</td>
<td>8.73%</td>
<td>5.68%</td>
<td>7.30%</td>
<td>5.38%</td>
<td>After including size effects, 50% riskier for pharmaceuticals than S&amp;P</td>
</tr>
<tr>
<td>Net income scaled by assets</td>
<td>9.09%</td>
<td>5.20%</td>
<td>6.41%</td>
<td>5.64%</td>
<td>Similar risk profile</td>
</tr>
<tr>
<td>Sales scaled by assets</td>
<td>23.84%</td>
<td>28.63%</td>
<td>22.45%</td>
<td>16.13%</td>
<td>Sales are more steady</td>
</tr>
<tr>
<td>ROI</td>
<td>21.89%</td>
<td>28.00%</td>
<td>18.06%</td>
<td>13.11%</td>
<td>ROI is also significantly impacted by extreme values</td>
</tr>
</tbody>
</table>

Source: Professors S.P. Kothari and Wayne Guay for KPMG LLP (U.S.), August 2007
Over the past 12 years, the industry has endured a cycle of volatility that peaked in 1999 and has since reached its lowest level since 1995 (see chart). Professor Kothari believes that this may, in part, reflect an increasing acknowledgement by the marketplace that the growth opportunities for the industry have diminished and are being fully disclosed. There may also have been some aggregate improvement in mitigating negative events.

He also notes that while we expect any one industry to be more volatile than the S&P 500, the influence of extreme performance events among the pharmaceutical firms is particularly disconcerting and indicative of high risk.

Given the industry’s current transformation and the challenges related to that transformation – expiring blockbuster patents, depleted pipelines, and cost pressures – Professor Kothari believes that the industry could well be entering another cycle of increased volatility. He notes that even though there may have been some improvement in managing extreme negative events, and that timely disclosures are likely to aid market perception, whether considering return on investment or aggregate market capitalization, the challenge remains to raise the bar and improve the overall business performance on the upside. The challenge is to reinvigorate entrepreneurial risk-taking while also improving the systematic management of risk to better anticipate and mitigate adverse outcomes.
Forces for ERM

In its 2007 report, *Emerging Governance Practices in Enterprise Risk Management*, the Conference Board cited a variety of external forces influencing companies to move forward with ERM, including “major legal developments:

- The interpretation of Delaware case law on fiduciary duties
- The New York Stock Exchange Listing Standards
- The SEC’s endorsement of self-regulatory frameworks (i.e., COSO) to manage financial risk
- The new Exchange Act requirement to consider risk factor disclosure in annual and quarterly reports
- Federal Sentencing Guidelines reform [with the related fines and costs of litigation]
- Best practice standards being implemented in highly regulated industries (e.g., banking and insurance)

We also view ERM as a potential enhancement to growth, recognizing that some impairment needs to be viewed as the cost of risk-taking that could also result in blockbuster rewards.

### Influences on Risk Management in Pharmaceuticals

- Satisfy evolving industry regulation, e.g., FDA Drug Safety
- Satisfy the increasing corporate governance requirements (e.g., Sarbanes-Oxley)
- Meet SEC requirements: 10-K description of “risk factors” in plain English
- Board’s duty of care in managing a corporate entity
- Pressure from Congress

- Meet enhanced NYSE public company listing requirements emphasizing board responsibilities and corporate governance
- Comply with rating agency guidance emphasizing a company’s ability to articulate and execute against a risk management strategy including infrastructure, processes, and documentation requirements

- Reduce cash flow volatility using derivatives, insurance, or improved controls
- Allocate and evaluate capital based on risk-based performance
- Integrate risk and business planning, investment, and M&A
- Reduce costs through risk consolidation and cross-functional efficiencies
- Reduce losses through coordinated enterprise risk monitoring and reporting

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4 The Conference Board, February 2007, Research report R-1398-07-WG
Pressure from Congress

We are seeing three consistent themes in congressional discussions about the drug industry: drug safety, risk management, and the avoidance of potential financial conflicts of interest. KPMG’s *Washington Healthcare Update* reports the passage of Public Law 110-85 that amends the Federal Food, Drug, and Cosmetic Act. It includes provisions for “drug-safety regulations and the renewal of industry user fees to fund the FDA’s review of medications and devices submitted for approval. The law calls for a computerized system to identify drug risks, strengthens the FDA’s enforcement powers, and requires greater disclosure of private and public clinical research and agency decision-making. In addition, it takes steps to reduce the FDA’s reliance on outside advisors with potential financial conflicts of interest and creates a new program to review drug companies’ advertising. Some observers have expressed concern about how the law may affect drug makers’ legal liability for FDA-approved drugs.”

