



# STANDARDS OUTCOME REPORT

Health Care

March 29, 2013



**Contents**

Executive Summary ..... 3

Introduction ..... 3

Part I: Description of SASB’s Process for Issue Identification, KPI Determination, and Response to Stakeholder Comments..... 3

Part II: Role of the Standards Council in Reviewing the Content of SASB’s Proposed Sustainability Accounting Standards for Health Care ..... 4

Part III: Examples of IWG and Public Feedback and Action Taken by SASB Research Team ... 5

    Example 1: Adding ‘Counterfeit Drugs’ to Biotechnology and Pharmaceuticals..... 5

    Example 2: Removing ‘Genetically Modified Organisms’ from Biotechnology ..... 6

    Example 3: Additional evidence for “Resource Efficiency’ in Health Care Delivery ..... 6

    Example 4: Adding ‘Supply Chain Management’ for Medical Equipment and Supplies, Biotechnology, and Pharmaceuticals ..... 7

Part IV: Issues for Special Consideration of the Standards Council..... 7

    Pharmaceutical Water Contamination ..... 8

    Orphan Drugs ..... 8

    Disease Migration ..... 9

    Epidemic Treatments ..... 9

    Climate Change and Natural Disaster Risks .....10

Appendix I: All Comments Received During IWG and Public Comment .....11

Appendix II: Assessment of Issue Materiality by IWG Members .....22

## Executive Summary

The following report provides a reference and framework for the SASB Standards Council 'Health Care Content Review' on April 4, 2013. Included are a brief description of SASB's research process (Part I), an account of the Industry Working Group and Public Comment participation rates (Part I), a description of the Standard Council's role (Part II), examples of how SASB responded to stakeholder feedback (Part III), and a list of issues that warrant special consideration by the Standards Council (Part IV). Although feedback on all content is welcome, SASB encourages the Standards Council to focus on the issues identified in Part IV of this report.

## Introduction

In the third quarter of 2012, SASB's research team identified the current and emerging sustainability issues that will impact shareholder value in six industries (biotechnology, pharmaceuticals, health care delivery, managed care, health care distributors<sup>1</sup>, and medical equipment and supplies) across the health care sector. These issues and the associated key performance indicators (KPIs) have subsequently been vetted by external stakeholders through the Industry Working Group (IWG) and Public Comment Period (PCP). These processes allowed for each issue and KPI to be evaluated on the basis of materiality, investor interest, and cost-benefit analysis.

The goal of this 'Content Review' is for the Standards Council to assess the feedback received during the health care IWG and PCP, and SASB's response to these comments.

## Part I: Description of SASB's Process for Issue Identification, KPI Determination, and Response to Stakeholder Comments

In an effort to develop industry-specific sustainability accounting standards, SASB identifies issues that are material, of interest to investors, and cost-beneficial. These issues are identified through an analysis of corporate reporting (10-Ks, annual reports, and social responsibility reports), news articles, and academic journals. The KPIs reflect what the research team determined to be the most cost-effective, comparable, and direct method of reporting on the risks and opportunities associated with each issue.

After the standards are developed, each issue and KPI is vetted by market participants, corporate representatives, and third party stakeholders through the IWG on the basis of the same criteria. A 'Process Review' by the Standards Council subsequently examined the

---

<sup>1</sup> The Distributors and Pharmacy Benefit Managers industry was reclassified after the initial standards were developed and the IWG was convened. The new industry classification, Health Care Distributors, includes only those companies that distribute health care products. The pharmacy benefit managers will be included in the Food & Drug Retailers & Convenience Stores industry, which is part of the Consumption sector.

strength and representativeness of the stakeholders who participated in the IWG, and performed an initial assessment of the overall feedback. The research team then responded to the IWG comments and integrated those that represent a consensus opinion or provide significant evidence for inclusion.

The standards were again vetted through the Public Comment Period, which provides another opportunity for revision. After this, the Standards Council undertakes a second review of the standards in the form of a 'Content Review'.

It is important to note that health care was the first Sector analyzed by SASB, and that the processes around the IWG and PCP were set-up for the first time and have not yet delivered the level of feedback that we expect for the other sectors, going forward. However, the IWG provided valuable insight into how companies, market participants, and third party stakeholders view materiality. In sum, 72 IWG (9 biotechnology, 22 pharmaceuticals, 12 medical equipment and supplies, 14 health care delivery, 5 health care distributors, and 10 managed care) surveys were completed throughout the six health care industries. New issues were suggested by 34 members, and participants assessed each existing issue on the basis of materiality. Further, KPIs were analyzed on the basis of several factors including: relevance, usefulness, comparability, and cost-effectiveness.

The Public Comment Period produced limited feedback. Eight surveys (1 health care delivery, 1 medical equipment and supplies, 3 biotechnology, and 3 pharmaceuticals) were completed during this process, and the majority of the comments provided were determined to be of limited use to the research process. In addition, open letters were received from two stakeholders during the PCP.

**Note:** The Public Comment Period will be open until March 30<sup>th</sup>, 2013. Any new comments received will be included in an addendum and distributed to the Standards Council prior to the meeting on April 4.

## Part II: Role of the Standards Council in Reviewing the Content of SASB's Proposed Sustainability Accounting Standards for Health Care

The goal of the 'Content Review' by the Standards Council is to assess the feedback received during the IWG and PCP. Similar to the assessment conducted by these external stakeholders, this review should focus on three inter-related dimensions: materiality, investor interest, and cost-benefit.

- **Material information.** 'Material information' is defined by the U.S. Supreme Court as presenting a substantial likelihood that disclosure of the omitted fact would have been viewed by the 'reasonable investor' as significantly altering the 'total mix' of information made available.

