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HASTINGS

## Survive or Thrive?

# Navigating the ESG Regulatory Landscape in Health Care

December 1, 2022



An aerial photograph of a multi-lane road on a bridge spanning a body of water. The water is a deep green color. Several cars are visible on the road, including a white car, a red car, and another white car further down. The road has white lane markings and a central divider.

# Agenda

1. What is ESG & Why Does ESG Matter?
2. Disclosure Developments
3. Select SASB Disclosure Recommendations
4. Some Trend Lines
5. Recommended Next Steps

1.

# What is ESG & Why Does ESG Matter?

# Key Focus Areas Within ESG

- Environmental, social, and governance (“ESG”) is a term used to represent an organization’s **corporate financial interests** that focus mainly on sustainable and ethical impacts.
- Capital markets use ESG to evaluate organizations and determine **future financial performance**.
- While ethics, sustainability, and corporate governance are considered non-financial performance indicators, their role is to ensure accountability and systems to manage a corporation’s impact.





# Trends and Campaigns

- Corporations are facing **growing pressure** from investors, shareholders, stakeholders, and regulators to identify, assess, and disclose ESG-related risks.



Environmental	Social	Governance	Human Rights
GHG emissions/ energy usage	Executive compensation	ESG/HR governance and oversight systems	Forced labor
Renewables	Gender pay gap	Board diversity and independence	Child labor
Water and waste	Turnover	Business ethics/ anti-corruption	Workplace health and safety
Environmental oversight (operations and supply chain)	Diversity & inclusion/ non-discrimination	Cyber security and data privacy	Fair & living wage
Climate impact/mitigation	Worker health and safety	Supplier code of conduct	Access to affordable health care
Scope 1, 2 and (potentially) 3 emissions	Child and forced labor (operations and supply chain)	External assurance	Worker rights (who is a “worker”?)
Board and management oversight	Human rights (operations and supply chain)	ESG/HR reporting and disclosures	Right to a sustainable environment and future

# Industry-Specific Considerations

- ESG and human rights risks vary depending on **industry sector**, applicable regulatory framework, geographic footprint, and supply/value chain.

Materiality assessment to identify relevant and prioritized risks

Consideration of industry-specific circumstances to develop a tailored approach to risk management

Mapping of value chain as well as operations

# How ESG Arises in Life Sciences and *Health Care*\*

*[\*Based on SASB recommendations]*

## R&D

- Clinical trials
- Informed consent

## Product Quality

- Manufacturing practice
- Falsified, substandard, or counterfeit drugs
- *Quality of care and patient satisfaction*

## Patient Safety

- *Drug safety*
- *Drug misuse & abuse*

## Pricing & Access

- *Pricing principles & methodology*
- *Transparency*
- *Access for low income patients*

## Privacy & Data Security

- *Patient, customer, and employee information*
- *Data breach response*

## Supply Chain

- Forced & child labor
- Conflict minerals
- Ecological footprint
- Safety

## Diversity & Inclusion

- *Employees, vendors/suppliers, clinical trial participants*
- *Board and C-suite*

## Climate & Environment

- *GHG emissions*
- *Energy management and consumption*
- *Waste Management*

## Business Ethics

- *Ethical business practices/fraud*
- Ethical marketing & labeling
- ABAC, competition, trade secrets



# ESG as A Component of Overall Risk Management



- As with many other risks managed across the enterprise, ESG risks should be assessed as part of an overall compliance risk management approach, taking into account the company's:

