

KNOWLEDGE, WEALTH AND INFORMATION: THE CASE FOR GLOBAL CORPORATE DISCLOSURE STANDARDS

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Allen L. White, Ph.D.
Vice President and Senior Fellow
Tellus Institute
Boston, USA
awhite@tellus.org

After two years of gradual revelations concerning undisclosed information on suicidal risks of anti-depressants to children, a US Federal Advisory Committee in September 2004 recommended that such drugs be labeled to alert physicians and consumers of the risk of suicidal behaviors associated with them. The recommendation, whose impetus was drug trial information developed by the UK-based firm GlaxoSmithKline (GSK), emerged amidst considerable scientific uncertainty and continuing public scrutiny of the quality and effectiveness of FDA's drug screening and approval process.

The episode began in 2002 when an FDA official, Dr. Andrew Mosholder, reviewed data submitted by GSK on its anti-depressant, Paxil, for FDA review.ⁱ In its filings, the company used the term "liability" for Paxil users relative to patients who received a placebo. In May 2003, supplemental company filings indicated higher rates of suicidal behavior than placebo recipients, and that the drug offered no better results than patients administered placebos.

After requesting similar information from other anti-depressant makers, including US and Swiss firms, covering 22 studies and 4,250 children, Mosholder concluded that children using drugs were nearly twice (1.89) as likely to become suicidal than those administered a placebo. The FDA questioned Mosholder's findings, and contracted with Columbia University to review and expand the inquiry. The results, released in 2004, essentially confirmed Mosholder's conclusion: the relative risk factor was 1.78 among anti-depressant users relative to placebo users. At that juncture, medical professionals and patients were left to decide whether the risks are worth the potential gains, a decision complicated by the paucity of alternative proven tools to combat childhood depression.

Disclosure in a globalizing world

The anti-depressant story is noteworthy in its own right, shedding light on the tangle of legal, regulatory, economic and ethical issues surrounding disclosure practices in the pharmaceutical industry. At the same time, it is instructive at a higher level of inquiry, one that emerges upon stepping back from the immediate controversy to the sources, ownership, and dissemination of knowledge in a globalizing world.ⁱⁱ

In the 21st century, business assets—capital and technology, goods and services—increasingly move unimpaired across frontiers. The march toward elimination of trade barriers and the creation of regional and global trade agreements continues to move forward, notwithstanding disagreements among nations as to its pace and details. While the emergence of a global economy is viewed by most as inevitable and probably irreversible, heated debates over who wins and who loses remain intense and unresolved. At the same time, international agreements and organizations that mirror and accelerate an increasingly interconnected world seem destined to become permanent fixtures of international relations in the 21st century. Agreements governing patent protections and world trade are critical lubricants in the transnational flow of tangible (petroleum and computers) and intangible (intellectual property and brands) assets embodied in goods and services.

Alongside these developments is a parallel international regime, still fluid and fragmented, but with an overarching focus of infusing a moral dimension into the global economy and the markets upon which it is built. This regime, sometimes called “soft law” owing to dependence on voluntarism and moral persuasion rather than legally enforceable agreements, comprises dozens of codes, principles, standards and guidelines.ⁱⁱⁱ Many are championed by multilateral organizations: the United Nations’ (UN) *Universal Declaration of Human Rights* and *Global Compact*, the Organization for Economic Cooperation and Development (OECD) *Guidelines for Multinational Enterprises* and *Principles of Corporate Governance*, and the International Labour Organization (ILO) *Core Labour Standards*. Others were given impetus by civil society organizations and evolved into multi-sectoral (business, civil society, labor and government) arrangements; e.g., the Global Reporting Initiative and Transparency International. Still others are the products of the business community; e.g., the *Caux Principles* and the International Chamber of Commerce’s *Principles for Sustainable Development*.

In the sweep of the last half-century, these two emergent, parallel regimes have served discrete but complementary purposes. In the aftermath of WWII, it was clear that new forms of global governance would be essential to both secure the peace and to establish the new ground rules of international relations to avert the catastrophic consequences of a third global conflict. This recognition spawned the International Monetary Fund, the World Bank, and the International Finance Corporation, which were designed to accelerate and spread economic development across nations and regions. The birth of the UN, the Universal Declaration of Human Rights, the development of “core labor standards” under the aegis of the ILO, and a host of environmental accords and conventions collectively represented an effort to infuse a moral dimension into the post-War geo-political landscape. Balancing the rights of those who benefit from globalization with a set of generally accepted obligations remains a work in progress.

While advances have been made on both fronts, it has been an erratic and uneven trajectory. The rights of corporations to trade freely in products and services are arguably the most mature, outpacing the evolution of enforceable, universal rights that protect

individuals, workers and the environment. The ability of corporations to mobilize and represent their shared interests is a powerful driver of such progress. Though the contours of corporate obligations are gradually becoming more sharply delineated,^{iv} the absence of accountability and enforceability at the international level remains a major stumbling block to achieving parity between rights and obligations. As recently as September 2004, UN Secretary General Kofi Annan made this point before the UN General Assembly: “Those who seek to bestow legitimacy must themselves submit to it, and those who invoke international law must themselves submit to it.”^v

Knowledge and wealth creation

For most of the five centuries since conception of the earliest corporations in Europe, wealth generation has been principally measured by tangible assets. Indeed, the early joint partnerships—the precursor to the modern “limited liability” corporation—brought together clusters of investors whose goals were to discover, transport and trade as many physical assets as possible. These assets encompassed both human and non-human, ranging from the minerals and crops slaves in the 17th and 18th centuries to manufactured goods in the 19th century and beyond.