- **Investor interest.** Related to the concept of material information, SASB seeks to create industry specific accounting standards, and therefore relies heavily on interest from the hypothetical ‘reasonable investor’. This interest is largely determined by the market participants who contribute to the IWG, and engage in investing primarily as an economic activity (mainstream, SRI, and others).
- **Cost-benefit.** Cost-benefit is an essential element of SASB’s proposed sustainability accounting standards. The elements of this analysis that SASB considers include costs to companies for incremental additional reporting and auditing, the current availability of the information, the cost savings to companies from more streamlined communication with investors on material issues. The benefits considered include not only the benefits to companies from improving performance on these issues that will improve operational and/or financial performance and the related attractiveness to the capital markets, but the benefits to investors from having readily available decision useful information with which to assess portfolio risks and opportunities, and the broader benefits to society from improved market stability and more sustainable outcomes.

**Note:** as part of the analysis suggested above, members of the Standards Council should pay particular attention to the total volume of disclosure implied by the proposed standards, at the industry level.

## Part III: Examples of IWG and Public Feedback and Action Taken by SASB Research Team

The following section provides examples of the comments received during the IWG and Public Comment Period along with SASB’s rationale for including or excluding the feedback, and the final action taken. KPIs are also included in cases where a new issue was added based on stakeholder feedback. A list of all comments appears in Appendix I of this report, and a materiality assessment of each KPI by the IWG appears in Appendix II.

### Example 1: Adding ‘Counterfeit Drugs’ to Biotechnology and Pharmaceuticals

**Comment and Issue:** Add ‘Counterfeit Drugs’ to the Biotechnology and Pharmaceuticals Briefs

**Source and Timing:** External stakeholder outside of IWG process.

**Rationale for Inclusion / Exclusion:** Although the comment was received by an independent stakeholder outside of the IWG process, the research team concluded that it was of material interest and warranted inclusion in the suggested briefs as well as the Health Care Distributors brief. SASB found that counterfeit drugs, which account for roughly one percent of the U.S. market and roughly \$431 billion globally, presents a significant threat to corporate value and consumer health. The materiality and societal concern surrounding this issue was articulated most recently in 2012 when fake Avastin

was distributed to pharmacies and doctors in the U.S. Avastin, a cancer medication produced by Roche Holdings' Genetech division, typically sells for \$2,400 per 400-milligram vial, and produced \$2.5 billion in sales in 2011.

**Action Taken:** This issue of counterfeit drugs was included with the following KPIs in the biotechnology, pharmaceuticals, and health care distributors briefs.

**Sample KPIs:**

- Description of methods and technologies used to maintain traceability of products throughout the supply chain (e.g. RFID, ePedigree, serialization, etc.).
- Description of process for alerting customers and business partners of potential or known risks associated with counterfeit products.
- Number (and description) of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.

**Example 2: Removing 'Genetically Modified Organisms' from Biotechnology**

**Comment / Issue:** Remove 'Genetically Modified Organisms' from the Biotechnology brief

**Source and Timing:** Both market participants and corporate representatives suggested removing this issue during the IWG on the basis that it was only relevant to a few companies, and was therefore of limited interest to investors.

**Rationale for Inclusion / Exclusion:** This issue was initially included against the backdrop of Proposition 37 in California, which SASB believed could have a material impact on the biotechnology companies that are engaged in genetically modified organisms. Proposition 37 failed, and the IWG survey indicated that a majority of participants did not believe this was a material issue for companies in this industry. Further, too few companies in this industry are engaged in developing genetically modified organisms to warrant inclusion.

**Action Taken:** 'Genetically Modified Organisms' and the associated KPIs were removed from the biotechnology brief.

**Example 3: Additional evidence for "Resource Efficiency" in Health Care Delivery**

**Comment / Issue:** Add evidence from a 2012 Commonwealth Fund study, *Can Sustainable Hospitals Help Bend the Health Care Cost Curve?*, to further support the 'Resource Efficiency' or 'Facilities Designed for Wellness' issue.

**Source and Timing:** The evidence was provided by a third party stakeholder (neither a market participant nor a corporate representative) during the IWG.

**Rationale for Inclusion / Exclusion:** The research team reviewed the study, and determined the findings to be significant. The Commonwealth Fund concluded that hospitals that implemented energy and waste reduction strategies coupled with efforts to

increase operating room supply efficiencies could save \$5.4 billion over five years, and \$15 billion over 10 years.

**Action Taken:** The evidence was included in the ‘Resource Efficiency’ issue in the Health Care Delivery brief.

#### Example 4: Adding ‘Supply Chain Management’ for Medical Equipment and Supplies, Biotechnology, and Pharmaceuticals

**Comment / Issue:** Include ‘Supply Chain Management’ as an issue in the Medical Equipment and Supplies, Biotechnology, and Pharmaceuticals briefs.

**Source and Timing:** The addition of this issue was suggested by several members of the IWG, representing market participants, corporations, and third party stakeholders.

**Rationale for Inclusion / Exclusion:** This issue was determined to be of material interest for investors. Currently, companies in these industries do not report on FDA enforcement actions despite the potential for these to result in significant fines, revenue disruptions, and potentially the loss of corporate independence. This issue also has significant implications for consumer health and safety as illustrated by the death of 44 people in 2012 that became ill after receiving contaminated steroid injections. Currently, information related to FDA enforcement actions is only available through the Freedom of Information Act.

**Action Taken:** ‘Operational Standards and Supply Chain Management’ was added as an issue with respective KPIs to the Medical Equipment and Supplies, Biotechnology, and Pharmaceuticals briefs.

#### **Sample KPIs:**

- Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP) including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution.
- Percentage of facilities and suppliers (by tier) participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program, or equivalent third-party audit programs for integrity of supply chain and ingredients (e.g. APIs, chemical, raw material, excipients, etc.).

## Part IV: Issues for Special Consideration of the Standards Council

The following section identifies several issues that warrant additional consideration by the Standards Council. Several of these issues were flagged for removal by IWG members who suggested that they were ‘prescriptive’ and subsequently penalized companies for not engaging in specific business lines. Other issues were indicated as being immaterial, and others were

suggested for inclusion. Each issue has been researched following comments that arose during the IWG or public comment period. A description of the issue and SASB's proposed action is included below.

