



# Recapturing the vision: Integrity driven performance in the pharmaceutical industry\*

PricewaterhouseCoopers' Health Research Institute

\*connectedthinking

PRICEWATERHOUSECOOPERS 





The foundation of any sustainable and profitable business model requires the trust of consumers, regulators, investors, and creditors. Relative to their counterparts in other sectors, however, pharmaceutical companies find themselves party to a more involved and demanding social contract. Scientific successes have positioned modern medicines as vital components to the overall state of public health; they are indispensable keys to survival and good health for millions of people. As such, the public expects pharmaceutical companies to address social needs as well as earn a financial return. It may be argued that in many cases this expectation exceeds what is reasonable or even possible. At the very least, it is a call for action far beyond the mandate of the ordinary profit-making company.

For many years, the pharmaceutical industry was highly respected for its role as a leader in the advancement and improvement of the human condition. The continuous innovation of new and improved drugs has driven the dramatic growth and profits of the industry. But recent highly visible compliance failures, some of which occurred despite existing legal requirements and established processes, have led consumers to believe that pharmaceutical companies have lost track of their original vision. Combined with the questions about the pervasiveness and appropriateness of Direct-to-Consumer advertising, drug safety complications, and the number of “me-too” drugs being commercialized in recent years instead of innovative ground-breaking treatments, the public and governments are forming the opinion that instead of bettering the human condition, the pharmaceutical industry is more interested in satisfying its shareholders.

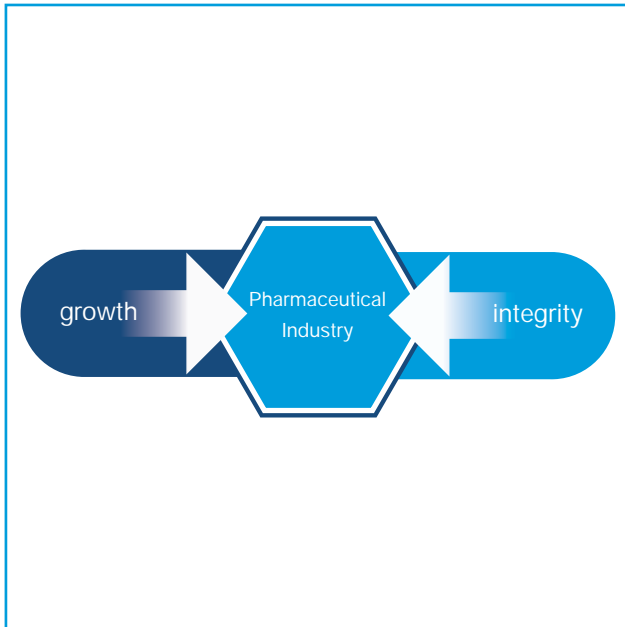
The damage to the industry has been pervasive, resulting in costly settlements on pricing and promotional practices, difficulty obtaining clinical trial subjects, high-profile drug withdrawals, and an inability to produce and sell product due to manufacturing halts. Moreover, compliance problems have led to new industry regulations, raising the industry's total costs of compliance as well as financial and reputational risks should noncompliance occur. Since 2000, pharmaceutical companies have paid a total of more than \$3 billion in regulatory settlements and criminal fines.

Meanwhile, other forces are exerting unique pressures on pharmaceutical companies:

- Between 2005 and 2007, 11 blockbuster drugs with combined sales of over \$20 billion will come off patent, resulting in a void not likely to be filled by sales from new drugs.
- Processes around discovery, development, and commercialization are becoming more complex as reflected in the significant investment and time required to commercialize new products, the growing use of outsourcing vendors to provide many of the services once performed internally by the pharmaceutical companies, and recent failures of some drug companies to comply with the myriad of applicable regulations.
- Direct and indirect price controls are squeezing margins in the US and abroad.
- Ongoing merger and acquisition activity in the industry could further exacerbate the issue of broken and inefficient processes as companies struggle to integrate new operations.

These pressures have exacted a toll on the pharmaceutical industry's reputation while fueling the political agenda. An even higher levy may be in store if the industry does not respond effectively to the issues and forces that have already threatened public trust. Aggressive investigations and expanding regulation

*To achieve success, pharmaceutical companies need to implement a strategy that balances the contending forces of profitable and sustained growth while effecting integrity-driven performance across their operations.*



have arguably distracted the industry from its key role as an innovator. And in the absence of trust, the public may demand that government further regulate the industry, driving it toward an alternative business model in which research, development, and drug sales are heavily monitored by the government; or worse, partially or completely annexed by the government. For example, the current concerns over drug safety, if unchecked, could lead regulators to demand lengthier clinical testing periods and slower time to market in the interest of promoting drug safety. Therefore, industry's ability to recover or even profit from costly and risky investments in research and development may be impaired.