Along this historical trajectory, applied science played a critical role in enabling the shift from cottage to factory production. The invention of the steam engine in 1712, arguably the most seminal event of the early industrial era, ushered in a new capacity to process raw materials into intermediate and final products at unprecedented scales and speed. The science and engineering embodied in such inventions was indispensable to the sweeping economic transformation of the late 18th century.

Wealth creation of this nature and scale spurred a parallel transformation in the character of the corporation itself. As new technology unleashed seemingly limitless potential for wealth generation, a wave of capital needs and capital owners’ rights swiftly followed. To meet such demands, the modern limited liability corporation gradually displaced the joint stock company in which small numbers of investors were close to or directly supervised day-to-day operations.^{vi} This occurred because the scale of capital required to support expansion outpaced the capital resources of small numbers of joint stock owners. As detached investors became the predominant owners, their sheer numbers led to the continuous devolution of decision-making to corporate management with minimal oversight from those who held stock in the company. The corporation that took shape in the mid-19th century would become the corporate form that dominated global commerce for the next century and a half.

By the 1920s, the frailties of largely unbridled corporate rights coupled with minimum responsibilities began to surface. As corporations such as AT&T, General Motors, Standard Oil and US Rubber witnessed unprecedented expansion, profitability, and influence, anxiety about the long-term social consequences of such a trajectory became increasingly prominent. The idea that corporations can and should be left totally unregulated underwent a wave of scrutiny. Triggered by a backlash against labor practices, monopolies/oligopolies and sheer unfettered growth, the notion that

government had a legitimate role in regulating corporate behavior gradually began to take hold.

The stage was set for unprecedented government intervention in the operations of corporations. The catalyst that unleashed such intervention was the collapse of the stock market in 1929 and the ensuing Great Depression that threatened to, though never succeeded in, remaking the fundamentals of both the form of the corporation and the capitalist economy in which it operated.

Enter standardized disclosure

While the fundamental corporate form and the capitalist economy remained intact, the New Deal did create a host of regulations and social safety nets for the various groups that suffered from the national economic free-fall. Job programs, social security, and securities regulations redefined the relationship between government, business, workers and the public. This redefinition of government's role produced another seminal outcome—the idea that publicly-held corporations, as part of their license-to-operate, must be held accountable to their shareholders through regular, consistent and audited disclosures of their financial condition.

While in retrospect it may seem unimaginable that such disclosures were essentially absent before the creation of the Securities and Exchange Commission (SEC) in the 1930s, this indeed was the case. The absence of such disclosures was arguably the most powerful force that a few years earlier drove the collapse of capital markets. By the early 1930s, even large corporations recognized that markets without reliable information could not survive, and that such conditions would undermine legitimacy and ultimately lead to even more aggressive governmental intervention.

Hence, the foundations of modern corporate financial reporting were put in place, and would continue to evolve through the present, spawning and redefining numerous quasi- and professional organizations such as the Federal Accounting Standards Board (FASB) and the American Institute of Certified Public Accountants. The definitions, protocols and scope of such reporting reflected the view that investors were the first and foremost audience for corporate disclosure. Workers, consumers, communities and other parties were essentially disregarded, and would remain so for the next half century. Accounting rules underlying the reporting mirrored the prevailing economic views that the performance of the corporation and the value of the organization were based on physical assets such as factories, equipment and inventory. Labor was an input, equivalent for accounting purposes to materials, energy, and water and, as such, something to be minimized and recorded as an expense for accounting purposes. Intangible assets—scientific knowledge, information systems, management systems and reputation—had essentially no place in the early accounting systems and the resulting corporate reports.

New forms of knowledge and value creation

While the dominant corporate form remained largely unchanged during the 20th century, the source of wealth creation has not. In the US, as in most industrial nations, profound structural changes have occurred in the makeup of the national economy, the role of knowledge in wealth creation, and the associated assets that business creates and seeks to protect. These changes, we will see, also led to major changes in the nature of corporate disclosures. Basic financial information such as income statements, balance sheets and cash flow—though still core disclosures—are increasingly recognized as inadequate to capture a complete picture of either the company’s financial condition or its performance relative to emerging norms of corporate responsibility.

Structural changes in the nation’s economy began in earnest after WWII. The economy moved from a predominantly industrial base dependent on materials throughput to create physical products, to knowledge-based industries in which value is rooted in human intelligence. As technology-intensive sectors such as medical instruments and semi-conductors have expanded, machine tools and appliances have declined. Meanwhile, the workforce of traditional manufacturing sectors—chemicals, autos, textiles—in the last half of the 20th century shifted to more knowledge-intensive industries tied to science and technology; e.g., biotechnology, semiconductors and aerospace.

Currently, even within traditional industries, value is being created in new ways. Auto manufacturers, witnessing a convergence in price and quality across producers, are investing major resources in technological innovation for hybrid fuel vehicles and in-car electronics such as global positioning systems and electronics to entertain backseat passengers. Segments of the chemical industry—DuPont, for example—are shifting dramatically away from bulk (commodity) chemicals to science-intensive advanced materials and biotechnology.

