Industry Summary

The pharmaceutical industry develops, manufactures, and markets a range of medications and healthcare products. The industry is driven by research and development, and a high risk of product failure. Pharmaceutical firms depend on a skilled workforce, and their products are subject to regulatory approval.1

The industry faces current challenges from an impending ‘patent cliff’, in which 104 drugs with combined annual sales of $97 billion are facing patent expiration between 2012 and 2016. Pricing pressures from generic competition and reimbursement agencies have contributed to declining margins and a period of consolidation. Industry growth will be driven by emerging markets, increased access in the US under the Patient Protection and Affordable Care Act, and pipeline prospects for new products.

Although traditional value drivers will continue to impact financial performance, intangible assets such as social and environmental capital increasingly contribute to market value. Additionally, management (or mismanagement) of material environmental, social, and governance (ESG) factors has the potential to affect traditional valuation by impacting revenue, cash flow, cost of capital, and management quality. To ensure that shareholders are able to evaluate these factors, pharmaceutical companies should report on the material ESG risks and opportunities that may affect value in the near and long term. Enhanced reporting will provide stakeholders with a more holistic (and comparable) view of performance that includes both positive and negative externalities, and the non-financial forms of capital that pharmaceutical companies rely on to create long term value. Firms that work to improve performance on these issues will position themselves well for the future.

The sustainability issues that drive competitiveness within the pharmaceuticals industry include:

1 A list of the top five companies by revenue appears in Appendix I

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Regulatory Trends in the Pharmaceuticals Sector

Although the regulatory environment that governs the pharmaceutical sector continues to evolve, regulatory trends have the potential to impact shareholder value and sustainability performance. The following section provides a brief summary of key legislative efforts that are likely to impact value in the industry and to further amplify the importance of environmental, social, and governance issues.

The Patient Protection and Affordable Care Act (PPACA) will increase the number of insured by an estimated 26 million.\(^1\) The law will subsequently expand demand for pharmaceuticals through increased rates of insurance coverage, but will also present certain challenges. These risks are associated with requirements for discounts and rebates for Medicare participants which could have negative impacts on profitability. Drug manufacturers are expected to pay $80 billion in fees and rebates to help fund the plan over ten years.\(^2\)

The American Recovery and Reinvestment Act of 2009 included provisions for $1.1 billion dollars in funding for the advancement of comparative effectiveness research (CER). The framework is intended to give health care providers the necessary information to make value based decisions. CER will encourage pharmaceutical companies to further substantiate the effectiveness of their products during clinical trials, and could result in increased emphasis on generics or alternative therapies.

ESG Risks and Opportunities

Recent trends in the regulatory environment suggest an ongoing effort to increase health insurance coverage, while reducing costs to consumers, and alleviating some barriers to entry for new products. Legislation also has the potential to further align the interests of society with those of long-term investors.

Subsequently, companies will not be able to maximize financial capital unless social and environmental capital are addressed as well. Firms that are able to negotiate new regulations, while addressing all forms of capital and limiting negative externalities will be better positioned to protect shareholder value in the long run.

The following section provides a brief description of how the pharmaceutical industry depends on each form of capital and the specific ESG issues that will drive performance including: evidence, value impact, and timing and uncertainty. Tables indicating the nature of the value impact, and the recommended disclosure framework appear in Appendix II and III.

Social Capital

Pharmaceutical companies require strong intellectual property protection to ensure returns on research and development investments. These protections create a significant link between the industry and social capital. This relationship is further intensified by the fact that pharmaceutical products must pass rigorous regulatory procedures. The industry's reliance on social capital is exemplified by the need for attracting, retaining, and ensuring the safety of highly skilled employees in a competitive market. In addition, the development of orphan drugs and treatments for epidemics present opportunities for market growth and the creation of social value.

Access-to-Medicines

The pharmaceutical industry has the opportunity to engage in the development of therapies that target priority diseases in developing nations, and to implement associated pricing schemes and partnerships that expand access. This is likely to be one of the industry’s most significant opportunities for innovation and growth. Different disease profiles in emerging countries will require additional research and development, clinical trials, and new partnerships.

Evidence: GlaxoSmithKline, the top ranked company on the most recent Access-to-

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\(^1\) Estimates range between 26 and 30 million for the number of people will become insured under the PPACA.
Medicines index, is researching new vaccines and treatments for HIV/AIDS, malaria, and tuberculosis, the three diseases identified as priorities by the World Health Organization. ViiV Healthcare, which was established by GlaxoSmithKline and Pfizer, offers its anti-retroviral portfolio to the World Bank’s low-income countries and all of sub-Saharan Africa at not-for-profit prices. In addition, companies continue to report that emerging markets represent a significant growth opportunity.