Pharmaceutical companies are acutely aware of the importance of trust issues. In fact, the public has witnessed the industry's past attempts to address trust issues through significant investments in compliance and governance processes. Many of these investments have occurred as a reaction to developments rather than a proactive assessment of risk. Moreover, new layers of added compliance load have led to bottlenecks and inefficiencies in the system, causing both increased costs as well as difficulty in obtaining the complete buy-in of operating management, potentially leading to future non-compliance and reputational damage.

In 1949, Charles Franklin Kettering warned that "we should all be concerned about the future because we will have to spend the rest of our lives there." Past failures have proven that a more

comprehensive and systematic approach must be built, based on a full understanding of risks, equipping employees with the tools to achieve compliance, building a culture of compliance that includes a clear and vocal tone at the top, and rewarding employees for behavior that supports public trust.

To renew public trust and begin to reverse the damage to the industry, we believe that pharmaceutical companies must demonstrate that they have recaptured their original humanitarian vision. During 2005 and extending into 2006, PricewaterhouseCoopers' Health Research Institute and pharmaceutical industry leaders will undertake a research agenda to explore issues that intersect with public trust. In this report, a preface to that research, we map a strategy that we believe will provide far-reaching benefit to pharmaceutical companies by enabling them to increase trust with stakeholders and prevent future breakdowns that could otherwise cause a return to the current situation. By implementing a strategy that will be further refined in our upcoming reports, we believe the pharmaceutical industry will have a greater ability to define, target, and manage its business, growth, profit, and communication strategies on its own terms, while also effectively managing regulatory and compliance requirements.

## **Aligning Corporate Behavior With Stakeholder Expectations**

Until recently, drug companies were perceived as profitable and powerful innovators. Championing the blockbuster model of

## CHART 1: NEW REALITIES

### Percentage of those surveyed who think industry is doing a good job serving their customers

*When it comes to reputation, pharmaceutical companies' star has fallen farther.*



Source: Harris Interactive Survey

improving and promoting health for profit, the pharmaceutical industry thrilled its stockholders with high rewards. But drug companies operate in a precarious world in which perception dictates reality, and today's reality is that the public's trust has been shaken. As illustrated in Chart 1, Harris Interactive survey data indicates that the pharmaceutical industry has suffered a decline of 35 percentage points since 1997.

We believe that pharmaceutical companies should better appreciate the breadth and severity of today's perception gap and the resultant impact that this gap can have on their business in the future. A failure to identify all stakeholders and their expectations without considering those views in their overall strategy and to effectively communicate the industry's continuing contributions to the quality of medical care could result in even more costly and invasive regulations, and could also fuel continued negative perception in the media. Serious implications exist longer term if an expectation gap is allowed to expand. For example, the pharmaceutical industry has recently experienced critical legislative scrutiny, due in part to the fact that the public's perception of the industry drives political agendas. Specifically, in the area of drug pricing, pharmaceutical companies struggle with the expectations of their shareholders for continued profit growth and return on investment, the expectations of the public as to availability and affordability of drugs, and the expectations of payors who already believe they are paying too much for drugs. Yet companies often fail to appropriately communicate the

tremendous benefit in terms of cost savings and quality of care that its products provide. If the expectation gap and corresponding issues are not reduced or resolved, the pharmaceutical industry could easily find itself at the mercy of legislators mandating price controls.

To remedy the situation, pharmaceutical companies must first define and understand an ever expanding list of stakeholders. Current stakeholders are arguably more savvy and less beholden to stock performance than the stakeholders of years past. Our research and interviews will provide clarity on the expectations and role that this group of public shareholders, government officials, physicians, clinical trial administrators and participants, academics, and other health industry executives seeks to have in shaping the future of the pharmaceutical industry. This article will seek to define the industry's key stakeholders and their expectations and provide a high-level assessment of the current expectation gaps that the industry must address as a first step to restore public trust.