Pharmaceuticals, by nature a knowledge-based industry, has been the single most profitable US business sector in the last few years. It regularly forms alliances, partnerships and joint ventures with kindred industries such as biotechnology, diagnostic, health care and information services—all knowledge-intensive sectors. Alan Greenspan, Chairman of the US Federal Reserve System, puts it succinctly: “An ever-increasing share of the Gross Domestic Product has reflected the value of ideas more than material substance or manual labor.”^{vii}

Paradoxically, it remains highly unusual to see quantitative measures of the scientific, technological and innovative capacity—or any other surrogate for knowledge-driven value creation—appearing in company annual reports in a consistent and comparable form. Indeed, balance sheets remain notably unbalanced when it comes to disclosing the quantity and quality of all forms of human capital, much less details of the scientific activities of the firm.

For this reason, it is hardly surprising that on Wall Street companies such as Microsoft, Intel, Cisco or GE often see their market value (value per share x number of shares)

exceed “book” value (dominated by traditional physical assets) by factors of five and higher. While this discrepancy is not entirely explained by the absence of knowledge assets in financial statements, it is a particularly powerful factor in science and technology-based companies. Consistent with the overall trend, 1997 marked the first time in US history that investments in intangibles such as research and development (R&D), training and brands, estimated to total \$1 trillion, exceeded investments in property, plant, equipment and other tangibles.^{viii}

Corporations as knowledge gatekeepers

The ongoing shift to a knowledge economy may not be a seamless and smooth economic transformation, as the dot.com bust vividly demonstrates, but surely it is a trend that will continue in the US and other industrial nations. In the view of many, the trend will accelerate in the coming decades in key emerging economies such as India and China, where science and technology education promises to compete in coming years with the traditional leadership of the US and Europe.

The developed countries will continue to increasingly rely on scientific and technological innovation to create and supply product and service markets. Efficiency gains in production processes combined with longevity gains in the lifespan of products tend to neutralize cost and quality differentiation among companies that produce comparable products. This leaves the application of cutting-edge science and technology—the next generation computer chip, a breakthrough HIV/AIDS drug, a hydrogen vehicle—as a future driver of value. Even in developing countries, “appropriate” technology is likely to play a leading role in meeting basic needs of the world’s poor for food, potable water, shelter, health services and education. Computer-based education and literacy programs, micro-enterprises based on mobile phones, and small-scale, dispersed renewable photovoltaic electricity production are examples of knowledge-based innovations that potentially alleviate poverty at the same time that they offer business opportunities to local, national and multinational entrepreneurship.^{ix}

As these trends unfold, the evidence of financial returns to knowledge assets emerges.^x A clear association exists between patent activity and share price as well as patent activity and market-to-book ratios (an indicator of the spread between investor perception of company prospects and the totality of its conventional, largely tangible assets). Consistent with these findings are related results: overall returns to R&D exceed corporate cost of capital (how much a corporation pays to borrow money or raise equity capital); and returns to basic (fundamental) research are substantially higher than returns to applied and process R&D. Thus, the more upstream the knowledge creation, the greater the interest of investors.

The implications of these trends for protecting and commercializing knowledge are profound. As the relationship between knowledge assets and financial returns intensifies, so will the pressure on corporations to protect the knowledge assets they possess and to pursue those they do not yet control. Of course, such behavior is not new. Indeed, the entire infrastructure that protects intellectual property—20 years, for example, in the case

a drug patents—is premised on the notion that knowledge owners deserve property rights, and that such protections are in the public interest because they reward and stimulate new inventions.^{xi}

Thus, as knowledge assets play an increasingly powerful role in the national and global economy, the stakes to secure and extend protective measures increase commensurately. It is no surprise that some of the most divisive episodes in international economic relations center on protection of property rights. Illustrative cases include consumer entertainment products in China, generic drug manufacturing in India, and European Community (EC) actions against Microsoft product protection. These reflect the unsettled state of international rules, and pressure to agree on rules that protect what companies, and evidently investors, perceive as essential sources of future value in the global economy.

The cost of non-disclosure

What, then, may be said of the social cost of non-disclosure? Earlier reference to the role of non-disclosure in triggering the 1929 stock market crash is a stark, early episode of the consequences of transparency breakdowns. This episode was a harbinger of a continuous debate over corporate disclosure that, to this day, remains very much unsettled and observable in various scales of corporate activities—site, national and global.

From the vantage point of the scope of disclosures, the inadequacies of conventional financial reporting become more acute with each step toward a knowledge-based economy. The gap is widening between accounting methods, measurement tools and financial reporting on the one hand, and the sources of value creation through knowledge assets on the other. Under the umbrella of “information asymmetries,” Baruch Lev suggests the following adverse consequences for one key stakeholder—the investor community—as well as society in general:^{xii}

- **Abnormal gains to informed investors**, for example, when managers hold inside information on the early results of drug trials that, once made public, will increase the stock they hold in the company
- **Deterioration in investors’ confidence in the integrity of markets**, leading to suboptimal trading volumes and transactions, and low overall efficiency in resource allocation across sectors and companies
- **Increasing cost of capital** drives investors to seek higher returns to offset the perceived higher risk of companies with substandard disclosure practices, translating to higher costs of goods and services for society as a whole

Corroborative findings have appeared recently in studies by ratings organizations that assess the risk and investment quality of publicly traded companies.^{xiii} Telling evidence appeared as early as the mid-1960s when over-the-counter markets saw a dramatic reduction in stock price volatility once mandatory disclosure standards were imposed. More recently, a 2002 Standard and Poor’s analysis of the disclosure practices of 1,500 companies found that the “amount of information companies provide in their annual

reports is correlated to the market risk and valuations,” specifically, a higher price-to-book ratio and the ability to lower the cost of capital.