- ✓ Overall risks presented
- ✓ Risk appetite

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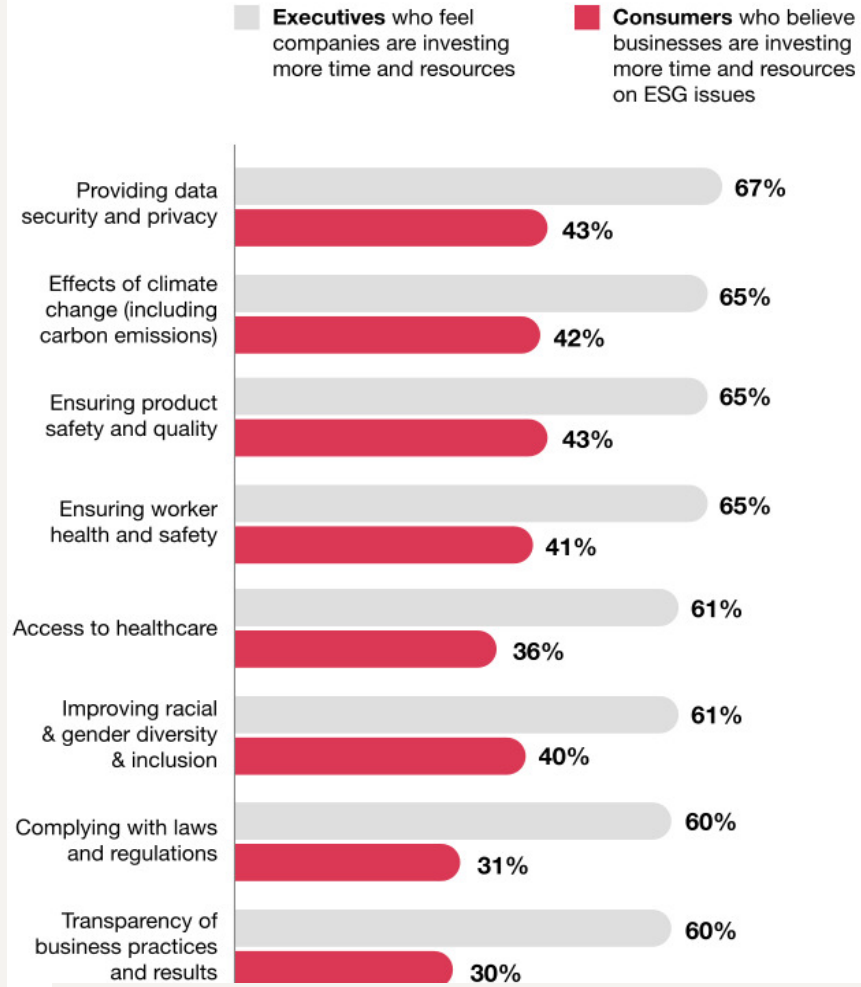
## Disclosure Developments

# Growing Demand for ESG Disclosures

- Stakeholders, including investors, consumers, and the market, are **increasingly prioritizing ESG disclosures and risks in evaluating investment opportunities.**
- In addition to investors, regulators and stock exchanges are similarly developing requirements around ESG disclosures.



## Consumers are not convinced that businesses are making adequate investments in ESG issues



Source: PwC Consumer Intelligence Series, June 2, 2021

## Key findings

# 51%

of respondents say environmental sustainability is more important to them today than it was 12 months ago.

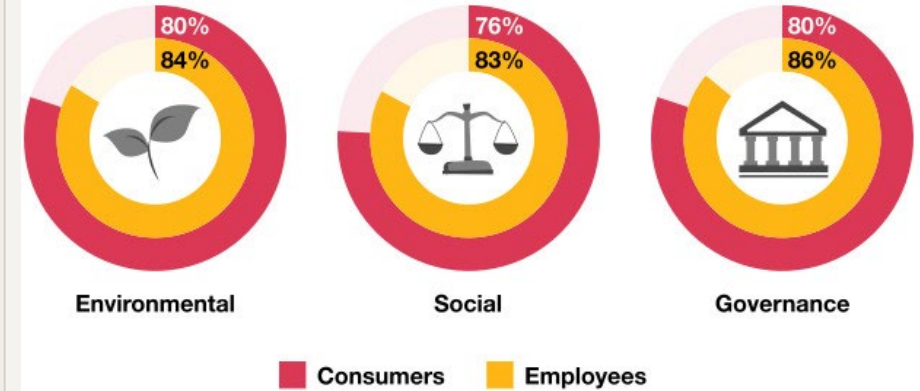
# 49%

of consumers say they've paid a premium for products branded as sustainable or socially responsible in the last 12 months.

Source: Research Brief: *Balancing sustainability and profitability*, IBM Institute for Business Value (2022).

## ESG commitments are driving consumer purchases and employee engagement

I am more likely to buy from / work for a company that stands up for...