### Pharmaceutical Water Contamination

**Comment / Issue:** Exclude 'Pharmaceutical Water Contamination' from the Biotechnology and Pharmaceuticals briefs.

**Source and Timing:** Almost half of the respondents to the biotechnology and pharmaceuticals IWG surveys suggested excluding this issue.

**Rationale for Inclusion / Exclusion:** Several IWG members indicated that this issue was only relevant for certain types of drugs, and was therefore of limited interest to investors. This response prompted the research team to look for additional evidence of materiality. Although this societal externality is not currently regulated and does not present a current material impact to shareholder value, SASB determined that developing scientific research on human and environmental health coupled with stakeholder concern warrants inclusion of this issue. A recent study that found changes in fish behavior due to dilute concentrations of Oxazepam, a generic anti-anxiety medication, indicates the potential for significant societal and environmental impacts relating to this issue. The associated KPIs were revised to shift the focus away from current manufacturing processes to product take back and efforts to better understand the issue.

**Proposed Action:** Keep 'Pharmaceutical Water Contamination' and the associated KPIs in the biotechnology and pharmaceutical briefs.

### Orphan Drugs

**Comment / Issue:** Remove 'Orphan Drugs' from the biotechnology and pharmaceuticals briefs.

**Source and Timing:** Nine pharmaceuticals and three biotechnology IWG members representing both market participants and corporations suggested excluding this issue.

**Rationale for Inclusion / Exclusion:** IWG members in favor of excluding this issue indicated that developing orphan drugs was not part of all companies' business model, and therefore it does not apply equally to all companies. SASB's research team concluded that the orphan drug market, which reached \$50 billion in 2011, presents a significant and material opportunity for value creation and societal benefit. This forward looking issue and the associated KPIs provide shareholders with a key understanding of how biotechnology and pharmaceuticals companies are positioned to capitalize on changing disease profiles. For companies that are not engaged in this business line, the reporting requirement will be minimal, and should not be viewed as punitive. This approach addresses the concern of some stakeholders that the issues and KPIs are backward-looking and do not address the strategic forward-looking elements of companies' sustainability performance.



**Proposed Action:** Keep ‘Orphan Drugs’ and the associated KPIs in the biotechnology and pharmaceuticals briefs.

### Disease Migration

**Comment / Issue:** Remove ‘Disease Migration’ from the biotechnology and pharmaceuticals briefs.

**Source and Timing:** This issue was identified for removal by four biotechnology and 10 pharmaceuticals IWG members.

**Rationale for Inclusion / Exclusion:** Members of the IWG indicated that although the issue is part of the business and regulatory strategy, it does not provide investors with useful information. Others suggested that the issue is best addressed through ‘Access to Medicines’ or neglected diseases. Although there is little current evidence of materiality, the SASB research team applied a forward looking adjustment and included this issue due to rising concern over this issue. As the ramifications of disease migration continue to change disease profiles and disrupt existing models, this issue will provide investors with insight into how companies are preparing to address and capitalize on the associated opportunities. As for the previous issue, this approach addresses the concern of some stakeholders that the issues and KPIs are backward-looking and do not address the strategic forward-looking elements of companies’ sustainability performance.

**Proposed Action:** Keep ‘Disease Migration’ and the associated KPIs in the biotechnology and pharmaceuticals brief.

### Epidemic Treatments

**Comment / Issue:** Remove ‘Epidemic Treatments’ from the biotechnology and pharmaceuticals briefs.

**Source and Timing:** In sum, 13 IWG participants suggested removing this issue from the biotechnology and pharmaceuticals reporting standard.

**Rationale for Inclusion / Exclusion:** The majority of comments called into question the scope of the issue, and the definition ‘epidemic’. Additionally, stakeholders suggested that this information is already made available to investors. Although both pharmaceuticals and biotechnology companies do provide some information on product development, the research team believes that companies should address the broader societal impact of their medications, and the potential for societal benefit as well as value creation. This forward looking issue and KPIs allow investors to understand how companies in these industries are planning to address the significant and emerging public health problems that have and will continue to impact society. As for the previous issue, this approach addresses the concern of some stakeholders that the issues and KPIs are backward-looking and do not address the strategic forward-looking elements of companies’ sustainability performance.

**Proposed Action:** The issue, renamed as 'Chronic Disease Prevention and Treatment', should remain in the brief.

### Climate Change and Natural Disaster Risks

**Comment / Issue:** Add issue relating to 'Climate Change and Natural Disaster Risks' to the managed care and health care delivery briefs.

**Source and Timing:** Feedback from a corporation representative during the IWG.

**Rationale for Inclusion / Exclusion:** The comment indicated that there are numerous health impacts associated with rising temperatures, new land patterns, and changing food systems which are linked to global climate change. The potential costs to the managed care and health care delivery industry are articulated by a 2011 study in *Health Affairs* that determined the health care costs of six climate change-related events were \$740 million. This represents more than 760,000 encounters with the health care system, and indicates significant challenges to both industries associated with the increased frequency of extreme weather events. Specifically, managed care companies are likely to face added costs, while the health care delivery industry may be forced to add capacity.

**Proposed Action:** 'Climate Change and Natural Disaster Risks' should be included in both the managed care and health care delivery briefs.

## Appendix I: All Comments Received During IWG and Public Comment

The following table provides a brief description of all the comments received during the IWG including: the industry, feedback type, issue, comment(s), and the action taken by SASB. Each comment is followed by brackets indicating the forum and the participant's position ([MP] = market participant, [CORP] = corporate representative, [OTHER] = third party, [VARI] = multiple stakeholders, [IWG] = industry working group, [PCP] = public comment period, and [OL] = open letter).