## Creating A Culture Of Integrity-driven Performance

Pharmaceutical companies are navigating a proliferation of new laws, regulations, and standards across the globe. They are challenged to do so in a way that supports performance objectives, sustains value, and protects the organization's brand while also balancing the identified stakeholder expectations and addressing related gaps.

# Drug companies operate in a precarious world in which perception dictates reality

Of course, issues of risk are not unique to pharmaceutical companies. The 2005 Global CEO Survey from PricewaterhouseCoopers focuses on governance, risk management, and compliance, (“GRC”) a subject of interest to CEOs across the world, and of particular importance to pharmaceutical companies. More than simply a response to burgeoning laws and regulations, GRC is being embraced by the global business community as a means to enhance reputation, brand, impact stakeholders, and drive growth.

PwC surveyed more than 1,300 CEOs to probe their attitudes about GRC, to gauge their progress, and to determine their perceptions of GRC benefits. We discovered that CEOs recognize the significance of GRC and of both the difficulties it entails and the benefits it can potentially provide, particularly at a time when these global leaders are exhibiting as much caution as optimism in their thinking and actions. Despite changing economic and social conditions, bold ambitions among the world’s business leaders persist. Realizing those ambitions requires careful choices. As the CEO survey report strongly suggests, effective GRC can provide the context within which such choices can be better assessed and executed.

We believe that the survey results are especially relevant to the pharmaceutical industry’s effort to renew the trust of their stakeholders, and invite you to read a copy of this report. For example, the survey reported:

- Very few CEOs (7 percent) view GRC as related solely to laws and regulations, and a majority (54 percent) consider GRC to be an integrated set of concepts and practices. Yet, only 25 percent state that they are managing GRC effectively, a concern for those in highly regulated industries, such as pharmaceuticals.
- While a majority of CEOs are very confident that their organizations can respond to GRC matters related to domestic laws and regulations (68 percent) and to internal policies and procedures in domestic business units (57 percent), only 26 percent are very confident that their organizations can respond to similar matters related to foreign laws and regulations and only 24 percent to matters related to internal policies and procedures in foreign business units.
- The CEOs indicate that, in various stages of development, eight significant elements of effective GRC, as further outlined in the CEO survey, are in place at their organizations. However, when asked about full development of these elements, responses ranged from a high of only 53 percent to a low of 22 percent.
- The majority of CEOs surveyed recognize that governance, risk management, and compliance have a positive effect on enhancing reputation and brand. Fifty-eight percent of the CEOs indicate that GRC expenditures are primarily an investment. These executives believe that GRC is a value

The integrated model should effectively coordinate the organization's people with process and technology capabilities so that an integrity driven performance strategy is embedded in the fabric of the organization and linked to individual reward and sustainable shareholder value

driver and a source of competitive advantage. However, only 17 percent of CEOs surveyed said that they can very accurately measure GRC costs.

To address the identified risks to its business model, we believe that pharmaceutical companies must re-engineer a performance model that integrates business integrity, ethics and values as drivers of success, while also positioning governance, risk and compliance accordingly. The integrated model should effectively coordinate the organization's people with process and technology capabilities so that an integrity driven performance strategy is embedded in the fabric of the organization and linked to individual reward and sustainable shareholder value. In this article, we will seek to build on the identified expectation gaps to define a best-practices approach to governance, risk and compliance issues customized to the needs of pharmaceutical companies and their stakeholders. We will also seek to define the elements of a strategy around integrity-driven performance for the pharmaceutical industry. Our ideas will focus on approaches that adapt existing governance, risk, and compliance activities to incorporate a vision that appropriately considers the needs of all relevant stakeholders and supports compliance with both the letter and spirit of relevant laws and regulations. The rewards of implementing such a strategy will also have a direct impact by improving reputation, efficiencies, and stakeholder satisfaction.

## Linking Enterprise Risks and Business Objectives

As drug companies have grown in size, so too have the size and complexity of their operations. Given the intricacies of today's pharmaceutical operating processes, drug companies, like many other large and complex organizations, have difficulty recognizing risks from both internal and external sources, and consequently struggle to effectively manage such risks. Furthermore, managing risk is more difficult as an organization's size increases. In the wake of growth, whether internally or through mergers and acquisitions, pharmaceutical companies must first learn to define and understand risk, and then to manage risk from a broader strategic enterprise view. A multi-faceted approach to break down risk management silos and connect all related compliance obligations, while also aligning external and internal risks with regulatory requirements, stakeholder expectations, and business processes will assist pharmaceutical companies in integrating a culture of integrity-driven performance while also providing a framework for monitoring performance. Had risk management tactics been in place in the past, we propose that the industry would not be situated in the defensive position in which it finds itself today, as it would have identified and reacted to problems earlier in the cycle and thus avoided many of the issues igniting recent attention.