Source: PwC Consumer Intelligence Series, June 2, 2021

# 88%

of investors believe companies that prioritize ESG initiatives represent better opportunities for long-term returns than companies that do not

Source: Edelman Trust Barometer Special Report: Institutional Investors



# Growing Scrutiny From Regulators



# The SEC's Increasing Focus on ESG



**March 2021**  
Establishment of the **Climate and ESG Task Force** in the SEC's Division of Enforcement

**March 2022**  
New proposed rules on **cybersecurity risk management** and **incident disclosure**

**March 2022**  
New proposed rules on **climate-related disclosures**

**April 2022**  
Mining company charged over **misleading statements** about safety

**May 2022**  
New proposed rules on **disclosures by investment companies and advisers & fund names**

**May 2022**  
Investment charged over **ESG misstatements and omissions**

**June 2022**  
Investment bank reportedly under investigation over its **ESG mutual funds.**

**Q4'22/Q1'23**  
Expected issuance of **final rules** on **climate-related disclosures**





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## Select SASB Disclosure Recommendations for Health Care Delivery Companies

# Energy Management and Disclosure

- The SEC proposed rules on ESG-related disclosures require companies to report actual or potential impacts on their strategy, business model, and outlook.
  - Companies would also be required to disclose how ESG-related impacts have been considered as part of their business strategy, financial planning, and capital allocation
- While SEC Climate Disclosure Rulemaking may not directly affect health care delivery companies, SASB recommends that they make specific disclosures on energy management as these companies typically operate energy-intensive facilities and rely on energy purchased from suppliers.
- Under SASB, health care delivery companies should make the following energy management disclosures:
  - Total amount of energy consumed
  - Percentage of energy consumed that was supplied by grid electricity
  - Percentage of energy consumed from renewable energy

# Waste Management

- SASB recommends disclosure on waste management as health care delivery companies generate a significant amount of medical and pharmaceutical waste.
- Medical Waste:
  - Total amount of medical waste generated from owned/operated facilities
  - Amount of federally- or state-regulated medical waste
  - Percentage of medical waste per final disposition method (e.g., incinerated, recycled or treated, and landfilled)
- Pharmaceutical Waste:
  - Total amount of hazardous and non-hazardous waste generated from owned/operated facilities
  - For both hazardous and non-hazardous waste, percentage of incinerated, treated or recycled, and landfilled
  - Percentage of medical waste per final disposition method (e.g., incinerated, recycled or treated, and landfilled)

# Patient Privacy

- Cyber threats proliferate, particularly given electronic health records.
- SASB sets out a number of disclosure recommendations, including with regard to:
  - Percentage of records that are stored electronic health records (EHR) certified as “meaningful use” under ARRA
  - Policies and practices relating to securing protected health information (PHI) and personally identifiable information (PII), including how the company collects, uses and retains customer information
  - Description of “information lifecycle” – collection, use. Retention, processing, disclosure and destruction and how these practices may affect individual privacy rights
  - Systems used to comply with HIPAA and HITECH Act, as well as administrative, physical and technical safeguards of system security
  - Total number of data breaches, and broken down by PII and PHI and total number of customers affected, and monetary losses incurred as a result of associated legal proceedings

# Patient Access, Quality, Satisfaction and Pricing Transparency

- Disclosure of how company manages provision of care to uninsured in order to allow shareholders to understand associated risks and opportunities, including impacts and effects of serving patients with mixed insurance statuses at their facilities
- Delivering quality care and patient satisfaction drives enterprise value and longevity, with increasing regulatory focus on readmission rates
  - SASB recommends quality-of-care disclosures, aggregated across all facilities operated by company: average hospital value-based purchasing (HVBP), total performance score (TPS), serious reportable events (SREs), hospital-acquired condition (HAC) score, excess readmission ration, readmissions payment adjustment amount
- Transparency in pricing and billing increasing in sector: SASB recommends disclosure on:
  - Policies and programs focused on transparency on pricing or procedures/treatments and alternatives
  - How information is provided on out-of-pocket versus insured procedures
  - Scope, format and mechanism for making information publicly available, including highest volume inpatient and outpatient services

# Employee Health/Safety, DEI and Climate Impact

- Skilled workforce, routinely exposed to injury, illness and infection, which can adversely impact employee health and welfare, performance, service quality, patient safety and more
- SASB recommends disclosing total recordable incident rate (TRIR) for work-related injuries/illnesses and days away, restricted or transferred (DART) rates
- Given demands of health care workers, emphasis on recruitment, development, and retention, SASB recommends disclosure of:
  - Voluntary and involuntary turnover of physicians, non-physician HCPs and other employees
- Given focus on DEI writ large, including as it relates to employees, patients served and quality of service to different demographics, and implicit biases that may exist, companies need to focus serious attention to their policies, procedures and programs, and constantly reassess
- Facilities may be adversely impacted by extreme weather events, infectious diseases, food/water scarcity and therefore preparedness is key. SASB recommends disclosure of policies and practices that address these risks to physical infrastructure and assets