The *Update* also notes that the Senate is reviewing a bipartisan bill – S. 2029 – that would require manufacturers of drugs, devices, and biologics to disclose the amount of money they give to physicians through payments, gifts, honoraria, travel, and other means. If adopted, the legislation’s requirements would apply to manufacturers with $100 million or more in annual gross revenues, and penalties for not reporting payments would range from $10,000 to $100,000 per violation.

Also introduced in March 2007 is *The Enhancing Drug Safety and Innovation Act of 2007* (H.R. 1561), the House counterpart to the Enzi-Kennedy drug safety bill (S. 484). Congressman Henry Waxman’s office writes that “S. 484 contains many important provisions that will: (1) strengthen FDA’s post-market drug safety system; (2) establish the Reagan-Udall Institute for Applied Biomedical Research, a new public-private partnership to advance FDA’s Critical Path Initiative; (3) establish mandatory clinical trials registry and results databases; and (4) reform procedures to manage conflicts of interest on FDA’s advisory Committees.

H.R. 1561 builds upon those provisions to further increase FDA’s post-market drug safety authority, provide greater FDA transparency, and enhance the mandatory clinical trial registry and results databases. “Specifically, H.R. 1561 will give the FDA enhanced tools to ensure post-market drug safety through the ‘Risk Evaluation and Mitigation Strategy’ (REMS) process, including: (1) increasing the possible moratorium on direct-to-consumer advertising from two years to three years; (2) adopting the Institute of Medicine (IOM) recommendation that the FDA place a symbol on the packaging of a product to let consumers know that the drug is new to the marketplace; and (3) requiring a review of drug products after they have been on the market for seven years (the average time it takes to detect most side effects…”

1 *Washington Healthcare Update*, Fall 2007, KPMG LLP
2 www.house.gov/waxman/issues/health/drug_safety.htm
FDA RiskMAPS

Background

One of the goals of the Prescription Drug User Fee Act (PDUFA) III was to provide guidance for the industry on risk management activities for drug and biological products. PDUFA III's Premarketing Guidance and the Pharmacovigilance Guidance focus on premarketing and postmarketing risk assessments, respectively. The RiskMAP (short for Risk Minimization Action Planning) Guidance focuses on risk minimization. Together, these guidelines form what the FDA calls “risk management” and reflects the FDA's commitment to harmonizing with international definitions and standards.

The FDA's Proposal for a RiskMAP

The FDA defines this risk management program as “a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. A RiskMAP targets one or more safety-related health outcomes or goals and uses one or more tools to achieve those goals.” The FDA does not prescribe any specific template, and its reviews of sponsors’ RiskMAPs are kept confidential.

Currently, only about 30 drugs are approved with restrictions on distribution and use what is known as a RiskMAP (see sidebar), and such restrictions are intended to remain an infrequent requirement under [this new bill]." Pharmaceutical companies can learn from this RiskMAP guidance to inform risk management in the early stages in controlling risks associated with their portfolio of products.

Pressure from Analysts – Views from the Ratings Agencies

The Conference Board notes that “A recent survey conducted by the Tillinghast business of Towers Perrin indicates that companies have planned to set up an ERM infrastructure or have decided to improve their current ERM program based on comments received from such major rating agencies as Standard & Poor’s and Moody’s.”

S&P has indicated that it may include an assessment of a pharmaceutical company’s risk management in its ratings, following its method for analyzing risk management in the financial sector (banking and insurance companies) that has been in use since 2005. (Note: At a KPMG-sponsored meeting, August 1, 2007, S&P clarified that it has not decided that all industries would have a risk assessment as part of its rating process.) Based on experience, it is expected that any issues S&P identifies are likely to be addressed directly with the companies, while companies with no ERM framework in place could find their credit ratings lower (see next page).

In November 2005, Standard & Poor’s (S&P) began to incorporate evaluations of ERM into its overall credit ratings of insurance and financial institutions. The ERM role in the ratings process was designed to facilitate a better understanding of how management viewed risk and promote a longer-term view of a company’s risk profile.

In November 2007, and again in January 2008, S&P requested comments on a proposal regarding ERM evaluations for non-financial services companies. S&P expects to decide later this year on whether to include ERM analysis, including methodology and a timetable for its introduction. S&P says its interest in codifying management analysis using ERM coincides with increased interest by many companies to initiate their own ERM programs – or other risk-management practices – to increase risk-adjusted returns, improve strategic judgment, and/or avoid extraordinary losses due to lawsuits, fines, operational failures, or negligence. Says S&P:

“The intersection of these interests is in the expectation that a firm’s future ability to meet financial obligations in full and on time is more likely to be enhanced by strong ERM or diminished by weak or nonexistent ERM. Our principal interest in evaluating ERM is to implement steps that will limit the frequency and severity of losses that could potentially affect ratings.”