Related to disclosures of a social and environmental nature is the financial performance of corporations that publish annual “sustainability reports” using the Global Reporting Initiative (GRI) framework. The GRI guidelines cover a wide range of environmental, social and economic indicators that reach well beyond conventional financial reporting.^{xiv} Among these indicators are many that, while less than perfect, act as rough proxies for the knowledge assets of the organization. Recent findings indicate that GRI reporters, which as of this writing number about 600 corporations in over 40 countries, show a moderately positive correlation with lower share price volatility, higher operating profits and revenue growth.

Collectively, these findings point to two critical aspects of the linkage between disclosure, value and assets. First, higher standards of disclosure in general build confidence and efficiency in capital markets, with attendant benefits accruing, at minimum, to investors and, at best, to other stakeholders such as employees and customers, depending on how these benefits ultimately are allocated across stakeholder groups. Second, disclosures specifically related to the quantity and quality of knowledge-based assets—capacity to innovate, resources dedicated to employee training and education, levels of R&D expenditures—contribute to value creation. The convergence of these two streams suggests that public policies that drive higher standards of non-financial disclosures, especially those that relate to knowledge-based assets, are likely to yield a range of social benefits that, at this juncture, remain only minimally realized.

Emerging international disclosure standards

Amidst a rising tide of questions surrounding the rights and obligations of corporations in a globalizing economy, disclosure standards is a key, cross-cutting issue that intersects virtually all aspects of the corporate responsibility agenda. Indeed, it has been argued that transparency in general is *the* defining issue of the 21st century in terms of fostering democracy and open societies in the 21st century.^{xv} While issues such as corporate governance, fair labor standards and environmental impacts are actively debated in business, civil society, labor and government circles, the question of how and when to disclose information occupies a central place in the corporate responsibility discussion. What should be the scope and content of such disclosures? In what form? To whom? Through what media? And how can users be assured that the information is complete, accurate and relevant to their needs?

These expectations have led to a multitude of principles, guidelines and standards that are gradually elevating the idea of corporate disclosure of non-financial information to a global norm.^{xvi} Originating in the “right-to-know” movement in the US, strengthened by related initiatives in the EC of the 1990s, and brought to the global stage via the “corporate accountability” theme at the UN’s 2002 World Summit on Sustainable Development in Johannesburg, corporate disclosure is now a central theme in virtually all debates concerning the future of the corporation. Meanwhile, the episodes of Enron,

WorldCom, Ahold, Parmalat and related transparency failures since 2000, while focused on traditional financial information, have deepened concerns with the quality of corporate reporting of non-financial information.

Among these many initiatives, GRI is particularly relevant to the knowledge assets that are the focus of this paper.^{xvii} Conceived in 1997 by CERES, the Boston-based environmental advocacy group, with technical leadership by Tellus Institute and a partnership with the United Nations Environment Programme (UNEP), GRI in less than five years grew from a bold, but untested vision to the leading international standards institution for non-financial reporting. Approximately analogous to the London-based International Accounting Standards Board (IASB) whose mission is to harmonize global financial accounting rules, GRI's mission is to create and continually enhance a generally accepted framework for reporting social, environmental and economic (apart from financial) performance at the organizational level.

The GRI story is instructive for several reasons. First, the initiative was conceived and brought to fruition as a global standards body under the leadership of civil society organizations, not business or government.^{xviii} After a decade of disparate, national-level efforts to strengthen social and environmental disclosure, GRI filled a leadership vacuum in corporate disclosure. By the late 1990s—a decade after the seminal events of the Bhopal chemical tragedy in India and the Exxon Valdez oil spill in Alaska—transparency practices were becoming increasingly troublesome for both reporters and report users. While increasing numbers of corporations were disclosing their environmental (and to a lesser extent, social) performance, the credibility of reports was severely undermined by the absence of an independent, neutral, legitimate mediating institution that could establish and steward a reporting framework. This was the need, and opportunity, that inspired GRI.

Second, unlike financial reporting whose principal audience is investors, social and environmental information has a far broader constituency, e.g., activists, employees, communities, consumers and suppliers. To create a credible, generally accepted framework, GRI would need to create a process in which the views and voices of multiple constituencies were convincingly represented. Thus, a multi-stakeholder approach to technical work and institutional governance became indispensable to GRI from its earliest stages onward.

Third, while many approaches to non-financial reporting had emerged beginning in the late 1980s, the field was essentially in its infancy at the moment of GRI's conception. This stands in contrast to 75 years of modern financial reporting, through which definitions, methods and protocols had evolved into an elaborate—though still imperfect and evolving—accounting and reporting framework. For GRI, such uncharted terrain was both a hurdle and an impetus. The principal hurdle was, and still is, the elevation of non-financial reporting to a level equivalent to financial reporting. Absent government mandates and institutions such as FASB and the SEC, GRI was faced with the concurrent challenge of demonstrating the *imperative* of standardized non-financial reporting at the

same time as achieving the *technical excellence* to establish itself as the global leader in the field.

This dual challenge was the impetus to action. Unlike financial reporting, which evolved on a country-by-country basis, GRI was conceived at the outset as a global framework, facing a pathway relatively free of powerful competing institutions and traditions such as national financial accounting boards, professional accounting bodies and securities commissions. While it would have to remain attentive to the many disparate corporate and national level efforts in non-financial reporting, a window of opportunity existed to build a global framework and institution without the inertia facing organizations such as IASB.