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Biotechnology	Counterfeit Drugs	Add issue	Add 'Counterfeit Drugs' as a new issue to briefs [OTHER] [IWG]	This issue and associated KPIs were added to biotechnology, pharmaceuticals, and distributors briefs
Biotechnology	Integrated Risk Management	Add issue	Integration and coordination of sustainability, EHS, and business continuity planning. [OTHER] [IWG]	This issue was not included. The issues identified get at the integration of sustainability in business planning
Biotechnology	Preventative and curative care	Add issue	Preventative care (eg, vaccines, cardiovascular risk management) has clearly been shown to reduce long term costs, and creates shared value by improving health, fitness, productivity, and decreasing downstream healthcare costs. Similarly, curative medicines (eg, HCV) reduce morbidity and mortality and accordingly, cost. For KPI's, we might consider % current or future revenues directed toward preventative/curative care, or % current/future R&D effort. [MP] [IWG]	The idea of preventative care was incorporated into 'epidemic treatments', and the issue is now called 'Chronic Disease Prevention and Treatment '.
Biotechnology	Disease Migration	Remove issue	<ul style="list-style-type: none"> <li>- This topic is rightly part of the medical and regulatory business strategy, not an operating best practice [OTHER] [IWG]</li> <li>- It's true that disease migration has increased as an issue in the past 50 years with access to cheaper and faster transportation. But migration per se is less a big sustainable opportunity [MP] [IWG].</li> <li>- Most companies aren't global in nature [MP] [IWG].</li> </ul>	No action taken. This issue was left in both the pharmaceuticals and biotechnology briefs.

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Biotechnology	Employee Relations	Remove issue	<ul style="list-style-type: none"> <li>- There is no evidence of financial impact</li> <li>- This is not useful for investors</li> <li>- The future impacts are likely to be nominal [VARI] [IWG]</li> </ul>	Feedback received through the PCP suggested that this issue was of interest to investors. No action taken. This issue was left in both the pharmaceuticals and biotechnology briefs.
Biotechnology	Epidemic Treatments / Chronic Disease Prevention and Treatment	Remove issue	<ul style="list-style-type: none"> <li>- This topic is rightly part of the medical and regulatory business strategy, not an operating best practice. [OTHER] [IWG]</li> <li>- There may be an obviousness problem with this issue, and complications with defining an epidemic. The issue relates to targeting costly chronic disease segments of the market (diabetes, etc). Regarding obviousness: targeting unmet medical needs in serious chronic diseases are a basic component of the biotechnology business model. I'm hard-pressed to think of a company NOT focusing on these segments. Regarding issues with reporting, how would you define epidemic? Why not include chronic kidney disease? HBV? Any growing segment over time without an obvious means to bend the curve can be called epidemic [MP].</li> <li>- Epidemic treatments isn't part of the business model of all biotech companies [MP] [IWG].</li> </ul>	The issue was not removed, but some of the language from the comment was incorporated and the issue was renamed to 'Chronic Disease Prevention and Treatment' in the biotechnology and pharmaceuticals briefs. Both the issue and the associated KPIs were broadened in scope to address these comments, while the exact definition will be addressed in the forthcoming technical protocol.
Pharmaceuticals	Chronic Disease Prevention and Treatment		Third question has to do with disease prevention versus cure. A fundamental question that's hard to answer. Are there any pharma companies thinking about this? Is it fair to ask the industry to grapple with this question? One way of getting at it is by asking about vaccines (a low margin product that only recently have pharma companies started to invest in). Another way would simply be to ask if they've ever thought about disease prevention as a core business strategy (OTHER) [PCP]	This comment will be incorporated in the next revision after the 'Content Review'.
Biotechnology	Affordability, Access and Fair Pricing	Add KPIs	... there are two indicators on pricing, one of which gets at the core sustainability challenges for the industry—affordability. The data point here (average increase of all product prices v. cost of living, which, my instincts tell me will be a nightmare to tell companies how to do consistently, but let's assume it's doable) is	The need for additional forward looking KPIs will be addressed during the Standards Council 'Content Review'.

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
			backward looking. Shouldn't there be a place here to ask management whether they think affordability is a problem—generally for their industry, as well as specifically for their company—and how they see their company, industry and society tackling that problem over the next ten to twenty years, not making it worse? Wouldn't that be a lot simpler to ask and wouldn't the answers tell us a lot more about how managements of different companies are thinking and contended with this issue long-term (if at all) than one backward looking datapoint? (OTHER) [PCP]	
Biotechnology	Genetically Modified Organisms	Remove issue	<ul style="list-style-type: none"> <li>- Biotech (drug companies) are not competitors for agriculture companies.</li> <li>- It is of interest to a limited group of people</li> <li>- This is not important to companies</li> <li>- This is not useful for investors</li> <li>- the future impact is likely to be nominal [VARI] [IWG]</li> </ul>	This issue was removed from the biotech brief
Biotechnology	Orphan Drugs	Remove issue	<ul style="list-style-type: none"> <li>- Orphan Drugs isn't part of the business model for all biotech/pharma companies [MP] [IWG]</li> <li>- This topic is rightly part of the medical and regulatory business strategy, not an operating best practice. [OTHER] [IWG]</li> </ul>	This issue was not removed, and was flagged for additional consideration by the Standards Council. This issue is forward looking and descriptive, allowing shareholders to ascertain a company's strategy in the face of emerging and changing disease profiles.
Biotechnology	Pharmaceutical Water Contamination	Remove issue	<ul style="list-style-type: none"> <li>- This is only applicable to certain types of drugs. It is not applicable to some very common types of drugs which use naturally occurring compounds. (Insulin for instance.) I do not think it appropriate to have a reporting requirement that is only relevant for some companies. Of course, companies which produce products for which this is an issue should provide information on how this is addressed. In my experience in this area, it is not of interest to investors.</li> <li>- It is of interest to a limited pool of people</li> <li>- This is not important to companies</li> <li>- There is no evidence of financial impact [VARI] [IWG]</li> </ul>	No action taken. Additional evidence was <del>be</del> added to strengthen this issue.