S&P views ERM as a comprehensive risk assessment and takes into account a company’s own view of its risks and how these align with the fundamental objectives of the organization. S&P also looks at how companies develop and maintain systems that measure retained risks such as the risk in strategic decision making, product design and pricing, M&A, and strategic and tactical investment selection. The ratings agency also weighs the risk of failure of a business strategy as well as failure within a business strategy. Finally, S&P understands that ERM is not the same in each sector and is not applied blindly to each firm. However, the ratings agency believes how companies approach ERM can separate them in the sector by distinguishing between high- or low-risk quality firms.

However, the difficulty associated with comparing financial and nonfinancial firms under the same rating system was highlighted in S&P’s request for comment:

“While using a commonly applied scale would make it easy to compare the ERM quality of, say, Unilever PLC with Citicorp, it would likely fail to provide differentiation among firms in financial or nonfinancial sectors. Risk management in financial services firms is fundamental to their very existence. Financial firms buy and sell risk, while nonfinancial firms accumulate risk as a consequence of making some other product or providing some other service. In other words, financial firms are fundamentally ‘riskier’ than nonfinancial firms. For this reason, we propose to use different scoring definitions for nonfinancial firms.”

S&P’s current ERM ratings of financial services institutions fall into four categories: Excellent (which currently comprises 3 percent of covered companies); Strong (10 percent); Adequate (82 percent); and Weak (5 percent). About a quarter to a third of “adequate” companies are actively moving up the scale. S&P says that ERM risk ratings have become “tipping points” in its overall company evaluations. In 15 cases, for instance, ERM was a major driver in a ratings outlook. After two years, S&P has concluded that financial companies that do ERM well fall into one of two categories: They either practice Six Sigma or have survived a “near death” experience that has almost resulted in their being put out of business.

ERM has served a pivotal role in evaluating insurers. In 2005, for instance, Hurricane Katrina cost insurers more than $41 billion, the largest loss event ever for the industry. In the wake of the disaster, ERM was a differentiating element when S&P reviewed insurer credit ratings. Some insurers with weaker ERM had losses that were as much as twice what they previously reported as their “probable maximum loss.” These insurers were unable to even estimate their losses several days after the event. On the other hand, insurers with stronger ERM could quickly estimate losses that were within 25 percent of actual claims. These insurers could quickly pinpoint where weaknesses were in their ERM processes and took immediate steps to rectify them.

Although S&P does not expect ERM to eliminate losses, it believes that firms with good ERM should not only have smaller losses in adverse times, but also rebound more quickly from those losses and establish better future practices. S&P is currently looking at other industries to review through the ERM lens in 2008. Health products and services companies are being considered, and S&P allows that both industries have a host of risk factors that are worth analysis, including:

- Failure to innovate
- Liability lawsuits
- Regulatory/legislative
- Reputation
- M&A/restructuring

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1 S&P Ratings Direct, November 15, 2007, Request for Comment: Enterprise Risk Management Analysis for Credit Ratings of Nonfinancial Companies
2 Ibid
Three Goals for Transforming the Business Model

As they face increasing pressure to improve their risk management processes, the major global pharmaceutical companies are all undertaking significant changes in their business model with no convergence around a single model as the industry standard. We see each company pursuing some combination of the three key strategies – reducing costs, restructuring the pipeline, and mobilizing the organization – with a tendency for each company to focus somewhat more on one strategy over the others. At the heart and common to all, however, is the vital need for growth, to optimize the pipeline, and to control risk.

We are seeing simultaneous efforts to grow the business, get the cost structure back into alignment, and enhance productivity by implementing quality/process programs such as SAP-enabled redesign with concomitant efforts at mobilizing the organization around this entrepreneurial new model. Some companies have been less affected by extreme pressures from the breakdown of blockbuster model and patent expirations so they are focusing on different aspects of this overall model. Some have more time or have elected to diversify. Meanwhile, we see the following imperatives and believe that top companies are focused accordingly:

Strategies to Reduce Costs: Enhance Productivity

All of the major pharmaceutical companies have some type of cost-reduction program underway, ranging from enterprise-wide initiatives with specific names to ad hoc process improvement programs. We have seen the scope and speed of these cost-reduction initiatives tending to be directly related to the size of the problem and inversely related to the time available to fix it.
As part of the drive for improvement in productivity, companies are looking to optimize their efforts across prescribers, payors, patients, and scientific leaders. They are reexamining their sales and marketing investments to rationalize and streamline sales efforts and use direct-to-consumer information services that are more targeted and less costly than advertising. They are engaging both internal and external resources to help with the programs of cost reduction.

The current cost reduction programs we see include:

- **System Standardization**: Companies are moving from many decentralized systems to few or one centralized system with common global processes, data, and systems including order to cash, source to settle, supply chain, finance, and human resources. One company, for example, is moving from 160 different systems for payroll to one.