Fourth, the nature of non-financial reporting has required innovation that builds on, but moves beyond, generally accepted practices in financial reporting. Three examples illustrate this critical point: principles of reporting, sector-specific disclosures, and qualitative indicators of performance.^{xix}

Core **principles** that transcend specific rules, protocols and metrics underlie contemporary financial reporting. Examples of such principles are timeliness, completeness, auditability and materiality (i.e. relevant to investor decision-making). For non-financial reporting, GRI similarly needed to develop principles to ensure rigor and comparability of non-financial reports that use the GRI framework. It could not, however, simply import wholesale those from the financial domain, because the nature of non-financial reporting, covering issues as wide-ranging as corporate governance, labor standards, product safety and worker health, speaks to audiences that include but are not limited to investors.

Thus, in GRI's reporting principles, in addition to adaptations of the familiar financial reporting principles, there appears "sustainability context" that situates reported information in a broader social and environmental context, e.g., nationally or internationally recognized goals or targets, beyond the boundaries of the reporting company. Also appearing is "inclusiveness," a signal to reporters that systematic stakeholder consultation is a precondition to shaping the final content and scope of disclosures contained in a GRI report. For example, applied to a pharmaceutical company,^{xx} these principles may imply that a reporting company describe its role in addressing national or global health priorities such as affordable drugs, remedies for widespread tropical diseases, or contributions to combating the HIV/AIDS pandemic. It also implies that the ultimate content of such reports would be based on serious consultations with the company's stakeholders such as medical professionals, health care institutions, patient groups, and underserved communities.

Sector-specific standards are a second point of divergence between financial and non-financial, GRI reporting. Why is this the case? Mining, auto and financial services share certain attributes that are amenable to comparison. All, for example, use energy in their products and services, have various salary levels, and are responsible for product and service safety. But within each sector, the significance of these shared attributes in

assessing an organization's social, environmental and economic performance varies widely. Energy use in financial services represents a substantially smaller fraction of the firm's total "footprint" than, say, an oil or auto company.

For this reason, GRI's reporting framework operates at two tiers: a generic set of indicators applicable to all sectors, combined with sector-specific indicators that capture the specifics of different types of organizations. Tons of carbon emitted per unit of production, reportable workplace accidents per 100,000 person-hours worked, and salary ratio between top paid and average employees exemplify the range of measures that help measure and communicate non-financial performance for all companies. But production and sales of toxic substances and company policies regarding disclosure of drug trial information are germane only to specific types of companies, in this case, producers and users of significant quantities of chemicals and drug companies, respectively. While Wall Street is accustomed to a few leading financial indicators and indices, non-financial performance—with all its complexities—lacks a common denominator (dollars) and thus cannot be reduced to such elegance.

Qualitative indicators are a third point of divergence, although this divergence is more one of weight than absolute difference. Although financial accounting rules strive to produce comparable, quantitative results across companies, the resulting financial reports are routinely accompanied by non-quantitative information. This is expected by investors to aid in understanding a company's strategy, technology innovations, competitive position and other critical aspects of its operations and financial prospects. Information of this nature is actually required under US SEC rules in so-called Management Decision and Analysis and similarly in the UK under the heading of Operating and Financial Review. In both countries, and in others like Canada, government regulators find themselves under increasing pressure to enlarge the scope of these disclosures to include environmental and social information that is pertinent to investor decision-making.^{xxi}

In the case of non-financial reporting, a much younger and more fluid field than financial reporting, no presumption of quantifiability exists. A review of the 2002 GRI Guidelines reveals a broad spectrum among the 50 core indicators as well as the additional (more experimental) ones; the consensus view of the GRI process is that to characterize social, environmental and economic performance requires more than numbers. Textual explanation must reveal how and why boards think, management decides, employees behave, customers respond and communities benefit from a company's actions.

This does not mean reporters must choose between the two approaches. The optimal mix of the quantitative and qualitative varies across companies, sectors and locations. For example, a start-up pharmaceutical company manufacturing generic drugs has a different story to tell, and a different way of telling its story, than a mid-size US firm that caters exclusively or primarily to US markets.

Mission and markets in the pharma sector

Just weeks after the anti-depressant disclosure episode was headline news, a second drug disclosure story with strikingly familiar features created its own waves in the medical, business, and government communities. “Good riddance to a bad drug” read an op-ed piece in a leading newspaper.^{xxii} Medicine and money, prescriptions and profits, again was headline news.

This case involves Vioxx, an arthritic pain drug with sales of \$2.5 billion produced by Merck, representing 11 percent of the company’s annual revenues, and used by 2 million people worldwide. An estimated 80 million people have used the drug. Vioxx is part of a family of drugs known as COX-2 inhibitors that generate some \$5 billion each year in the US and \$6 billion worldwide. Pfizer’s Celebrex and Bextra are in the same family; another six related drugs in development by Merck, Novartis, GSK, Pfizer, Yamanouchi and Sankyo are in the FDA approval process.^{xxiii}

Merck’s decision to suddenly remove the drug from the market came in the wake of rising concern about associated risks of heart attacks and strokes after FDA originally approved the drug in 1999. As early as 2001, a study published in the *Journal of American Medical Association* found that Vioxx was associated with five times greater risks than an over-the-counter anti-inflammatory with similar benefits. In the following years, various studies of Vioxx’s risks and benefits were conducted, including the most recent by Merck itself, which triggered withdrawal of the drug. The latter, focused on the benefits of Vioxx in reducing colon polyps, yielded the surprising and “stunning” (in the words of Merck’s president of research) result that the drug increased risk of heart attacks and strokes from 1.9 to 3.5 percent relative to a placebo.