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Distributors & PBMs	Chemical disclosure	Add issue	Chemical information is vital to human health and the lack of a toxic chemical reform act is a risk. [CORP] [IWG]	This language was incorporated into 'Product Safety'
Distributors & PBMs	Counterfeit Drugs	Add issue	Add 'Counterfeit Drugs' as a new issue to briefs [OTHER] [IWG]	Added to biotechnology, pharmaceuticals, and distributors briefs along with associated evidence and KPIs.
Distributors & PBMs	Organic matter	Add issue	Use of natural products that break down naturally. [OTHER] [IWG]	No action taken. This was not determined to be material, since the companies in this industry do not manufacture the products.
Distributors & PBMs	Supply Chain Management	Add issue	from direct experience, majority of Healthcare companies Environmental Impact Value is in Scope 3 - this would appear to be of mandatory importance even if not addressed largely by companies or ESG investors - they are missing the majority issue. [OTHER] [IWG]	No action taken. This issue is addressed in 'Resource Efficiency'.
Health Care Delivery	General Comment	Add issue	Here though I see one huge question that isn't asked—which is "Is the for-profit model appropriate for health care delivery?" There are arguments on both sides—and only about 15% of the hospitals in the country now are for-profit. But the very existence of for-profit hospitals raises difficult questions and that is compounded by the challenges inherent in the business models of a for-profit versus a non-profit hospital. There is obviously no metric to get at this question, but shouldn't we be asking at least one question of the management of for-profit hospitals about how they view this issue, what arguments they would be making for for-profits, what they see happening to the quality and affordability of healthcare in this country if for-profits end up with 50%, 75% of the market, how they manage the competing claims of shareholder wealth creation and appropriate levels of patient care (too much, being as likely to be the problem, as too little)? (OTHER) [PCP]	A management disclosure will be added during the next revision to address this comment.

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Health Care Delivery	Compliance with HIPAA	Add issue	Federal HIPAA mandates security and privacy of patient data. HIPAA violations are of material interest to investors. [CORP] [IWG]	Changed 'Electronic Medical Records' to 'Patient Privacy and Electronic Medical Records', and incorporated language specific to HIPAA in the brief and associated KPI.
Health Care Delivery	Patient Satisfaction	Add issue	Through surveys, measuring patient experience associated with treatment or visit. [OTHER] [IWG]	Changed "Quality of Care" issue to 'Quality of Care and Patient Satisfaction'. The associated language was already included in this issue.
Health Care Delivery	Resource Efficiency / Facilities Designed for Wellness	New data point	Update briefs with new evidence figure. "Greening" activities could save \$5.4 billion over 5 years across all US hospitals. [OTHER] [IWG]	New evidence was included.
Health Care Delivery	Employee Recruitment, Development, and Retention	Revise KPIs	-Add KPI relating to nurse : patient staffing ratios -Add KPI relating to union representation -Add KPI relating to violations of labor laws or complaints (wage and hour violations, EEOC complaints, labor related class action lawsuits, OSHA data) -Add KPI relating to CEO to median employee pay ratios [OTHER] [OL]	The suggested KPIs will be incorporated after the Standards Council during the next revision.
Health Care Delivery	Pricing and Billing Transparency	Revise KPIs	-Measuring access to care is best performed by requiring disclosure of hospital rates for Medicare, insurance and self-pay patients relative to the hospital chargemaster [OTHER] [OL]	The suggested KPI will be incorporated after the Standards Council during the next revision.
Health Care Delivery	Fraud and Unnecessary Procedures	Revise KPIs	-The proposed KPIs correctly ask for disclosure of 'legal and regulatory, fines, and settlements', but the KPIs are limited to medical practice. [OTHER] [OL]	No action taken. The current KPI is not limited to medical malpractice.
Managed Care	Climate change and natural disaster risks	Add issue	Numerous health impacts of rising temperatures and changing land/food systems. [CORP] [IWG]	This issue was not included, and was flagged for additional consideration by the Standards Council.

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Managed Care	Guaranteed Access	Add issue	The ACA requires that insurers accept all risks, and not turn anyone away for pre-existing conditions other health status [OTHER] [IWG]	The suggested language was incorporated in the 'Access to Coverage' issue.
Managed Care	National Information Technology Standards	Add issue	It is critical that the elimination of redundant data and more consistent standard processing and shared databases start to emerge to eliminate administrative costs and confusion. [CORP] [IWG]	No action taken. This issue is addressed in 'Customer Privacy and Technology Standards'.
Managed Care	Willingness to accept risk	Add issue	Willingness of payers to shift business from the current Fee For Service model to a capitated model that puts some of their skin in the game. It aligns their incentives to lower costs and keeping people healthy. [CORP] [IWG]	This issue is addressed in 'Improved Outcomes'.
Managed Care	Provider Relations	Remove issue	- This would be a business and financial strategy-most likely redundant as disclosed in financials. [MP] [IWG] - it's important to the business, but isn't really an ESG related metric. They need good relationships for the business, but there's no enviro or social issue with having bad provider relations. It's just bad for their business. [CORP] [IWG]	No action taken. This issue was determined to be of value to shareholders.
Medical Equipment & Supplies	Access to Health	Add issue	Providing access and affordability to vulnerable populations in order to support global health challenges. Often referred to in the industry as "Access & Affordability". Potential KPIs/Management Disclosures include: Access strategies to facilitate better availability and affordability of life saving medical technologies (disclosure); Percentage of sales related to "Access" strategies (KPI); Number of people affected by access/affordability programs (KPI) [CORP] [IWG]	This issue and associated KPIs was added to the Medical Equipment and Supplies brief as 'Affordability, Access, and Fair Pricing'.
Medical Equipment & Supplies	Employee Relations	Add issue	Competition for qualified employees (as listed for Pharma). [OTHER] [IWG]	This issue was determined not to be material for this industry.
Medical Equipment & Supplies	Research and Development on Novel Compounds	Add issue	Detailed clinical study data are often held as proprietary. All clinical studies should be publicly registered, and all data available to the public. [CORP] [IWG]	This language was incorporated into 'Product Safety'.



Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Medical Equipment & Supplies	Supply Chain Management	Add issue	A lot of impacts (environmentally and socially) are in the supply chain, especially in medical equipment industry since the depth of manufacturing is low (mostly assembly). In addition, there are already regulations. Effects of a bad management here might be disruption of supply chain (suppliers closed by government or trade restrictions) or reputational effects (e.g. fatalities) [CORP] [IWG]	This issue and associated KPIs was added to the Medical Equipment and Supplies brief as 'Operational Standards and Supply Chain Management'.
Pharmaceuticals	Counterfeit Drugs	Add issue	Add 'Counterfeit Drugs' as a new issue to briefs [OTHER] [IWG]	This issue and associated KPIs were added to biotechnology, pharmaceuticals, and distributors briefs
Pharmaceuticals	Integrated Risk Management	Add issue	Integrated Risk Management: Coordinated strategy and planning for sustainability, EHS, business continuity, and disaster recovery. [OTHER] [IWG]	This issue was not included. The issues identified get at the integration of sustainability in business planning
Pharmaceuticals	Investment in Green Chemistry	Add issue	Minimization of Persistent Bioaccumulative Toxins (PBTs) and biodegradability of metabolites [OTHER] [IWG]	This comment was incorporated in the 'Product Safety' issue.
Pharmaceuticals	Patients Reached / Volumes Sold	Add issue	Investors, and regulators, should be able to figure out if an increase in sales means more sold or higher prices [OTHER] [IWG]	This comment was included as a KPI under the 'Affordability and Fair Pricing' issue in both the pharmaceuticals and biotechnology briefs.
Pharmaceuticals	Research and Development on Novel Compounds	Add issue	New approaches to diseases for patients who do not respond to current therapies [OTHER] [IWG]	This issue was not included as it is addressed in other issues.
Pharmaceuticals	Supply Chain Management	Add issue	<ul style="list-style-type: none"> <li>- Assurance of ethical, social and environment standards among at risk suppliers [CORP] [IWG].</li> <li>- Actions to minimize risks anywhere along the supply chain, from the sourcing of the pharmaceutical raw materials to the manufacture of the medicinal ingredients, and also to the finished dosage form (medicine) itself in its packaging and its distribution to a patient or consumer. Rx360 initiative [OTHER] [IWG].</li> <li>- Supply chain management. Counterfeit drugs Suggested KPIs = %suppliers subject to risk assessment; participation in Rx-360, the Pharmaceutical Supply Chain</li> </ul>	This comment was incorporated in the newly created issues of 'Operational Standards and Supply Chain Management' and 'Counterfeit Drugs' in both the biotechnology and pharmaceuticals briefs.

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
			Initiative or similar industry programs. [OTHER] [IWG]	
Pharmaceuticals	Employee Recruitment, Development, and Retention	Split Issue and Add New KPIs	<ul style="list-style-type: none"> <li>-Inappropriate to lump employee safety with recruiting. Important on its own.</li> <li>-Needs employee engagement measure</li> <li>-Employee retention should move to governance</li> <li>-Some disclosure on talent strategy (if they aren't a primary research shop than the scientist item is not material)</li> <li>-Diversity measures [MP][PCP]</li> </ul>	Although employee safety is an important issue, it was deemed not to be material on its own for this industry. Diversity was found not to be material, and the current KPI framework addresses talent strategy.
Pharmaceuticals	Disease Migration	Remove issue	<ul style="list-style-type: none"> <li>- Given the patent-oriented nature of NME development and the fact most tropical disease are located at the area where many patients cannot afford, opportunity-oriented KPIs would rather be covered by traditional reporting. Also, tropical disease can be covered at the access to medicine or rather as "neglected diseases" to emphasize the current lack of access/treatments [MP] [IWG].</li> <li>- I think companies should collaborate in public-private partnerships to address disease containment and prevention, but in many cases these are public policy issues with many factors. It is quite complicated for a company to report on the impact of the piece they are involved in. Reporting thus just becomes a list of what you do, which isn't that useful for investors.[OTHER] [IWG]</li> </ul>	This issue was not removed, and was flagged for additional consideration by the Standards Council. This issue is forward looking and descriptive, allowing shareholders to ascertain a company's strategy in the face of emerging and changing disease profiles.

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Pharmaceuticals	Epidemic Treatments	Remove issue	<p>- The KPI regarding the “epidemic treatments” need to be described with broader social impact of promoting these drugs as block buster products especially given the fact disease such as hypertension needs to be addressed through dietary/life-style change rather than “innovative hypertension drugs” especially given the number of drugs available in the market. Not to mention serious safety issues directly associated with these “epidemic treatments”, which might not be inseparable issue. I’m not comfortable with the current description presented, which seems it is a KPI because it will make money. Also, presenting the “epidemic treatments” with only positive implications seems like no difference from the information the companies have been reporting. If these are the case, I don’t see the point of creating this issue as new “sustainability” KPI. [MP] [IWG]</p> <p>- Development in very large disease areas such as diabetes/obesity is very expensive and not feasible by everyone. (...) New viral epidemics with no good alternatives are a priority and should be a focus. [MP]</p> <p>- it does not necessarily apply to ALL Pharma companies and hence must not be part of the minimum set [OTHER].</p> <p>- Very important but not applicable for ALL companies in the pharma space. [OTHER] [IWG].</p>	<p>The issue was not removed, but some of the language from the comment was incorporated and the issue was renamed to ‘Chronic Disease Prevention and Treatment’ in the biotechnology and pharmaceuticals briefs. Both the issue and the associated KPIs were broadened in scope to address these comments, while the exact definition will be addressed in the forthcoming technical protocol.</p>