Many organizations are utilizing the recently established COSO ERM framework, which is quickly becoming the accepted standard for enterprise risk management (“ERM”). ERM is a comprehensive, systematic approach for helping organizations identify events and measure, prioritize and respond to the risks challenging their most critical objectives and related projects, initiatives, and day-to-day operating practices. We believe that pharmaceutical companies must use enterprise risk management techniques to understand and embed risk management into business processes, including strategic planning, capital budgeting and performance management and reporting, to drive a successful and reputable business model. Otherwise, pharmaceutical companies will continue to take a reactive approach to issues and challenges, and risk additional compliance and reporting regulation requirements.

In this article, we will describe a framework and considerations for implementing an ERM approach that operationalizes integrity-driven performance strategy to adapt or build the infrastructure necessary to meet refined corporate objectives, stakeholder expectations, and management expectations. ■

## About PricewaterhouseCoopers

### Global Pharmaceutical Industry Group

PricewaterhouseCoopers’ Global Pharmaceutical Industry Group is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and healthcare products companies. As the global leader serving the industry, we have extensive experience in working with companies on industry-specific strategic, operational and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialized capabilities in regulatory compliance, risk management and performance improvement. In helping our clients, we draw on the full knowledge and skills of the firm’s professionals. More than 120,000 people in 143 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.

### Health Research Institute

PricewaterhouseCoopers’ Health Research Institute provides new intelligence, perspective and analysis on trends affecting all health-related industries, including healthcare providers, pharmaceuticals, health and life sciences and payers. The Institute helps executive decision-makers and stakeholders navigate change through a process of fact-based research and collaborative exchange that draws on a network of more than 4,000 professionals with day-to-day experience in the health industries. The Institute is part of PricewaterhouseCoopers’ larger initiative for the health-related industries that brings together expertise and allows collaboration across all sectors in the health continuum.

## PricewaterhouseCoopers Contacts

### Pharmaceutical Industry Group

**Anthony Farino**

US Pharmaceutical Advisory Services Leader  
+1.312.298.2631  
anthony.l.farino@us.pwc.com

**Mark Simon**

US Pharmaceutical Industry Leader  
+1.973.236.5410  
mark.d.simon@us.pwc.com

**Simon Friend**

Global Pharmaceutical Industry Leader  
+44.207.213.4875  
simon.d.friend@uk.pwc.com

**Peter Claude**

Partner  
+1.973.236.4289  
peter.claude@us.pwc.com

**Pat Roche**

Partner  
+1.973.236.4844  
pat.d.roche@us.pwc.com

### Advisory Board

**Brian Riewerts**

Partner  
+1.410.783.8920  
brian.riewerts@us.pwc.com

**Jonathon Kellerman**

Director  
+1.267.330.2466  
jonathan.l.kellerman@us.pwc.com

### Health Research Institute

**James H. Henry**

Partner and Chairman Health Industries Group  
+1.678.419.2328  
jim.henry@us.pwc.com

**Kelly Barnes**

Partner in Charge  
+1.214.754.5172  
kelly.a.barnes@us.pwc.com

**Sandy Lutz**

Director  
+1.214.754.5434  
sandy.lutz@us.pwc.com

**Alison Detwiler**

Research Manager  
+1.703.610.7459  
alison.detwiler@us.pwc.com

---

For copies of this report and also to obtain a copy of  
PricewaterhouseCoopers' 8<sup>th</sup> Annual Global CEO survey,  
please contact:

**Attila Karacsony**

Marketing Director, Global Pharmaceutical Industry Group  
+1.973.236.5640  
attila.karacsony@us.pwc.com

**Lucy Mair**

Senior Marketing Manager, European Pharmaceutical Industry Group  
+44.121.265.5360  
lucy.mair@uk.pwc.com

NY-FP-05-1026-A © 2005 PricewaterhouseCoopers LLP. "PricewaterhouseCoopers" refers to PricewaterhouseCoopers LLP, a Delaware limited liability partnership or, as the context requires, the network of member firms of PricewaterhouseCoopers International Limited, each of which is a separate and independent legal entity.

[www.pwc.com/pharma](http://www.pwc.com/pharma)