# Oversight, Governance & Risk Management

- Stakeholder expectations and increasing regulatory requirements stress the importance of oversight and management of ESG-related risks by a company's Board of Directors, as well as senior management, such as:

Board of Directors	Senior Management
<ul style="list-style-type: none"><li>• Board members or board committees responsible for oversight of ESG-related risks</li><li>• Processes and frequency by which board or board committee is informed about ESG-related risks and discusses such at board meetings</li><li>• Whether/how board or board committee considers these risks as part of its business strategy, risk management, and financial oversight</li><li>• Whether/how board or board committee sets priorities/goals, and how it oversees progress against those targets or goals</li></ul>	<ul style="list-style-type: none"><li>• Management positions or committees responsible for assessing and managing ESG-related risks</li><li>• Relevant expertise of the responsible management personnel or committees</li><li>• The processes and frequency by which the responsible managers or management committees are informed about and monitor ESG-related risks</li><li>• Whether the responsible managers or management committees report to the board or board committee on these risks and, if so, how frequently that occurs</li></ul>

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## Some Trend Lines

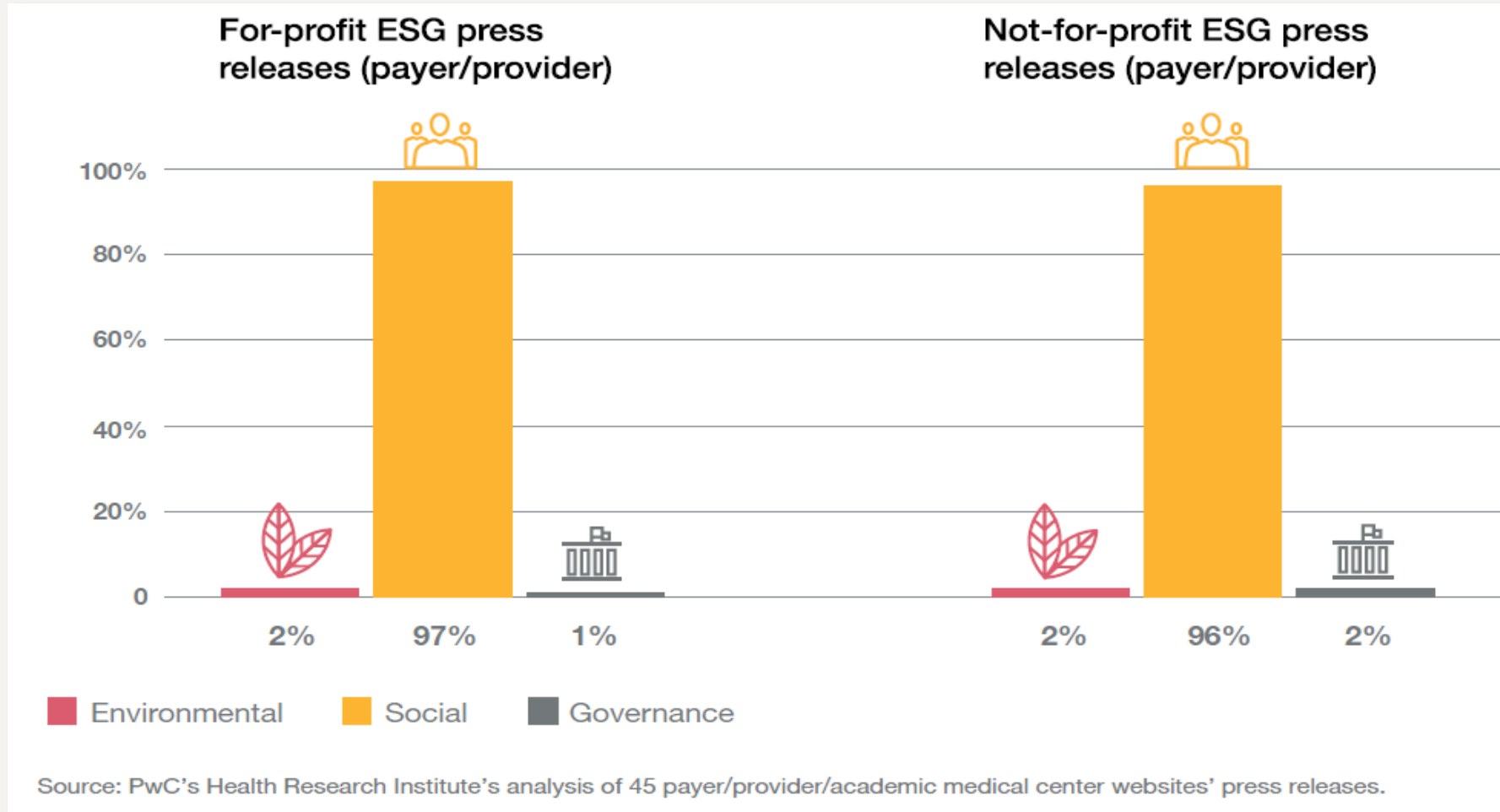
# Some interesting Stats: ESG Steps taken by 45 Insurers and Providers