- **Shared Services**: Companies are consolidating and centralizing back-office service centers, such as IT, HR, and finance, to reduce complexity and maximize throughput. We have seen issues arise in moving processes to shared services groups when they receive nonstandardized programs, nonstandardized processes, and nonstandardized techniques. The shared service group must then not only provide the required deliverables but also improve their operations “on the fly” and, in effect, assess key issues such as outsourcing after the fact.

- **Outsourcing/Offshoring**: Companies are moving business processes, such as sales, finance, IT, and HR as well as research and clinical trials, to lower-cost companies and/or geographies (e.g., India, China, Czech Republic, the Philippines, etc.). It is well recognized that the inherent risks include quality control matters, counterfeiting, regulatory compliance, and ultimately the potential for further regulations. In addition, if the outsourced processes were “unhealthy” to start, the outsourcer will need to fix them and is likely to charge a premium for taking on that level of dysfunction.

While some of the business functions mentioned above are common to many industries, pharmaceutical companies are also looking for help in clinical research outsourcing, especially with the stage-three trials. With the increased reliance on mini-busters, their need will grow. In looking to outsource clinical research, questions arise such as:

- Where will they find those groups of dedicated people in the trial?
- How will they find the investigators to conduct these trials?
- How are they monitored?
- How do they ensure data quality, integrity, and privacy?
- How can the pharmaceutical company be sure of compliance with the terms of the outsourcing contract when litigation is not an attractive option and the impact on revenue of not getting the drug to market can be significant?
• **Direct to Pharmacy:** Companies are looking to reduce the “costs” of distribution through intermediaries and to sell directly to pharmacies. Here, harmonizing with Pharmacy Benefits Managers (PBM) is an issue in that PBMs manage by cost per prescription while pharmaceutical companies manage on throughput and product volume. So a challenge in looking to sell direct is how does the organization balance the PBMs’ desire to medicate with its drug at a low-cost per script with the company’s own drive for revenue and market share?

• **Marketing and Sales Reorganization:** As part of transforming the business model, companies are reorganizing the sales force with more decentralized instead of centralized control and a goal of consolidating the sales force so that fewer people call on each doctor and may be equipped to promote a larger number of products.

• **Process Improvement Initiatives:** Companies are constantly looking for ways to streamline processes and reduce complexity and time at the operating level that ultimately translate into savings. These initiatives range from ad hoc efforts around a specific process that may be viewed as the “Incremental Fix It Approach” to the more programmatic efforts such as Six Sigma and related methodologies, and Define, Measure, Analyze, Improve, and Control (DMAIC). A caution regarding ad hoc efforts is the potential for unexpected consequences in other processes that were not considered in the analysis, while the more programmatic approach risks dampening the entrepreneurial efforts of the overall organization and slowing down the process of business decision-making.

**Restructure the Pipeline: Growth**

Companies are striving to do a better job of managing their products from innovation to “retirement.” In addition to tracking the costs of development, manufacturing and distribution, and associated revenues, they are looking to optimize the timing of key milestones in each product’s life cycle, including options for disposal such as withdrawal from the market or sale to another party. A key concern today is that investing in drugs with little further upside potential will impede more productive investments in the next, better opportunity.

Blockbusters, the drugs that contribute $1 billion or more each in annual revenue, are now fewer and farther between so that multiple drugs – minibusters – are expected to drive revenue. Because of their lower volume, however, minibusters are not as cost-efficient, which requires an even greater stream of new products for comparable revenue generation. Organizations are reevaluating their current pipeline, accelerating development of certain drugs through aggressive investments, decelerating investments in other drugs, and selling, buying, or partnering for late-stage opportunities to fill the gaps.
The strategies we see companies using to enhance growth include:

- **Pipeline Productivity**: Companies are restructuring their pipeline development process in some cases by continuing to focus on franchises (widespread diseases) governed by therapeutic areas – such as cardiovascular, diabetes, oncology, etc. – or refocusing their development effort to a narrower geographic region. Others may be redefining the focus of R&D around the implications of mapping the genetic code or around expanded views of wellness/healthcare.

- **Price Controls**: Companies are looking to effectively capture data in clinical trials that supports premium pricing once the drug has been approved.

- **R&D Investment – Portfolio Management Process**: Companies are focusing on their ability to make effective investment decisions and related trade-off decisions across the portfolio to advance drugs in an optimum fashion.

- **Loss of Patent/Marketing Exclusivity**: Companies are focusing on their ability to defend patents and to manage patent expiry from an organizational survivability perspective.