**Value Impact:** Companies that are able to develop innovative operating models that provide lower price points, and increase access to medicines will have the opportunity to capitalize on significant growth opportunities, and to increase shareholder value.

**Timing and Uncertainty:** The research, development, and release of new products targeting priority diseases in developing nations take multiple years, but will likely have a positive effect on shareholder value in the long-term.

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**Drug Safety and Side Effects**

The pharmaceutical sector faces significant risks associated with product safety, and potential recalls. A company’s ability to manage and communicate these issues to stakeholders is a strong indicator of value protection.

**Evidence:** In 2010, product recalls and related plant slowdowns due to safety concerns cost Johnson & Johnson $900 million. Estimates indicate that the recall of four Novartis products in 2011 resulted in lost revenue of between $560 and $750 million, or 1.4% to 1.8% of gross profit. In November 2012, the Supreme Court will hear Amgen Inc v. Connecticut Retirement Plans & Trust Funds, which will examine whether a class certification should be upheld for a class-action lawsuit accusing the company of failing to disclose drug safety information. The suit alleges that the safety issues were material and subsequently should have been disclosed.

**Value Impact:** Recent anecdotal evidence suggest that failures to ensure product safety and consistency can negatively impact shareholder value.

**Timing and Uncertainty:** Problems relating to drug safety and side effects can have both near and long term implications for shareholders. In the near term, planned revenues and cash flow from product recalls are reversed. Long term implications include diminished brand reputation, potential litigation, settlement costs, and fines.

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**Safety of Clinical Trial Participants**

Ensuring the safety of clinical trial participants is a critical indicator of a company’s ability to successfully bring a product to approval. This issue is of increasing importance as the number of clinical trials conducted in emerging countries continues to rise. A 2010 report by the Department of Health and Human Services indicates that in 2008, 80% of approved applications for drugs and biologics contained data from foreign clinical trials. However, the FDA inspected less than 1% of foreign sites. As a result, companies in the pharmaceutical sector manage the associated risks with limited oversight.

**Evidence:** The death of a patient in a Bristol-Meyers Squibb clinical trial for a hepatitis C drug resulted in a drop in analysts’ sales estimates of between $34 and $800 million for 2016. The company experienced a subsequent 10% drop in stock value.

**Value Impact:** Companies that effectively manage the safety of their clinical trial participants have an increased likelihood of achieving regulatory approval, and therefore increasing shareholder value. Industry tendencies toward publishing positive results while withholding ineffective or problematic trials can lead to approval, but these practices will make pharmaceutical companies vulnerable to severe consequences for patients and a subsequent decrease in value.

**Timing and Uncertainty:** Failure to conduct safe and effective clinical trials will result in the loss of initial investments. Further, companies that fail to manage these risks will not be able to actualize the
predicted revenue stream generated from new products. This will result in a chronic negative impact on valuation. Intangibles such as brand reputation suffer from safety issues as well.

**Affordability, Access and Fair Pricing**

Currently, pharmaceutical companies are subject to contractual benefits that prevent institutional buyers such as Medicare from negotiating prices. Future legislation may alter this arrangement, and prevent companies from engaging in anti-competitive behavior. In addition, increased interest in the US and abroad on comparative effectiveness research will result in further downward pricing pressure.

**Evidence:** The Congressional Budget Office estimates that prohibiting drug originators from paying generic manufacturers to delay production would save the federal government $4 billion dollars between 2012 and 2021.\(^8\) Future legislation could reduce company revenues, and impact their ability to develop new drugs under current business models that depend on such payments.

**Value Impact:** Reliance on anti-competitive practices increases exposure to future legislation, and could lead to decreased market share.

**Timing and Uncertainty:** Firms that continue to protect their products and value through anti-competitive behavior are likely to experience long term financial loses.

**Ethical Marketing**

The US is currently one of two countries to permit consumer-directed advertisements for prescription drugs. While, this results in increased market share, failure on the part of pharmaceutical companies to effectively manage their marketing efforts can result in financial losses.