*[Source: PwC's Health Research Institute ESG Insights (2021)]*

Environmental	Social	Governance
Carbon neutralist goals reached within 5-10 years	Significant financial contribution toward social determinants of health strategies, and expanding access to health care for underserved communities	Comprehensive corporate social responsibility report to track and share measurable ESG progress
Advanced waste management practices, including improved disposal of toxic waste and antimicrobial resistance prevention	Investing in and updating technology and talent to protect from breaches and cyber attacks	ESG Leader appointed
	Robust supplier diversity programs	Gender and racial diversity within governing board
	Comprehensive diversity and inclusion programs such as recruitment and mentorship programs	Pay equity goals
		Ethics, compliance and fraud policies

# Some interesting Stats: Social Pillar

[Source: PwC's Health Research Institute ESG Insights (2021)]



# Some interesting Stats: Environmental Gaining

*[Source: PwC's Health Research Institute ESG Insights (2021)]*

- In addition to LEED/green buildings, some are including additional environmental initiatives in operations
- For instance:
  - **Providence Portland Medical Center:** switching from sevoflurane from desflurane as anesthetic agent and estimated reducing GHG by 1,100 metric tons of CO<sup>2</sup> equivalent
  - **Cardinal Health Sustainable Technologies:** single use medical device collections, reprocessing and recycling for resale to hospitals, estimated to extending the life of 16M devices and diverting 324K+ pounds of single use devices from landfills in 2019
  - **Community Health Systems:** diverted 5.9M containers of sharps from landfills through medical recycling program
  - **OptumRx:** introduced fully sustainable medication packaging, replacing foam and polystyrene with 100% renewable cotton, delivering 5M+ prescriptions producing annual savings of 3M pounds of CO<sup>2</sup>, 27M gallons of water and 4M kilowatt hours of energy

# Some interesting Stats: Social Action

*[Source: PwC's Health Research Institute ESG Insights (2021)]*

- Increasing focus on tracking impact of social initiatives, in particular board diversity, strengthening DEI programs, workplace safety
- For instance:
  - **UnitedHealth Group with OptumRx:** helped pass legislation in Kansas to allow unused medications to go to adult care homes or federally qualified health centers, clinics serving indigenous peoples and community mental health centers, diverting over \$30M in prescription medicines from waste since 2008
  - **UPMC:** supplier diversity initiative resulted in increasing its diverse spending from \$101M in FY14 to \$246M in FY20
  - **CVS Health:** invested \$8.7M in new affordable housing in Orlando to address homelessness
  - **BCBS of Arizona:** invested \$10M over 3 years in Mobilize AZ program to reduce misuse of opioids and other substances, serving 28K+ individuals, helping 618 providers become certified, and creating 18,500 additional treatment spots in 2019