- **Reliance on Third Parties**: Big pharmaceutical companies are entering into agreements with peers, mid-tier companies, and smaller biotechnology firms to co-promote, co-produce, co-develop, or co-research particular drugs. Before entering into such relationships, our experience suggests the importance of undertaking as comprehensive due diligence as feasible. We have seen that the more information that a company has about an alliance partner, and the faster it gets this information, the better the potential outcome. We also recognize that there are risks for the ongoing fundamental business in the implementation of these alliances. Managers will be challenged to drive both the alliance and their own usual operations without additional resources, while needing to address issues of independence and confidentiality that may arise from the “co-opetition.”

- **Mergers and Acquisitions**: Global pharmaceutical companies continue to acquire other “Big Pharma” as well as biotechnology companies, smaller pharmaceutical companies, and the divisions of other companies that no longer fit with their strategies or business models.
Mobilize the Organization: Enable the Transformation of the Business Model

This third key goal, which, in fact, enables cost reduction and growth, involves mobilizing the organization to change its culture, break down silos, and stimulate more creative and consensual decision-making.

The strategies we see companies pursuing as they transform the business model include:

- **Corporate Leadership Change:** Companies are looking for fresh perspectives and to show the market that change is on the way. From July 2006 to March 2008, five new CEOs and six new CFOs were named at the 20 largest global pharmaceutical companies.

- **Corporate Strategy Implementation:** Companies are seeking to help translate corporate strategy into discernable performance measures inside the organization and build effective teams to carry out their strategies. Tactics include culture assessment surveys, change management programs, and leadership and employee development. In addition, companies are increasing their communications programs both internally (e.g., town halls and “brown bag lunches”) and externally with press releases to clarify where the company is going and provide rationale for cost-cutting measures.

- **Marketing and Sales Compliance/Ethical Misconduct:** Companies are developing risk detection frameworks to anticipate potential ethical misconduct, including off-label promotion, while encouraging good promotional practices in healthcare professional interactions. Some companies are using modules on top of ERP platforms that allow them to track governance risk compliance (GRC) issues. The GRC program can help these companies manage their compliance programs as they go through the transformation process.
Top Risks in a Time of Transformation

When considering this overall transformation model and its three key goals, we are concerned that the drive to accelerate products through the pipeline, combined with systemic and ad hoc cost-cutting measures, is changing the risk profile of the industry. If a company’s approach is to detect and correct risks, it may be missing many emerging risks. Where there are gaps between silos and incomplete handoffs between departments, the risks multiply and, we would suggest, that the longer it takes to disclose negative events, the greater the potential impairment of value. As a result, there may be unwelcome surprises in the new model when certain controls previously in place may have been cut away as part of the process improvement process.

KPMG International has analyzed the most recent financial filings of a selection of leading global pharmaceuticals companies over the past several years, as part of KPMG International’s annual report on risks and disclosures in the global pharmaceuticals industry (see Heat Map below). What we are seeing disclosed with a good deal of uniformity are the risks that are the reason for transformation, including 1) expiration of propriety rights, including patents; and 2) unsuccessful strategic alliances. The former is an impetus to transformation while the latter is one of its common strategies. We are not yet seeing disclosures of the risks arising in transformation itself.

This heat map “shows the change in risks disclosed by pharmaceutical companies from 2005 to 2006. Those risks in the red area were disclosed in more companies than in 2005; those in the amber area were not disclosed more or less than in 2005; and those in the green area were disclosed as a key risk less frequently in 2006 than in 2005.”
KPMG’s Pharmaceuticals Practice sees this heat map as one potential tool for companies undertaking their own risk assessments to use as a starting point for their consideration. In addition, and as noted above, pharmaceutical companies are vulnerable to the risks arising from transformation itself. They may fail to execute their transformation strategies successfully. They may fail to deliver on the results they have promised to the marketplace. At the same time, management, distracted by the transformational activities, may put at risk the ongoing operations of the enterprise that are not involved in the transformation. Questions also arise about management’s ability to drive the necessary radical changes. In addition, cost-cutting measures may inadvertently strip away some of the controls that had been in place under the historical detect-and-correct approach, creating new risks related to transformation.

**Transformation Execution Risks**

In addition to these higher-level, strategic risks of transformation, we have seen a number of issues in the planning and implementation of transformational programs that can create obstacles to the successful execution of the program. Failure to identify, manage, and mitigate such risks can lead to cost overruns, delays in implementation, and dysfunctional behaviors undercutting the goals of the program. Transformation execution risks include:

- Unrealistic expectations
- A noncompelling business case
- A transformation program that fails to consider all the dimensions of change, including people, process, and technology
- Inadequate sponsorship by leadership
- Resistance by employees
- Poor project management
- Inadequate regulatory and compliance requirements
- A program whose scope lacks clarity and expands over time
- An IT perspective that is not integrated into planning
- A transformation process that occurs in silos, where there is no horizontal view
- Project roles that are not transitioned to the business
- Process expertise that is underutilized
- A lack of organizational change designed to enable the program
- An organization that is not taught to use the capabilities of the transformed business
- A postimplementation commonality that is not promoted
- Poorly defined metrics
As part of transformation, we recommend that organizations also assess their readiness for the conversion to International Financial Reporting Standards (IFRS). A properly planned conversion addresses issues beyond accounting and reporting. The project must identify issues relevant to the entire company as a result of converting to IFRS.