**Evidence:** In recent years, significant fines have been levied against companies for illegal marketing of products. In 2012, GlaxoSmithKline paid $3 billion for marketing two of its products for off-label use, and for making false statements about another drug.\(^9\) Abbot Laboratories paid $1.5 billion for marketing Depakote for off-label use, which amounts to approximately 17.5% of estimated profits for 2012.\(^8\)

**Value Impact:** Recent examples of fines associated with illegal marketing demonstrate the potential for such practices to have acute negative impacts on shareholder value, and to tarnish the brand in the long term.

**Timing and Uncertainty:** The impact on value from unethical marketing practices can be both acute (fines) and chronic (brand management).

**Orphan Drugs**

Current estimates indicate that 250 new rare diseases are identified annually. In sum, rare diseases affect approximately 25 million people in the US. In effort to encourage drug manufacturers to target these diseases, Congress passed the Orphan Drug Act, offering seven years of market exclusivity and a tax credit of 50% of the cost of clinical trials to developers of orphan drugs. These incentives combined with increasing demand, present considerable opportunities for growth and innovation in the pharmaceutical sector.\(^\text{x}\)

**Evidence:** The orphan drug market reached $50 billion in 2011 with Sensipar, the orphan drug with the highest annual sales, generating over $500 million in revenue in 2011.\(^\text{xi}\)

**Value Impact:** Opportunities relating to orphan drug development have the potential to create significant value for shareholders.

**Timing and Uncertainty:** Extended exclusivity, decreased susceptibility to biosimilars, and shorter and smaller clinical trials suggest that orphan drugs can generate prolonged returns for shareholders.
Epidemic Treatments

A recent study indicates that 36% of adults and 17% of children between the ages of two and nine are obese. If current trajectories are maintained, half of U.S. adults will be obese by 2030. The obesity epidemic and the increasing incidence of related illnesses such as diabetes, coronary heart disease, and hypertension provide significant opportunities for growth in the pharmaceuticals industry.

Evidence: In 2012, the U.S. Food and Drug Administration cleared medications used in the treatment of obesity for the first time in 13 years. This will likely lead to renewed research and development related to obesity. Arena Pharmaceuticals and Eisai’s Belviq was approved in June, while Vivus’s Qsymia received approval in July. Both drugs demonstrated the ability to help obese patients lose 5 to 10% of their body weight during clinical trials. Market valuations for Arena and Vivus have subsequently increased by more than $1 billion and $1.5 billion respectively.

Value Impact: Companies that are able to develop effective treatments for obesity, and its associated illnesses will be positioned to capitalize on a significant growth market, thereby creating positive shareholder.

Timing and Uncertainty: The scale of the obesity epidemic in the U.S. suggests that this market will provide a chronic opportunity for growth.

Employee Relations

Pharmaceutical companies face intense competition for qualified employees. This issue is of particular interest in emerging markets where the industry continues to expand its presence. In addition, recent incidents of safety issues at laboratory facilities have put an increased spotlight on practices and standards.

Evidence: In 2010, a jury awarded $1.37 million to a former Pfizer molecular biologist after she was fired for raising questions about safety at the company’s laboratories. The biologist had been infected by a genetically engineered virus at Pfizer’s Groton, CT facility. The Occupational Safety and Health Administration acknowledges that its standards are not sufficient for current laboratory practices, and is developing new guidelines.

Value Impact: Employee relations have the potential to negatively and positively impact shareholder value. Incidents of employee injury or death can result in litigation. On the other hand, practices that encourage employee development and retention can positively impact value.

Timing and Uncertainty: Although isolated incidents of employee injury can present acute implications for value, the issue of health, development, and retention affects value in the near and long term.

Environmental Capital

Pharmaceutical companies engage in research and manufacturing processes that rely heavily on environmental capital. Firms in this industry depend on the ability to utilize purchased resources (i.e. energy, water, and organic materials). In addition, companies have been afforded the opportunity to generate negative externalities through air emissions and water pollution. As resources become limited, and legislation seeks to address these externalities, investors must understand how individual companies within this industry manage these risks and adhere to societal expectations.

Pharmaceutical Water Contamination

A 2008 report by the Associated Press found that an estimated 270 million pounds of pharmaceutical compound residue is released into waterways each year. The report concluded that the drinking water of approximately 46 million Americans has subsequently been contaminated with pharmaceuticals. The release of certain compounds during the manufacturing process coupled with hospital practices of disposal and the release of additional compounds after consumer ingestion, has led to significant concern over
pharmaceutical contamination in water. The issue has been exacerbated by the fact that most municipal wastewater treatment processes are not equipped to deal with complex organic compounds and their metabolites, which are increasing in use year after year. In 2011, the U.S. Government Accountability Office issued a report calling for the EPA to examine the issue of pharmaceuticals in drinking water. In the meantime, this issue remains one of the industry’s most significant externalities.