# Some interesting Stats: Governance

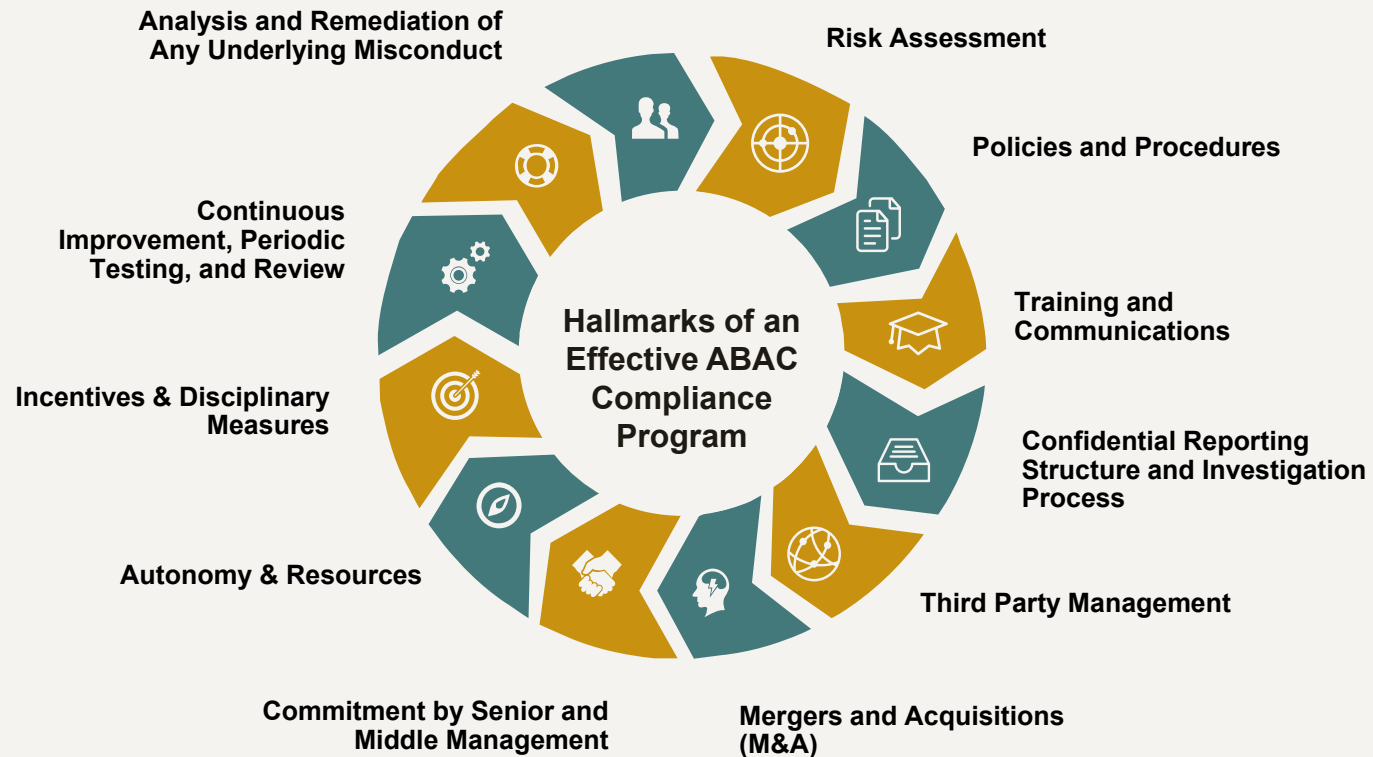
*[Source: PwC's Health Research Institute ESG Insights (2021)]*

- Pillar requiring more focus and room for improvement
- With focus on board oversight and governance writ large, should be priority for all companies
- Quality of data still an area of need
- Most in sector did not have officers focused on ESG initiatives
- Of 45 healthcare organizations analyzed:
  - For-Profit:
    - 53% - No ESG leadership role
    - 47% - ESG leadership role
  - Not-for-Profit:
    - 62% - No ESG leadership role
    - 38% - ESG leadership role

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## Recommended Next Steps

# Elements of an Effective Compliance Program



## Three Fundamental Questions:

- 1 Is the compliance program well-designed?
- 2 Is the program adequately resourced and empowered?
- 3 Does the program function effectively in practice?

# Evaluation of Existing ESG Practices

- **Take action to evaluate ESG risks and opportunities**, including through:
  - Ensuring that current and future disclosures satisfy reporting requirements;
  - Preemptively bolstering any potential gaps that could negatively attract the attention of investors or regulators; and
  - Monitoring anticipated developments in ESG disclosure requirements.