**Considerations in Planning for Transformation**

We recognize that pharmaceutical companies have made progress in recent years in developing an assessment of their overall risks, reporting on risk to the board which has oversight and, in some instances, implementing ongoing processes to identify risks more timely across the normal silos of the organization.

Nevertheless, we believe it is time for companies to review their overall risk management approach and consider whether it fully meets their needs as they transform the business model. Research conducted last year by KPMG LLP and The Economist Intelligence Unit among 265 executives in U.S.-based companies across industries suggests that an increasing “desire to reduce their financial losses and improve their business performance is driving [companies] to invest in ERM implementation programs. Regulatory compliance requirements and the desire to increase risk accountability were also cited as important.”

We believe that the business leaders of pharmaceutical companies should judge their current efforts in terms of whether their risk management processes are solely detective and corrective or whether they are moving to become more proactive and preventive. We believe that companies can build on their experience with S-O – the skills and the processes for documenting controls and identifying areas for improvement – in their approach to managing risks from operations, including regulatory compliance. We think they should view their operations in a comprehensive way across silos and bridge the gaps between the silos, taking into consideration security, compliance, and controls; the readiness of Internal Audit to assist in the process; and the potential tax implications on a global basis.

These fundamental requirements should be considered throughout the transformation. For example, a company should not leap forward into accelerating its Research & Development process without considering the implications for security in its IT infrastructure. Nor should it shut down company-owned plants without considering the implications for product quality and potential disruption of supply. A view to achieving cost reduction, growth, or organizational change cannot be one dimensional but needs to consider the adequacy and efficiency of security, controls, and compliance at every juncture and from end-to-end. The organization needs to have Internal Audit primed to assist in the documentation and ongoing monitoring.

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10 The Economist Intelligence Unit, 2007, *Best practice in risk management: A function comes of age*
And it needs to consider not only the apparent benefits of the initiatives but also their potential costs in terms of tax liabilities. Our experience suggests that treating these factors as afterthoughts is both expensive and potentially risky.

As the value of a pharmaceutical company is largely driven by its portfolio – top line in terms of marketed products, bottom line in terms of premarketing pipeline – risk across this entire value chain must be identified, assessed, controlled, and monitored. An effective ERM program should help ensure that prioritized risks are minimized while strategic goals are secured.

**Conclusion**

Over the past two years, pharmaceutical companies have made significant strides in assessing and managing their risks. But it is not enough. They are also undergoing a period of transformation that is expected to strengthen their ability to compete and do business in the years ahead. Managing risk is an inherent part of that transformation process, and it is important for companies to appreciate that all risks are not negative. There are considerable upside opportunities for those companies that choose to reinvigorate their entrepreneurial character.
One Approach to an ERM Framework

A KPMG’s Pharmaceuticals Practice forum on ERM in the pharmaceutical industry discussed a potential approach to structuring a comprehensive approach to ERM that extends from the top tier of the company down through the divisions, business units, and regions to the product level (see diagram). This ensures that the risk management process, which is blessed by senior management, is embedded throughout the organization.

Process
A group of seven executives reports into compliance and helps facilitate risk management reviews three times annually: at the beginning, middle, and end of the year. One of the keys is getting people from different disciplines to discuss risks. For instance, product safety risk has many components that touch several functions, including media relations, financial, patient issues, and legal. To deal with these and other issues, the company’s approach to risk management fits into two buckets: Process Characteristics and Sustainability.

Process Characteristics
The company looks at the impact risk might have on the company based on several different criteria. These impact criteria include:

- Near vs. long term
- Brand reputation
- Financial
- People (customers, patients, regulators, employees)

This approach drives a more holistic view of the risk discussion and forces people to think longer term strategically. It also ties accountability into the process, since people will be accountable for certain risks that impact their specific departments. In addition, the company recommends that people review their risk practice at least twice a year with their top 15 risks to keep the risk profile active and fresh. These risks are also put into a heat map where they can be seen and managed.

Second, the company conducts a root cause analysis of current and potential risks. Risk is sometimes a symptom of a bigger issue that may be out of the control of the environment in which the executive is working. In fact, risk issues could be buried across multiple functions. This root cause analysis encourages sharing information across the organization. Findings from these root cause analyses have sometimes led the organization to see that they were taking a risky path and took a less risky path that had more upside.