Merck’s decision to withdraw the drug came at a high cost. The company spent \$45 million promoting the product in the first half of 2004 alone, an example of direct-to-consumer marketing that increasingly characterizes the industry.^{xxiv} Removal of the drug was as much a business story as medical one. Merck’s stock fell 27 percent, and its market value fell by \$25 billion. It was largely responsible for a decline of 0.6 percent in the Dow Jones Industrial average, the leading indicator of overall market performance.

The Vioxx incident illustrates once again the complexities and crosscurrents of managing and disclosing critical knowledge assets—in this case, those embodied in a leading revenue generator. In the five years since its FDA approval, the drug was scrutinized for its possible risks at the same time that company employees and their consultants published results that challenge such hypotheses. In April 2002, as a result of ongoing research, FDA requested that Merck add heart attack risks to Vioxx’s label, which it did. This form of disclosure to consumers is commonplace in the warnings—both verbal and written—that accompanies the direct-ad campaigns that appear in the mass media.

The larger context of the Vioxx story is seen often in the development and marketing of new drugs.^{xxv} For many years, trends in the pharmaceutical sector have revealed a changing business model. While large sums of R&D funds support drug research, far more—an estimated three times more—is spent on marketing and administration.^{xxvi} Moreover, the industry’s emphasis increasingly is on variations of existing products rather than breakthroughs. The economics of such developments are compelling, since patent protections can be granted for relatively minor changes in a drug’s make-up. If accompanied by effective advertising, these minor differences allow sibling drugs to generate new revenue streams while incurring relatively low R&D costs. The economics are made even more favorable since the “R” in R&D is heavily subsidized by public support of the government’s vast medical research infrastructure.

Disclosure practices in the \$200 billion pharmaceutical sector^{xxvii} are influenced heavily by economic considerations. Company involvement in funding and designing drug trials is pervasive. A typical study compares a drug’s effectiveness against a placebo, rather than against an existing drug of a comparable nature. Drug trials, pre- and post-approval, are subject to negotiation with FDA, rather than decided by an independent body with no financial interests in their outcome and working in the public interest. The net result of these conditions is a bias in what appears in journals as well as labels; information is effectively weighted as much by the financial interests of drug makers as by the need to understand and regulate the drugs themselves.

This disclosure culture manifests itself at a higher level as well. With very few exceptions,^{xxviii} non-financial reporting among drug companies lags behind other sectors in terms of best practice. In GRI’s experience, amidst keen interest from telecommunications, financial services, auto and other sectors to develop sector-specific reporting frameworks, the pharmaceutical sector has resisted such an initiative. Pharmaceutical companies, intensely competitive and highly sensitive to proprietary information, have lagged behind these other sectors. Though most of the major firms produce some type of non-financial “sustainability,” “social” or “citizenship” report, it is rare that such reports represent leading-edge disclosure standards.

The irony of this situation is that drug companies—more than most other industries—represent an industry whose business literally is the preservation and enhancement of life. Yet by current disclosure standards—either at the specific drug or corporate level—it is difficult to find leading practices. The recent stories of anti-depressants and arthritic drugs are a reminder of how serious the shortfalls are and how far the industry has to go before meeting emerging global expectations and standards of disclosure.

Visioning pharma disclosure

Disclosure has been brewing for some time as a volatile issue in the pharmaceutical industry. The last two decades have witnessed a marked shift in virtually all aspects of the drug “chain”—research, trials, approval, education, information—from public to private sector. As government funding sources have declined and the costs of medical

care have spiraled upward, the influence of pharmaceutical companies has increased exponentially.

Such influence has not been accompanied by a commensurate upswing in transparency. Indeed, its reputation for secrecy is well-deserved, despite the fact that it relies heavily on public regulation to maintain its competitive advantage. NIH-funded research remains the cornerstone of basic pharmaceutical research, which companies rely on for eventual commercialization of new drugs. Federal government approval via FDA is the lifeline of the industry, a fact undiminished by the companies' funding since 1992 of a portion of new drug approvals.^{xxix} And patent protection of both new and variant products (minor changes to an original formulation) ensures revenue streams for many years. In short, perhaps more than any other sector, pharmaceuticals is intimately entwined with public agencies and public monies.

The implications of this relationship for disclosure are profound. If public regulation, monies and health are so closely coupled, then the case for high standards of transparency becomes even more compelling than the case in other business sectors. Unlike most other consumer products, which are tied to convenience or fad, drugs are unique in terms of their impact on human well-being. Transparency becomes not only a question of ethics and integrity. It is equally a matter of survival for those who elect to consume the prescribed medicine.

A future disclosure regime must be based on the principle that medical knowledge is a public good. A disclosure regime must begin with best practices emerging in other industries, such as those in GRI's auto, mining, telecommunications and other sector supplements. This would be a starting point, but not an end in itself. Pharmaceuticals must step beyond emerging standards to disclose information at all stages of the product chain, including research, development and post-commercial use.