**Evidence:** Manufacturer financed drug take back programs have been developed internationally and similar models have been proposed in the US. In British Columbia, drug manufacturers finance a system in which 98% of pharmacies take back unused drugs. In Maine, a legislative effort to address this issue and concern over the circulation of excess drugs has resulted in a law that limits the size of first time prescriptions for certain medications.

**Value Impact:** The potential for required facility retrofits and company financed take back programs suggest that pharmaceutical water contamination has the potential to negatively affect value in the medium term, but these investments will protect shareholders in the long term.

**Timing and Uncertainty:** The future of regulations concerning the release of pharmaceutical compounds into the environment remains unclear. However, companies that address this issue ahead of legislation will be better positioned to avoid potential fines, litigation, and capital costs in the long term, as well as increased scrutiny by environmental and public health organizations related to the presence of trace pharmaceutical compounds in the environment, and the toxicological effects.

### Resource Efficiency

The research and manufacture of pharmaceutical products is resource intensive. Companies in this industry are subsequently exposed to water scarcity and fluctuations in energy costs. In addition, pharmaceutical processes require large quantities of organic materials which typically have high costs of disposal.

**Evidence:** Estimates suggest that the pharmaceutical industry spends $1 billion per year for the energy required to keep their facilities running. Pfizer reports that it avoided $85 million in energy costs between 2008 and 2012 through measures taken to improve energy efficiency.\(^{111}\)

**Value Impact:** Innovative approaches to resource efficiency allow companies to reduce operating costs, thereby increasing value for shareholders. Poor performance in this area could lead to increased costs, exposure to energy price fluctuations, and decreased value.

**Timing and Uncertainty:** Resource efficiency has the potential to impact value in both the near and long term. Although a positive return on investment may take years to be actualized, the impact on shareholder value is expected to be positive in the long term.

### Disease Migration

Globalization, population mobility, and climate change are among the factors contributing to disease migration. As diseases spread to new geographic areas, there is likely to be increased demand for associated vaccines and treatments.

**Evidence:** The extent to which climate change is contributing to disease migration remains unclear. However, diseases, such as malaria, that have traditionally been limited to tropical regions, are considered a threat to move to different regions as temperatures rise.

**Value Impact:** Companies that are able to develop vaccines or treatments that target the relevant diseases will be well positioned to capitalize on a significant growth opportunity.

**Timing and Uncertainty:** Factors that contribute to disease migration are persistent. The potential for increased revenue for pharmaceutical companies that can introduce associated products will be chronic.
Governance

Strict regulatory environments and competition in the pharmaceutical industry increase the importance of strong governance. Management structures must be able to negotiate international laws while avoiding the risks associated with issues such as corruption and bribery. Information on governance performance is essential for shareholders to understand management quality and a company’s ability to protect value.

Corruption and Bribery

As the competitive landscape continues to shift, and increased emphasis is placed on access and cost, companies that violate federal and international laws to gain an advantage will put shareholders at risk.

Evidence: Recent examples of bribery have demonstrated the potential for material impacts in companies that fail to manage this risk. Earlier this year, the Securities and Exchange Commission announced a $60 million dollar settlement with Pfizer relating to the bribery of doctors and healthcare workers to increase drug sales. In 2011, Johnson & Johnson agreed to pay $70 million in fines for similar practices.

Value Impact: Examples of recent bribery settlements demonstrate how these practices can negatively impact shareholder value.

Timing and Uncertainty: The nature of bribery settlements suggests that the impact on shareholder value is likely to be acute.

Traditional Investment Screening Issues

ESG issues including political contributions, animal testing, and controversial areas of research such as stem cells are sometimes raised as concerns by stakeholders in the pharmaceutical industry. These issues have been used as screening factors in certain types of investment portfolios that are concerned with ESG performance. However, they are not believed to present material negative economic impact in and of themselves, nor are they industry issues relevant to all companies. Therefore, they were not considered for routine disclosure. However, pharmaceutical companies should be aware that involvement in these activities could have the potential to limit access to capital from certain types of investors.
Appendix I
Top Five Pharmaceuticals Companies by Revenue

- Pfizer Inc.
- Merck & Co. Inc.
- Abbot Laboratories
- Johnson & Johnson
- Eli Lilly & Co.