Sustainability
To sustain the risk management process, all risks are mapped to a risk dictionary. This allows the company to see themes, signals, or trends. It also helps determine how these risks are managed as well as who is responsible for overseeing them. The company collects the data that has been prioritized. Out of 300 risk items, 20 to 30 percent have active management plans. Most significantly, every risk has a member of senior management attached to it. The risk processes and data are reviewed at the board level, and Internal Audit is responsible for managing the policies, training, and tools necessary to maintain the company’s risk management process.
Recommendations

In our ongoing analysis of risk management in the pharmaceutical industry, we have been in regular discussion with senior executives at large and mid-tier pharmaceutical companies. What we hear from these executives has led us to four key recommendations:

**Revisit the purpose of ERM and its guiding principles with management and the board.** Experience suggests that top management support is vital to the success of ERM. It cannot be an offshoot of Regulatory Compliance if it is expected to foster more effective risk taking throughout the organization.

The organization also needs to agree on the desired outcomes. In the past the board or an adverse event or a concern about the ratings agencies might have triggered a reassessment of ERM. Now the organization needs to step back and ask what the purpose of ERM is, why should we be involved? Each company needs to identify the guiding principles for its ERM—the benefits it is looking to achieve—and needs to shape its ERM program accordingly.

The ideal would be to set a goal for a financial return on investment. There are various efforts underway to quantify risk, but this is still a long-term goal and may be difficult to accomplish in the pharmaceutical industry. Issues around the implications of clinical data and the importance of intangible risks such as reputational risk make pure quantification and common standards somewhat harder. We view this as an ongoing challenge and a continuing area for development and discussion.

**Example of Risk Management Principles**

<table>
<thead>
<tr>
<th></th>
<th>Common Language</th>
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<tbody>
<tr>
<td>1</td>
<td>One view of risk, a common language drives effective risk-management actions and decisions</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Risk information takes into consideration all the constituencies of the enterprise, e.g., board, management, customers, vendors, regulators and, rating agencies, and aligns to strategic objectives and drives business value</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>The organization needs a clear risk management structure with independence and clear accountability for the content, the process, and the compliance with companywide principles and policies</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Thorough and sustainable comprehensive risk-management process that is efficient and integrated/consistent. Process to include risk identification, quantification, management reporting across current and emerging risks</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Risk savvy culture with risk-management competency embedded in the business and operating philosophy</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Continuously improving risk-management process that is forward-looking, proactive, and continues to identify trends/opportunities for advancement</td>
<td></td>
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</table>
Reboot the risk assessments. The consensus around the key risks at the C-Level is critical to ERM. Historically, risk assessments in many pharmaceutical companies were largely a product of Internal Audit – good at reporting on the past but insufficient for helping to manage the business for the future.

A company’s risk profile is unlikely to represent the current and emerging threats to its current strategy. It is likely to be outdated, especially if it was treated as a static profile. The underlying business is not static, and the speed of change accelerates with transformation. The probabilities of specific risks also change, so the likelihood of an adverse outcome may vary with circumstances over time.

In addition, the historic risk assessment may not have identified the interrelationships among risks, creating a possible snowball effect. (This is particularly evident in the subprime mortgage situation among financial service companies.) The strategic point of view may not have been brought into the risk assessment, particularly if the risk assessment was performed from the bottom up without consideration for its relevance to the go-forward strategy. And, risk assessments may not necessarily pick up the emerging risks.

For example, as companies revitalize their pipeline through alliances or by conducting trials in emerging countries, they need to ask if the risks that they have identified are both forward looking and sufficiently specific to identify the root cause. While it is appropriate to disclose a weak product pipeline as a way of setting the market’s expectations, business owners need to identify the very specific threats and obstacles that might produce this outcome. An additional challenge is to ensure that the plans for the product pipeline remain aligned with the growing global market for healthcare and the company’s own strategic focus in that market.

In the pharmaceutical industry, risk assessment has historically been backward looking, linked solely to operations and siloed. The company needs to reboot its risk assessment so that it is forward looking, relevant to the current strategy, and recognizes the interrelationships of risks across the enterprise.

Realign the risk management structure. The ERM process needs to be sustainable to deliver value to the organization. While it is critical to align with the strategy and to achieve a consensus around key risks at the top of the organization, ERM will not be effective unless there is a structure and processes that make it part of doing business on the front lines. As the company transforms its operations, its existing risk management structure needs to be reexamined.
The organization needs a clear risk management structure with independence and accountability for the content, the process, and the compliance with the company’s principles and policies.