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
Pharmaceuticals	Orphan Drugs	Remove issue	<p>- Orphan drug development is important but not accessible to all companies. While companies should always seek to serve unmet needs, they do not always fall in orphan class. [MP] [IWG]</p> <p>- Orphan drugs are a part of some companies' business models and not of others. Generally, companies should describe their business model and that is what they should be assessed on. In the description of business models and lines of business, it is clear whether a company is involved in orphan drugs. But I see no value, particularly to investors, in companies being forced to report that they DON'T focus on orphan drugs. [OTHER] [IWG]</p> <p>- The topic does not equally apply to all Pharma companies [OTHER] [IWG].</p> <p>- I think that orphan drugs is an important opportunity, however, it may not be applicable to all pharmaceutical companies. I am considering the audience before the market leaders - e.g., smaller players, upstarts, generic providers, etc.). I'd recommend this be optional when it does not apply. [OTHER] [IWG]</p>	<p>This issue was not removed, and was flagged for additional consideration by the Standards Council. This issue is forward looking and descriptive, allowing shareholders to ascertain a company's strategy in the face of emerging and changing disease profiles.</p>
General Comment			<p>Second overall comment is that the KPIs are all backward looking, if I'm not mistaken. This is my perennial worry about the quantifiable, comparable, auditable approach versus sustainability concepts and concerns. This to me remains a conceptual problem worth thinking about. What does a sustainable pharmaceutical industry look like and do these questions help investors and others understand whether corporate management is aware of these issues and is tackling them seriously, integrating them into their core business models and strategic management planning [OTHER] [PCP]</p>	<p>Issues such as 'Orphan Drugs' and 'Disease Migration' are forward looking issues that seek to address this issue. The potential need for additional forward looking KPIs will be addressed during the Standards Council 'Content Review'.</p>

Industry	ESG Issue	Feedback	Comment	Action Taken / Explanation
General Comment			<p>There may be only ten general areas of KPIs, but the total number of indicators is 40 as I count them. My guess is this number may expand slightly after the public comment period. I see a danger here. The reporting system will look burdensome to companies (and the SEC) perhaps not as burdensome as GRI, but it's getting up into that territory. I worry that the reports based on these indicators when you go into pilot mode will be large and cumbersome. It will be interesting to see, but I would definitely keep an eye out for that. [OTHER] [PCP]</p> <p>At the same time these ten KPIs won't satisfy those who want "complete" GRI type reporting. We're in danger of being neither fish nor fowl, satisfying neither the SEC/companies nor the NGOs/larger society. [OTHER] [PCP]</p>	Concern relating to the volume of KPIs will be a focal point of discussion during the Standards Council 'Content Review'.
General Comment			Collection of this information and ensuring auditable data quality will pose a barrier as reaching this level for all of the KPIs in the exposure draft will require a lot of work, as reporting externally comes with a greater pressure and expectation in terms of data quality and governance for these processes. I foresee a great barrier here as this will be very time consuming. [CORP] [PCP]	Concern relating to the volume of KPIs will be a focal point of discussion during the Standards Council 'Content Review'.

## Appendix II: Assessment of Issue Materiality by IWG Members

The following tables provide a summary (by industry) of how each interest group assessed the materiality of the environmental, social, and governance issues that SASB identified. The number in parenthesis indicates the total number of IWG participants for each category.

<b>Material Issues by Interest Group</b>				
<b>Industry</b>	<b>Biotechnology</b>			
	<b>Interest Group</b>			
<b>Material Issue</b>	<b>All (9)</b>	<b>Corporation (1)</b>	<b>Market Participant (2)</b>	<b>Others (6)</b>
<b>Access to Medicines</b>				
Material.	89%	0%	100%	100%
Priority Score.	5.0	1.0	4.0	5.8
<b>Affordability and Fair Pricing</b>				
Material.	78%	0%	67%	100%
Priority Score.	5.8	4.0	3.0	6.5
<b>Corruption and Bribery</b>				
Material.	100%	100%	100%	100%
Priority Score.	6.4	9.0	6.0	6.0
<b>Disease Migration</b>				
Material.	56%	100%	33%	71%
Priority Score.	10.0	10.0	11.0	9.8
<b>Drug Safety and Side Effects</b>				
Material.	89%	0%	100%	100%
Priority Score.	1.6	2.0	1.0	1.7
<b>Employee Relations</b>				
Material.	56%	0%	67%	71%
Priority Score.	8.8	7.0	8.0	9.2
<b>Epidemic Treatments</b>				
Material.	56%	100%	33%	71%
Priority Score.	8.4	11.0	9.0	7.8
<b>Ethical Marketing</b>				
Material.	100%	100%	100%	100%
Priority Score.	4.3	5.0	7.0	3.7
<b>Genetically Modified Organisms</b>				
Material.	67%	100%	33%	86%
Priority Score.	11.4	13.0	13.0	10.8
<b>Orphan Drugs</b>				
Material.	67%	100%	67%	71%

Priority Score.	8.5	6.0	2.0	10.0
<b>Pharmaceutical Water Contamination</b>				
Material.	56%	100%	33%	71%
Priority Score.	9.3	12.0	12.0	8.3
<b>Resource Efficiency</b>				
Material.	78%	0%	67%	100%
Priority Score.	7.9	8.0	5.0	8.3
<b>Safety of Clinical Trial Participants</b>				
Material.	78%	0%	67%	100%
Priority Score.	3.9	3.0	10.0	3.0

<b>Material Issues by Interest Group</b>				
Industry	Distributors & PBMs			
	<b>Interest Group</b>			
<b>Material Issue</b>	<b>All (5)</b>	<b>Corporation (2)</b>	<b>Market Participant (1)</b>	<b>Others (2)</b>
<b>Corruption and Bribery</b>				
Material.	88%	100%	100%	80%
Priority Score.	2.8	0.0	2.0	3.0
<b>Product Lifecycle Management</b>				
Material.	88%	100%	0%	100%
Priority Score.	3.3	0.0	4.0	3.0
<b>Product Safety</b>				
Material.	100%	100%	100%	100%
Priority Score.	1.3	0.0	1.0	1.3
<b>Resource Efficiency</b>				
Material.	88%	75%	100%	100%
Priority Score.	2.8	0.0	3.0	2.7