The disclosure system must divorce commercial interest from scientific content, which is a situation far from the current reality. It must be dynamic and in real-time, such that information relevant to decision-making by medical professionals is delivered in a timely manner from sources and through conduits that have no commercial interest in the content of the published information. It must be a system that puts to rest the anxiety that decisions may be based on information tainted by self-serving drug-makers. It must achieve—indeed exceed—the test of integrity that truly independent audits of financial statements bring to company financial reporting. And it must adhere to the principles of inclusivity, timeliness, completeness, relevance and other emerging norms applied to non-financial disclosure.

Prescriptions to overcome the disclosure shortcomings of the pharmaceutical industry, spurred by the recent flurry of transparency breakdowns, range from moderate to radical. Already, voluntary Internet posting of information on *all* drug trials is underway by some major drug companies, prompted by revelations of non-disclosure of trials partially completed and/or those that demonstrate negative or inconclusive results. This is a small step in the right direction. But it begs two fundamental questions: Who owns medical

science? And should the pharmaceutical industry, by nature of its products, be classified as a kind of public utility with regulated expenditures, rates of return, and the standards of transparency that well exceed other sectors less vital to human well-being and survival?^{xxx} The trends during the last decade in corporate-government-academic relations suggest that these questions deserve serious attention in health policy debates in the coming years.

Way forward

All signs point to the continued emergence of social, environmental and economic disclosures as an integral and indispensable component of corporate responsibility. This evolution, still little more than a decade old, remains a work in progress in terms of scope, scale and content. It stands where financial disclosure was a half century ago—formative and experimental.

For companies operating in global markets, a shift in perception and practice relative to disclosure is clearly discernible. In the 1990s, a few pioneering companies in North America and Europe, largely prompted by bad press surrounding environmental or human rights incidences, began publishing non-financial reports. Hundreds more followed these early innovators, recognizing such reports as an emerging best practice. By the year 2000, an estimated 1,500-2,000 companies had adopted the practice, with numbers steadily increasing each year. This trend continues today.

As non-financial reporting has swiftly moved from the extraordinary to the exceptional to the expected, the case of global standards becomes more compelling. Full and balanced disclosure is taking its place along side human, labor and environmental rights as a generally accepted, universal norm for business. Like these rights, the “right to know” is part of doing business in the 21st century. Integration of global capital markets, the capacity of information technology to virtually instantaneously transmit both good and bad news, and sales of products and services worldwide create both a business and an ethical foundation for full disclosure.

The case of pharmaceutical firms forcefully illustrates this point. The handful of firms that dominate global markets sell their products worldwide. There simply is no justification for dual disclosure standards across countries or regions. Critical information on company R&D programs, drug trial activities, and marketing practices is of equal interest to US, Japanese, and South African consumers, investors and other company stakeholders. As the recent anti-depressant and arthritis cases reveal, the consequences of company decisions—like the companies themselves—know no frontiers.

The contours of a generally accepted disclosure framework are identifiable at this juncture, especially at the generic, cross-sectoral level. At the same time, details of sector-specific disclosures remain fluid; it will take time to achieve the levels of rigor and comparability essential for credibility. For pharmaceutical companies, for example, when and in what form should drug trial information be disclosed? In what form—

qualitative or quantitative—should lobbying activities, funding of academic institutions, and relationships with medical professionals be disclosed? And how must drug-specific disclosure along all steps of the product chain—research, development, approval, use—be meshed with corporate-level reporting? The issues need to be articulated, the indicators defined, and the measurement protocols developed.

Though company stakeholders are a diverse and dispersed group, they have a right to know what is relevant to their decisions as consumers, investors, workers and communities. The consequences of deferred, incomplete, or inaccurate information are too evident and too frequent. The greater the social, environmental and economic footprint of the sector, the more urgent is the case for moving rapidly toward generally accepted disclosure standards at the global level.

“Information is the best medicine” read the headline of a recent commentary on the antidepressant controversy. This fundamental truth needs to be translated into steady progress toward global standards.

ⁱ Barry Meier, “Glaxo to begin posting drug trial results,” *New York Times*, September 1, 2004, C2; Gardner Harris, “New warnings sought on antidepressants,” *New York Times*, September 12, 2004, A19; Jerry Avorn, “Prescription anxiety,” *Boston Globe*, September 20, 2004, A11.

ⁱⁱ “Knowledge” in this paper is broadly construed to mean scientific understanding and information. The knowledge economy refers to economic value based on human intelligence as opposed to physical materials. Knowledge industries and knowledge assets constitute elements of the knowledge economy.

ⁱⁱⁱ Deborah Leipziger, *The Corporate Responsibility Code Book*. London: Greenleaf, 2003. Halina Ward, “Following up the World Summit on Sustainable Development Commitments on Corporate Social Responsibility.” London: The Royal Institute of International Affairs, August 2004. Draft.

^{iv} UN Sub-Commission on the Promotion and Protection of Human Rights, “Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights,” UN Doc. E/CN.4/Sub.2/2003/12/Rev.2 (2003). Online: <<http://www1.umn.edu/humanrts/links/norms-Aug2003.html>>, July 2004.

^v Warren Hoge, “Annan Reiterates his misgivings about legality of war in Iraq,” *New York Times*, September 22, 2004, p. A6.

^{vi} Joel Bakan, *The Corporation*. New York: Free Press, 2004.

^{vii} Quoted in Jonathan Low and Pam Cohen Kalafut, *Invisible Advantage: How Intangibles are Driving Business Performance*. Cambridge MA: Perseus, 2002, p. 183.

^{viii} Low and Kalafut, p. 27.