One model for consideration is a vertical risk management structure:

- **1st line of defense**: Operations, which is responsible for identifying, managing, and mitigating business risk. Operations owns the content of emerging risks and one benefit of this approach is that they may be encouraged to focus more on entrepreneurial risk-taking.

- **2nd line of defense**: The “standard setters” who own the process. They define the requirements for the risk management process and set policy.

- **3rd line of defense**: The auditors/enforcers who ensure that the first and second lines are functioning according to the policies and principles that have been developed.

In this approach, the board may be viewed almost as a “4th line of defense” given its responsibility for the governance over risk. Board members need sufficient line of sight into the risk management structure, process, and content so that they are comfortable with the ERM, unlikely to be surprised by risk-taking in any major way, and able to communicate with the market about their enterprise risks, if needed.

**Reinforce the risk management process for identifying, managing, and mitigating risks.** Pharmaceutical companies need to step back now and ask how well their current risk management process is working. Is it designed to identify emerging risks, mitigate and monitor them, and communicate them to the appropriate levels for decision-making on a timely basis? Does the process ensure that there are common standards across the enterprise? Are there processes for communicating across silos and for bridging the gaps between functions, such as the hand-off from Research & Development to Marketing and Sales?

A recent study by IBM with the Wharton School and The Economist Intelligence Unit suggests that enterprises are looking to the CFO for leadership in risk management. The study says that risk management is about orchestration from the board level to middle management. “Currently, enterprises are struggling to understand their holistic enterprise risk profile. Moreover, the simple risk/reward equation means that all performance is intrinsically linked to risk. Two actions are key to managing risk: the CFO’s orchestration of risk management and the convergence with performance management.”

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We have seen that companies take varying approaches to the process of ERM, depending on the needs of the organization and its risks. A company’s approach, and the choices it reflects, affects the extent to which it makes ERM an active part of its governance and an effective tool of its ongoing business operations. We think there are also opportunities to use ERM to help the organization make decisions about strategic initiatives and realign the programs accordingly.

We encourage pharmaceutical companies to take the next steps to implementing a more comprehensive framework for risk management that is integrated, anticipatory, and preventive in approach. One size will not fit all. Each company’s risk framework needs to take into account the implications and issues around the company’s strategies for transformation. We also recognize the challenge to all of us in the industry to identify scorecards to demonstrate the value of ERM and to continue to improve our ability to measure and manage risk on a more timely basis.
Appendix: Innovation Is the Key to Efficiency

For a recent white paper from KPMG International, *The Evolution of Risk and Controls: From Scorekeeper to Business Partner*, The Economist Intelligence Unit conducted a survey of 435 senior executives from a cross section of industries.

“When asked about the steps they are taking to overcome barriers to effective risk and controls management, the second most popular response, behind a higher profile for risk and controls, is the use of a more innovative approach to the functions. This is closely followed in third place by the need for greater reliance on technology. Among the methods gaining popularity are continuous monitoring and auditing, controls transformation, enterprise risk management and the use of executive dashboards (see box).

### Innovations in risk and controls management: definitions

**Continuous monitoring and auditing:**
The ability to review and report on business information in real time or near real time. This eliminates the traditional gap between the completion of fieldwork and the issue of an audit report and, implemented correctly, greatly enhances the decision-making ability of management.

**Controls transformation:**
A program of process and performance improvement of controls to help the function to become more closely aligned with the needs of the business.

**Enterprise risk management:**
An organization-wide framework for risk management that aligns risk and business strategy and helps to identify and manage enterprise-wide risks.

**Executive dashboard:**
A business intelligence technology that provides managers with up-to-date information and alerts on a range of key indicators. These dashboards are sometimes updated as often as three or four times a day and are intended to help managers spot emerging opportunities as well as risks.

There is clearly a strong appetite among the survey respondents for these innovations. The majority of respondents have either implemented all four already or plan to do so in the next three years. The most established is enterprise risk management, which is already up and running in 30 percent of companies surveyed, while controls transformation is seen as the ‘must-have’ innovation, with 56 percent intending to implement it over the next three years.”

<table>
<thead>
<tr>
<th>Innovation</th>
<th>% Respondents</th>
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<tbody>
<tr>
<td>Real-time review and analysis of business information (continuous monitoring and auditing)</td>
<td>26.1% - 43.4% - 21.8% - 8.7%</td>
</tr>
<tr>
<td>Automation and process improvement in controls (controls transformation)</td>
<td>18.4% - 55.9% - 17.5% - 8.2%</td>
</tr>
<tr>
<td>Enterprise risk management</td>
<td>30% - 41.7% - 17.4% - 10.9%</td>
</tr>
<tr>
<td>Use of executive dashboards</td>
<td>24.3% - 36.5% - 21.2% - 18%</td>
</tr>
</tbody>
</table>

Source: The Economist Intelligence Unit, 2007
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