Appendix II
Value Impact of Material ESG Issues

<table>
<thead>
<tr>
<th>Access-to-Medicines</th>
<th>Revenue Growth(^3)</th>
<th>Returns on Capital(^4)</th>
<th>Management(^5)</th>
<th>Management Quality(^6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Safety and Side Effects</td>
<td>✓</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Safety of Clinical Trial Participants</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affordability and Fair Pricing</td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>Ethical Marketing</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Orphan Drugs</td>
<td></td>
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<td>✓</td>
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<tr>
<td>Epidemic Treatments</td>
<td>✓</td>
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<tr>
<td>Employee Relations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Pharmaceutical Water Contamination</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>Resource Efficiency</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease Migration</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Corruption and Bribery</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Appendix III

\(^3\) Revenue growth: Issue is related to product growth and differentiation, or ability to charge a price premium.
\(^4\) Returns on Capital: Issue has an impact on operational efficiency, workforce efficiency, or borrowing costs.
\(^5\) Risk Management: Issue has an impact on brand reputation, business continuity, supply chain or regulatory environment.
\(^6\) Management Quality: Issue has an impact on leadership development and long term strategy.
## Sustainability Accounting Standards – Pharmaceuticals

<table>
<thead>
<tr>
<th>ESG Issue</th>
<th>Performance Indicators</th>
<th>Management Disclosures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access-to-Medicines</td>
<td>Ranking in the Access to Medicines Index. [ATM]</td>
<td>Initiatives to promote access to healthcare products in priority countries as defined by Access to Medicines [SASB]</td>
</tr>
<tr>
<td>Drug Safety and Side Effects</td>
<td>Number of products listed by the FDA in the Adverse Event Reporting System (AERS) in the past five years. [SASB]</td>
<td>Number of fatalities due to side-effects. [SASB]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number and value of products recalled by sales in the past five years [SASB]</td>
</tr>
<tr>
<td>Safety of Clinical Trial Participants</td>
<td>Lost revenue due to slowed or terminated clinical trials.</td>
<td>Disclose information about the result of all of its clinical trials conducted in ATM Index Countries regardless of the outcome and whether the trial was conducted in-house or through a third-party (i.e. CRO). [ATM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discuss any breach of international codes or lawsuits related to its clinical trial practices in the (ATM) Index Countries during the last five years [ATM]</td>
</tr>
<tr>
<td>Affordability and Fair Pricing</td>
<td>Reverse payments to manufacturing companies, to delay or prevent the production of biosimilars or generics. [SASB]</td>
<td></td>
</tr>
<tr>
<td>Ethical Marketing</td>
<td>Warning letters or amount ($) of settlements regarding false claim allegations. [SASB]</td>
<td>Adoption and enforcement of code of ethics governing interactions with healthcare professionals. [SASB]</td>
</tr>
<tr>
<td>Orphan Drugs</td>
<td>Revenue from orphan drugs as a percentage of total revenue.</td>
<td>Discussion of ongoing efforts to address orphan diseases</td>
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<tr>
<td>Epidemic</td>
<td></td>
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<tr>
<td>Employee Relations</td>
<td>Total injury rate – Recordable cases per 200,000 hours worked (OSHA)</td>
<td>Research relating to treatments for obesity and associated illnesses</td>
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<tr>
<td></td>
<td>Lost time injury rate – Lost time cases per 200,000 hours worked (OSHA)</td>
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<tr>
<td></td>
<td>Number of incidents of employee infection in laboratory facilities</td>
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<tr>
<td>Pharmaceutical Water Contamination</td>
<td>% of wastewater treated for drug compounds produced by company</td>
<td>Product stewardship initiatives to promote reuse or adequate disposal at the end of the lifecycle. [SASB]</td>
</tr>
<tr>
<td></td>
<td>Amount of product recovered through take-</td>
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</table>
back programs divided by total sales [SASB].

Efforts to understand metabolites and potential for environmental migration of drugs into waterways and ecosystems [SASB]

### Resource Efficiency
- Total annual energy consumption (Gigajoules)
  - % Renewable Energy
- Total annual greenhouse gas emissions (Metric Tonnes CO2e)
  - Scope 1
  - Scope 2
  - Scope 3
- Total annual water used (Cubic Meters)
  - % Reused
- Total annual waste generated (Tons)
  - % Diverted from landfills

*Note: normalization factors for resource efficiency TBD, and may include sales or other*

### Disease Migration
- Research relating to treatments and vaccines for malaria, dengue fever, and other associated diseases

### Corruption and Bribery
- Total number and amount of fines attributed to corruption or bribery
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