^{ix} C. Prahalad, *The Fortune at the Bottom of the Pyramid*. Philadelphia: Wharton Press, 2004.

^x Baruch Lev, *Intangibles: Measurement, Management and Reporting*. Washington, D.C.: Brookings Institute, 2001.

^{xi} This was recognized over two centuries ago by the founding fathers and enshrined in the US Constitution by enabling Congress to secure “for limited times to authors and inventors the exclusive right to their writings and discoveries” (Article 1, Section 8).

^{xii} Lev, pp. 93-98.

^{xiii} Sandeep A. Patel and George S. Dallas, “Transparency and Disclosure: Overview of Methodology and Study Results - United States” (October 16, 2002). Online: <<http://ssrn.com/abstract=422800>>.

^{xiv} Linstock Consulting, “Added values? Measuring the ‘value relevance’ of sustainability reporting.” London, February 2004. Also see www.globalreporting.org. Further discussion of GRI as an emerging global standard for non-financial reporting appears below.

^{xv} Ann Florini, *The Coming Democracy: New Rules for Running a New World*. Washington: Island Press, 2003.

^{xvi} This proliferation of corporate responsibility initiatives has led to a wide, and some argue bewildering, array of initiatives. These include: codes and principles of corporate conduct that establish broad behavioral norms; reporting standards that describe the content of disclosed information; and management and standards that specify specific expectations or targets for corporations to achieve relative to social, environmental and governance procedures, activities and outcomes.

^{xvii} Among other leading, complementary initiatives with a prominent disclosure component are: the OECD *Guidelines for Multinational Enterprises*; the OECD *Corporate Governance Principles*; and the AA 1000 series. See www.oecd.org and www.accountability.org.

^{xviii} GRI positioned itself as a voluntary initiative, seeking to build a strong coalition of business and non-business groups while advancing the case and generally accept framework for voluntary non-financial reporting. As the program evolved, governments—especially in Europe and Japan—became increasingly attentive to GRI’s progress. Government embrace of non-financial reporting, and GRI specifically, continues to intensify and expand: for example, in France, mandatory social and environmental reporting applies to all companies listed on the Paris Stock Exchange; Australia has adopted a voluntary national environmental reporting framework based heavily on GRI; the South Africa King Commission on Corporate Governance advocates GRI as the a component of its best corporate governance practices; and Japan’s environmental reporting guidelines (which in the Japan is tantamount to mandatory) reflect much of GRI’s content. For a brief history of GRI, see Allen L. White, "Improving sustainability disclosure: the Global Reporting Initiative Guidelines," in Sissel Wage, *Ants, Galileo, & Ghandi: Designing the Future of Business through Nature, Genius, and Compassion*. Sheffield, UK: Greenleaf Publishing, 2003.

^{xix} See *2002 Sustainability Reporting Guidelines* at www.globalreporting.org.

^{xx} As of September 2004, 25 “health care products” companies worldwide report using the GRI framework, including eight US-based firms: Abbot Laboratories, Allergan, American Home Products, Baxter International, Bristol-Myers Squibb, Genecor International, Lilly, and Wyeth. The remaining are companies based in the UK, France, Germany, Japan, Ireland, Switzerland, Denmark, and Sweden. See www.globalreporting.org/guidelines/reports.

^{xxi} Sanford Lewis and Tim Little, *Fooling Investors & Fooling Themselves: How Aggressive Corporate Accounting & Asset Management Tactics Can Lead to Environmental Accounting Fraud*. The Rose Foundation for Communities and the Environment, July 2004. In the UK, social and environmental disclosures have been prominent in debates in the Company Law Review process.

^{xxii} Eric J. Topol, “Good riddance to a bad drug,” *New York Times*, October 2, 2004, p. A27.

^{xxiii} Andrew Pollack, “New scrutiny of drugs in Vioxx’s family,” *New York Times*, October 4, 2004, p. C1.

^{xxiv} Barry Meier, “For Merck, defense of a drug crumbles at a difficult time: earlier trials raised questions of safety,” *New York Times*, October 1, 2004. p. C1.

^{xxv} Pfizer Corporation’s Celebrex recently joined the ranks of pain medicines under scrutiny for incomplete disclosure of the results of early clinical trials. Alex Berenson and Gardiner Harris, “Pfizer says 1999 trials revealed risk with Celebrex,” *New York Times*, February 1, 2005, p. C1.

^{xxvi} Marcia Angell, *The Truth About the Drug Companies*. New York: Random House, 2004. See also Jerry Avorn, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*. New York: Alfred Knopf, 2004.

^{xxvii} Angell, p. 4. This is the amount Americans spent on prescription drugs in 2002. Sales worldwide are in the \$400 billion range.

^{xxviii} Novo Nordisk, the Danish diabetes drug firm, is the most notable. Its corporate social reporting is widely regarded as the best in the sector and among the best in any sector. Also noteworthy is Bristol-Myers Squibb, among the pioneers of GRI reporting, though its emphasis has been heavily environmental. Novartis’ report is noteworthy for its consolidation of financial and non-financial information.

^{xxix} The 1992 Prescription Drug User Fee Act (PDUFA) requires companies to pay a \$300,000 fee for each new drug application. The result is that such fees cover an estimated 50% of the cost of such applications. John Abramson, M.D. *Overdosed America: The Broken Promise of American Medicine*. New York: HarperCollins, 2004, p. 58.

^{xxx} The public utility scenario is raised by both Avorn, p. 415 and Angell, p. 253.