<b>Material Issues by Interest Group</b>				
Industry	Health Care Delivery			
	<b>Interest Group</b>			
<b>Material Issue</b>	<b>All (14)</b>	<b>Corporation (7)</b>	<b>Market Participant (0)</b>	<b>Others (7)</b>
<b>Access for Low Income and Uninsured Patients</b>				

Material.	83%	88%	100%	78%
Priority Score.	3.9	3.6	4.0	4.1
<b>Electronic Medical Records</b>				
Material.	78%	75%	100%	78%
Priority Score.	6.6	7.6	3.0	6.4
<b>Employee Relations</b>				
Material.	89%	88%	100%	89%
Priority Score.	5.8	5.8	5.0	5.9
<b>Facilities Designed for Wellness</b>				
Material.	78%	75%	100%	78%
Priority Score.	7.3	7.4	8.0	7.1
<b>Fraud and Unnecessary Procedures</b>				
Material.	94%	100%	100%	89%
Priority Score.	4.4	4.2	7.0	4.1
<b>Preventative Care and Improved Outcomes</b>				
Material.	78%	75%	100%	78%
Priority Score.	4.5	3.8	1.0	5.4
<b>Pricing and Billing Transparency</b>				
Material.	72%	50%	100%	89%
Priority Score.	6.1	6.4	6.0	5.9
<b>Quality of Care</b>				
Material.	94%	100%	100%	89%
Priority Score.	1.6	1.0	2.0	2.0
<b>Resource Efficiency</b>				
Material.	94%	100%	100%	89%
Priority Score.	4.8	5.2	9.0	4.0

<b>Material Issues by Interest Group</b>				
Industry	Managed Care			
	Interest Group			
Material Issue	All (10)	Corporation (3)	Market Participant (4)	Others (3)
<b>Access to Coverage</b>				
Material.	90%	100%	80%	100%
Priority Score.	2.8	3.0	2.7	0.0
<b>Customer Privacy</b>				
Material.	90%	100%	100%	75%
Priority Score.	3.8	5.3	2.3	0.0
<b>Improved Outcomes</b>				



Material.	80%	100%	100%	50%
Priority Score.	1.7	1.0	2.3	0.0
<b>Plan Performance</b>				
Material.	100%	100%	100%	100%
Priority Score.	3.8	3.7	4.0	0.0
<b>Pricing Transparency and Plan Literacy</b>				
Material.	90%	100%	80%	100%
Priority Score.	3.7	3.7	3.7	0.0
<b>Provider Relationships</b>				
Material.	60%	67%	60%	75%
Priority Score.	5.2	4.3	6.0	0.0

<b>Material Issues by Interest Group</b>				
Industry	Medical Equipment & Supplies			
	<b>Interest Group</b>			
<b>Material Issue</b>	<b>All (12)</b>	<b>Corporation (7)</b>	<b>Market Participant (1)</b>	<b>Others (4)</b>
<b>Corruption and Bribery</b>				
Material.	100%	100%	100%	100%
Priority Score.	3.2	3.0	4.0	3.3
<b>Ethical Marketing</b>				
Material.	93%	89%	100%	100%
Priority Score.	3.8	4.4	5.0	2.3
<b>Product Lifecycle Management</b>				
Material.	100%	100%	100%	100%
Priority Score.	3.1	2.6	3.0	4.0
<b>Product Safety</b>				
Material.	100%	100%	100%	100%
Priority Score.	1.3	1.6	1.0	1.0
<b>Resource Efficiency</b>				
Material.	100%	100%	100%	100%
Priority Score.	3.6	3.4	2.0	4.3

<b>Material Issues by Interest Group</b>				
Industry	Pharmaceuticals			

	<u>Interest Group</u>			
<b>Material Issue</b>	<b>All (22)</b>	<b>Corporation (4)</b>	<b>Market Participant (9)</b>	<b>Others (9)</b>
<b>Access to Medicines</b>				
Material.	83%	100%	70%	90%
Priority Score.	5.2	4.7	5.6	5.0
<b>Affordability and Fair Pricing</b>				
Material.	92%	100%	90%	90%
Priority Score.	3.3	1.3	2.6	4.4
<b>Corruption and Bribery</b>				
Material.	96%	100%	90%	100%
Priority Score.	5.4	4.3	4.9	6.0
<b>Disease Migration</b>				
Material.	58%	75%	60%	50%
Priority Score.	9.6	9.3	9.7	9.5
<b>Drug Safety and Side Effects</b>				
Material.	96%	100%	90%	100%
Priority Score.	2.2	2.3	2.1	2.1
<b>Employee Relations</b>				
Material.	71%	50%	70%	80%
Priority Score.	7.9	9.0	7.9	7.5
<b>Epidemic Treatments</b>				
Material.	63%	75%	60%	60%
Priority Score.	8.0	6.7	7.7	8.6
<b>Ethical Marketing</b>				
Material.	88%	100%	90%	80%
Priority Score.	5.8	6.3	4.9	6.3
<b>Orphan Drugs</b>				
Material.	63%	50%	70%	60%
Priority Score.	9.3	10.7	9.4	8.8
<b>Pharmaceutical Water Contamination</b>				
Material.	71%	50%	80%	70%
Priority Score.	9.0	10.0	9.3	8.5
<b>Resource Efficiency</b>				
Material.	88%	75%	90%	90%
Priority Score.	8.0	9.3	9.0	6.9
<b>Safety of Clinical Trial Participants</b>				
Material.	92%	100%	80%	100%
Priority Score.	4.6	4.0	5.0	4.4