## Action Items

1. Conduct Risk Assessment
2. Develop Comprehensive ESG Strategy
3. Appoint Risk Owner
4. Develop or Enhance ESG Policies
5. Evaluate Existing Disclosures
6. Establish Tone at the Top
7. Implement and Train on Effective Controls

# Assessment of ESG Risks

- Conducting an internal ESG risk assessment is the most effective mechanism to **establish a baseline of your company's existing ESG risks and responsive policies and procedures.**
- The risk assessment should:
  - Confirm that existing ESG practices meet regulatory standards; and.
  - Identify any gaps in ESG practices that may create ESG risk exposure.



## Risk Assessment Best Practices

- ✓ Review existing policies and procedures.
- ✓ Establish how policies and procedures have been executed in practice.
- ✓ Identify instances in which application of policies did not match stated standards.
- ✓ Evaluate whether new/updated policies may be required to meet regulator expectations.
- ✓ Assess any gaps or areas of exposure.

# Development of ESG Strategy & Policies

- A thoughtful and comprehensive approach is more likely to ensure that reporting:
  - Aligns with investors', regulators', and exchanges' disclosure expectations and guidance; and.
  - Avoids the ESG-related reporting misconduct that regulators seek to identify.
- The Board should be satisfied that implementation of ESG policies and procedures appropriately address the company's ESG objectives, align with the company's overarching strategy, and effectively mitigate risks posed.

## *If you have . . .*

### No Current ESG Strategy/Policies

Create:

- A **playbook** that defines the ESG factors that are paramount to your company
- An **approach** for ensuring that those factors are accurately and consistently reported

### Preliminary ESG Strategy/Policies

- Periodically reevaluate both the strategy and the policies to confirm alignment with expectations arising from increased focus on and monitoring of ESG reporting
- Deploy an ESG-focused internal communications campaign

# Implementation of Internal ESG Controls

- **Internal controls should be designed to address those ESG factors critical to your business.**
- The framework should monitor relevant risks and ESG metrics identified for disclosure, and be designed to identify potential issues or increasingly relevant ESG-related metrics.
- Controls must ensure that ESG-related requirements are met and that public disclosures reflect actual practices.



## Internal Controls

- ✓ **Defensible Policies and Procedures.** The company's governance structures and compliance program should include the metrics against which the company will assess and evaluate ESG programs. This enables the company to assess the efficacy of existing written standards, as well as the need for new/updated written standards.
- ✓ **Monitoring and Internal Audit.** The Board should be involved in establishing systems that provide material information to management and the Board about existing risks, the impact of those risks, and risk mitigation efforts. Periodic audits and monitoring can confirm whether the company is meeting its ESG commitments, and can identify any new or evolving risks that must be addressed.
- ✓ **Due Diligence Considerations.** Existing due diligence criteria should be updated to include those ESG factors essential to the business.

# Speaker Bio: Tara K. Giunta



**Tara K. Giunta**, a partner in the Litigation Department of Paul Hastings, is Co-Chair of its ESG Risk, Strategy and Compliance Group and a Member of the firm’s Investigations and White Collar Defense practice, which is routinely recognized by the *Global Investigations Review (GIR)* as a leading investigations practice and one of a handful of global “elite” practice groups. Ms. Giunta is a recognized risk, strategy and compliance expert and advisor to global companies on corporate governance and enterprise risk management. She advises C-suites and boards in identifying and mitigating risks, developing and enhancing compliance programs, investigating and remediating wrongdoing and/or internal control weaknesses, conducting compliance-related due diligence in M&A and other commercial transactions, and developing reporting and disclosure frameworks. Her work has spanned the globe, performing risk assessments, conducting investigations and rolling out comprehensive compliance programs in Africa, the Middle East, South America, and Asia.

Ms. Giunta was recognized by *GIR* in its inaugural Women in Investigations list, which recognized 100 women across the globe who are “achieving great things in a competitive and notoriously tough area of law.” She is also Co-Chair of the firm’s Global Diversity Council and Chair of the firm’s Women’s Initiative. Ms. Giunta is Founder and Editor of the firm’s publication, Breaking the Glass Ceiling: Women in the Boardroom, now in its Fifth Edition, and speaks often on corporate governance, ESG compliance and risk. Ms. Giunta was a recipient of Corporate Counsel’s 2019 Women, Influence & Power in Law Awards under the Thought Leadership category.





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